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# Instructions for filling out the form
# Authorizations, Certificates and Visits

**RUPA:** Unique Register of Accredited Persons (RUPA), is the computerized interconnection and systematization of the Registries of Accredited Persons, which are a registration that allows individuals (individuals and legal entities) to carry out procedures before decentralized agencies and agencies, through through a unique identification number based on the Federal Taxpayer Registry. The purpose of RUPA is to integrate government information on the constitution and operation of companies. The corresponding documents are delivered only once and a single registration number is received that is used for different procedures in all Federal Government dependencies. Which you can request on the page http://www.rupa.gob.mx where you will find all the necessary information to carry out this procedure.

## 1. Homoclave, name and modality of the procedure

Write the HOMOCLAVE, NAME and MODALITY OF THE PROCESS as described below:

**License application:**

**Due to registration or new COFEPRIS-05-001-A** Request for Issuance of Sanitary License for Establishment of Health Supplies.
Modality A.- Factory or Laboratory of Raw Materials for the Manufacture of Medicines or Biological Products for Human Use.

**COFEPRIS-05-001-B** Request for the issuance of a Sanitary License for the Establishment of Health Supplies.
Modality B.- Factory or Laboratory of Medicines or Biological Products, for Human Use.

**COFEPRIS-05-001-C** Application for the issuance of a Sanitary License for the Establishment of Health Supplies.
Modality C.- Laboratory of Chemical, Biological, Pharmaceutical or Toxicology Control, for the Study, Experimentation of Medicines and Raw Materials, or Auxiliary of Sanitary Regulation.

**COFEPRIS-05-001-D** Application for the issuance of a Sanitary License for the Establishment of Health Supplies.
Modality D.- Medicines or Biological Products Conditioning Warehouse.

**COFEPRIS-05-001-E** Application for the issuance of a Sanitary License for the Establishment of Health Supplies.
Modality E.- Warehouse for Deposit and Distribution of Controlled Medications or Biological Products, for Human Use.

**COFEPRIS-05-001-F** Request for the issuance of a Sanitary License for the Establishment of Health Supplies.
Modality F.- Mixing Centers for the Preparation of Nutritional and Medication Parenteral Mixtures.

**COFEPRIS-05-001-G** Application for the issuance of a Sanitary License for the Establishment of Health Supplies.
Modality G.- Pharmacy or Apothecary (With Sale of Controlled Medications)

**COFEPRIS-05-001-H** Request for the issuance of a Sanitary License for the Establishment of Health Supplies.
Modality H.- Drugstore or Homeopathic Pharmacy (With Preparation of Homeoatic Medications)

**COFEPRIS-05-022-A** Sanitary License Application for Establishment of Pesticides, Plant Nutrients and Toxic or Dangerous Substances.
Modality A.- For Urban Fumigation, Disinfection and Pest Control Services.

**COFEPRIS-05-022-B** Sanitary License Application for Establishment of Pesticides, Plant Nutrients and Toxic or Dangerous Substances.
Modality B.- For Establishment that Manufactures, Formulates, Mixes or Packages Pesticides and/or Plant Nutrients

**COFEPRIS-05-022-C** Sanitary License Application for Establishment of Pesticides, Plant Nutrients and Toxic or Dangerous Substances.
Modality C.- For Establishment that Manufactures Toxic or Dangerous Substances.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**By modification COFEPRIS-05-002-A** Request for Modification of the Sanitary License for the Establishment of Health Supplies.
Modality A.- Factory or Laboratory of Raw Materials for the Manufacture of Medicines or Biological Products for Human Use.

**COFEPRIS-05-002-B** Request for Modification of the Sanitary License for the Establishment of Health Supplies.
Modality B.- Factory or Laboratory of Medicines or Biological Products, for Human Use.

**COFEPRIS-05-002-C** Request for Modification of the Sanitary License for the Establishment of Health Supplies.
Modality C.- Laboratory of Chemical, Biological, Pharmaceutical or Toxicology Control, for the Study, Experimentation of Medicines and Raw Materials, or Auxiliary of Sanitary Regulation.

**COFEPRIS-05-002-D** Request for Modification of the Sanitary License for the Establishment of Health Supplies.
Modality D.- Medicines or Biological Products Conditioning Warehouse.

**COFEPRIS-05-002-E** Request for Modification of the Sanitary License for the Establishment of Health Supplies.
Modality E.- Warehouse for Deposit and Distribution of Controlled Medications or Biological Products, for Human Use.

**COFEPRIS-05-002-F** Request for Modification of the Sanitary License for the Establishment of Health Supplies.
Modality F.- Mixing Centers for the Preparation of Nutritional and Medication Parenteral Mixtures.

**COFEPRIS-05-002-G** Request for Modification of the Sanitary License for the Establishment of Health Supplies.
Modality G.- Pharmacy or Apothecary (With Sale of Controlled Medications).

**COFEPRIS-05-002-H** Request for Modification of the Sanitary License for the Establishment of Health Supplies.
Modality H.-Drugstore or Homeopathic Pharmacy (With Preparation of Homeoatic Medications)

**COFEPRIS-05-044-A** Request for Modification of the Sanitary License for the Establishment of Pesticides, Nutrients Vegetables and Toxic or Dangerous Substances.
Modality A.- For Urban Fumigation, Disinfection and Pest Control Services.

**COFEPRIS- 05-044-B** Request for Modification of the Sanitary License for the Establishment of Pesticides, Nutrients Vegetables and Toxic or Dangerous Substances.
Modality B.- For Establishment that Manufactures, Formulates, Mixes or Packages Pesticides and/or Vegetable Nutrients.

**COFEPRIS- 05-044-C** Application for Modification of the Sanitary License for the Establishment of Pesticides, Nutrients Vegetables and Toxic or Dangerous Substances.
Modality C.- For Establishment that Manufactures Toxic or Dangerous Substances.

**Permit Request:**

**Due to registration or new COFEPRIS-03-003** Application for Acquisition Permit in Plaza of Raw Materials or Medications that Are or Contain Narcotic or Psychotropic Drugs.

**COFEPRIS-03-005** Permit from Narcotics and Psychotropic Control Books.

**COFEPRIS-05-015-A** Permit for the Sale or Distribution of Biological Products and Hemoderivatives.
Modality A.- Biological Products and Hemoderivatives.

**COFEPRIS-05-015-B** Permit for the Sale or Distribution of Biological Products and Hemoderivatives.
Modality B.- Antibiotics.

**COFEPRIS-05-015-C** Permit for the Sale or Distribution of Biological Products and Hemoderivatives.
Modality C.- Request for Reduction of Analytical Tests.

**COFEPRIS-05-015-D** Permit for the Sale or Distribution of Biological Products and Hemoderivatives.
Modality D.- Request for Inclusion of Product in Simplified Procedure.

**COFEPRIS-05-015-E** Permit for the Sale or Distribution of Biological Products and Hemoderivatives.
Modality E.- Renewal of Inclusion of Products in Simplified Procedure.

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**Application for import or export permit**

**Due to registration or new COFEPRIS-01-002-A** Prior Sanitary Permit for the Importation of Products.
Modality A.- Import of Products.

**COFEPRIS-01-002-B** Prior Sanitary Permit for the Importation of Products.
Modality B.- Import of Samples or Personal Consumption (For donation, personal consumption, scientific research, laboratory tests and exhibition).

**COFEPRIS-01-002-C** Prior Sanitary Permit for the Importation of Products.
Modality C.- Import by Return of Products.

**COFEPRIS-01-009-A** Sanitary Permit for the Importation of Raw Materials or for Medicines that are not or Contain Narcotic or Psychotropic Drugs, which have a Sanitary Registry.
Modality A.- Sanitary Permit for the Importation of Raw Materials.

**COFEPRIS-01-009-B** Sanitary Permit for the Importation of Raw Materials or for Medicines that are not or Contain Narcotic or Psychotropic Drugs, which have a Sanitary Registry.
Modality B.- Sanitary Permit for the Importation of Raw Materials Destined for the Manufacture of Medicines with Sanitary Registration.

**COFEPRIS-01-009-C** Sanitary Permit for the Importation of Raw Materials or for Medicines that are not or Contain Narcotic or Psychotropic Drugs, which have a Sanitary Registry.
Modality C.- Sanitary Permit for the Importation of Medicines with Sanitary Registration.

**COFEPRIS-01-010-A** Sanitary Permit to Import Medicines that Are Not or Contain Narcotics or Psychotropic drugs that do not have a Sanitary Registry.
Modality A.- Sanitary Permit for the Importation of Medicines and Raw Materials Destined for Human Research.

**COFEPRIS-01-010-B** Sanitary Permit to Import Medicines that Are Not or Contain Narcotics or Psychotropic drugs that do not have a Sanitary Registry.
Modality B.- Sanitary Permit to Import Medicines and Raw Materials Destined for Maquila.

**COFEPRIS-01-010-C** Sanitary Permit to Import Medicines that Are Not or Contain Narcotics or Psychotropic drugs that do not have a Sanitary Registry.
Modality C.- Sanitary Permit to Import Medicines Destined for Special Treatments (In low-incidence diseases with social repercussions)

**COFEPRIS-01-010-D** Sanitary Permit to Import Medicines that Are Not or Contain Narcotics or Psychotropic drugs that do not have a Sanitary Registry.
Modality D.- Sanitary Permit for the Importation of Medications Destined for Personal Use.

**COFEPRIS-01-010-E** Sanitary Permit to Import Medicines that Are Not or Contain Narcotics or Psychotropic drugs that do not have a Sanitary Registry.
Modality E.- Sanitary Permit for the Importation of Medications Destined for Donation.

**COFEPRIS-01-010-F** Sanitary Permit to Import Medicines that Are Not or Contain Narcotics or Psychotropic drugs that do not have a Sanitary
Registration Modality F.- Sanitary Permit for the Importation of Medicines and Raw Materials Destined for Lab tests

**COFEPRIS-01-012**
Sanitary Permit for the Importation of Herbal Remedies.

**COFEPRIS-01-014-A** Sanitary Permit for the Importation of Medical Devices with Sanitary Registration that Are Not or Contain Narcotic or Psychotropic Drugs.
Modality A.- Import of Medical Devices that have a Sanitary Registry.
(Such as: medical equipment, X-ray devices, heart valves, internal prostheses, pacemakers, prostheses, supplies for dental use, surgical materials, healing materials, and hygienic products with Sanitary Registration)

**COFEPRIS-01-014-B** Sanitary Permit for the Importation of Medical Devices with Sanitary Registration that Are Not or Contain Narcotic or Psychotropic Drugs.
Modality B.- Importation of Radiation Sources.
(Includes diagnostic reagents or agents with radioactive isotopes)



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**COFEPRIS-01-015-A** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, without Registration or in the Experimentation Phase.
Modality A.- Import of Medical Devices for Maquila.

**COFEPRIS-01-015-B** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, without Registration or in the Experimentation Phase.
Modality B.- Import of Medical Devices for Personal use.

**COFEPRIS-01-015-C** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, without Registration or in the Experimentation Phase.
Modality C.- Import of Medical Devices for Medical Use.

**COFEPRIS-01-015-D** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, without Registration or in the Experimentation Phase.
Modality D.- Import of Medical Devices for Human Research.

**COFEPRIS-01-015-E** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, without Registration or in the Experimentation Phase.
Modality E.- Importation of Medical Devices for Donation.

**COFEPRIS-01-015-F** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, without Registration or in the Experimentation Phase.
Modality F.- Import of Medical Devices, without Registration, Used.

**COFEPRIS-01-015-G** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, without Registration or in the Experimentation Phase.
Modality G.- Sanitary Permit for the Importation of Medical Devices Destined for Laboratory Tests.

**COFEPRIS-01-016** Sanitary Permit for the Importation of Supplies that Are Not or Contain Narcotic or Psychotropic Drugs, by Return.

**COFEPRIS-03-012** Permiso Sanitario de Importación de Materias Primas o Medicamentos que Sean o Contengan Narcotics or Psychotropics.

**COFEPRIS-03-013** Permiso Sanitario de Exportación de Materias Primas o Medicamentos que Sean o Contengan Narcotics or Psychotropics.

**By modification COFEPRIS-01-005** Modification to the Prior Sanitary Permit for the Importation of Products.

**COFEPRIS-01-017** Modification to the Sanitary Permit for the Importation of Health Supplies that Are Not or Contain Narcotic or Psychotropic Drugs.

**COFEPRIS-03-019** Modification to the Prior Sanitary Permit for the Importation of Raw Materials or Medications that Are or Contain Narcotic or Psychotropic Drugs.

**registration request**

**Sanitary of medical devices Due to**

**Registration or New COFEPRIS-04-001-A** Application for Sanitary Registration of Medical Devices.
Modality A.- Products of National Manufacture.

**COFEPRIS-04-001-B** Application for Sanitary Registration of Medical Devices.
Modality B.- Import Products (Foreign Manufacture)

**COFEPRIS-04-001-C** Application for Sanitary Registration of Medical Devices.
Modality C.- Nationally Manufactured Products that are Manufactured by another Establishment.

**COFEPRIS-04-001-D** Application for Sanitary Registration of Medical Devices.
Modality D.- Products with Class I FDA Registration (USA and Canada Equivalence Agreement)

**COFEPRIS-04-001-E** Application for Sanitary Registration of Medical Devices.
Modality E.- Products with Class II and III FDA Registration (USA and Canada Equivalence Agreement)



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**COFEPRIS-04-001-F** Application for Sanitary Registration of Medical Devices
Modality F.- Products with Registration Class II, III and IV HEALTH CANADA (USA and Canada Equivalence Agreement)

**COFEPRIS-04-001-G** Application for Sanitary Registration of Medical Devices.
Modality G.- Designated Controlled Medical Devices (class II with established conformity criteria) with a Certificate Issued by a Certification Body Registered with the MHLW of Japan (Japan Equivalence Agreement)

**COFEPRIS-04-001-H** Application for Sanitary Registration of Medical Devices.
Modality H.- Class II Medical Devices (class II without established conformity criteria), III and IV with Letter of Approval Issued by the MHLW of Japan (Japan Equivalence Agreement).

**COFEPRIS-04-001-I** Application for Sanitary Registration of Medical Devices.
Modality I.- Nationally Manufactured Products Considered Low Risk.

**COFEPRIS-04-001-J** Application for Sanitary Registration of Medical Devices.
Modality J.- Import Product (Foreign Manufacture) Considered Low Risk.

**COFEPRIS-04-001-K** Application for Sanitary Registration of Medical Devices.
Modality K.- Nationally Manufactured Products Considered Low Risk that are Manufactured by Another Establishment.

**By Modification COFEPRIS-04-002-A** Request for Modification of the Conditions of the Sanitary Registry of Medical Devices.
Modality A.- Administrative Modifications: Assignment of Rights, due to Change of Address of the National or Foreign Distributor, due to Change of Name or company name of the Manufacturer or Distributor, due to Change of the Authorized Distributor in the National Territory.

**COFEPRIS-04-002-B** Request for Modification of the Conditions of the Sanitary Registry of Medical Devices.
Modality B.- Technical Modifications: Radiation Sources, due to Change of National or Foreign Maquiladora, Supplies with Exclusive Presentation for Public Health or Social Security Institutions, Change of Manufacturing Site of the National or Foreign Manufacturer Including Subsidiary Companies, due to New Origins As Long as They Are Affiliates or Subsidiaries, due to Change of Primary Packaging Material and Reclassification of the Device, due to Formula Change that Does Not Involve Substitution of the Active Ingredient, due to Change of Commercial Name and/or Product Catalog Number.

**COFEPRIS-04-002-C** Request for Modification of the Conditions of Sanitary Registration of Medical Devices.
Modality C.- Administrative Modifications to Registrations of Medical Devices Granted under the "USA and Canada Equivalence Agreement": Assignment of Rights, due to Change of Address of the National or Foreign Distributor, due to Change of Name or company name of the Manufacturer or of the Distributor, due to Change of Authorized Distributor in the National Territory.

**COFEPRIS-04-002-D** Request for Modification of the Conditions of Sanitary Registration of Medical Devices.
Modality D.- Technical Modifications to Medical Device Registries Granted under the "USA and Canada Equivalence Agreement": Radiation Sources, due to Change of National or Foreign Maquiladora, Supplies with Exclusive Presentation for Public Health or Security Institutions Change of Manufacturing Site of the National or Foreign Manufacturer, Including Affiliate or Subsidiary Companies, for New Origins Provided they are Affiliates or Subsidiaries, for Change of Material of the Primary Packaging and for Reclassification of the Device, for Change of Formula that does not Involve Substitution of the Active Ingredient, by Change of Trade Name and/or Product Catalog Number.

**COFEPRIS-04-002-E** Request for Modification of the Conditions of Sanitary Registration of Medical Devices.
Modality E.- Administrative Modifications to Registrations of Medical Devices Granted under the "Japan Equivalence Agreement": Assignment of Rights, due to Change of Address of the National or Foreign Distributor, due to Change of Name or company name of the Manufacturer or Distributor , by Change of Authorized Distributor in the National Territory.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**COFEPRIS-04-002-F** Request for Modification of the Conditions of Sanitary Registration of Medical Devices.
Modality F.- Modifications of a Technical Type to Registries of Medical Devices Granted under the "Japan Equivalence Agreement": Radiation Sources, due to Change of National or Foreign Maquiladora, Change of Manufacturing Site of the National or Foreign Manufacturer Only Subsidiary Companies or Subsidiaries, due to New Origins as long as they are Affiliates or Subsidiaries, due to Change of Primary Packaging Material and Reclassification of the Device, due to Formula Change that does not Involve Substitution of the Active Ingredient, due to Change of Commercial Name and/or Catalog Number of Product.

**COFEPRIS-04-002-G** Request for Modification of the conditions of the Sanitary Registry of Medical Devices.
Modality G.- Modification of the Administrative Type of Products Considered Low Risk: Assignment of Rights, due to Change of Address of the National or Foreign Distributor, due to Change of Name or company name of the Manufacturer or Distributor, due to Change of the Authorized Distributor in the Territory National due to Change of Commercial Name and/or Catalog Number without Technical Changes.

**COFEPRIS-04-002-H** Request for Modification of the conditions of the Sanitary Registry of Medical Devices.
Modality H.- Modifications of Technical Type of Products considered Low Risk: by Change of National or Foreign Maquiladora, Supplies with Exclusive Presentation for Public Health or Social Security Institutions, Change of Manufacturing Site of the National or Foreign Manufacturer Including Subsidiary Companies , for new Origins as long as they are Affiliates or Subsidiaries, for Change of Commercial Name and/or Product Catalog Number and For New Presentations of the Product that are not with Technological Advances that Modify the Main Purpose of use.

**by extension**

**COFEPRIS-04-021-A** Request for Extension of the Sanitary Registry of Medical Devices.
Modality A.- Products of National Manufacture.
(Medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical and healing material, hygienic products, instruments and other devices for medical use).

**COFEPRIS-04-021-B** Request for Extension of the Sanitary Registry of Medical Devices.
Modality B.- Nationally Manufactured Products that are Manufactured by Another.
(Medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical and healing material, hygienic products, and other devices for medical use).

**COFEPRIS-04-021-C** Request for Extension of the Sanitary Registry of Medical Devices.
Modality C.- Import Products (Foreign Manufacture).
(Medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical and healing material, hygienic products, instruments and other devices for medical use)

**COFEPRIS-04-021-D** Request for Extension of the Sanitary Registry of Medical Devices.
Modality D.- Registration of Medical Devices Granted under the USA and Canada Equivalence Agreement.

**COFEPRIS-04-021-E** Request for Extension of the Sanitary Registry of Medical Devices.
Modality E.- Registries of Designated Controlled Medical Devices (Class II with Established Compliance Criteria) Granted under the Japan Equivalence Agreement.

**COFEPRIS-04-021-F** Request for Extension of the Sanitary Registry of Medical Devices.
Modality F.- Records of Medical Devices Class II (Class II without Established Compliance Criteria), III and IV. Granted under the Japan Equivalence Agreement.

**COFEPRIS-04-021-G** Request for Extension of the Sanitary Registry of Medical Devices.
Modality G.- Nationally Manufactured Products Considered Low Risk.

**COFEPRIS-04-021-H** Request for Extension of the Sanitary Registry of Medical Devices.
Modality H.- Import Products (Foreign Manufacture) Considered Low Risk.

**COFEPRIS-04-021-I** Request for Extension of the Sanitary Registry of Medical Devices.
Modality I.- Nationally Manufactured Products Considered Low Risk that are Manufactured by Another Establishment.

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**registration request**

**medicine toilet**

**By Registration or New COFEPRIS-04-004-A** Sanitary Registry of Allopathic Medications, Vaccines and Blood Products.
Modality A.- Sanitary Registry of Nationally Manufactured Allopathic Medications, Vaccines and Blood Products. (New Molecule).

**COFEPRIS-04-004-B** Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products.
Modality B.- Sanitary Registry of Nationally Manufactured Allopathic Medications, Vaccines and Blood Products. (Generic)

**COFEPRIS-04-004-C** Sanitary Registry of Allopathic Medications, Vaccines and Blood Products.
Modality C.- Sanitary Registration of Allopathic Medicines, Vaccines and Blood Products of Foreign Manufacture (New Molecule)

**COFEPRIS-04-004-D** Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products.
Modality D.- Sanitary Registration of Allopathic Medicines, Vaccines and Blood Products of Foreign Manufacture (Generic)

**COFEPRIS-04-004-E** Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products.
Modality E.- Sanitary Registration of Nationally Manufactured Innovative Biotechnological Medicine.

**COFEPRIS-04-004-F** Sanitary Registry of Allopathic Medications, Vaccines and Blood Products.
Modality F.- Sanitary Registration of Innovative Biotechnological Medicine of Foreign Manufacture.

**COFEPRIS-04-004-G** Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products.
Modality G.- Sanitary Registry of Nationally Manufactured Biocomparable Biotechnological Medicines.

**COFEPRIS-04-004-H** Sanitary Registry of Allopathic Medications, Vaccines and Blood Products.
Modality H.- Sanitary Registry of Biocomparable Biotechnological Medicines of Foreign Manufacture.

**COFEPRIS-04-004-I** Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products.
Modality I.- Sanitary Registration of Biological Product whose Active Ingredient is not Registered in the United Mexican States, but is Authorized for Sale in the European Union, Switzerland, the United States of America, Canada or Australia (Under the Agreements of Equivalence)

**COFEPRIS-04-004-J** Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products.
Modality J.- Sanitary Registration of Biotechnological Medication whose Active Ingredient is not Registered in the United Mexican States, but is Authorized for Sale in the European Union, Switzerland, the United States of America, Canada or Australia (Under the Agreements of Equivalence)

**COFEPRIS-04-004-K** Sanitary Registry of Allopathic Medications, Vaccines and Blood Products.
Modality K.- Sanitary Registration of Allopathic Medication whose Active Ingredient is not Registered in the United Mexican States, but it is registered for sale in the European Union, Switzerland, the United States of America, Canada or Australia (Under Equivalence Agreements)

**COFEPRIS-04-005** Sanitary Registration of Specialized Enteral Feeding Formulas of National or Foreign Manufacture.

**COFEPRIS-04-006-A** Sanitary Registry of Herbal Medicines.
Modality A.- Sanitary Registry of Nationally Manufactured Herbal Medicines.

**COFEPRIS-04-006-B** Sanitary Registry of Herbal Medicines.
Modality B.- Sanitary Registration of Foreign Manufactured Herbal Medicines.

**COFEPRIS-04-007-A** Sanitary Registry of Homeopathic Medicines.
Modality A.- Sanitary Registration of Homeopathic Medicines of National Manufacture.

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**COFEPRIS-04-007-B** Sanitary Registry of Homeopathic Medicines.
Modality B.- Sanitary Registration of Foreign Manufactured Homeopathic Medicines.

**COFEPRIS-04-008-A** Sanitary Registry of Vitamin Medications.
Modality A.- Sanitary Registry of Nationally Manufactured Vitamin Medications.

**COFEPRIS-04-008-B** Sanitary Registry of Vitamin Medications.
Modality B.- Sanitary Registration of Foreign Manufactured Vitamin Medications.

**Due to Modification COFEPRIS-04-014-A** Request for Modification to the Sanitary Registration of Medications, due to Change of Manufacture National to Foreign and from Foreign to National.
Modality A.- Change from Foreign to National Manufacture of Homeopathic Medicines.

**COFEPRIS-04-014-B** Request for Modification to the Sanitary Registration of Medications, due to a Change from National to Foreign Manufacture and from Foreign to National.
Modality B.- Change from Foreign to National Manufacture of Allopathic and Vitamin Medicines.

**COFEPRIS-04-014-C** Request for Modification of the Sanitary Registry of Medications, due to a Change from National to Foreign Manufacture and from Foreign to National.
Modality C.- Change from National to Foreign Manufacture of Medicines.

**COFEPRIS-04-014-D** Request for Modification to the Sanitary Registry of Medications, due to a Change from National to Foreign Manufacture and from Foreign to National.
Modality D.- Change from Foreign to National Manufacture of Herbal Medicines.

**COFEPRIS-04-015-A** Modification to the Conditions of Sanitary Registration of Medicines without Change in the Process of Manufacturing.
Modality A.- Modification of the Name or Address of the Holder of the Registry or of the National Maquiladora.

**COFEPRIS-04-015-B** Modification to the Conditions of Sanitary Registration of Medicines without Change in the Manufacturing Process.

Modality B.- Modification of the Trade Name of the Medication.

**COFEPRIS-04-015-C** Modification to the Conditions of Sanitary Registration of Medicines without Change in the Manufacturing Process.

Modality C.- Modification of the Secondary Packaging.

**COFEPRIS-04-015-D** Modification to the Conditions of Sanitary Registration of Medicines without Change in the Manufacturing Process.

Modality D.- Modification to the Information Texts to Prescribe in its Extended and Reduced Version.

**COFEPRIS-04-015-E** Modification to the Conditions of Sanitary Registration of Medicines without Change in the Manufacturing Process.

Modality E.- Modification to the Conditions of Sale and Supply to the Public.

**COFEPRIS-04-015-F** Modification to the Conditions of Sanitary Registration of Medications without Change in the Process of Manufacturing.
Modality F.- Modification to the Presentation and Content of Containers.

**COFEPRIS-04-015-G** Modification to the Conditions of Sanitary Registration of Medicines without Change in the Manufacturing Process.

Modality G.- Modification by Change of Additives or Excipients without Changes in the Dosage Form or Active Ingredients.

**COFEPRIS-04-015-H** Modification to the Conditions of Sanitary Registration of Medicines without Change in the Manufacturing Process.

Modality H.- Modification due to Change of Primary Packaging.

**COFEPRIS-04-015-I** Modification to the Conditions of Sanitary Registration of Medications without Change in the Manufacturing Process.

Modality I.- Modification of the Expiration Term.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**COFEPRIS-04-015-J** Modification to the Conditions of Sanitary Registration of Medications without Change in the Manufacturing Process.

Modality J.- Modification due to Change of Therapeutic Indication.

**COFEPRIS-04-015-K** Modification to the Conditions of Sanitary Registration of Medications without Change in the Process of Manufacturing.
Modality K.- Modification of Generic Drugs.

**COFEPRIS-04-016** Modification to the Conditions of the Sanitary Registration of Medications with Changes in the Manufacturing Processes.

**COFEPRIS-10-001** Assignment of Rights of the Sanitary Registry of Medicines.

**by extension**

**COFEPRIS-04-022-A** Request for Extension of the Sanitary Registration of Herbal Medicines, Vitamins and Homeopathic.
Modality A.- Extension of the Sanitary Registration of Nationally Manufactured Herbal, Vitamin and Homeopathic Medicines.

**COFEPRIS-04-022-B** Request for Extension of the Sanitary Registry of Herbal, Vitamin and Homeopathic Medicines.

Modality B.- Extension of the Sanitary Registration of Herbal, Vitaminic, Homeopathic Medicines of Foreign Manufacture.

**COFEPRIS-04-023-A** Request for Extension of the Sanitary Registry of Allopathic Medications, Vaccines, Blood Products and Biomedications.

Modality A.- Extension of the Sanitary Registration of Allopathic Medications, Vaccines, Blood Products and Biomedicine of National Manufacture.

**COFEPRIS-04-023-B** Request for Extension of the Sanitary Registry of Allopathic Medications, Vaccines, Blood Products and Biomedications.

Modality B.- Extension of the Sanitary Registration of Allopathic Medicines, Vaccines, Blood Products and Biomedicine of Foreign Manufacture.

**By Revocation COFEPRIS-04-012** Request for Revocation of the Sanitary Registry and Other Authorizations.

**Authorization request**

**COFEPRIS-04-009-A** Request for Alphanumeric Code of Herbal Remedies.
Modality A.- Request for Alphanumeric Code of Herbal Remedies of National Manufacture.

**COFEPRIS-04-009-B** Application for Alphanumeric Code of Herbal Remedies.
Modality B.- Request for Alphanumeric Code of Herbal Remedies of Foreign Manufacture.

**COFEPRIS-04-010-A** Request for Authorization of Research Protocol in Human Beings.
Modality A.- Medicines, Biologicals and Biotechnologicals.

**COFEPRIS-04-010-B** Request for Authorization of Research Protocol in Human Beings.
Modality B.- Drugs (Bioequivalence Studies)

**COFEPRIS-04-010-C** Request for Authorization of Research Protocol in Human Beings.
Modality C.- New Resources (study of materials, grafts, transplants, prostheses, physical, chemical and surgical procedures) and other methods of prevention, diagnosis, treatment and rehabilitation carried out on human beings or their biological products, except pharmacological ones .

**COFEPRIS-04-010-D** Request for Authorization of Research Protocol in Human Beings.
Modality D.- Research without Risk.
(Observational studies that use documentary research techniques and methods and those in which no intentional intervention or modification is made to the physiological, psychological and social variables of the research subjects)



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**COFEPRIS-07-001** Third Party Authorization Request.

**COFEPRIS-07-005** Request for Extension of the Validity of Third Party Authorization.

**COFEPRIS-09-012** Request for Modification or Amendment to the Research Protocol Authorization.

**COFEPRIS-09-013** Request for Authorization for Commercialization and Import for its Commercialization of Genetically Modified Organisms.

**Request for export certificate: By registration or new COFEPRIS-01-007-A** Request for Certificate for Export Support.
Modality A.- Request for Certificate for Free Export Sale. (Food, Alcoholic, Non-Alcoholic Beverages, etc.)

**COFEPRIS-01-007-B** Request for Export Support Certificate.
Modality B.- Request for Export Certificate.

**COFEPRIS-01-007-C** Request for Export Support Certificate.
Modality C.- Request for Certificate for Export of Conformity of Good Sanitary Practices.

**COFEPRIS-01-007-D** Request for Export Support Certificate.
Modality D.- Request for Certificate for Product Analysis Export.

**COFEPRIS-01-019** Export Certificate for Health Supplies that are not or do not contain Narcotic or Psychotropic Drugs.

**COFEPRIS-05-016-A** Certificate of Support for the Export of Health Supplies.
Modality A.- Certificate of Good Manufacturing Practices for Health Supplies.

**COFEPRIS-05-016-B** Certificate of Support for the Export of Health Supplies.
Modality B.- Certificate of Free Sale of Medicines.

**COFEPRIS-05-016-C** Certificate of Support for the Export of Health Supplies.
Modality C.- Certificate of Free Sale of Medical Devices.

**COFEPRIS-07-002** Sanitary Report on Bacteriological Effectiveness of Germicidal Equipment or Substances for Domestic Type Water Purification.

**COFEPRIS-07-004** Application for Certificate of Accreditation of Bivalve Mollusk Processing Plants.

**COFEPRIS-07-007** Application for Certificate of Sanitary Quality of Water in the Area of Production and Cultivation of Bivalve molluscs.

**By Modification COFEPRIS-01-008** Modification of Certificate for Export.
(Certificate for Free Sale Export, Products for Export, Product Analysis and Compliance with Good Sanitary Practices)

**Sanitary verification visit requests: COFEPRIS-01-020**
Sanitary Verification Visit Request for Export.

**COFEPRIS-01-029** Sanitary Verification Visit Request for Certification of Good Manufacturing Practices for Drugs, Medications and Other Health Supplies in Establishments Located in Mexico and Abroad for the Granting or Extension of Sanitary Registration.

**COFEPRIS-03-001** Verification Visit Request for Sampling and Release of Narcotic and Psychotropic Drugs.

**COFEPRIS-03-018-A** Request for Visit to Verify Raw Materials and Medicines that are or Contain Drugs or Psychotropic Drugs.
Modality A.- Destruction.

**COFEPRIS-03-018-B** Request for Visit to Verify Raw Materials and Medicines that are or Contain Drugs or Psychotropic Drugs.
Modality B.- Stamp and Sealing (Only export of psychotropic and narcotic drugs)



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C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**COFEPRIS-03-018-C** Request for Visit to Verify Raw Materials and Medicines that are or Contain Drugs or Psychotropic Drugs.
Modality C.- Balance.

**COFEPRIS-09-004** Request for Advice on Sanitary Engineering.

**Sanitary control card requests:**

**Due to registration or new COFEPRIS-05-084** Request for Sanitary Control Card for Tattoo Artists, Micropigmenters and Piercers.

**By modification COFEPRIS-05-087** Request for Extension or Modification of the Sanitary Control Card for Tattoo Artists, Micropigmenters and Piercers.

## 2. Data of the owner

### Physical person

**Natural person:** It is an individual with the capacity to contract obligations and exercise rights.
**RFC:** The Federal Taxpayer Registry under which the owner is registered before the Ministry of Finance and Public Credit (SHyCP).
**CURP (optional):** Unique Population Registry Code, only for natural persons.
**Name(s):** Full name without abbreviations under which the owner is registered with the Ministry of Finance and Public Credit (SHyCP).

**First surname:** Full first surname without abbreviations under which the owner is registered with the Ministry of Finance and Public Credit (SHyCP).

**Second last name:** Full second last name without abbreviations under which the owner is registered with the Ministry of Finance and Public Credit (SHyCP).

**Call, Telephone and Extension:** Telephone number(s), including call code. Example: Lada: 01 (55)

Telephone: 57 31 49 52

Extension (when applicable): 1494

**Email:** Email address in lower case and without leaving blank spaces of the owner.

### Moral person

**Moral person:** It is a group of people who come together for a specific purpose, for example, a commercial company, a civil association.
**RFC:** The Federal Taxpayer Registry under which it is registered with the Ministry of Finance and Public Credit (SHyCP).
**Denomination or company name:** Full name without abbreviations under which the Denomination or company name is registered with the Ministry of Finance and Public Credit (SHyCP).

### Legal representative or proxy requesting the procedure

**RFC:** The Federal Taxpayer Registry under which it is registered with the Ministry of Finance and Public Credit (SHyCP).
**CURP (optional):** Unique Population Registry Code, only for natural persons.
**Name(s):** Full name without abbreviations of the legal representative or proxy requesting the procedure.
**First surname:** Full first surname without abbreviations of the legal representative or proxy requesting the procedure.
**Second last name:** Full second last name without abbreviations of the legal representative or proxy requesting the procedure.
**Call, Telephone and Extension:** Telephone number(s), including call code. Example: Lada: 01 (55)

Telephone: 57 31 49 52

Extension (when applicable): 1494

**Email:** Email address in lower case and without leaving blank spaces of the legal representative or proxy requesting the procedure.

### Tax address of the owner

Note: Address under which it is registered with the Ministry of Finance and Public Credit (SHyCP)
**Postal code:** Full number of the postal code that corresponds to the tax address of the company.

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**Type and name of road:** Type and full name without abbreviations of (the) Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others where the company's fiscal domicile is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway.
**Exterior number:** Indicate the exterior number of the company's tax address.
**Internal number:** If you have an internal number or letter at the company's tax address, also write it down.
**Type and name of the colony or human settlement:** Type and full name without abbreviations of the colony, condominium, farm, ranch, subdivision, section, sector, among others where the company's fiscal domicile is located, For example: Naples, Rancho las Americas.
**City:** City where the company's tax domicile is located (when applicable).
**Municipality or mayor's office:** Full name without abbreviations of the political delegation or municipality, where the company's tax domicile is located.
**Federal Entity: Federal entity** where the company's tax domicile is located. For example: Mexico City, Baja California, State from Mexico.
**Between roads and roads (type and name):** Between which avenue, boulevard, street, highway, road, private, dirt road, among others, where the company's fiscal domicile is located, for example: Avenida Periférico, Cerrada de San Ignacio, Carretera Picacho Ajusco.
**Subsequent road (type and name):** Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others after where the company's fiscal domicile is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway .
**Call, Telephone and Extension:** Telephone number(s), including call code. Example: Lada:
01 (55)
Telephone: 57 31 49 52
Extension (when applicable): 1494

## 3. Establishment data

**RFC:** The Federal Taxpayer Registry under which it is registered with the Ministry of Finance and Public Credit (SHyCP).
**Name or company name:** Full name without abbreviations of the establishment (Example: Farmacia Lupita, Laboratorios Terra, SA de CV, Procesadora de Alimentos S. de RL de CV, etc.)

**Indicate the code and description of the line of business that corresponds to the establishment according to the North American Industrial Classification System:**

**SCIAN Code:** Complete number of the North American Industrial Classification System, you can indicate more than one.
**SCIAN description:** Description of the activity(ies) carried out by the establishment corresponding to the selected key.
**Sanitary license number or indicate if you submitted a notice of operation:** Full number of the sanitary license or indicate if you submitted a notice of operation.

## health manager

**RFC:** The Federal Taxpayer Registry under which the health officer is registered with the Ministry of Finance and Public Credit (SHyCP).

**CURP (optional):** Unique Population Registry Code.
**Name(s):** Full name without abbreviations of the health manager.
**First surname:** Full first surname without abbreviations of the healthcare manager.
**Second last name:** Full second last name without abbreviations of the health manager.

## Only for the discharge of health license

**Hours of Operation:** Mark the days of the week that the establishment will be open and write the hours of operation or customer service opening and closing hours.
Example:

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| D | **XXXXX** | S | of | | | | | **09:00** HH:MM | a | **19:00** HH:MM |
| D | L | M | M | J | V | **X** | de | **09:00** HH:MM | a | **14:00** HH:MM |

**Operations start date:** Indicate the date on which the establishment will start activities approximately starting with the day, month and year.
Example:

| | | | | |
|---|---|---|---|---|
| **21** DD | / | **07** MM | / | **2017** AAAA |



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Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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Address of the establishment

**Postal code:** Full number of the postal code that corresponds to the address where the address of the company's establishment is located.
**Type and name of road:** Type and full name without abbreviations of (the) Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others where the address of the establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio , Picacho Ajusco Highway.
**Exterior number:** Indicate the exterior number of the address where the address of the company's establishment is located.
**Internal number:** If you have an internal number or letter at the address where the address of the company's establishment is located, also write it down.

**Type and name of the neighborhood or human settlement:** Type and full name without abbreviations of the (the) neighborhood, condominium, farm, ranch, subdivision, section, sector, among others where the domicile of the company establishment is located, for example : Naples, Rancho las Americas.

**Town:** Town of the domicile where the domicile of the company's establishment is located (when applicable).
**Municipality or mayor's office:** Full name without abbreviations of the political delegation or municipality, where the domicile of the company's establishment is located.
**Federal Entity: Federal entity** where the domicile of the company establishment is located. For example: Mexico City, Baja California, State of Mexico.

**Between road and road (type and name):** Between which avenue, boulevard, street, highway, road, private, dirt road, among others where the address of the company establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway.
**Subsequent road (type and name):** Avenue, Boulevard, Street, Highway, Road, Private, Terracería, among others after where the address of the establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway.
**Call, Telephone and Extension:** Telephone number(s), including call code. Example: Lada:
01 (55)
Telephone: 57 31 49
52 Extension (when applicable): 1494

Legal representative(s) and authorized person(s)

Legal representative

**Legal Representative:** (Article 19 of the Federal Law of Administrative Procedure) The representation of natural or legal persons before the Federal Public Administration to make requests, participate in the administrative procedure, file appeals, withdraw and waive rights, must be accredited by instrument public, and in the case of natural persons, also through a power of attorney signed before two witnesses and ratified by the signatures of the grantor and witnesses before the authorities themselves or notary public, or declaration in personal appearance of the interested party.
**CURP (optional):** Unique Population Registry Code. only for natural persons.
**Name(s):** Full name without abbreviations of the legal representative **First surname:** Full first surname without abbreviations of the legal representative **Second surname:** Second full surname without abbreviations of the legal representative **Lada,**
**Telephone and Extension:** Telephone number(s), including area code. Example: Lada: 01
(55)
Telephone: 57 31 49
52 Extension (when applicable): 1494
**Email:** Email address in lower case and without leaving blank spaces of the legal representative or proxy.

Authorized person

**Authorized Person:** (Article 19 of the Federal Administrative Procedure Law) Notwithstanding the foregoing, the interested party or his legal representative by means of a signed writing may authorize the person or persons he deems appropriate to hear and receive notifications, carry out procedures, procedures and appearances that are necessary for the processing of said procedure, including the filing of administrative appeals.
**CURP (optional):** Unique Population Registry Code.
**Name(s):** Full name without abbreviations of the authorized person.
**First surname:** Full first surname without abbreviations of the authorized person.
**Second last name:** Full second last name without abbreviations of the authorized person.
**Call, Telephone and Extension:** Telephone number(s), including call code. Example: Lada:
01 (55)
Telephone: 57 31 49
52 Extension (when applicable):
1494 **Email:** Email address in lower case and without leaving blank spaces of the authorized person.

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## 4. Modification and/or extension

**Select an option:** Check the type of procedure to carry out.
**Document number:** Write the document number to be modified and/or extended in case of modification in which the changes to be made in the corresponding field, according to the following illustrative but not limitative list:

ÿ Name or company name ÿ New
lines or services ÿ Address ÿ
Product ÿ
Process ÿ
Assignment
of rights ÿ Owner ÿ Line
or business ÿ
To the conditions
of registration of medicines ÿ To the conditions of
registration of medical devices ÿ To the facilities of
establishments that handle toxic or dangerous substances determined to be of high risk to health, when
involve new security systems

**It says / authorized condition:** Write down the data as notified through the notice of operation or license application or data of the authorization that you want to be modified.
**It must say / condition requested:** Write down the complete data as it should be.

## 5. Product data

### Product

**1) Name of the classification of the product or service:** Write the name of the classification of the product or service for which you are going to carry out your Procedure. See point 5.A of these instructions.

2) **Specify:** If the product belongs to a subclassification of the product chosen in table 5.A of the format; See point 5.A of these instructions and choose from the list of each product the name of the specific classification to which it belongs. If the product belongs to class II or III in accordance with article 83 of the Health Supplies Regulation.
For the export of fishery products to the European Union, write if the product is from "aquaculture" or, if applicable, from "fishery".

**3) Specific name of the product:** Particular name that a product receives and that is associated with the characteristic(s) that distinguishes it within a general classification and restricts it in application, effect, structure , function and particular use except medicines.
(For example: Ultra-pasteurized skimmed chocolate milk, Balloon coronary angioplasty catheter).

**4) Name (trademark) or distinctive name:** Brand under which the product is marketed. For health supplies, the name that the laboratory or manufacturer assigns to its pharmaceutical specialties as a trademark in order to distinguish them from other similar ones (example: “Lala”, “Agiocat”)

**5) International Common Name (DCI) or generic or scientific name or unique identifier of the OECD:** In the case of medicines, the DCI and the generic name is the name that identifies the internationally recognized drug or active substance.
Example: Ampicillin. In the case of medical devices. (Example Catheter)
In the case of Herbal Remedies, specify the scientific name (genus and species) of the plant or its parts. Example of aneroid newspaper library (Mexican Arnica). In the case of other products, the Generic name represents each of the different types or classes into which they can be grouped. (Example: Milk) In the case of Genetically Modified Organisms, indicate the unique identifier of the OECD.

**6) Pharmaceutical form or physical form:** Pharmaceutical form to the mixture of one or more drugs with or without additives, which present certain physical characteristics for their adequate dosage, conservation and administration (tablets, suspensions, etc.); and the physical state can be: solid, liquid and gaseous.

**7) Type of product:** Select the number corresponding to the type of product:

1. Raw material,
2. Additive,
3. Finished product,
4. Bulk product, 5.
Others (anyone that does not fall within the previous classification)

**8) Tariff Fraction:** Tariff classification to which the merchandise to be imported belongs.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**9) Quantity of batches:** Write down with number the quantity of batches to be acquired, exported, imported or acquired in the market or specify the number of batches to be released, of psychotropic and narcotic drugs and food, food supplements, alcoholic and non-alcoholic beverages, cleaning and cleaning, perfumery and beauty.

**10) Unit of measurement:** Abbreviation according to the international system of units for the case of food, food supplements, alcoholic and non-alcoholic beverages, tobacco, grooming and cleaning, and cosmetic products. In the case of medicines, it must correspond to the pharmaceutical form requested.

**11) Quantity or total volume:** Write with Arabic numerals the quantity or total volume of the imported or exported product. In the case of narcotics, psychotropics and chemical precursors the total amount must be raw material. When apply.

**12) Number of pieces to be manufactured:** Write the quantity with number of pieces to be manufactured. (Tablets, capsules, vials, etc.)

**13) Kilograms or grams per lot:** Write the amount in kilograms (kg). or grams (g) per batch, only for narcotic and psychotropic drugs or pharmochemicals.

**14) Import or export sanitary permit number or alphanumeric code:** Write the import sanitary permit number (applies only to the release of narcotic and psychotropic drugs and sale or distribution of biologicals and blood products).

**15) Sanitary registration number:** Sanitary Registry number or alphanumeric code of the product issued by the health authority.

**16) Record number:** Write the release record number. Only in case of release of psychotropic and narcotic drugs.

**17) Presentation:** Presentation per unit, for medicines (bottle with 120 ml of 10 mg/ml, box with 20 tablets of 5 mg, etc.) and medical devices (container with one piece, bottle with 240 ml, box or bottle with 100 test strips, etc.). In the case of food, alcoholic and non-alcoholic beverages, hygiene and cleaning, cosmetic products and food supplements (box with 10 cans, 200 ml bottle, 250 g can, 10 kg marqueta, etc.). In the case of Pesticides (aqueous suspension, solid, liquid, gas, etc.)

**18) Specific use or process:** Write the number or numbers corresponding to the specific use or process that will be given to the product according to the following list:

1. Obtaining, 2. Elaboration, 3. Preparation, 4. Manufacture, 5. Formulation, 6. Mixed, 7. Packaging, 8. Conservation, 9. Conditioning, 10. Storage, 11. Handling, 12. Distribution, 13. Transportation, 14. Sale or marketing, 15. Maquila, 16. Donations, 17. Analysis or laboratory tests, 18. Scientific research, in laboratory or experimentation, 19. Sample, 20. Promotion, 21. Projects, 22. Transfer, 23. Direct use or application 24. Personal use or consumption, 25. Medical use and 26. Return

Indicate as many uses or processes as required, according to the type of application and product (for example, preparation and packaging).

**19) Key of the lot(s):** Number or key that the lots have.

**20) Indications for use:** The action of the product for herbal remedies and/or medical devices.

**21) Concentration:** Write the concentration of the product in percentage.

**22) Therapeutic indications:** The action of the drug.

**23) Date of manufacture:** Date on which the product was manufactured, starting with the day, month and year.

**24) Expiration date:** Date on which the product will expire, starting with the day, month and year.

**25) Storage temperature:** Specify the product storage temperature in °C.

**26) Transport temperature:** Specify the transport temperature of the product in °C.

**27) Means of transport or entry customs:** Specify the means of transport or entry customs in the case of visits and permission to release and sampling of psychotropic and narcotic drugs.

**28) Identification of containers:** Write the number or numbers of the containers in which the product is transported.

**29) Primary packaging:** Material from which the packaging that is in direct contact with the product is made, as well as its specifications and ability.

**30) Secondary packaging:** Material with which the container is made, which may contain one or more containers, as well as its specifications and ability.

**31) Type of packaging and number of packaging units:** Specify the type of packaging (containers, boxes, etc.) and number of packaging units. packaging.



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C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**32) Item number:** Indicate the corresponding item number.

**33) Key to the basic chart or catalog of the health sector (CBSS):** Key to the basic chart or catalog of the health sector to which the product. (Only applies to medical devices)

**34) Presentation intended for:** Check according to the corresponding presentation for your sale of the product (Health sector only applies to registration of medical devices).

» Export » " Health sector
Generic " Sale

**35) Manufacture of the product:** Check if the declared product is of national or foreign manufacture.

**36) Unit of measure of application of the TIGIE (UMT):** Key corresponding to the unit of measure of application of the TIGIE (Ley de los Impuestos Generales de Importación y Exportación), in accordance with Appendix 7 of Annex 22 of the rules of character General in Foreign Trade Matters, in force.

**37) Quantity of unit of measure of application of the TIGIE:** Quantity corresponding to the unit of measure of the TIGIE (Ley de los Impuestos Generales de Importación y Exportación), in accordance with Appendix 7 of Annex 22 of the General rules in Foreign Trade Matter, in force. In the case of internal transit operations, this field will be left empty.

**38) Type of genetically modified organism (GMO) only one product per request:** Select the number corresponding to the type of GMOs:

1. Those intended for human use or consumption, including grains; 2. Those intended for the processing of food for human consumption; 3. Those that have public health purposes; 4. Those intended for bioremediation;

(GMOs for human use or consumption are also considered those that are for animal consumption and that can be consumed directly by humans (Genetically Modified Organisms Biosafety Law, Article 91))

**39) IMMEX program number (only for companies that are within the program for the manufacturing, maquiladora and export services industry):** Number assigned by the Ministry of Economy corresponding to the program number for the manufacturing, maquiladora and export services industry. export.

## 5.A. Product or service classification

Consult the following classification of the product or service and choose the product for which you are going to carry out the procedure; Use this information to fill out section 5, fields 1 and 2 of the form.

**1) Medicines / drug:**

I. Allopathic
II. Homeopathic
III. herbalists
IV. vitamin

**2) Medical devices (Article 262 section I to VI of the General Health Law and Article 83 of the Health Supplies Regulations):** IV. Supplies for dental use V. Surgical and healing materials VI. Hygienic products **3) Herbal remedies:** The preparation of medicinal plants, or their parts, individual or combined, and their derivatives, presented in pharmaceutical form, to which it is attributed by popular or traditional knowledge, the relief of some participating or isolated symptoms of a disease.

I. Medical equipment or instruments
II. Prosthesis, orthosis and functional aids
III. diagnostic agents

**4) Biological:** Article 229 of the General Health Law.

I. Toxoids, vaccines and bacterial preparations for parenteral use II. Viral vaccines for oral or parenteral use III. Sera and antitoxins of animal origin IV. blood products

V. Vaccines and microbial preparations for oral use VI. Biological materials for diagnosis that are administered to the patient;

VII. antibiotics

VIII. Macromolecular hormones and enzymes IX. Health Supplies Class I X. Class II Health Supplies

XI. Class III Health Supplies

**5) Narcotics:** Specify the drug (refer to chapter V article 234 of the General Health Law and annexes).

**6) Psychotropic:** Specify psychotropic (refer to chapter VI article 245 of the General Health Law and annexes).



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C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**7) Chemical precursors:** Specify chemical precursor (refer to the Federal Law for the Control of Chemical Precursors, Chemical Products Essentials and Machines to Manufacture Capsules, Tablets and/or Tablets)

**8) Food:** Any substance or product, solid or semi-solid, natural or transformed, that provides the organism with elements for its nutrition. And its additives.

**9) Bivalve molluscs:** clams, oysters, mussels.

**10) Non-alcoholic beverages:** Any liquid, natural or processed, that provides the body with elements for its nutrition.

**11) Alcoholic beverages:** Alcoholic beverages are considered to be those that contain ethyl alcohol in a proportion of 2% and up to 55% by volume. Any other containing a higher proportion may not be marketed as a beverage (article 217 of the General Health Law).

**12) Cleaning and cleaning:**

I. Soaps II. Detergents III. Cleaners IV. bleaches V. Starches for external use SAW. disassemblers VII. Disinfectants VIII. Deodorants and air fresheners **13) Cosmetic products:**

According to article 269 of the General Health Law.

**14) Food supplements:** Any herbal product, plant extracts, traditional foods, dehydrated or fruit concentrates, with or without added vitamins or minerals, which can be presented in pharmaceutical form and whose purpose of use is to increase dietary intake total, complement it or replace any of its components.

**15) Pesticides:**

I. Chemicals II. Biochemists III. Microbials IV. Botanicals V. Miscellaneous **16)**

**Plant Nutrients:**

I. Fertilizers II. growth regulators III. Inoculantes IV. Soil improvers V. Soil humectant

**17) Sources of radiation (diagnosis):** Services of conventional radiography, fluoroscope, mammography, tomography, dental panoramic or hemodynamics.

**18) Toxic or dangerous substances:**

I. Basic organic chemist II. Basic inorganic chemical **19) Genetically**

**modified organisms:** Specify the living organism, with the exception of human beings, that has acquired a novel genetic combination generated through the specific use of modern biotechnology techniques.

## 6. Information for certificates

**Use of the certificate (for export, registration, extension and others):** Write down the final use that will be given to the requested certificate. (Example: For export, for registration or registration extension purposes and others)
**Country of destination:** In the case of an export certificate at the request of the interested party, indicate the name of the country that requires the certificate in question.
**Specify characteristics:** At the request of the interested party, indicate when applying the characteristics and information that the requested certificate must contain. (Example: For export to the European Union, specify if they are from aquaculture or fishing).

***Note:*** For certificates of good manufacturing practices at the request of the interested party, indicate when it applies for registration of medical devices or tenders.

## 7. Information for research protocol

**Select if the protocol is "New" or "Modification or Amendment".**
**Protocol title:** Full name without keys or abbreviations of the title of the protocol to be investigated.
**Route of administration (medications or medical devices):**
» For medications: Oral, intravenous, intramuscular, etc. according to your presentation.
» For medical devices: implantable products, topical use, mucosa, etc.
**Name of the principal investigator:** Full name with title without abbreviations of the investigator in charge.



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contacto@cofepris.gob.mx

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**Name(s) of the institution(s) where the research will be carried out:** Full name without abbreviations of the institution(s) that will carry out the research.

## 8. Information for the sanitary registration of health supplies

### 8.A. For manufactured product

#### Physical person

**Natural person:** It is an individual with the capacity to contract obligations and exercise rights.
**RFC:** ( ) **:** Federal Taxpayer Registry under which the person who made up the product is registered with the Ministry of Finance and Public Credit (SHyCP).

**CURP (optional):** Unique Population Registry Code.
**Name(s):** Full name without abbreviations of the national or foreign maquiladora.
**First surname:** Full first surname without abbreviations of the national or foreign maquiladora.
**Second surname:** Complete second surname without abbreviations of the national or foreign maquiladora. (a) Only when the establishment is national.

#### Moral person

**Moral person:** It is a group of people who come together for a specific purpose, for example, a commercial company, a civil association.
**RFC:** ( ) **:** The Federal Taxpayer Registry under which the establishment that manufactured the product is registered with the Ministry of Finance and Public Credit (SHyCP). **Name or company name:** Full name without abbreviations of the
national or foreign maquiladora. (a) Only when the establishment is national.

#### Data of the health manager

**RFC:** The Federal Taxpayer Registry under which it is registered with the Ministry of Finance and Public Credit (SHyCP).
**CURP (optional):** Unique Population Registry Code, only for natural persons.
**Name(s):** Full name without abbreviations of the health manager.
**First surname:** Full first surname without abbreviations of the healthcare manager.
**Second last name:** Full second last name without abbreviations of the health manager.
**Call, Telephone and Extension:** Telephone number(s), including call code. Example: Lada: 01 (55)

Telephone: 57 31 49 52

Extension (when applicable): 1494

**Email:** Email address in lower case and without leaving blank spaces of the maquiladora or legal representative or health officer.

**Stage of the manufacturing process:** Write down the manufacturing stages that were assembled (Formulation, conditioning, mixing, packaging, etc.)
**Sanitary license number or notice of operation:** The number of the sanitary license (only for medicines) or indicate if an operating notice was presented.

#### Address for manufactured product

**Postal code:** Full number of the postal code that corresponds to the address where the establishment that manufactured the product is located.

**Type and name of road:** Type and full name without abbreviations of (the) Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others where the address of the establishment that manufactured the product is located, for example: Avenida Periférico, Closed to San Ignacio, Picacho Ajusco Highway.

**Exterior number:** Indicate the exterior number that corresponds to the address where the establishment that manufactured the product is located.
**Internal number:** If you have an internal number or letter that corresponds to the address where the establishment that manufactured the product is located, also write it down.

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**Type and name of the colony or human settlement:** Type and full name without abbreviations of the colony, condominium, farm, ranch, subdivision, section, sector, among others where the address of the establishment that manufactured the product is located. Example: Nápoles, Rancho las Américas.

**Town:** Town that corresponds to the address where the establishment that manufactured the product is located (when applicable).
**Municipality or mayor's office:** Full name without abbreviations of the political delegation or municipality, which corresponds to the address where the establishment that manufactured the product is located.
**Federal Entity: Federal entity** where the address of the establishment that manufactured the product is located. For example: Mexico City, Baja California, State of Mexico.

**Between road and road (type and name):** Between which avenue, boulevard, street, highway, road, private, dirt road, among others, where the address of the establishment that manufactured the product is located, for example: Avenida Periférico, Cerrada de San Ignacio , Picacho Ajusco Highway.
**Subsequent roads (type and name):** Avenue, Boulevard, Street, Highway, Road, Private, Terracería, among others after where the address of the establishment that manufactured the product is located, for example: Avenida Periférico, Cerrada de San Ignacio, Highway Picacho Ajusco.

## 8.B. Data from the manufacturer abroad for imported or national products

### Physical person

**Natural person:** It is an individual with the capacity to contract obligations and exercise rights.
**RFC:** ( ) **:** Federal Taxpayer Registry under which the manufacturer is registered with the Ministry of Finance and Public Credit (SHyCP).
**CURP (optional):** Unique Population Registry Code. only for natural persons.
**Name(s):** Full name without abbreviations of the manufacturer abroad for imported products.
**First surname:** Full first surname without abbreviations of the manufacturer abroad for imported products.
**Second last name:** Full second last name without abbreviations of the manufacturer abroad for imported products. (a) Only when the establishment is national.

### Moral person

**Moral person:** It is a group of people who come together for a specific purpose, for example, a commercial company, a civil association.
**RFC:** ( ) **:** The Federal Taxpayer Registry under which the manufacturer's establishment is registered with the Ministry of Finance and Public Credit (SHyCP).

**Name or business name:** Full name without abbreviations of the manufacturer's establishment abroad for imported products. (a) Only when the establishment is national.

### Address of the manufacturer abroad for imported or national products

**Postal code:** Complete number of the postal code that corresponds to the address where the manufacturer's establishment is located abroad for imported products.

**Type and name of road:** Type and full name without abbreviations of (the) Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others where the address of the manufacturer's establishment is located abroad for imported products, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway.

**Exterior number:** Indicate the exterior number that corresponds to the address where the manufacturer's establishment is located abroad for imported products.

**Internal number:** In case of having an internal number or letter that corresponds to the address where the manufacturer's establishment is located abroad for imported products, also write it down.
**Type and name of the colony or human settlement:** Type and full name without abbreviations of the colony, condominium, farm, ranch, subdivision, section, sector, among others where the domicile of the manufacturer's establishment is located abroad for import products, For example: Nápoles, Rancho las Américas.

**City:** City that corresponds to the domicile where the manufacturer's establishment is located abroad for imported products (when applicable).

**Municipality or mayoralty:** Full name without abbreviations of the political delegation or municipality, which corresponds to the address where the manufacturer's establishment is located abroad for imported products.
**Federal Entity: Federal entity** where the domicile of the manufacturer's establishment abroad for imported products is located. For example: Mexico City, Baja California, State of Mexico.

**Country:** Full country name without abbreviations where the manufacturer's establishment abroad for imported products is located.

**Between road and road (type and name):** Between which avenue, boulevard, street, road, road, private, dirt road, among others where the address of the manufacturer's establishment abroad for imported products is located, for example: Avenida Periférico , San Ignacio Closed, Picacho Ajusco Highway.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**Subsequent roads (type and name):** Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others after where the domicile of the manufacturer's establishment is located abroad for imported products, for example: Avenida Periférico, Closed from San Ignacio, Picacho Ajusco Highway.

## 8.C. Supplier or distributor data (for health supplies)

### Physical person

**Natural person:** It is an individual with the capacity to contract obligations and exercise rights.
**RFC:** ( ) **:** Federal Taxpayer Registry under which the provider or distributor is registered with the Ministry of Finance and Public Credit (SHyCP).

**CURP (optional):** Unique Population Registry Code. only for natural persons.
**Name(s):** Full name without abbreviations of the supplier or distributor.
**First surname:** Full first surname without abbreviations of the supplier or distributor.
**Second last name:** Full second last name without abbreviations of the supplier or distributor. (a) Only when the establishment is national.

### Moral person

**Moral person:** It is a group of people who come together for a specific purpose, for example, a commercial company, a civil association.
**RFC:** ( ) **:** The Federal Taxpayer Registry under which the establishment of the supplier or distributor is registered before the Ministry of Finance and Public Credit (SHyCP).

**Name or business name:** Full name without abbreviations of the supplier or distributor establishment. (a) Only when the establishment is national.

### Address of the supplier or distributor (for health supplies)

**ZIP Code:** ( ) **:** Complete number of the postal code that corresponds to the address where the establishment of the supplier or distributor is located.

**Type and name of road:** Type and full name without abbreviations of (the) Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others where the address of the supplier or distributor establishment is located, for example: Avenida Periférico, Closed to San Ignacio, Picacho Ajusco Highway.

**Exterior number:** Indicate the exterior number that corresponds to the address where the establishment of the supplier or distributor is located.
**Internal number:** If you have an internal number or letter that corresponds to the address where the supplier or distributor's establishment is located, also write it down.

**Type and name of the colony or human settlement:** Type and full name without abbreviations of the colony, condominium, farm, ranch, subdivision, section, sector, among others where the domicile of the supplier or distributor establishment is located. Example: Nápoles, Rancho las Américas.

**Town:** Town that corresponds to the address where the establishment of the supplier or distributor is located (when applicable).
**Municipality or delegation:** ( ) **:** Full name without abbreviations of the political delegation or municipality, which corresponds to the address where the establishment of the supplier or distributor is located.
**Federal Entity:** ( ) **:** Federal entity where the domicile of the supplier or distributor is located. For example: Mexico City, Baja California, State of Mexico.

**Between road AND road (type and name):** Between which avenue, boulevard, street, highway, road, private, dirt road, among others where the address of the supplier or distributor establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway.
**Subsequent roads (type and name):** Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others after where the address of the supplier or distributor establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Carretera Picacho I adjust. (a) Only when the establishment is national.

## 8.D. Data of the establishment that will condition or store the health supplies

### Physical person

**Natural person:** It is an individual with the capacity to contract obligations and exercise rights.
**RFC:** ( ) **:** Federal Taxpayer Registry under which the person who will condition or store health supplies is registered with the Ministry of Finance and Public Credit (SHyCP).

**CURP (optional):** Unique Population Registry Code. only for natural persons.

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**Name(s):** Full name without abbreviations of the person who will condition or store the health supplies.
**First surname:** Full first surname without abbreviations of the person who will condition or store the health supplies.
**Second surname:** Complete second surname without abbreviations of the person who will condition or store the health supplies. (a) Only when the establishment is national.

Moral person

**Moral person:** It is a group of people who come together for a specific purpose, for example, a commercial company, a civil association.
**RFC:** ( ) **:** The Federal Taxpayer Registry under which the establishment that will condition or store the health supplies is registered with the Ministry of Finance and Public Credit (SHyCP).

**Name or company name:** Full name without abbreviations of the establishment that will condition or store the health supplies. (a) Only when the establishment is national.

Address of the establishment that will condition or store the health supplies

**Postal code:** Full number of the postal code that corresponds to the address where the establishment that will condition or store the health supplies is located.

**Type and name of road:** Type and full name without abbreviations of (the) Avenue, Boulevard, Street, Highway, Road, Private, Terracería, among others where the address of the establishment that will condition or store the health supplies is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway.

**Exterior number:** Indicate the exterior number that corresponds to the address where the establishment that will condition or store the health supplies is located.

**Internal number:** If there is an internal number or letter that corresponds to the address where the establishment that will condition or store the health supplies is located, also write it down.

**Type and name of the colony or human settlement:** Type and full name without abbreviations of the colony, condominium, farm, ranch, subdivision, section, sector, among others, where the address of the establishment that will condition or store the supplies is located. for health, For example: Nápoles, Rancho las Américas.

**Town:** Town that corresponds to the address where the establishment that will condition or store the health supplies is located (when applicable).

**Municipality or delegation:** ( ) **:** Full name without abbreviations of the political delegation or municipality, which corresponds to the address where the establishment that will condition or store the health supplies is located.
**Federal Entity:** ( ) **:** Federal entity where the address of the establishment that will condition or store the health supplies is located. For example: Mexico City, Baja California, State of Mexico.
**Between road AND road (type and name):** Between which avenue, boulevard, street, highway, road, private, dirt road, among others where the address of the establishment that will condition or store health supplies is located, for example: Avenida Periférico , San Ignacio Closed, Picacho Ajusco Highway.

**Rear road (type and name):** Avenue, Boulevard, Street, Highway, Road, Private, Terracería, among others after where the address of the establishment that will condition or store the health supplies is located, for example: Avenida Periférico, Closed from San Ignacio, Picacho Ajusco Highway. (a) Only when the establishment is national.

9. Information for import, export and other authorizations

**Import regime (only for importers):** Select the type of import regime (only for imports) "Temporary", "Definitive" or "Fiscal deposit"

**Country of origin:** Indicate the name of the country where the product was manufactured (only for imports).
**Country of origin:** Indicate the name of the country where the product comes from (only for imports).
**Country of destination:** Indicate the name of the country of destination for export.
**Customs office of entry or exit (Specify only one):** Indicate only one customs office of entry or exit of the product (import / export).

» In the case of chemical and psychotropic precursors, the authorized customs offices are: Mexico City International Airport; veracruz, Veracruz; Manzanillo, Colima; and Nuevo Laredo, Tamaulipas.
» For pseudoephedrine, the authorized customs offices are: Mexico City International Airport; Veracruz, Veracruz; Manzanillo, Colima.
» For narcotics, the authorized customs offices are: Mexico City International Airport.

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## 9.A. Manufacturer information

### Physical person

**Natural person:** It is an individual with the capacity to contract obligations and exercise rights.
**RFC:** ( ) **:** Federal Taxpayer Registry under which the manufacturer is registered with the Ministry of Finance and Public Credit (SHyCP).
**CURP (optional):** Unique Population Registry Code. only for natural persons.
**Name(s):** Full name without abbreviations of the manufacturer.
**First surname:** Full first surname without manufacturer's abbreviations.
**Second surname:** Full second surname without manufacturer's abbreviations. (a) Only when the establishment is national.

### Moral person

**Moral person:** It is a group of people who come together for a specific purpose, for example, a commercial company, a civil association.
**RFC:** ( ) **:** The Federal Taxpayer Registry under which the manufacturer is registered with the Ministry of Finance and Public Credit (SHyCP).
**Name or business name:** Full name without abbreviations of the manufacturer's establishment. (a) Only when the establishment is national.

### Manufacturer's address

**Postal code:** Full number of the postal code that corresponds to the address where the manufacturer's establishment is located.
**Type and name of road:** Type and full name without abbreviations of (the) Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others where the address of the manufacturer's establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway.

**Exterior number:** Indicate the exterior number that corresponds to the address where the manufacturer's establishment is located.
**Internal number:** If you have an internal number or letter that corresponds to the address where the manufacturer's establishment is located, also write it down.

**Type and name of the neighborhood or human settlement:** Type and full name without abbreviations of the neighborhood, condominium, farm, ranch, subdivision, section, sector, among others where the address of the manufacturer's establishment is located, for example: Naples, Ranch the Americas.
**Town:** Town that corresponds to the address where the manufacturer's establishment is located (when applicable).
**Municipality or delegation:** ( ) **:** Full name without abbreviations of the political delegation or municipality, which corresponds to the address where the manufacturer's establishment is located.
**Federal entity:** ( ) **:** Federal entity where the domicile of the manufacturer's establishment is located. For example: Mexico City, Baja California, State of Mexico.

**Country:** Full country name without abbreviations where the manufacturer's establishment is located.
**Between road and road (type and name):** Between which avenue, boulevard, street, highway, road, private, dirt road, among others where the address of the manufacturer's establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, highway Picacho Adjust.
**Later road (type and name):** Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others after where the address of the manufacturer's establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway .

## 9.B. Supplier or distributor data

### Physical person

**Natural person:** It is an individual with the capacity to contract obligations and exercise rights.
**RFC:** ( ) **:** Federal Taxpayer Registry under which the provider or distributor is registered with the Ministry of Finance and Public Credit (SHyCP).

**CURP (optional):** Unique Population Registry Code. only for natural persons.
**Name(s):** Full name without abbreviations of the supplier or distributor.
**First surname:** Full first surname without abbreviations of the supplier or distributor.
**Second last name:** Full second last name without abbreviations of the supplier or distributor. (a) Only when the establishment is national.

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Moral person

**Moral person:** It is a group of people who come together for a specific purpose, for example, a commercial company, a civil association.
**RFC:** ( ) **:** The Federal Taxpayer Registry under which the supplier or distributor is registered with the Ministry of Finance and Public Credit (SHyCP).

**Name or business name:** Full name without abbreviations of the supplier or distributor establishment. (a) Only when the establishment is national.

Address of the supplier or distributor

**Postal code:** Full number of the postal code that corresponds to the address where the establishment of the supplier or distributor is located.

**Type and name of road:** Type and full name without abbreviations of (the) Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others where the address of the supplier or distributor establishment is located, for example: Avenida Periférico, Closed to San Ignacio, Picacho Ajusco Highway.

**Exterior number:** Indicate the exterior number that corresponds to the address where the establishment of the supplier or distributor is located.
**Internal number:** If you have an internal number or letter that corresponds to the address where the supplier or distributor's establishment is located, also write it down.

**Type and name of the colony or human settlement:** Type and full name without abbreviations of the colony, condominium, farm, ranch, subdivision, section, sector, among others where the domicile of the supplier or distributor establishment is located. Example: Nápoles, Rancho las Américas.

**Town:** Town that corresponds to the address where the establishment of the supplier or distributor is located (when applicable).
**Municipality or delegation:** ( ) **:** Full name without abbreviations of the political delegation or municipality, which corresponds to the address where the establishment of the supplier or distributor is located.
**Federal Entity:** ( ) **:** Federal entity where the domicile of the establishment of the supplier or distributor is located. For example: Mexico City, Baja California, State of Mexico.

**Country:** Name of the full country without abbreviations where the establishment of the supplier or distributor is located.
**Between road AND road (type and name):** Between which avenue, boulevard, street, highway, road, private, dirt road, among others where the address of the supplier or distributor's establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway.
**Subsequent roads (type and name):** Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others after where the address of the supplier or distributor's establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Highway Picacho Ajusco.
(a) Only when the establishment is national.

9.C. Recipient details (final destination)

Physical person

**Natural person:** It is an individual with the capacity to contract obligations and exercise rights.
**RFC:** Federal Taxpayer Registry under which the recipient (final destination) is registered with the Ministry of Finance and Public Credit (SHyCP).

**CURP (optional):** Unique Population Registry Code. only for natural persons.
**Name(s):** Full name without abbreviations of the recipient (final destination).
**First surname:** Full first surname without abbreviations of the recipient (final destination).
**Second surname:** Second full surname without abbreviations of the recipient (final destination). (a) Only when the establishment is national.

Moral person

**Moral person:** It is a group of people who come together for a specific purpose, for example, a commercial company, a civil association.
**RFC:** The Federal Taxpayer Registry under which the recipient (final destination) is registered with the Ministry of Finance and Public Credit (SHyCP).

**Name or business name:** Full name without abbreviations of the recipient's establishment (final destination).
(a) Only when the establishment is national.

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Recipient address (final destination)

**Postal code:** Full number of the postal code that corresponds to the address where the recipient's establishment is located (final destination).

**Type and name of road:** Type and full name without abbreviations of (the) Avenue, Boulevard, Street, Highway, Road, Private, Terracería, among others where the address of the recipient's establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway.

**Exterior number:** Indicate the exterior number that corresponds to the address where the recipient's establishment is located (final destination).

**Internal number:** If you have an internal number or letter that corresponds to the address where the recipient's establishment (final destination) is located, also write it down.
**Type and name of the colony or human settlement:** Type and full name without abbreviations of the colony, condominium, farm, ranch, subdivision, section, sector, among others where the address of the recipient's establishment is located, For example: Naples, Rancho las Americas.

**Town:** Town that corresponds to the address where the recipient's establishment (final destination) is located (when applicable).
**Municipality or delegation:** (:)Full name without abbreviations of the political delegation or municipality, which corresponds to the address where the recipient's establishment is located (final destination).
**Federal Entity:** ( ) **:** Federal entity where the address of the establishment of the recipient is located (final destination). For example: Mexico City, Baja California, State of Mexico.
**Country:** Full country name without abbreviations where the recipient's establishment (final destination) is located.
**Between road AND road (type and name):** Between which Avenue, Boulevard, Street, Highway, Road, Private, Terracería, among others where the address of the recipient's establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Highway Picacho Ajusco.
**Subsequent road (type and name):** Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others after where the address of the recipient's establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway . (a) Only when the establishment is national.

9.D. Data of the invoicer

Physical person

**Natural person:** It is an individual with the capacity to contract obligations and exercise rights.
**RFC:** Federal Taxpayer Registry under which the invoicer is registered with the Ministry of Finance and Public Credit (SHyCP).
**CURP (optional):** Unique Population Registry Code. only for natural persons.
**Name(s):** Full name without abbreviations of the biller.
**First Last Name:** Full first last name without biller abbreviations.
**Second last name:** Full second last name without biller abbreviations. (a) Only when the establishment is national.

Moral person

**Moral person:** It is a group of people who come together for a specific purpose, for example, a commercial company, a civil association.
**RFC:** The Federal Taxpayer Registry under which the invoicer is registered with the Ministry of Finance and Public Credit (SHyCP).
**Name or company name:** Full name without abbreviations of the billing establishment. (a) Only when the establishment is national.

Biller's address

**ZIP Code:** Full number of the ZIP code that corresponds to the address where the biller's establishment is located.
**Type and name of road:** Type and full name without abbreviations of (the) Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others where the address of the biller's establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway.

**Exterior number:** Indicate the exterior number that corresponds to the address where the biller's establishment is located.
**Internal number:** If you have an internal number or letter that corresponds to the address where the biller's establishment is located, also write it down.

**Type and name of the neighborhood or human settlement:** Type and full name without abbreviations of the neighborhood, condominium, farm, ranch, fractionation, section, sector, among others where the address of the billing establishment is located, For example: Naples, Rancho las Americas.

**Town:** Town that corresponds to the address where the biller's establishment is located (when applicable).

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**Municipality or mayor's office:** Full name without abbreviations of the political delegation or municipality, which corresponds to the address where the biller's establishment is located.

**Federal Entity: Federal entity** where the biller's domicile is located. For example: Mexico City, Baja California, State of Mexico.

**Country:** Full country name without abbreviations where the billing establishment is located.
**Between road AND road (type and name):** Between which Avenue, Boulevard, Street, Highway, Road, Private, Terracería, among others where the address of the biller's establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Highway Picacho Ajusco.
**Subsequent roads (type and name):** Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others after where the address of the billing establishment is located, for example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway . (a) Only when the establishment is national.

## 10. Information for the authorization of third parties

### 10.A. Test laboratory

**Check the type of service you intend to provide:** In the field labeled Other (specify) you must write down the area in which you are requesting authorization.

» Analysis of food, beverages and nutritional supplements and perfumery and beauty products.
» Analysis of drugs and medical devices » Analysis of pesticides,
fertilizers and plant nutrients » Other (specify)

### 10.B. verification units

**Check the type of service you intend to provide:** In the field labeled Other (specify) you must write down the area in which you are requesting authorization.

» Verification of establishments
» Sampling
" Other (specify)

### 10.C. Interchangeability tests for interchangeable generic drugs

**Check the type of service you intend to provide:**
» Clinical unit to carry out bioavailability and/or bioequivalence studies
» Analytical unit to perform bioavailability and/or bioequivalence studies
» Analytical unit for studies of dissolution profiles

## 11. Data of the person who performs tattoos, micropigmentation and/or piercings

### Physical person

**Natural person:** It is an individual with the capacity to contract obligations and exercise rights.
**RFC:** The Federal Taxpayer Registry under which the person who performs tattoos, micropigmentation and/or piercings is registered before the Ministry of Finance and Public Credit (SHyCP).

**CURP (optional):** Unique Population Registry Code, only for natural persons.
**Name(s):** Full name without abbreviations under which the person who performs tattoos, micropigmentation and/or piercings is registered before the Ministry of Finance and Public Credit (SHyCP).
**First surname:** Full first surname without abbreviations under which the person who performs tattoos, micropigmentation and/or piercings is registered before the Ministry of Finance and Public Credit (SHyCP).
**Second last name:** Full second last name without abbreviations under which the person who performs tattoos, micropigmentation and/or piercings is registered before the Ministry of Finance and Public Credit (SHyCP).
**Call, Telephone and Extension:** Telephone number(s), including call code. Example: Lada: 01 (55)

Telephone: 57 31 49 52
Extension (when applicable): 1494

**Email:** Email address in lower case and without leaving blank spaces of the person who performs tattoos, micropigmentation and/or piercings.

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**Hours of Operation:** Mark the days of the week that the person who performs tattoos, micropigmentation and/or piercings will be at the establishment and write the opening and closing hours for the public. Example:

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| D **XXXXX** S of | | | | | | | | **09:00** HH:MM | a | **19:00** HH:MM |
| DLMMJV **X** de | | | | | | | | **09:00** HH:MM | a | **14:00** HH:MM |

**In case of extension, indicate the number of the sanitary control card:** Complete number of the sanitary control card which is going to be extended.

**Photo:** Paste a photograph of the person who will carry out tattoos, micropigmentation and/or perforations in the original format.

Private address of the person who performs tattoos, micropigmentation and/or piercings

**Postal code:** Complete number of the postal code that corresponds to the private address of the person who performs tattoos, micropigmentation and/or piercings.

**Type and name of road:** Type and full name without abbreviations of (the) Avenue, Boulevard, Street, Highway, Road, Private, Dirt Road, among others where the private address of the person who performs tattoos, micropigmentation and/or piercings is located For example: Avenida Periférico, Cerrada de San Ignacio, Picacho Ajusco Highway.
**Exterior number:** Indicate the exterior number that corresponds to the private address of the person who performs tattoos, micropigmentation and/or piercings.

**Internal number:** If there is an internal number or letter that corresponds to the private address of the person who performs tattoos, micropigmentation and/or piercings, also write it down.
**Type and name of the colony or human settlement:** Type and full name without abbreviations of the colony, condominium, farm, ranch, subdivision, section, sector, among others where the private address of the person making tattoos is located, micropigmentation and/or perforations, For example: Nápoles, Rancho las Américas.

**Town:** Town that corresponds to the private address of the person who performs tattoos, micropigmentation and/or piercings (when applicable).
**Municipality or mayor's office:** Full name without abbreviations of the political delegation or municipality, which corresponds to the private address of the person who performs tattoos, micropigmentation and/or piercings.
**Federal Entity: Federal entity** where the private address of the person who performs tattoos, micropigmentation and/or perforations is located. For example: Mexico City, Baja California, State of Mexico.
**Between road AND road (type and name):** Between which Avenue, Boulevard, Street, Highway, Road, Private, Terracería, among others where the private address of the person who performs tattoos, micropigmentation and/or piercings is located, for example: Periférico Avenue, San Ignacio Closed, Picacho Ajusco Highway.

**Subsequent road (type and name):** Avenue, Boulevard, Street, Highway, Camino, Privada, Dirtroad, among others after where the private address of the person who performs tattoos, micropigmentation and/or piercings is located, for example: Avenida Periférico , San Ignacio Closed, Picacho Ajusco Highway.

I declare under protest to tell the truth that I comply with the applicable requirements and regulations, without exempting me from the health authority verifying their compliance, this without prejudice to the sanctions that I may incur for false statements given to an authority. And I accept that the notification of this procedure is carried out through the Integral Services Center or offices in the states corresponding to the Federal Sanitary System. (Article 35 section II of the Federal Law of Administrative Procedure)

**The data or attachments may contain confidential information, do you agree to make them public?:**

" Yeah
» No

**Full name and autograph signature of the owner or legal representative or health officer:** Full name without abbreviations and autograph signature of the health officer, legal representative or owner (notified before the Federal Commission for the Protection against Sanitary Risks).

For any clarification, doubt and/or comment regarding this procedure, please call the COFEPRIS Call Center, in Mexico City or from anywhere in the country dial toll free at 01-800-033-5050 **and** at If you require the entry and/or tracking number of your procedure sent to the Foreign Processing area, dial toll free at **01-800-420-4224.**



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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# Filling Guide and Documentary Requirements for the Authorizations, Certificates and Visits format

In this document you will find the guide for filling out and documentary requirements that you must submit with your requests for procedures corresponding to authorizations such as: licenses, permits, registrations and other authorizations, as well as requests for certificates and sanitary verification visits.

For each procedure that you carry out, you must submit a duly completed **"Authorizations, Certificates and Visits"** format in accordance with the Quick Fill Guide that appears below, and, if applicable, the technical guides and auxiliary formats for each type of procedure, located at the end of this guide. Also the voucher for "Electronic payment of rights, products and use" scheme e5five in one original and two copies.
A copy will be returned to the user, leaving the original and the other copy in the institution where the procedure is carried out.

**NOTE 1:** You may not be required to present more documentation than that indicated in the requirements, except for those provided for in article 15 of the Federal Law of Administrative Procedure, referring to the accreditation of legal personality.

**NOTE 2:** The documentation must be submitted by the interested party, legal representative or authorized person, in accordance with the provisions of **article 19 of the Federal Law of Administrative Procedure.**

## 1. License application

### 1.1. By high or new

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-05-001-A** | Request for the issuance of a Sanitary License for the Establishment of Health Supplies.<br>Modality A.- Factory or Laboratory of Raw Materials for the Manufacture of Medicines or Biological Products for Human Use. |
| **COFEPRIS-05-001-B** | Request for the issuance of a Sanitary License for the Establishment of Health Supplies.<br>Modality B.- Factory or Laboratory of Medicines or Biological Products, for Human Use. |
| **COFEPRIS-05-001-C** | Application for the issuance of a Sanitary License for the Establishment of Health Supplies.<br>Modality C.- Laboratory of Chemical, Biological, Pharmaceutical or Toxicology Control, for the Study, Experimentation of Medicines and Raw Materials, or Auxiliary of Sanitary Regulation. |
| **COFEPRIS-05-001-D** | Application for the issuance of a Sanitary License for the Establishment of Health Supplies.<br>Modality D.- Medicines or Biological Products Conditioning Warehouse. |
| **COFEPRIS-05-001-E** | Application for the issuance of a Sanitary License for the Establishment of Health Supplies.<br>Modality E.- Warehouse for Deposit and Distribution of Controlled Medications or Biological Products, for Human Use. |
| **COFEPRIS-05-001-F** | Request for the issuance of a Sanitary License for the Establishment of Health Supplies.<br>Modality F.- Mixing Centers for the Preparation of Nutritional and Medication Parenteral Mixtures. |
| **COFEPRIS-05-001-G** | Application for the issuance of a Sanitary License for the Establishment of Health Supplies.<br>Modality G.- Pharmacy or Apothecary or Drugstore (With Sale of Controlled Medications) |
| **COFEPRIS-05-001-H** | Request for the issuance of a Sanitary License for the Establishment of Health Supplies.<br>Modality H.- Drugstore or Homeopathic Pharmacy (With Preparation of Homeoatic Medications) |

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5<br>**{Fields:1 and 2}** |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ In the case of Legal Entities:



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
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contacto@cofepris.gob.mx

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» Original and copy for comparison of the constitutive act or power of attorney that accredits the legal representative.
» Copy of official identification of the legal representative and authorized persons. (Credential of the National Electoral Institute (INE) or current passport or card or driving licence).
" Federal taxpayer registration. ÿ In the case of Individuals:
» Copy of official identification of the legal representative and authorized persons. (INE, current passport or driver's license).
" Federal taxpayer registration.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-05-022-A** Sanitary License Application for Establishment of Pesticides, Plant Nutrients and Toxic or Dangerous Substances.

Modality A.- For Urban Fumigation, Disinfection and Pest Control Services.

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5<br>**{Fields:1 and 2}** |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Blood cholinesterase test of the applicator personnel. (Original) ÿ Plan of the establishment where the areas are specified and the flow of personnel, materials and equipment, the dimensions and boundaries with other properties are identified. ÿ Master plan for pest control. In which the criteria are established to coordinate and carry out a pest control service, as well as to prepare and generate the required documentation in order to guarantee safe, effective and quality services; content: » Objective.

» Reach.
» Responsibilities.
» Document number.
" Revision number.
" Date of implementation.
» Signature, date of the person who prepares, reviews and authorizes.
» Attachments:

ÿ Pests that are controlled indicating common name, scientific name, characteristics and habits. ÿ Sites where pests will be controlled. ÿ Definitions, criteria and design of: • Service contracting sheet. • Order of service.
That includes: Service number, general data of the service contracting party, requested service (pest to be controlled), technical personnel assigned to perform the service, applicable procedure, service start date, dates of the stages that make up the service, end date of service, results obtained, name and signature of the health manager, observations.
• Procedures. That contemplate: Objective, scope, responsibilities, document number, revision number, implementation date, signature and date of the person who prepares, reviews and authorizes, development, bibliography. Attach the specific procedures for: * Site inspection.
* Identification of the pest.
* Implementation of pest control measures and their monitoring.
* Application techniques to be used.
• Protocols and field reports. •
Service sheets for the user on each phase of the service performed. •
Certificate of service. That includes: Name of the company that performs the service, address and telephone numbers, health license number, number of services, controlled pest, pesticides and doses applied, treated area, instructions on what to do in case of emergency, start and end date of the service, signature of the health manager.
ÿ Pesticide application equipment and acquisition criteria, review of operation, operation and performance of the same. ÿ Initial list of pesticides: Trade name, Sanitary Registry number (urban, domestic and gardening), active ingredient, commercial presentation, application technique.
" Bibliography.



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Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-05-022-B** Sanitary License Application for Establishment of Pesticides, Plant Nutrients and Toxic or Dangerous Substances.

Modality B.- For establishment that Manufactures, Formulates, Mixes or Packages Pesticides and/or Vegetable Nutrients

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5** **{Fields:1 and 2}** |

The surveillance program in accordance with the technical guide and auxiliary formats, published on the website

Documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ General plan of the establishment where the different areas, manufacturing equipment and flow of personnel and material are indicated, dimensions, as well as the location sketch of these.

ÿ Training and dissemination program for workers. Indicate topics, duration, staff who will attend. ÿ Safety data sheet of the toxic or dangerous substances that are handled in the establishment. ÿ Employee health surveillance program.

» Characteristics of construction, methods of control of risk factors and environmental conditions of the establishment in its different areas.

» Identification of the risks and health effects of occupationally exposed personnel (POE) generated by chemical, physical and biological agents by production line and/or process area, of the means by which the identified agents can spread and their effects to health.

» Identification of the SOP: Names, positions, process area to which they belong, summary description of the activities of each one associated with a risk factor.

» Identification and programming of medical controls and biological monitoring applicable to POE to monitor the effects on health due to exposure to polluting agents in the work environment.

» Program for monitoring the occupational environment of chemical, physical and/or biological agents that includes laboratory data accredited and authorized that will carry out the corresponding monitoring.

» Preventive measures by production line and/or process area: List the sanitary procedures that the establishment has applicable to this point; describe in detail the characteristics and contribution to the reduction of risks that the engineering of the establishment's facilities, machinery or production equipment, equipment, systems or mechanisms for the control of polluting agents in the work environment has (here describe the systems it has and its characteristics), work clothes and personal protective equipment.

» Include signature and professional license number of the responsible doctor and health responsible.

ÿ List of special constructions (sprinkler systems, smoke detectors, leak detection alarms, capture systems of fumes and vapors).

ÿ Technical information certificate of establishments in accordance with the technical guide and auxiliary formats for the presentation of the Requirements documentaries to the request format: »

Description of the industrial process by production line, with its process flow chart.

» Characteristics of machinery and equipment by production line.

» Raw materials per production line:

- CAS number. ÿ

Common and chemical name. -

Capacity and type of container. ÿ

Monthly consumption or production in Kg, ton, L, m3.

» Products by production line: ÿ Common and chemical name. - Type of container and capacity. ÿ Monthly production in Kg, ton, L, m3. ÿ List of products that require single registration before the Inter-ministerial Commission for the Control of the Process and Use of Pesticides, Fertilizers and Toxic Substances:

- Trade name.

• Common name.



**Contacto:**
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C.P. 03810.
Teléfono 01-800-033-5050
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• Active ingredients. •
Registration number. •
Date of issue and Expiration of the registration.

» Inventory of hazardous substances that generate industrial waste: ÿ CAS number. ÿ Origin and destination of the substance. - Common name. ÿ Raw material. ÿ Product. ÿ CRETIB code. ÿ Solids, liquids, sludges and others. - Final disposition.

» Industrial Waste: ÿ Describe the characteristics of industrial waste. ÿ Quantities, daily average. ÿ Describe the treatments for discharge or final disposal. ÿ Periodicity of downloads and dispositions.

| homoclave | Name, modality and quick filling guide |
|---|---|

**COFEPRIS-05-022-C** Sanitary License Application for Establishment of Pesticides, Plant Nutrients and Toxic or Dangerous Substances.

Modality C.- For Establishment that Manufactures Toxic or Dangerous Substances.

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 **{Fields:1 and 2}** |

The surveillance program in accordance with the technical guide and auxiliary formats, published on the website

Documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ General plan of the establishment where the different areas, manufacturing equipment and flow of personnel and materials are indicated, dimensions, as well as the location sketch of these.

ÿ Training and dissemination program for workers. Indicate topics, duration, staff who will attend. ÿ Safety data sheet of the toxic or dangerous substances that are handled in the establishment. ÿ Employee health surveillance program. According to the technical guide and auxiliary formats for the presentation of the Documentary requirements for the application format.

» Characteristics of construction, methods of control of risk factors and environmental conditions of the establishment in its different areas.

» Identification of the risks and health effects of occupationally exposed personnel (POE) generated by chemical, physical and biological agents by production line and/or process area, the means by which the identified agents can spread and their effects on health. Identification of the POE: Names, positions, process area to which they belong, summary description of the activities of each one associated with a risk factor.

» Identification and programming of medical controls and biological monitoring applicable to POE to monitor the effects on health due to exposure to polluting agents in the work environment.

» Program for monitoring the occupational environment of chemical, physical and/or biological agents that includes laboratory data accredited and authorized that will carry out the corresponding monitoring.

» Preventive measures by production line and/or process area: List the sanitary procedures that the establishment has applicable to this point, describe in detail the characteristics and contribution to risk reduction that the engineering of the establishment's facilities has, production machinery or equipment, equipment, systems or mechanisms for the control of polluting agents in the work environment (here describe the systems available and their characteristics), work clothes and personal protective equipment.

» Include signature and professional license number of the responsible doctor and health responsible.

ÿ List of special constructions (sprinkler systems, smoke detectors, leak detection alarms).

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ÿ Technical information card for establishments, in accordance with the technical guide and auxiliary formats for the presentation of the Requirements documentaries to the application format.

» Description of the industrial process by production line, with its process flow diagram.
» Characteristics of machinery and equipment by production line.
» Raw materials per production line:
- CAS number. ÿ Common and chemical name. - Capacity and type of container. ÿ Presentation (liquid, solid, gas) and type of formulation (only pesticides). ÿ Monthly consumption or production in Kg, ton, L, m3.
» Products by production line: ÿ Common and chemical name. - Type of container and capacity. ÿ Monthly production in Kg, ton, L, m3.
» List of products that require a single registration before the Intersecretarial Commission for the Control of the Process and Use of Pesticides, Fertilizers and Toxic Substances: ÿ Trade name. - Common name. - Active ingredients. - Registration number. - Issue date. ÿ Expiration.

» Inventory of hazardous substances that generate industrial waste:
ÿ CAS number.
ÿ Origin and destination of the substance. - Common name. ÿ Raw material. ÿ Product.

ÿ CRETIB code. ÿ Solids, liquids, sludges and others. ÿ Treatment. - Final disposition.

" Industrial waste:
ÿ Describe the characteristics of industrial waste. ÿ Quantities, daily average.
ÿ Describe the treatments for discharge or final disposal. ÿ Periodicity of downloads and dispositions.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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1.2. by modification

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-05-002-A** | Request for Modification of the Sanitary License for the Establishment of Health Supplies.<br>Modality A - Factory or Laboratory of Raw Materials for the Manufacture of Medicines or Biological Products for Human Use. |
| **COFEPRIS-05-002-B** | Request for Modification of the Sanitary License for the Establishment of Health Supplies.<br>Modality B - Factory or Laboratory of Medicines or Biological Products, for Human Use. |
| **COFEPRIS-05-002-C** | Request for Modification of the Sanitary License for the Establishment of Health Supplies.<br>Modality C - Laboratory of Chemical, Biological, Pharmaceutical or Toxicology Control, for the Study, Experimentation of Medicines and Raw Materials, or Auxiliary of Sanitary Regulation |
| **COFEPRIS-05-002-D** | Request for Modification of the Sanitary License for the Establishment of Health Supplies.<br>Modality D - Medicines or Biological Products Conditioning Warehouse. |
| **COFEPRIS-05-002-E** | Request for Modification of the Sanitary License for the Establishment of Health Supplies.<br>Modality E - Warehouse for Deposit and Distribution of Controlled Medications or Biological Products, for Human Use. |
| **COFEPRIS-05-002-F** | Request for Modification of the Sanitary License for the Establishment of Health Supplies.<br>Modality F - Mixing Centers for the Preparation of Nutritional and Medication Parenteral Mixtures. |
| **COFEPRIS-05-002-G** | Request for Modification of the Sanitary License for the Establishment of Health Supplies.<br>Modality G - Pharmacy or Apothecary (With Sale of Controlled Medications) |
| **COFEPRIS-05-002-H** | Request for Modification of the Sanitary License for the Establishment of Health Supplies.<br>Modality H - Drugstore or Homeopathic Pharmacy (With Preparation of Homeoatic Medications) |

| | | | | |
|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | 5<br>**{Fields:1 and 2}** |

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Sanitary License.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS- 05-044-A** | Request for Modification of the Sanitary License for the Establishment of Pesticides, Plant Nutrients and Toxic or Dangerous Substances.<br>Modality A - For Urban Fumigation, Disinfection and Pest Control Services. |

| | | | | |
|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | 5<br>**{Fields:1 and 2}** |

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Attach information that supports the requested change



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS- 05-044-B** | Request for Modification of the Sanitary License for the Establishment of Pesticides, Plant Nutrients and Toxic or Dangerous Substances.<br>Modality B.- For Establishment that Manufactures, Formulates, Mixes or Packages Pesticides and/or Vegetable Nutrients. |
| **COFEPRIS- 05-044-C** | Request for Modification of the Sanitary License for the Establishment of Pesticides, Plant Nutrients and Toxic or Dangerous Substances.<br>Modality C.- For Establishment that Manufactures Toxic or Dangerous Substances. |

**1** ÿ **2** ÿ **3** ÿ **4** ÿ [ ] [ ] [ ] 5 **{Fields:1 and 2}**

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Plans and descriptive memories of the modifications made. ÿ Technical information certificate with information on the modifications. ÿ Health surveillance program updated due to the modifications made, the content is the same as for the discharge procedures of sanitary license.

## 2. Application for permission

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-03-003** | Application for Permit for the Acquisition of Raw Materials or Medicines that Are or Contain Narcotic or Psychotropic Drugs |

**1** ÿ **2** ÿ **3** ÿ [ ] [ ] 5 **{Fields: 1, 2, 4, 5, 6, 7, 9, 10, 11, 12, 13, 15, 17, and 18}** ÿ **9.B** [ ]

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-03-005** | Permit for Narcotics and Psychotropic Control Books. |

**1** ÿ **2** ÿ **3** [ ] [ ]

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Copy of the Sanitary License. ÿ Copy of the Health Responsible Notice. ÿ Books.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-05-015-A** Permit for the Sale or Distribution of Biological Products and Hemoderivatives.
Modality A.- Biological Products and Hemoderivatives.

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5<br>**{Fields: 1, 2, 4, 5, 6, 7, 10, 11, 15, 19, 23, 24, 25, 32, 34, and 35}** |

Consult the technical guide for the presentation of attached documents, which can be found on the website

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Sanitary License. ÿ Notice of Health Responsible. ÿ Certificate of non-presence of HIV or Hepatitis, endorsed by the regulatory entity. ÿ Summary manufacturing protocol in accordance with the technical guide and auxiliary formats for the presentation of documents annexed to the request format.
ÿ Copy of Sanitary Registry and authorized tags. ÿ Certificate of the country of origin and/or proof of good manufacturing practices. ÿ Invoice. ÿ Certificate of analysis of finished product. ÿ Import permit. ÿ Guide land, sea, area.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-05-015-B** Permit for Sale or Distribution of Biological Products and Blood Products Modality B.- Antibiotics

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5<br>**{Fields: 1, 2, 4, 5, 6, 7, 10, 11, 15, 19, 23, 24, 25, 32, 34, and 35}** |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-05-015-C** Permit for the Sale or Distribution of Biological Products and Hemoderivatives Modality C.- Request for Reduction of Analytical Tests.

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5**<br>**{Fields: 1, 2, 3, 4, 5, 6, 7, 15, 17, 21, 22, 25, 26, and 35}** |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ The scientific support for each test requested is reduced. ÿ Statistical analysis that demonstrates the equivalence between the manufacturer and the CCAyAC or a Third Party Authorized by COFEPRIS for each proof they request is reduced.

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ÿ If the reduction is requested before being marketed in the United Mexican States, you must support the request before COFEPRIS by writing that fully explains the reason and attaching a copy of all the documents that support it (for example, medical, scientific, technological studies, etc. .)

ÿ Simple copy of the Sanitary Registry (to demonstrate ownership thereof). ÿ Indicate the corresponding monograph of the Pharmacopoeia of the United Mexican States that applies to you, or failing that, attach a copy of the monograph of another Pharmacopoeia or in the absence of the latter, a copy of the Manufacturer's Analytical Certificate.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-05-015-D** Permit for the Sale or Distribution of Biological Products and Hemoderivatives.
Modality D.- Request for Inclusion of Product in Simplified Procedure.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | **5** **{Fields: 1, 2, 3, 4, 5, 6, 15, 17, 21, 22, 25, 26, and 35}** | ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights.
Documentary evidence of a minimum period of three years immediately prior to the application that demonstrates that: ÿ The manufacturing process of the product over time does not involve changes or alterations to the process under which the current Sanitary Registration was granted, which impact on the product quality; (It is recommended to submit annual product reports). ÿ Certificate of Good Manufacturing Practices in force issued by COFEPRIS based on a verification visit carried out by it.
COFEPRIS for each of the manufacturers involved in the product manufacturing process.
ÿ Indicate the entry numbers of the pharmacovigilance reports submitted to COFEPRIS, or an official copy dated no less than six months issued by the National Pharmacovigilance Center indicating that the product represents an acceptable risk to health. of the population.

ÿ Statistical analysis of the behavior of the analytical results of all the tests indicated in the FEUM or, failing that, in those indicated in another Pharmacopoeia and in the absence of such, to those indicated in the Analytical Certificate of the manufacturer of at least twenty batches of the product, demonstrating that they are consistent with respect to their specifications.
ÿ Indicate the corresponding monograph of the Pharmacopoeia of the United Mexican States that applies to you, or failing that, attach a copy of the monograph of another Pharmacopoeia or in the absence of the latter, a copy of the Manufacturer's Analytical Certificate.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-05-015-E** Permit for the Sale or Distribution of Biological Products and Hemoderivatives.
Modality E.- Renewal of Inclusion of Product in Simplified Procedure.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | **5** **{Fields: 1, 2, 3, 4, 5, 6, 15, 17, 21, and 22}** | ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights.
Documentary evidence that demonstrates that in the period elapsed after the authorization of the simplified procedure was issued: ÿ The manufacturing process of the product over time does not involve changes or alterations to the process under which the current Sanitary Registration was granted, which impact on The product quality; (It is recommended to submit annual product reports). ÿ Certificate of Good Manufacturing Practices in force issued by COFEPRIS based on a verification visit carried out by it.
COFEPRIS for each of the manufacturers involved in the product manufacturing process.
ÿ Indicate the entry numbers of the pharmacovigilance reports submitted to COFEPRIS, or an official copy dated no less than six months issued by the National Pharmacovigilance Center indicating that the product represents an acceptable risk to health. of the population.

ÿ Statistical analysis of the behavior of the analytical results of all the tests indicated in the FEUM or, failing that, in those indicated in another Pharmacopoeia and in the absence of such, to those indicated in the Analytical Certificate of the manufacturer of at least twenty batches of the product, demonstrating that they are consistent with respect to their specifications.
ÿ Indicate the corresponding monograph of the Pharmacopoeia of the United Mexican States that applies to you, or failing that, attach a copy of the monograph of another Pharmacopoeia or in the absence of the latter, a copy of the Manufacturer's Analytical Certificate.

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ÿ In those cases that have made a change, attach the document that justifies it as well as the impact it had on the product duly supported.

3. Application for import or export permit

3.1. by high

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-01-002-A** Prior Sanitary Permit for the Importation of Products. Modality A.- Import of Products. | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5** **{Fields: 1, 2, 3, 4, 7, 8, 10, 11, 19, 23, 24, 36, and 37}** | ÿ **9** ÿ **9.A** ÿ **9.C** | | | |

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Original and copy of the health certificate or health certificate, for comparison and return of the original in

ÿ Original and copy of the certificate of free sale for comparison and return of the original. ÿ Physicochemical and microbiological analysis for each batch.

In addition to the above, you must submit ÿ Specific analysis, as appropriate:

» For edible products from fishery in polluted seas (North Sea): analysis for the determination of heavy metals (lead, arsenic, cadmium and mercury).

» For fresh and frozen edible fish products from Central, South America and Asian countries and where they are presents infection with Vibrio cholerae: analysis or determination of Vibrio cholerae.

» For edible oils and fats: analysis or determination of the Peroxide Index.

» For food products from countries or areas affected by nuclear accidents, particularly Europe and Asia: certificate stating a maximum of 370 (three hundred and seventy) becquerels per kilogram of radioactive contamination for milk intended for human consumption, dairy products and food products intended for to infants during the first four to six months of life and a maximum of 600 (six hundred) becquerels per kilogram for all other agricultural products intended for human consumption; ÿ Original label of origin. ÿ Original label in Spanish with which it will be marketed in Mexico.

**NOTE 1:** The comparison will be made during the evaluation and the return of the original will be upon delivery of the resolution.

**NOTE 2:** You may not be required to present more documentation than that indicated in the requirements, except for those provided for in article 15 of the Federal Law of Administrative Procedure referring to the accreditation of legal personality, and in case of health alerts that may put the health of the population at risk.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-01-002-B** Prior Sanitary Permit for the Importation of Products Modality B.- Importation of Samples or Personal Consumption. (For donation, personal consumption, scientific research, laboratory tests and exhibition) | |

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|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5** **{Fields: 1, 2, 3, 4, 7, 8, 10, 11, 19, 23, 24, 36, and 37}** | ÿ **9** ÿ **9.A** ÿ **9.C** | | | |

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Invoice or receipt that indicates samples without commercial value, or air, sea or land guide that covers the products to be imported. ÿ Letter indicating the use that will give the product. ÿ Labels of origin of food supplements, if applicable.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-01-002-C** | Prior Sanitary Permit for the Importation of Products.<br>Modality C.- Import by Return of Products. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5<br>**{Fields: 1, 2, 3, 4, 7, 8, 10, 11, 19, 23, 24, 36, and 37}** | ÿ **9** ÿ **9.A** ÿ **9.C** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the export petition. ÿ Export invoice that covers the product that was exported, specifying the quantity, name and full address of the recipient.
ÿ Rejection letter issued by the health authority of the country to which it was exported, indicating the reason for the rejection; in case of not being rejection by the authority a letter on the company's letterhead indicating the reason for the return.
ÿ Letter from the importer indicating the quantity, destination and use that will be given to the product, batch and expiration date, if applicable, on paper company letterhead. ÿ Labels with which it will market in Mexico, if applicable.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-01-009-A** | Sanitary Permit for the Importation of Raw Materials or for Medications that Are Not or Contain Narcotic or Psychotropic Drugs, that Have Sanitary Registration.<br>Modality A.- Sanitary Permit for the Importation of Raw Materials. |

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|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5<br>**{Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 17, 18, 36, and 37}** | ÿ **9** ÿ **9.A** ÿ **9.B** ÿ **9.C** ÿ **9.D** | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the current Sanitary License, with the corresponding money order. ÿ Copy of the Notice of Operation, only for sale or distribution. ÿ Copy of the Notice of Responsible.

**In the case of pharmaceutical chemicals,** the fractions provided for in article 1 section B of the Agreement of September 27, 2007 and which refer to the following substances: d-2-(6-methoxy-s-naphthyl) propionic acid (naproxen), and its sodium salt; 1,4-Dihydro-2,6-dimethyl-4-(2-nitrophenyl)-3,5-pyridine dicarboxylic acid dimethyl ester (Nifedipine); 4-chloro-N-(2-furylmethyl)-5-sulfamoylanthranilate acid (Furosemide); Vitamina B12 o cobalaminas; Selfish penicilina sodica; Selfish penicillin; procainica; N,N' Dibencilethylenediamino bis (Bencilpenicilina); Ampicillin; and its salts; Amikacin and its salts; 3-(2,6-Dichlorophenyl)-5-methyl-4-isoxazolyl penicillin sodium (Dicloxacillin sodium), in addition to the above documentary requirements, the following must be attached:
» Certified copy of the certificate or explanatory document issued by the health authority of the country of origin, which verifies that the The pharmaceutical chemical to be imported complies with current good manufacturing practices.
» Copy of the current certificate of analysis issued by the manufacturer of the pharmacist on letterhead with the name, signature and position of the responsible chemist that guarantees that the product to be imported meets the quality specifications established in the Pharmacopoeia of the United Mexican States.

**In the case of the raw materials tadalafil, sildenafil, raloxifene and clenbuterol,** as well as their salts and derivatives of all of the above, in addition to the above documentary requirements, the following must be attached: »
Copy(s) of the health record(s) (s) in force (s) of the medicine to be prepared.
» List of clients, which must be declared in section 8C of the format in "NAME OF RECIPIENT (FINAL DESTINATION)", indicating Name or company name and address, indicating the business of the establishment according to the SCIAN description.
» Justify the total quantity to be imported according to the number of clients.

**NOTE:** Documents coming from abroad must be authenticated by a notary public and notarized in the Mexican consulate of the country of origin or apostilled and translated by an expert translator.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-009-B** Sanitary Permit for the Importation of Raw Materials or for Medicines that Are Not or Contain Narcotics or Psychotropic drugs, which have a Sanitary Registry.
Modality B.- Sanitary Permit for the Importation of Raw Materials Destined for the Manufacture of Medicines with Sanitary Registration.

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|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, 37, and 39} | ÿ **9** ÿ **9.A** ÿ **9.B** ÿ **9.C** ÿ **9.D** | | | | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the current Sanitary License with the corresponding money order. ÿ Copy of the Responsible Notice. ÿ Copy of the current Sanitary Registry and its modifications and/or Marbete projects, if applicable. (Only for drugs for which require Sanitary Registration).

ÿ **In the case of pharmaceutical chemicals,** the fractions provided for in article 1 section B of the Agreement of September 27, 2007 and that refer to the following substances: d-2-(6-methoxy-s-naphthyl) propionic acid (naproxen), and its sodium salt; 1,4-Dihydro-2,6-dimethyl-4-(2-nitrophenyl)-3,5-pyridine dicarboxylic acid dimethyl ester (Nifedipine); 4-chloro-N-(2-furylmethyl)-5-sulfamoylanthranilate acid (Furosemide); Vitamina B12 o cobalaminas; Selfish penicilina sodica; Selfish penicillin; procainica; N,N' Dibencilethylenediamino bis (Bencilpenicilina); Ampicillin; and its salts; Amikacin and its salts; 3-(2,6-Dichlorophenyl)-5-methyl-4-isoxazolyl penicillin sodium (Dicloxacillin sodium), in addition to the above documentary requirements, the following must be attached:
» Certified copy of the certificate or explanatory document issued by the health authority of the country of origin, which verifies that the The pharmaceutical chemical to be imported complies with current good manufacturing practices.
» Copy of the current certificate of analysis issued by the manufacturer of the pharmacist on letterhead with the name, signature and position of the responsible chemist that guarantees that the product to be imported meets the quality specifications established in the Pharmacopoeia of the United Mexican States.

ÿ **In the case of raw materials tadalafil, sildenafil, raloxifene and clenbuterol,** as well as their salts and derivatives of all of the above, In addition to the above documentary requirements, the following must be attached:
» Copy(s) of the current health record(s) of the medication to be prepared.
» List of clients themselves that must be declared in section 8C of the format in "NAME OF RECIPIENT (FINAL DESTINATION)", indicating Name or company name and address), indicating the business of the establishment according to the SCIAN description.
» Justify the total quantity to be imported according to the number of clients.

**NOTE:** Documents from abroad must be authenticated by a notary public and notarized in the Mexican consulate of the country of origin or apostilled and translated by an expert translator.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-009-C** Sanitary Permit for the Importation of Raw Materials or for Medications that Are Not or Contain Narcotic or Psychotropic Drugs, that Have Sanitary Registration.
Modality C.- Sanitary Permit for the Importation of Medicines with Sanitary Registration.

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|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, and 37} | ÿ **9** ÿ **9.A** ÿ **9.B** ÿ **9.C** ÿ **9.D** | | | | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the current Sanitary License with the corresponding money order. ÿ Copy of the Notice of Operation, only for sale or distribution. ÿ Copy of the Responsible Notice. ÿ Copy of Sanitary Registry and its modifications and/or Marbete projects, if applicable. (Only for drugs for which require Sanitary Registration).

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-010-A** Sanitary Permit for the Importation of Medications that Are Not or Contain Narcotic or Psychotropic Drugs, that are Not They have a Sanitary Registry.
Modality A.- Sanitary Permit for the Importation of Medicines and Raw Materials Destined for Human Research.

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|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 {Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, and 37} | ÿ **9** ÿ **9.A** ÿ **9.B** ÿ **9.C** ÿ **9.D** | | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Sanitary License or Notice of Operation. ÿ Copy of the official letter of approval of the investigation protocol authorized by the Federal Commission for the Protection against Risks Sanitary and its amendments, (Only in the case of research in human beings).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-010-B** Sanitary Permit for the Importation of Medications that Are Not or Contain Narcotic or Psychotropic Drugs, that are Not They have a Sanitary Registry.
Modality B.- Sanitary Permit to Import Medicines and Raw Materials Destined for Maquila.

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|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 {Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 17, 18, 36, 37, and 39} | ÿ **9** ÿ **9.A** ÿ **9.B** ÿ **9.C** ÿ **9.D** | | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the authorization document issued by the Ministry of Economy or, if applicable, indicate the IMMEX number.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-010-C** Sanitary Permit for the Importation of Medications that Are Not or Contain Narcotic or Psychotropic Drugs, that are Not They have a Sanitary Registry.
Modality C.- Sanitary Permit for the Importation of Medications Destined for Special Treatments.
(In Low Incidence Diseases with Social Repercussion).

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|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 {Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, and 37} | ÿ **9** ÿ **9.A** ÿ **9.B** ÿ **9.C** ÿ **9.D** | | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Professional certificate of the doctor. ÿ Letter from the importer indicating the destination of the product and justifying the importation. ÿ Copy of the Sanitary Registry, if applicable, and its modifications and/or Marbete projects, if applicable. ÿ Copy of the Sanitary License or Notice of Operation, if applicable.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-010-D** Sanitary Permit for the Importation of Medications that Are Not or Contain Narcotic or Psychotropic Drugs, that are Not They have a Sanitary Registry.
Modality D.- Sanitary Permit for the Importation of Medications Destined for Personal Use.

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 {Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 17, 18, 36, and 37} | ÿ **9** ÿ | **9.A** ÿ | **9.B** ÿ | **9.C** ÿ | **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Current medical prescription, including professional license number and covering the product and quantity. (Not required in case of free-sale supplies).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-010-E** Sanitary Permit for the importation of Medications that are not or contain Narcotic or Psychotropic Drugs, that are not They have a Sanitary Registry.
Modality E. Sanitary Permit to Import Medicines Destined for Donation.

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| **1** ÿ **2** ÿ **3** ÿ | | | 5 {Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, and 37} | ÿ **9** ÿ | **9.A** ÿ | **9.B** ÿ | **9.C** ÿ | **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Donation letter issued by the donor on letterhead, signed and of recent date. ÿ Letter of acceptance of the donation on the letterhead of public, social or private health service establishments, signed and of recent date, which includes a non-commercialization commitment. ÿ Simple copy of the professional certificate of the doctor responsible for the donation. ÿ For public, social or private health service establishments, copy of the Sanitary License or copy of the Notice of Operation, where appropriate with the corresponding turn.
ÿ Copy of the Sanitary Registry, if applicable, and its modifications and/or Marbete projects, if applicable.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-010-F** Sanitary Permit for the Importation of Medications that Are Not or Contain Narcotic or Psychotropic Drugs, that are Not They have a Sanitary Registry.
Modality F.- Sanitary Permit for the Importation of Medicines and Raw Materials Destined for Laboratory Tests.

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 {Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, and 37} | ÿ **9** ÿ | **9.A** ÿ | **9.B** ÿ | **9.C** ÿ | **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of current Sanitary License, if applicable. ÿ Copy of the Sanitary Registry, if applicable, and its modifications and/or Marbete projects, if applicable. (Only for drugs for that require Sanitary Registration).



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-012** Sanitary Permit for the Importation of Herbal Remedies.

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| **1** ÿ **2** ÿ **3** ÿ | | | **5** **{Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, and 37}** | ÿ **9** | ÿ **9.A** | ÿ **9.B** | ÿ **9.C** | ÿ **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Notice of
Operation. ÿ Copy of the Responsible
Notice. ÿ Copy of the alphanumeric
code and its corresponding modifications, including a copy of its authorized tags.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-014-A** Sanitary Permit for the Importation of Medical Devices with Sanitary Registration that Are Not or Contain Drugs or Psychotropic Drugs.
Modality A.- Import of Medical Devices that have a Sanitary Registration (Such as: medical equipment, X-ray devices, heart valves, internal prostheses, pacemakers, prostheses, supplies for dental use, surgical materials, healing materials and hygienic products with Registration Sanitary)

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|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5** **{Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, and 37}** | ÿ **9** | ÿ **9.A** | ÿ **9.B** | ÿ **9.C** | ÿ **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Sanitary License
or the Notice of Operation with the corresponding money order. ÿ Copy of the Sanitary Registry
and its corresponding modifications, including a copy of its authorized labels.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-014-B** Sanitary Permit for the Importation of Medical Devices with Sanitary Registration that Are Not or Contain Drugs or Psychotropic Drugs.
Modality B.- Importation of Radiation Sources.
(includes diagnostic reagents or agents with radioactive isotopes)

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|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 **{Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, and 37}** | ÿ **9** | ÿ **9.A** | ÿ **9.B** | ÿ **9.C** | ÿ **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Sanitary License
issued by the Federal Commission for the Protection against Sanitary Risks or, where appropriate, a copy of the Notice of Operation with the corresponding turn.
ÿ Copy of the Sanitary Registry and its corresponding modifications, including a copy of its authorized labels. ÿ Copy of the
Import Permit issued by the National Commission for Nuclear Safety and Safeguards.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-015-A** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, Without Registration or in the Experimentation Phase.
Modality A.- Import of Medical Devices for Maquila.

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ | **2** ÿ | **3** ÿ | | | 5 **{Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 17, 18, 36, 37, and 39}** | ÿ **9** | ÿ **9.A** | ÿ **9.B** | ÿ **9.C** | ÿ **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the authorization letter from the Ministry of Economy or, if applicable, indicate the IMMEX code number.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-015-B** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, Without Registration or in Phase of Experimentation.
Modality B.- Import of Medical Devices for Personal Use.

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ | **2** ÿ | **3** ÿ | | | 5 **{Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 17, 18, 36, and 37}** | ÿ **9** | ÿ **9.A** | ÿ **9.B** | ÿ **9.C** | ÿ **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Current medical prescription, including professional license number and covering the product and quantity (Not required in case of free-sale supplies).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-015-C** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, Without Registration or in Phase of Experimentation.
Modality C.- Import of Medical Devices for Medical Use.

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ | **2** ÿ | **3** ÿ | | | 5 **{Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 17, 18, 36, and 37}** | ÿ **9** | ÿ **9.A** | ÿ **9.B** | ÿ **9.C** | ÿ **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Sanitary License or copy of the Notice of Operation. ÿ Copy of the professional certificate of the doctor. ÿ In the case of radiation sources, a copy of the Sanitary License issued by the Federal Commission for Protection against Risks Sanitary with the corresponding turn.

ÿ **In the case of X-ray devices, you must also present the following:**
» Copy of the Sanitary License issued by the Federal Commission for the Protection against Sanitary Risks with the transfer correspondent.
» Copy of the Permit of the Person Responsible for the Operation and Functioning of the X-ray equipment.

ÿ **In the case of class II and III health supplies, you must also present the following:**
» Copy of the Manufacturer's Certificate of Good Practices, issued by the health authority of the country of origin.
» Copy of the Certificate of Free Sale issued by the health authority of the country of origin.

ÿ **In the case of used equipment, the following must also be presented:**
» Invoice certified before a notary public (notary or public broker) indicating that the equipment is used.
» Evidence of Facts before a notary or public broker or its equivalent abroad, of the guarantees of effectiveness and proof of the correct functioning of the used equipment and that it is suitable for use.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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» In the case of used X-ray devices, original of the supporting documents that certify compliance with NOM-229-SSA1-2002, Environmental Health. Technical requirements for facilities, sanitary responsibilities, technical specifications for equipment and radiological protection in X-ray medical diagnosis establishments, prepared by the manufacturer or the Specialized Advisor in Radiological Safety, authorized by this Federal Commission, signed jointly with the importer under protest
to tell the truth

**NOTE:** Documents coming from abroad must be authenticated by a notary public and notarized in the Mexican consulate of the team's country of origin or apostilled.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-015-D** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, Without Registration or in the Experimentation Phase.
Modality D.- Import of Medical Devices for Human Research

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|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | 5 {Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, and 37} | ÿ **9** ÿ **9.A** ÿ **9.B** ÿ **9.C** ÿ **9.D** | | | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Sanitary License or Notice of Operation with the corresponding money order. ÿ Copy of the official letter of approval of the investigation protocol authorized by the Federal Commission for the Protection against Risks Sanitary and their amendments, if applicable. Only in the case of research in humans.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-015-E** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, Without Registration or in Phase of Experimentation.
Modality E.- Import of Medical Devices for Donation

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | 5 {Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, and 37} | ÿ **9** ÿ **9.A** ÿ **9.B** ÿ **9.C** ÿ **9.D** | | | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Letter of donation and letter of acceptance that includes a non-commercial commitment. ÿ **In the case of public, social or private health service establishments, in addition:**
» Copy of the Sanitary License, or Notice of Operation, if applicable.
» Copy of the professional certificate of the responsible doctor.
ÿ In the case of radiation sources, a copy of the health license issued by the Federal Commission for Protection against Risks Sanitary with the corresponding turn.
ÿ **In the case of X-ray devices:** » Copy of the sanitary license issued by the Federal Commission for the Protection against Sanitary Risks with the corresponding money order.
» Copy of the Permit of the Person Responsible for the Operation and Functioning of the X-ray equipment.
ÿ **In the case of used equipment:**
» Invoice certified before a notary public (notary or public broker) indicating that the equipment is used » Evidence of Facts before a notary or public broker or its equivalent abroad, of the guarantees of effectiveness and proof of the correct functioning of the used equipment and that it is fit for use.
ÿ **In the case of used X-ray devices, original of the supporting documents that certify compliance with NOM-229-SSA1-2002, Environmental Health. Technical requirements for facilities, sanitary responsibilities, technical specifications for equipment and radiological protection in X-ray medical diagnosis establishments, prepared by the manufacturer or the Specialized Advisor in Radiological Safety, authorized by this Federal Commission, signed jointly with the importer under protest to tell the truth**



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**NOTE:** Documents from abroad must be authenticated by a notary public and notarized in the Mexican consulate of the team's country of origin or apostilled.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-015-F** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, Without Registration or in Phase of Experimentation.
Modality F.- Import of Medical Devices, Without Registration, Used.

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 **{Fields: 1, 2, 4, 7, 8, 10, 11, 15, 17, 18, 36, and 37}** | ÿ **9** | ÿ **9.A** | ÿ **9.B** | ÿ **9.C** | ÿ **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Sanitary License or Notice of Operation. ÿ Invoice certified before a notary public (notary or public broker) indicating that the equipment is used. ÿ Evidence of Facts before a notary or public broker or its equivalent abroad, of the guarantees of effectiveness and proof of correctness operation of the equipment used and that it is fit for use.
ÿ In the case of used X-ray devices, original of the supporting documents that certify compliance with NOM-229-SSA1-2002, Environmental Health. Technical requirements for facilities, sanitary responsibilities, technical specifications for equipment and radiological protection in X-ray medical diagnosis establishments, prepared by the manufacturer or the Specialized Advisor in Radiological Safety, authorized by this Federal Commission, signed jointly with the importer under protest to tell the truth

**NOTE:** Documents coming from abroad must be authenticated by a notary public and notarized in the Mexican consulate of the team's country of origin or apostilled.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-015-G** Sanitary Permit for the Importation of Medical Devices that Are Not or Contain Narcotic or Psychotropic Drugs, Without Registration or in Phase of Experimentation.
Modality G.- Sanitary Permit for the Importation of Medical Devices Destined for Laboratory Tests.

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 **{Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 36, and 37}** | ÿ **9** | ÿ **9.A** | ÿ **9.B** | ÿ **9.C** | ÿ **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the valid Sanitary License or Notice of Operation, if applicable. ÿ Copy of the Sanitary Registry, if applicable, and its modifications and/or tag projects, if applicable. (Only for medical devices that require Sanitary Registration)

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-016** Sanitary Permit to Import Supplies that Are Not or Contain Narcotic or Psychotropic Drugs for Return.

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 **{Fields: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 15, 17, 18, 24, 36, and 37}** | ÿ **9** | ÿ **9.A** | ÿ **9.B** | ÿ **9.C** | ÿ **9.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the export petition.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Copy of the export invoice that covers the product that was exported, where the quantity, name and full address are specified. of the recipient.

ÿ Rejection letter issued by the health authority of the country to which it was exported, indicating the reason for the rejection; in case of not being the rejection by the authority, a writing on the letterhead of the company abroad where the reason for the return is indicated. ÿ Letter from the importer indicating quantity, destination and use of the product, batch and expiration date, if applicable, on company letterhead. company.

ÿ Copy of the Sanitary License or the Notice of Operation with the corresponding money order.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-03-012** Sanitary Permit for the Importation of Raw Materials or Medications that Are or Contain Narcotic or Psychotropic Drugs.

**1** ÿ **2** ÿ **3** ÿ | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 15, 17, 18, and 36}** ÿ **9** ÿ **9.A** ÿ **9.C** ÿ **9.D** | | |

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ In the case of importation of Psychotropic, Narcotic Drugs and Chemical Precursors (Personal Use):

» Medical prescription, including professional license number. In case of narcotics, special prescription with the barcode.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-03-013** Sanitary Permit for the Export of Raw Materials or Medicines that Are or Contain Narcotic Drugs or psychotropic

**1** ÿ **2** ÿ **3** ÿ | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 15, 17, 18, 36, and 37}** ÿ **9** **{Enter only the data of the final destination}** ÿ **9.C**

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Import permit issued by the health authority of the country of destination, or an updated document indicating that a permit is not required (in the case of exports).

3.2. by modification

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-005** Modification of the Prior Sanitary Permit for the Importation of Products.

**1** ÿ **2** ÿ **3** ÿ 4 | | |

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Original Sanitary Permit Prior to Import in force.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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| homoclave | Name, modality and quick filling guide |
|---|---|
| COFEPRIS-01-017 | Modification to the Sanitary Permit for the Importation of Health Supplies that Are Not or Contain Narcotic or Psychotropic Drugs. |

**1** ÿ **2** ÿ **3** ÿ 4

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Original of the corresponding current health permit.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-03-019** | Modification to the Prior Sanitary Permit for the Importation of Raw Materials or Medicines that Are or Contain Narcotic Drugs or Psychotropic Drugs |

**1** ÿ **2** ÿ **3** ÿ 4

documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Import or Export Permit of raw materials or medicines that are or contain Narcotic or Psychotropic Drugs issued by the Federal Commission for the Protection against Sanitary Risks, complete (the original and both copies).

## 4. Application for registration

**All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer.**

**Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulations)**

### 4.1. Sanitary registration of medical devices

#### 4.1.1. By high or new

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-001-A** | Application for Sanitary Registration of Medical Devices. Modality A.- Products of National Manufacture. |

**1** ÿ **2** ÿ **3** ÿ 5 **{Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 29, 30, 34, and 35}** ÿ **8.B** ÿ **8.C** ÿ **8.D**

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Technical and scientific information to demonstrate that the input meets the safety and efficacy characteristics. ÿ Label project in Spanish, under the terms of the corresponding official Mexican standard.



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Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Instructions, if applicable, for its use or operation manual in Spanish. ÿ General description of the manufacturing process that is carried out to obtain the product. ÿ Description of the structure, materials, parts and functions, if applicable. ÿ Evidence of good manufacturing practices. ÿ Laboratory tests to verify the specifications of the input. ÿ Bibliographical references, if applicable. ÿ Maquila agreement. ÿ Others established by the SSA in the corresponding Official Mexican Standards.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-001-B** Application for Sanitary Registration of Medical Devices.
Modality B.- Import Products (Foreign Manufacture).

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 29, 30, 34, and 35} | ÿ | **8.B** {Do not fill in the RFC data} Product imported | ÿ | **8.C** {Do not fill in the RFC data} | ÿ **8.D** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Technical and scientific information to demonstrate that the input meets the safety and efficacy characteristics. ÿ Label project in Spanish, under the terms of the corresponding official Mexican standard. ÿ Instructions, if applicable, for its use or operation manual in Spanish. ÿ General description of the manufacturing process that is carried out to obtain the product. ÿ Description of the structure, materials, parts and functions of the medical device, if any. ÿ Laboratory tests to verify the specifications of the input. ÿ Bibliographic references. ÿ Others established by the SSA in the corresponding Official Mexican Standards. ÿ
In addition to the above documents, the following must be included:

» Certificate of free sale or equivalent, issued by the health authority of the country of origin.
» Letter of representation from the manufacturer, authenticated by the legal procedure that exists in the country of origin, in Spanish or in another language, with its respective translation into Spanish by an expert translator, if the product is not manufactured by the parent company or factory or laboratory that requests the Sanitary Registry in Mexico.
» Certificate of good manufacturing practices issued by the health authority of the country of origin.
» Copy of the certificate of analysis issued by the company that produces the product, on letterhead and duly signed by the responsible for quality control.
» Copy of the Notice of Operation of Health Supplies establishments.
» Copy of the Health Responsible Notice.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-001-C** Application for Sanitary Registration of Medical Devices
Modality C.- Nationally Manufactured Products that are Manufactured by another Establishment

| | | | | | | |
|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | 5 {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 29, 30, 34, and 35} | ÿ | **8.A** manufactured product |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Technical and scientific information to demonstrate that the input meets the safety and efficacy characteristics. ÿ Label project in Spanish, under the terms of the corresponding official Mexican standard. ÿ Instructions, if applicable, for its use or operation manual in Spanish. ÿ General description of the manufacturing process that is carried out to obtain the product. ÿ Description of the structure, materials, parts and functions, if applicable. ÿ Evidence of good manufacturing practices. ÿ Laboratory tests to verify the specifications of the input. ÿ Bibliographical references, if applicable. ÿ Maquila agreement. ÿ Others established by the SSA in the corresponding Official Mexican Standards.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-001-D** Application for Sanitary Registration of Medical Devices
Modality D - Products with Class I FDA Registration (USA and Canada Equivalence Agreement)

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ | **2** ÿ | **3** ÿ | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 29, 30, 34, and 35} | ÿ | **8.B** {Do not fill in the RFC data} Imported product | ÿ | **8.C** {Do not fill in the RFC data} | ÿ **8.D** |

documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Notice of Operation. ÿ Copy of the Notice of the Sanitary Responsible. ÿ Label Project in Spanish, under the terms of the corresponding Standard. ÿ Instructions for use, if applicable, or operation manual in Spanish. ÿ Monograph, issued by the manufacturer duly signed by the person in charge of quality assurance of the medical device; that contain the following information: »
Trade name.

» Generic name (when applicable).
» Description of the Medical Device and purpose of use.
» Diagram of the structure, parts, materials and functions, if applicable, or, if applicable, qualitative-quantitative formula indicating the function of the ingredients in it, of the Medical Device.
» Specifications of the finished product.
» Summary of the manufacturing process or flowchart of the manufacturing process.
» If applicable, indicate the sterilization method.
» If applicable, summary of non-toxicity or biocompatibility tests.
» If applicable, expiration date and summary of the stability study that supports it.
» Characteristics of primary and secondary packaging.
» Presentations, codes or models.
» If applicable, a summary of the pre-clinical laboratory studies and the clinical studies carried out on humans with their conclusions, and
» Bibliographical references, if they exist.

ÿ Certificate of analysis issued by the manufacturer of the medical device, with letterhead of its name or company name signed by the responsible chemist of the foreign company.

ÿ Original or notarized copy of the certificate to foreign government (certificate to foreign government) issued by the Food and Drug Administration.

ÿ The last establishment inspection report that has been made to the manufacturer of the Device Doctor.

ÿ Copy of the document issued by the Food and Drug Administration in which the Medical Device is approved, which mentions the information of classification of it.

ÿ Letter of Representation from the Manufacturer, if the product is not manufactured by the parent company or factory or laboratory that requests registration in Mexico.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-001-E** Application for Sanitary Registration of Medical Devices
Modality E.- Products with Class II and III FDA Registration (USA and Canada Equivalence Agreement)

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 29, 30, 34, and 35} | ÿ | **8.B** {Do not fill in the RFC data} Imported product | ÿ | **8.C** {Do not fill in the RFC data} | ÿ | **8.D** |

Documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Notice of Operation. ÿ Copy of the Notice of the Sanitary Responsible. ÿ Label Project in Spanish, under the terms of the corresponding Standard. ÿ Instructions for use, if applicable, or operation manual in Spanish. ÿ Monograph, issued by the manufacturer duly signed by the person in charge of quality assurance of the medical device; that contain the following information: »
Trade name.

» Generic name (when applicable).
» Description of the Medical Device and purpose of use.
» Diagram of the structure, parts, materials and functions or, where appropriate, qualitative-quantitative formula indicating the function of the ingredients in it, of the Medical Device.
» Specifications of the finished product.
» Summary of the manufacturing process or flowchart of the manufacturing process.
» If applicable, indicate the sterilization method.
» If applicable, summary of non-toxicity or biocompatibility tests.
» If applicable, expiration date and summary of the stability study that supports it.
» Characteristics of primary and secondary packaging.
» Presentations, codes or models.
» If applicable, a summary of the pre-clinical laboratory studies and the clinical studies carried out on humans with their conclusions, and
» Bibliographical references, if they exist.

ÿ Certificate of analysis issued by the manufacturer of the medical device, with letterhead of its name or company name signed by the responsible chemist of the foreign company.

ÿ Original or notarized copy of the certificate to foreign government (certificate to foreign government) issued by the Food and Drug Administration.

ÿ The last establishment inspection report that has been made to the device manufacturer doctor.

ÿ Summary or proof of the last report of techno-surveillance or post-commercialization surveillance of the product, translated into Spanish in the terms provided by article 153 of the Regulation; and ÿ Copy of the document issued by the FDA approving the Medical Device that mentions the classification information of the same.

ÿ Letter of Representation from the Manufacturer, if the product is not manufactured by the parent company or factory or laboratory that requests registration in Mexico.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-001-F** Application for Sanitary Registration of Medical Devices
Modality F: Products with Class II, III and IV Health Canada Registration (USA and Canada Equivalence Agreement)

| 1 ÿ 2 ÿ 3 ÿ | | 5 {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 29, 30, 34, and 35} ÿ | 8.B {Do not fill in the RFC data} Imported product ÿ | 8.C {Do not fill in the RFC data} ÿ 8.D |
|---|---|---|---|---|

Documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Notice of Operation. ÿ Copy of the Notice of the Sanitary Responsible. ÿ Label Project in Spanish, under the terms of the corresponding Standard. ÿ Instructions for use, if applicable, or operation manual in Spanish. ÿ Monograph, issued by the manufacturer duly signed by the person in charge of quality assurance of the medical device; that contain the following information: »

Trade name.

» Generic name (when applicable).
» Description of the Medical Device and purpose of use.
» Diagram of the structure, parts, materials and functions or, where appropriate, qualitative-quantitative formula indicating the function of the ingredients in it, of the Medical Device.
» Specifications of the finished product.
» Summary of the manufacturing process or flowchart of the manufacturing process.
» If applicable, indicate the sterilization method.
» If applicable, summary of non-toxicity or biocompatibility tests.
» If applicable, expiration date and summary of the stability study that supports it.
» Characteristics of primary and secondary packaging.
» Presentations, codes or models.
» If applicable, a summary of the pre-clinical laboratory studies and the clinical studies carried out on humans with their conclusions, and
» Bibliographical references, if they exist.

ÿ Certificate of analysis issued by the manufacturer of the medical device, with letterhead of its name or company name signed by the responsible chemist of the foreign company. ÿ Notarized copy of current medical device license issued by Health Canada. ÿ Simple copy of the current certificate of compliance with the CAN/CSA-ISO 13485:03 standard, Medical Devices - Information Management Systems Quality – Requirements for Regulatory Objectives.

ÿ Simple copy of the current certificate of compliance with the ISO 17021 Conformity Assessment - Requirements for entities that provide the audit service and certification of management systems by the authorized third party (Registrar) that *issued* the certificate referred to in the previous paragraph.

ÿ Copy of current authorization issued by Health Canada to the authorized third party (registrar) that issued the CAN/CSA-ISO certificate 13485:03.

ÿ Letter of Representation from the Manufacturer, if the product is not manufactured by the parent company or factory or laboratory that requests registration in Mexico, translated into Spanish.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-001-G** Application for Sanitary Registration of Medical Devices
Modality G - Designated Controlled Medical Devices (class II with established conformity criteria) with a Certificate Issued by a Certification Body Registered with the MHLW of Japan (Japan Equivalence Agreement)

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 29, 30, 34, and 35} | ÿ | **8.B** {Do not fill in the RFC data} Imported product | ÿ | **8.C** {Do not fill in the RFC data} | ÿ | **8.D** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Operation Notice of the establishment or its most recent modification notice. ÿ Certification issued by the Registered Certification Body, including the sheets where the items detailed below are specified, translated into Spanish by an expert translator and legalized: » Description.

» Indication of use.
» Formula and/or composition, when applicable.
» Stability when applicable »
Sterility period, when applicable.
» Primary and secondary packaging, when applicable.

ÿ Export Notification translated into Spanish with the following specifications: » Description.

» Indication of use.
» Presentations with code (catalog number, part number, etc.) including accessories.
» Formula and/or composition, when applicable.
» Stability when applicable »
Sterility period, when applicable.
» Primary and secondary packaging, when applicable.

ÿ Original Certificate of Free Sale with code and issued no more than a year ago translated into Spanish by an expert translator and legalized. ÿ Letter of representation, in case of not being a subsidiary, translated into Spanish by an expert translator and legalized.
ÿ Label project for commercialization in Mexico in accordance with the applicable and current legal provisions. ÿ Instructions for use for marketing in Mexico in accordance with the applicable and current legal provisions.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-001-H** Application for Sanitary Registration of Medical Devices
Modality H - Class II Medical Devices (class II without established conformity criteria), III and IV with Letter of Approval Issued by the MHLW of Japan (Japan Equivalence Agreement).

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 29, 30, 34, and 35} | ÿ | **8.B** {Do not fill in the RFC data} Imported product | ÿ | **8.C** {Do not fill in the RFC data} | ÿ | **8.D** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Operation Notice of the establishment or its most recent modification notice. ÿ Letter of Approval issued by the MHLW, including the sheets where the items detailed below are specified, translated into Spanish by an expert translator and legalized: » Description.

» Indication of use.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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» Formula and/or composition, when applicable.
» Stability when applicable.
» Sterility period, when applicable.
» Primary and secondary packaging, when applicable.

ÿ Export Notification translated into Spanish with the following specifications:
" Description.
» Indication of use.
» Presentations with code (catalog number, part number, etc.) including accessories.
» Formula and/or composition, if applicable.
» Stability, if applicable.
» Sterility period, if applicable.
» Primary and secondary packaging, if applicable.

ÿ Original Certificate of Free Sale with code and issued no more than a year ago translated into Spanish by an expert translator and legalized. ÿ Letter of representation, if not affiliated, translated by an expert translator and legalized. ÿ Label project for commercialization in Mexico in accordance with the applicable and current legal provisions. ÿ Instructions for use for marketing in Mexico in accordance with the applicable and current legal provisions.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-001-I** Application for Sanitary Registration of Medical Devices.
Modality I.- Nationally Manufactured Products Considered Low Risk

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|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 34, and 35} | ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ The label project in Spanish, in the terms of the corresponding standard. ÿ Simple copy of the "Notice of Operation and Health Responsible of the Establishment of Supplies for Health" or its modification more recent.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-001-J** Application for Sanitary Registration of Medical Devices.
Modality J.- Import Product (Foreign Manufacture) Considered Low Risk.

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| **1** ÿ **2** ÿ **3** ÿ | | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 34, and 35} | ÿ | **8.B** {Do not fill in the RFC data} | ÿ | **8.C** {Do not fill in the RFC data} | ÿ **8.D** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ The label project in Spanish, in the terms of the corresponding standard. ÿ Simple copy of the "Notice of Operation and Health Responsible of the Establishment of Supplies for Health" or its modification more recent

ÿ The letter of representation from the manufacturer, if the product is not manufactured by the parent company or factory or laboratory that requests registration in Mexico.

**NOTE:** The letter of representation must be presented in Spanish, or otherwise, its respective translation into Spanish by an expert translator must be attached, likewise it must be apostilled or legalized (Art. 153 of the Health Supplies Regulation).



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-001-K** Application for Sanitary Registration of Medical Devices.
Modality K.- Nationally Manufactured Products Considered Low Risk that are Manufactured by Another Establishment.

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| **1** ÿ **2** ÿ **3** ÿ | | | | **5** **{Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 34, and 35}** | ÿ **8.A** | |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ The label project in Spanish, in the terms of the corresponding standard. ÿ Simple copy of the "Notice of Operation and Health Responsible of the Establishment of Supplies for Health" or its modification more recent.

4.1.2. by modification

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-002-A** Request for Modification of the Conditions of the Sanitary Registry of Medical Devices.
Modality A.- Administrative Modifications: Assignment of Rights, due to Change of Address of the National or Foreign Distributor, due to Change of Name or company name of the Manufacturer or Distributor, due to Change of the Authorized Distributor in the National Territory.

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| **1** ÿ **2** ÿ **3** ÿ **4** ÿ **5** | | | | **{Fields: 1 and 2}** |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Technical and scientific information to demonstrate that the input meets the safety and efficacy characteristics. ÿ Technical, scientific and legal information that justifies the modification. ÿ Draft label or counter-label, instructions for use, if applicable, or operation manual in Spanish. ÿ Copy of the Notice of Operation. ÿ Copy of the Sanitary Registry and its modifications, if applicable, as well as its corresponding annexes.

» **For transfer of rights, in addition to everything indicated above, they must present:**
ÿ Certified copy before a notary public (notary or public broker) of the legal documents evidencing the transfer of rights such as: purchase-sale contract or the assignment of rights agreement between the companies involved.
ÿ Authenticated letter of representation from the manufacturer by the legal procedure that exists in the country of origin, in Spanish or in another language, with its respective translation, performed by expert translator.
» **To change authorized distributor in national territory, in addition to everything indicated above, they must present:**
ÿ Authenticated letter of representation from the manufacturer by the legal procedure that exists in the country of origin, in Spanish or in another language, with its respective translation, performed by expert translator.
» **To change the address of the national or foreign distributor, in addition to everything indicated above, they must Submit:** ÿ
Written letter from the manufacturer and/or foreign distributor, stating the justification for the change.
» **To change the name or business name of the manufacturer or distributor, in addition to all of the above, must submit:** ÿ Original
or certified copy before a notary public (notary or public broker) of the official document that supports the change of name or company name. (National) ÿ Original or certified copy before a notary public (notary or public
broker) of the letter issued by the manufacturer where the change of the Denomination or company name is reported, authenticated by the legal procedure that exists in the country of origin.

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**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-002-B** Request for Modification of the Conditions of the Sanitary Registry of Medical Devices Modality B.- Modifications of a Technical Type: Radiation Sources, due to Change of National or Foreign Maquiladora, Supplies with Exclusive Presentation for Public Health Institutions or of Social Security, Change of Manufacturing Site of the National or Foreign Manufacturer Including Subsidiary Companies, for New Origins As long as they are Subsidiaries or Subsidiaries, for Change of Material of the Primary Packaging and for Reclassification of the Device, for Formula Change that Does Not Involve Substitution of the Active Ingredient, by Change of Trade Name and/or Product Catalog Number.

| 1 ÿ 2 ÿ 3 ÿ 4 ÿ 5 | | {Fields: 1 and 2} |
|---|---|---|

Documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Technical, scientific and legal information that justifies the modification. ÿ Draft label or counter-label, instructions for use, if applicable, or operation manual in Spanish. ÿ Copy of the Notice of Operation. ÿ Copy of the Sanitary Registry and its modifications, if applicable, as well as its corresponding annexes.

» **To change the site of a national or foreign manufacturer, including affiliated companies, in addition to everything indicated above, they must present:** ÿ
Certificate of Good Manufacturing Practices issued by the competent Health Authority of the country of origin in the case of foreign manufacture or by the Federal Commission for Protection against Sanitary Risks in the case of national manufacture.
ÿ Original certificate of analysis or quality report of the finished product. ÿ
Certificate of Free Sale issued by the health authority of the country of origin.

» **For new origins of the product as long as they are affiliates or subsidiaries, in addition to everything indicated above, they must present:** ÿ
Certificate of Good Manufacturing Practices issued by the competent Health Authority of the country of origin in the case of foreign manufacture or by the Federal Commission for Protection against Sanitary Risks in the case of national manufacture.
ÿ Original certificate of analysis or quality report of the finished product. ÿ
Certificate of Free Sale issued by the health authority of the country of origin.

» **For a change of national maquiladora, in addition to everything indicated above, they must present:** ÿ
Submit a certified maquila agreement or contract before a notary public (notary or public broker). ÿ Certificate of Good Manufacturing Practices issued by the Federal Commission for Protection against Sanitary Risks. ÿ Original certificate of analysis or quality report of the finished product.

» **For change of foreign maquiladora, in addition to everything indicated above, they must present:**
ÿ Original or certified copy of the maquila agreement or contract authenticated by the legal procedure that exists in the country of origin.
ÿ Certificate of Good Manufacturing Practices issued by the competent health authority of the country of origin. ÿ Original certificate of analysis or quality report of the finished product.

» **Reclassification of the medical device based on the level of health risk, in addition to everything indicated above, They must present:**
ÿ Justification of the classification or reclassification based on the level of health risk.

» **Due to a change in the material of the primary and/or secondary packaging previously, they must present:**
ÿ Technical, scientific and legal information that justifies the modification. (See Guidelines for obtaining the Sanitary Registration of a medical device, as well as the authorization to modify the registration conditions on the website http://www.cofepris.gob.mx).

ÿ Draft label or counter-label, instructions for use, if applicable, or operation manual in Spanish. ÿ Copy of the Notice of Operation. ÿ Copy of the Sanitary Registry and its modifications, if applicable, as well as its corresponding annexes.

» **Due to a change in the expiration date, in addition to everything indicated above, they must present:**



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Report of the stability study in the primary packaging that determines the expiration period.

» **For new presentations of the product that are not with technological advances that modify the main purpose of use, In addition to all of the above, they must submit:** ÿ Certificate of free sale issued by the health authority of the country of origin. ÿ Original certificate of analysis or quality report of the finished product.

» **For formula changes (that do not involve substitution of the active ingredient) and that do not affect the main purpose of use, in addition to everything indicated above, they must present: ÿ** Technical, scientific and legal information that justifies the modification. (See Guidelines for obtaining the Sanitary Registration of a medical device, as well as the authorization for the modification of the registration conditions on the website http://www.cofepris.gob.mx)

ÿ Draft label or counter-label, instructions for use, if applicable, or operation manual in Spanish. ÿ Copy of the Notice of Operation. ÿ Copy of the Sanitary Registry and its modifications, if applicable, as well as its corresponding annexes.

» **To change the commercial name and/or catalog number of the product, in addition to everything indicated above, they must Submit:** ÿ Written from the manufacturer stating the justification for the change of trade name and/or product catalog number.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-002-C** Request for Modification of the Conditions of Sanitary Registration of Medical Devices.
Modality C.- Administrative Modifications to Medical Device Registries granted under the USA and Canada Equivalence Agreement: Assignment of Rights, due to change of address of the National or Foreign Distributor, due to Change of Name or business name of the Manufacturer or Distributor , by Change of Authorized Distributor in the National Territory.

| | | | | |
|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** **{Fields: 1, 2 and 15}** |

Documentary requirements

**Information that justifies the modification:** ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Sanitary Registry and the annexes that correspond to the registry, if such annexes exist. ÿ Label Project in Spanish, under the terms of the corresponding Standard. ÿ Instructions for use, if applicable, or operation manual in Spanish. ÿ Simple copy of the "Notice of Operation and Health Responsible of the Establishment of Supplies for Health" or its modification more recent.

» **For transfer of rights, in addition to everything indicated above, they must present:**
ÿ Certified copy before a notary public (notary or public broker) of the legal documents evidencing the assignment of rights such as: purchase-sale contract or the agreement of assignment of rights between the companies involved, among others. ÿ Original or certified copy of the Letter of Representation of the manufacturer authenticated by the legal procedure that exists in the country of origin in Spanish or another language.

» **To change authorized distributor in national territory, in addition to everything indicated above, they must present:**
ÿ Original or certified copy of the Letter of Representation of the manufacturer authenticated by the legal procedure that exists in the country of origin in Spanish or another language.

» **To change the address of the national or foreign distributor, in addition to everything indicated above, they must present:** ÿ Original or certified copy of the Writ of the manufacturer and/or foreign distributor, indicating the justification for the change.

» **To change the name or business name of the manufacturer or distributor, in addition to all of the above, They must present:**
ÿ Original or certified copy before a notary public (notary or public broker) of the official document that supports the change of name or company name. (National). ÿ Original or certified copy before a notary public (notary or public broker) of the letter issued by the manufacturer informing of the change in the Denomination or company name, authenticated by the legal procedure that exists in the country of origin.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-002-D** | Request for Modification of the Conditions of Sanitary Registration of Medical Devices.<br>Modality D.- Technical Modifications to Medical Device Registries granted under the USA and Canada Equivalence Agreement: Radiation Sources, due to change of National or Foreign Maquiladora, supplies with exclusive presentation for public health or social security institutions, Change of Manufacturing Site of the National or Foreign Manufacturer, including Affiliate or Subsidiary Companies, due to New Origins as long as they are Affiliates or Subsidiaries, due to Change of Primary Packaging Material and Reclassification of the Device, due to Change of Formula that DOES NOT involve Substitution of the Ingredient Active, due to Change of Commercial Name and/or Product Catalog Number. |

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| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5**<br>**{Fields: 1, 2 and 15}** | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | | | |

documentary requirements

**Technical, scientific and legal information that justifies the modification:** ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Sanitary Registry and the annexes that correspond to the registry, if such annexes exist. ÿ Label Project in Spanish, under the terms of the corresponding Standard. ÿ Instructions for use, if applicable, or operation manual in Spanish. ÿ Simple copy of the "Notice of Operation and Health Responsible of the Establishment of Supplies for Health" or its modification more recent

» **To change the site of a national or foreign manufacturer, including affiliated companies, in addition to everything indicated above, they must submit:** ÿ Original or certified copy of the Certificate of Good Manufacturing Practices or its equivalent issued by the competent authority of the country of origin in the case of foreign manufacturing or by the Federal Commission for the Protection against Sanitary Risks in the case of national manufacturing .

ÿ Certificate of analysis or quality report of the finished product issued by the company that manufactures the medical device, with the letterhead of its name or business name signed by both the person responsible for its quality and by the health officer of the applicant for registration.

ÿ Certificate of Free Sale or equivalent issued by the health authority of the country of origin.

» **For new origins of the product as long as they are affiliates or subsidiaries, in addition to everything indicated above, they must submit:** ÿ Original or certified copy of the Certificate of Good Manufacturing Practices or its equivalent issued by the competent authority of the country of origin in the case of foreign manufacturing or by the Federal Commission for the Protection against Sanitary Risks in the case of national manufacturing .

ÿ Certificate of analysis or quality report of the finished product issued by the company that manufactures the medical device, with the letterhead of its name or business name signed by both the person responsible for its quality and by the health officer of the applicant for registration.

ÿ Certificate of Free Sale or equivalent issued by the health authority of the country of origin.

» **For change of national maquiladora, in addition to everything indicated above, they must present:**

ÿ Submit a copy of the certified maquila agreement or contract before a notary public (notary or public broker). ÿ Certified Copy of the Certificate of Good Manufacturing Practices issued by the Federal Commission for the Protection against Sanitary risks.

ÿ Certificate of analysis or quality report of the finished product issued by the company that manufactures the medical device, with the letterhead of its name or business name signed by both the person responsible for its quality and by the health officer of the applicant for registration.

» **For change of foreign maquiladora, in addition to everything indicated above, they must present:**

ÿ Original or certified copy of the maquila agreement or contract authenticated by the legal procedure that exists in the country of origin.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Original or certified copy of the Certificate of Good Manufacturing Practices or its equivalent issued by the competent authority of the country of origin in the case of foreign manufacturing or by the Federal Commission for Protection against Sanitary Risks in the case of national manufacturing.

ÿ Certificate of analysis or quality report of the finished product issued by the company that manufactures the medical device, with the letterhead of its name or business name signed by both the person responsible for its quality and by the health officer of the applicant for registration.

» **Reclassification of the medical device based on the level of health risk, in addition to everything indicated above, They must present:**

ÿ Justification of the classification or reclassification based on the level of health risk.

» **Due to a change in the material of the primary and/or secondary packaging previously, they must present:**

ÿ Characteristics of primary and/or secondary packaging. ÿ If applicable, expiration date and summary of the stability study of the product in the primary packaging, endorsed by the manufacturer of the medical device, with a letterhead of its name or company name signed by both the person responsible for its quality and by the registrant's health officer.

» **Due to a change in the expiration date, in addition to everything indicated above, they must present:**

ÿ Report of the stability study in the primary packaging that determines the expiration period issued by the manufacturer of the medical device, with a letterhead of its name or company name signed by both the person responsible for the quality of the same and by the applicant's health officer. from the register.

» **For new presentations of the product that are not with technological advances that modify the main purpose of use, in addition to everything indicated above, they must present: ÿ Original** or certified copy of the Certificate of free sale or equivalent issued by the health authority of the country of origin. ÿ Certificate of analysis or quality report of the finished product issued by the company that manufactures the medical device, with the letterhead of its name or business name signed by both the person responsible for its quality and by the health officer of the applicant for registration.

» **For formula changes (that do not involve substitution of the active ingredient) and that do not affect the main purpose of use, in addition to everything indicated above, they must present: ÿ** Technical justification of the modification.

» **To change the commercial name and/or catalog number of the product, in addition to everything indicated above, they must Submit:** ÿ Written from the manufacturer stating the justification for the change of trade name and/or product catalog number.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

| homoclave | Name, modality and quick filling guide |
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| **COFEPRIS-04-002-E** | Request for Modification of the conditions of the Sanitary Registry of Medical Devices. Modality E - Administrative modifications to Medical Device Registries granted under the Japan Equivalence Agreement: Assignment of Rights, due to Change of Address of the National or Foreign Distributor, due to Change of Name or business name of the Manufacturer or Distributor, due to Change of Authorized Distributor in the National Territory. |

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| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** **{Fields: 1, 2 and 15}** |

Documentary requirements

**Information that justifies the modification:**

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Notice of Operation or its most recent modification. ÿ Copy of the Sanitary Registry and the annexes that correspond to the registry, if such annexes exist. . ÿ Label Project in Spanish, under the terms of the corresponding Standard. ÿ Instructions for use, if applicable, or operation manual in Spanish.

» **For transfer of rights, in addition to everything indicated above, they must submit:**

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ÿ Certified copy before a notary public (notary or public broker) of the legal documents evidencing the assignment of rights such as: purchase-sale contract or the agreement of assignment of rights between the companies involved, among others. ÿ Original or certified copy of the Letter of Representation of the manufacturer authenticated by the legal procedure that exists in the country of origin in Spanish or another language.

» **To change authorized distributor in national territory, in addition to everything indicated above, they must present:**
ÿ Original or certified copy of the Letter of Representation of the manufacturer authenticated by the legal procedure that exists in the country of origin in Spanish or another language.

» **To change the address of the national or foreign distributor, in addition to everything indicated above, they must present:** ÿ Original or certified copy of the Writ of the manufacturer and/or foreign distributor, indicating the justification for the change.

» **To change the name or business name of the manufacturer or distributor, in addition to all of the above, They must present:**
ÿ Original or certified copy before a notary public (notary or public broker) of the official document that supports the change of name or company name. (National). ÿ Original or certified copy before a notary public (notary or public broker) of the letter issued by the manufacturer informing of the change in the Denomination or company name, authenticated by the legal procedure that exists in the country of origin.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-002-F** Request for Modification of the conditions of the Sanitary Registry of Medical Devices.
Modality F.- Technical modifications to Medical Device Registries Granted under the Japan Equivalence Agreement: Radiation Sources, due to Change of National or Foreign Maquiladora, Change of Manufacturing Site of the National or Foreign Manufacturer Only Affiliate or Subsidiary Companies, Due to New Origins As long as they are Affiliates or Subsidiaries, due to Change of Primary Packaging Material and Reclassification of the Device, due to Formula Change that does not Involve Substitution of the Active Ingredient, due to Change of Commercial Name and/or Product Catalog Number.

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| **1** ÿ | **2** ÿ | **3** ÿ | **4** ÿ | | | **5** {Fields: 1, 2 and 15} | ÿ | **8.A** ÿ | **8.B** ÿ | **8.C** ÿ | **8.D** |

documentary requirements

**Technical, scientific and legal information that justifies the modification:** ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Notice of Operation or its most recent modification. ÿ Copy of the Sanitary Registry and the annexes that correspond to the registry, if such annexes exist. ÿ Label Project in Spanish, under the terms of the corresponding Standard. ÿ Instructions for use, if applicable, or operation manual in Spanish.

» **To change the site of a national or foreign manufacturer, including affiliated companies, in addition to everything indicated above, they must submit:** ÿ Original or certified copy of the Certificate of Good Manufacturing Practices or its equivalent issued by the competent authority of the country of origin in the case of foreign manufacturing or by the Federal Commission for the Protection against Sanitary Risks in the case of national manufacturing .

ÿ Certificate of analysis or quality report of the finished product issued by the company that manufactures the medical device, with the letterhead of its name or business name signed by both the person responsible for its quality and by the health officer of the applicant for registration.

ÿ Certificate of Free Sale or equivalent issued by the health authority of the country of origin.

» **For new origins of the product as long as they are affiliates or subsidiaries, in addition to everything indicated above, they must submit:** ÿ Original or certified copy of the Certificate of Good Manufacturing Practices or its equivalent issued by the competent authority of the country of origin in the case of foreign manufacturing or by the Federal Commission for the Protection against Sanitary Risks in the case of national manufacturing .



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Certificate of analysis or quality report of the finished product issued by the company that manufactures the medical device, with the letterhead of its name or business name signed by both the person responsible for its quality and by the health officer of the applicant for registration.

ÿ Certificate of Free Sale or equivalent issued by the health authority of the country of origin.

» **For change of national maquiladora, in addition to everything indicated above, they must present:**

ÿ Submit a copy of the certified maquila agreement or contract before a notary public (notary or public broker). ÿ Certified Copy of the Certificate of Good Manufacturing Practices issued by the Federal Commission for the Protection against Sanitary risks.

ÿ Certificate of analysis or quality report of the finished product issued by the company that manufactures the medical device, with the letterhead of its name or business name signed by both the person responsible for its quality and by the health officer of the applicant for registration.

» **For change of foreign maquiladora, in addition to everything indicated above, they must present:**

ÿ Original or certified copy of the maquila agreement or contract authenticated by the legal procedure that exists in the country of origin.

ÿ Original or certified copy of the Certificate of Good Manufacturing Practices or its equivalent issued by the competent authority of the country of origin in the case of foreign manufacturing or by the Federal Commission for Protection against Sanitary Risks in the case of national manufacturing.

ÿ Certificate of analysis or quality report of the finished product issued by the company that manufactures the medical device, with the letterhead of its name or business name signed by both the person responsible for its quality and by the health officer of the applicant for registration.

» **Reclassification of the medical device based on the level of health risk, in addition to everything indicated above, They must present:**

ÿ Justification of the classification or reclassification based on the level of health risk.

» **Due to a change in the material of the primary and/or secondary packaging previously, they must present:**

ÿ Characteristics of primary and/or secondary packaging. ÿ If applicable, expiration date and summary of the stability study of the product in the primary packaging, endorsed by the manufacturer of the medical device, with a letterhead of its name or company name signed by both the person responsible for its quality and by the registrant's health officer.

» **Due to a change in the expiration date, in addition to everything indicated above, they must present:**

ÿ Report of the stability study in the primary packaging that determines the expiration period issued by the manufacturer of the medical device, with a letterhead of its name or company name signed by both the person responsible for the quality of the same and by the applicant's health officer. from the register.

» **For new presentations of the product that are not with technological advances that modify the main purpose of use, in addition to everything indicated above, they must present: ÿ Original** or certified copy of the Certificate of free sale or equivalent issued by the health authority of the country of origin. ÿ Certificate of analysis or quality report of the finished product issued by the company that manufactures the medical device, with the letterhead of its name or business name signed by both the person responsible for its quality and by the health officer of the applicant for registration.

» **For formula changes (that do not involve substitution of the active ingredient) and that do not affect the main purpose of use, in addition to everything indicated above, they must present: ÿ** Technical justification of the modification.

» **To change the commercial name and/or catalog number of the product, in addition to everything indicated above, they must Submit:** ÿ Written from the manufacturer stating the justification for the change of trade name and/or product catalog number.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-002-G** Request for Modification of the conditions of the Sanitary Registry of Medical Devices.
Modality G - Modification of the Administrative Type of Products Considered Low Risk: Assignment of Rights, due to Change of Address of the National or Foreign Distributor, due to Change of Name or company name of the Manufacturer or Distributor, due to Change of the Authorized Distributor in the Territory National due to Change of Commercial Name and/or Catalog Number without Technical Changes

| | | | | |
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| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** **{Fields: 1 and 2}** |

Documentary requirements

**For nationally manufactured products for modifications of: change of address of the national or foreign distributor or change of address of the manufacturer without involving a change of physical location / change of name or corporate name of the manufacturer or distributor / change of trade name and/or product catalog number, as long as there is no technical change in the already authorized conditions, you must submit:** ÿ Authorizations, Certificates and Visits Form, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ The label project in Spanish, in the terms of the corresponding standard. ÿ Simple copy of the "Notice of Operation and Health Responsible of the Establishment of Supplies for Health" or its modification more recent.

**For a foreign-made product, in addition to the above, you must present:** ÿ The manufacturer's representation letter, if the product is not manufactured by the parent company or factory or laboratory that requests registration in Mexico.

**For assignment of rights, in addition to all of the above, they must submit:** ÿ Certified copy before a notary public (notary or public broker) of the legal documents evidencing the assignment of rights such as: purchase-sale contract or agreement of assignment of rights between the companies involved. ÿ Letter of representation (authenticated from the manufacturer by the legal procedure that exists in the country of origin, in Spanish or in another language, with its respective translation, made by an expert translator).

**To change the authorized distributor in national territory, in addition to everything indicated above, they must present:** ÿ Letter of representation (authenticated from the manufacturer by the legal procedure that exists in the country of origin, in Spanish or in another language, with their respective translation, carried out by an expert translator).

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-002-H** Request for Modification of the conditions of the Sanitary Registry of Medical Devices.
Modality H - Modifications of Technical Type of Products considered Low Risk: by Change of National or Foreign Maquiladora, Supplies with Exclusive Presentation for Public Health or Social Security Institutions, Change of Manufacturing Site of the National or Foreign Manufacturer Including Subsidiary Companies , for new Origins as long as they are Affiliates or Subsidiaries, for Change of Commercial Name and/or Product Catalog Number and For New Presentations of the Product that are not with Technological Advances that Modify the Main Purpose of use

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| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** **{Fields: 1 and 2}** |

Documentary requirements

**For nationally manufactured products:**
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ The label project in Spanish, in the terms of the corresponding standard. ÿ Simple copy of the "Notice of Operation and Health Responsible of the Establishment of Supplies for Health" or its modification more recent.

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**For a foreign-made product, in addition to the above, you must present:** ÿ The manufacturer's representation letter, if the product is not manufactured by the parent company or factory or laboratory that requests registration in Mexico.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulations)

4.1.3. by extension

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-021-A** | Request for Extension of the Sanitary Registry of Medical Devices.<br>Modality A.- Products of National Manufacture.<br>(Medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical and healing material, hygienic products, instruments and other devices for medical use). |

| | | | | |
|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5**<br>**{Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 29, 30, 34, and 35}**<br>**national product** |

documentary requirements

**For the request for extension of the Sanitary Registry, you must submit in the following order and with the request exclusively the following:**

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Number or simple copy of the Sanitary Registry of which the extension is requested and its modifications ÿ Labels in use, instructions or manuals, previously authorized ÿ Technovigilance report by product, in terms of the applicable regulations ÿ Certificate of analysis issued by the company that produces the product, with the letterhead of its Denomination or company name and signed by the health officer or equivalent

ÿ Certificate of good manufacturing practices for the product, issued by the Secretariat. In the event that the applicant does not present this certificate, the Secretariat will set, within a period not exceeding twenty business days, the date on which the verification visit will be carried out, in accordance with the procedure established by the Secretariat and published in the Official Gazette of the Federation. If this visit is not carried out on the scheduled date for reasons attributable to the Secretariat, it will be rescheduled as a priority

ÿ In accordance with the provisions of article 391 bis of the Law, the Secretariat may issue certificates based on the information, verification of facts or technical recommendations provided by authorized third parties

Upon notification of the resolution corresponding to the extension request, the holder of the record must deliver to the notifier the original of the sanitary authorization and, where appropriate, its modifications.

If you do not have the original of the registration, you must present the original of the complaint made to the Public Ministry of the loss or theft.

Requests for extensions must be submitted no later than **one hundred and fifty calendar days** before the date on which the validity of the corresponding registration ends.

The Secretariat will resolve the requests for extension of Inputs within a maximum period of one hundred and fifty calendar days following the presentation of the request. When the last day of the period is a non-business day, it will be understood as Extended until the next business day. In the event that the Secretariat does not issue the respective resolution within the periods indicated in this article, the request shall be deemed appropriate.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-021-B** Request for Extension of the Sanitary Registry of Medical Devices.
Modality B.- Nationally Manufactured Products that are Manufactured by Another.
(Medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical and healing material, hygienic products, and other devices for medical use).

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|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 29, 30, 34, and 35} | ÿ | **8.A** manufactured product |

Documentary requirements
**For the request for extension of the Sanitary Registry, you must present in the following order and with the request exclusively the following:** ÿ Form of
Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of
the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Number or simple copy of the Sanitary Registry
of which the extension and its modifications are requested. ÿ Labels in use, instructions or manuals,
previously authorized. ÿ Technovigilance report by product, in terms of
applicable regulations. ÿ Certificate of analysis issued by the company that produces the
product, with the letterhead of its Denomination or company name and signed by the
health officer or equivalent.
ÿ Certificate of good manufacturing practices for the product, issued by the Secretariat. In the event that the applicant does not present this certificate, the Secretariat will set, within a period not exceeding twenty business days, the date on which the verification visit will be carried out, in accordance with the procedure established by the Secretariat and published in the Official Gazette of the Federation. If this visit is not carried out on the scheduled date for reasons attributable to the Secretariat, it will be rescheduled as a priority.
ÿ In accordance with the provisions of article 391 bis of the Law, the Secretariat may issue certificates based on the information, verification of facts or technical recommendations provided by authorized third parties.

Upon notification of the resolution corresponding to the extension request, the holder of the record must deliver to the notifier the original of the sanitary authorization and, where appropriate, its modifications.

If you do not have the original of the registration, you must present the original of the complaint made to the Public Ministry of the loss or theft.

Requests for extensions must be submitted no later than **one hundred and fifty calendar days** before the date on which the validity of the corresponding registration ends.

The Secretariat will resolve the requests for extension of Inputs within a maximum period of one hundred and fifty calendar days following the presentation of the request. When the last day of the period is a non-business day, it will be understood as extended until the next business day. In the event that the Secretariat does not issue the respective resolution within the periods indicated in this article, the request shall be deemed appropriate.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-021-C** Request for Extension of the Sanitary Registry of Medical Devices.
Modality C.- Import Products (Foreign Manufacture).
(Medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical and healing material, hygienic products, instruments and other devices for medical use).

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|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 29, 30, 34, and 35} | ÿ | **8.B** {Do not fill in the RFC data} Imported product | ÿ | **8.C** {Do not fill in the RFC data} | ÿ **8.D** | |

Documentary requirements
**For the request for extension of the Sanitary Registry, you must present in the following order and with the request exclusively the following:** ÿ Form of
Authorizations, Certificates and Visits, duly completed.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Number or simple copy of the Sanitary Registry of which the extension and its modifications are requested. ÿ Labels in use, instructions or manuals, previously authorized. ÿ Technovigilance report by product, in terms of applicable regulations. ÿ Certificate of analysis issued by the company that produces the product, with the letterhead of its Denomination or company name and signed by the health officer or equivalent.

ÿ The document that accredits a legal representative domiciled in the United States of Mexico. ÿ Certificate of good manufacturing practices of the product, issued by the Secretariat, or by the competent authority of the country of origin. ÿ For Class I, II and Class III products, the Good Manufacturing Practices certificate will be accepted as equivalent to the ISO certificate. 13485 in force or the CE mark certificate, issued by an authorized certification body.

ÿ In the event that the applicant presents the certificate of the competent authority of the country of origin and comes from countries with which the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat may carry out a sanitary visit to the establishment. to verify compliance with good manufacturing practices. In this case, the authority will set the date on which the verification visit will be carried out within a period of no more than twenty business days, in accordance with the procedure established by the Secretariat and published in the Official Gazette of the Federation. If this visit is not carried out on the scheduled date for reasons attributable to the Secretariat, it will be rescheduled as a priority.

ÿ In accordance with the provisions of article 391 bis of the Law, the Secretariat may issue certificates based on the information, verification of facts or technical recommendations provided by authorized third parties.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

Upon notification of the resolution corresponding to the extension request, the holder of the record must deliver to the notifier the original of the sanitary authorization and, where appropriate, its modifications.

If you do not have the original of the registration, you must present the original of the complaint made to the Public Ministry of the loss or theft.

Requests for extensions must be submitted no later than **one hundred and fifty calendar days** before the date on which the validity of the corresponding registration ends.

The Secretariat will resolve the requests for extension of Inputs within a maximum period of one hundred and fifty calendar days following the presentation of the request. When the last day of the period is a non-business day, it will be understood as Extended until the next business day. In the event that the Secretariat does not issue the respective resolution within the periods indicated in this article, the request shall be deemed appropriate.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-021-D** Request for Extension of the Sanitary Registry of Medical Devices.
Modality D: Registrations of Medical Devices granted under the USA and Canada Equivalence Agreement.

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ | **2** ÿ | **3** ÿ | **4** ÿ | | | **5** {Fields: 1, 2 and 15} | ÿ | **8.B** {Do not fill in the RFC data} Imported product | ÿ | **8.C** {Do not fill in the RFC data} | ÿ | **8.D** |

Documentary requirements

**For the request for extension of the Sanitary Registry, you must present in the following order and with the request exclusively the following:** ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Number or simple copy of the Sanitary Registry of which the extension is requested. ÿ Labels in use, instructive or manual, (according to the last authorized). ÿ Technovigilance report by product, in terms of applicable regulations. ÿ Certificate of analysis or quality report of the finished product issued by the manufacturer of the medical device, with the letterhead of its name or business name signed by both the person responsible for its quality and the health officer of the applicant for registration. ÿ Document that accredits a legal representative domiciled in the United States of Mexico.

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ÿ Original or certified copy of the Certificate of Good Manufacturing Practices or its equivalent issued by the competent authority of the country of origin in the case of foreign manufacturing or by the Federal Commission for the Protection against Sanitary Risks in the case of national manufacturing.

ÿ For Class I, II and Class III products, the following will be accepted as equivalent to the Certificate of Good Manufacturing Practices: » Current ISO 13485 certificate or the CE mark certificate, issued by an authorized certification body. » Last establishment inspection report that has been made to the establishment issued by the FDA.

» Current certificate of compliance with the CAN/CSA-ISO 13485:03 standard, Medical Devices -Quality Management Systems- Requirements for Regulatory Objectives.

» Simple copy of the current certificate of compliance with the ISO 17021 Conformity Assessment - Requirements for entities that provide the audit service and certification of management systems by the authorized third party (Registrar) that issued the certificate referred to in the previous *paragraph* .

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

Upon notification of the resolution corresponding to the extension request, the holder of the record must deliver to the notifier the original of the sanitary authorization and, where appropriate, its modifications. If you do not have the original of the registration, you must present the original of the complaint made to the Public Ministry of the loss or theft.

Requests for extensions must be submitted no later than **one hundred and fifty calendar days** before the date on which the validity of the corresponding registration ends.

The Secretariat will resolve the requests for Extension of Registrations of Medical Devices granted under the Equivalence Agreement of the USA and Canada in accordance with the provisions therein.

When the last day of the period is a non-business day, it will be understood as extended until the next business day. In the event that the Secretariat does not issue the respective resolution within the periods indicated in this article, the request shall be deemed appropriate.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-021-E** Request for Extension of the Sanitary Registry of Medical Devices.
Modality E.- Registries of designated controlled Medical Devices (class II with established conformity criteria)
Granted under the Japan Equivalence Agreement.

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | | **5** {Fields: 1, 2 and 15} | ÿ | **8.B** {Do not fill in the RFC data} Imported product | ÿ | **8.C** {Do not fill in the RFC data} | ÿ | **8.D** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Notice of Operation of the establishment or its most recent modification. ÿ Copy of the Sanitary Registry to be extended and its modifications, if applicable, as well as its corresponding annexes. ÿ Certification issued by the Registered Certification Body, including the sheets where the items detailed below are specified, translated into Spanish by an expert translator and legalized: » Description.

» Indication of use.
» Formula and/or composition, when applicable.
» Stability when applicable.
» Sterility period, when applicable.
» Primary and secondary packaging, when applicable.

ÿ Export Notification translated into Spanish with the following specifications:
" Description.
» Indication of use.
» Presentations with code (catalog number, part number, etc.) including accessories.
» Formula and/or composition, when applicable.

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» Stability when applicable.
» Sterility period, when applicable.
» Primary and secondary packaging, when applicable.

ÿ Original Certificate of Free Sale with code and issued no more than a year ago translated into Spanish by an expert translator and legalized. ÿ Technovigilance report in Mexico for the last 5 years. ÿ Letter of representation, in case of not being a subsidiary, translated into Spanish by an expert translator and legalized. ÿ Label project for commercialization in Mexico in accordance with the applicable and current legal provisions. ÿ Instructions for use for marketing in Mexico in accordance with the applicable and current legal provisions.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

Upon notification of the resolution corresponding to the extension request, the holder of the record must deliver to the notifier the original of the sanitary authorization and, where appropriate, its modifications. If you do not have the original of the registration, you must present the original of the complaint made to the Public Ministry of the loss or theft.

Requests for extensions must be submitted no later than **one hundred and fifty calendar days** before the date on which the validity of the corresponding registration ends.

The Secretariat will resolve the requests for Extension of Registrations of Medical Devices granted under the Japan Equivalence Agreement as established therein.

When the last day of the period is a non-business day, it will be understood as extended until the next business day. In the event that the Secretariat does not issue the respective resolution within the periods indicated in this article, the request shall be deemed appropriate.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-021-F** | Request for Extension of the Sanitary Registry of Medical Devices.<br>Modality F.- Class II Medical Device Registries (class II without established conformity criteria), III and IV.<br>Granted under the Japan Equivalence Agreement. |

| 1 ÿ 2 ÿ 3 ÿ 4 ÿ | | | 5 {Fields: 1, 2 and 15} | ÿ | 8.B {Do not fill in the RFC data} Imported product | ÿ | 8.C {Do not fill in the RFC data} | ÿ 8.D |
|---|---|---|---|---|---|---|---|---|

Documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Notice of Operation of the establishment or its most recent modification. ÿ Copy of the Sanitary Registry to be extended and its modifications, if applicable, as well as its corresponding annexes. ÿ Letter of Approval issued by the MHLW, including the sheets where the items detailed below are specified, translated into Spanish by an expert translator and legalized: » Description.

» Indication of use.
» Formula and/or composition, when applicable.
» Stability when applicable.
» Sterility period, when applicable.
» Primary and secondary packaging, when applicable.

ÿ Export Notification translated into Spanish with the following specifications:
" Description.
» Indication of use.
» Presentations with code (catalog number, part number, etc.) including accessories.
» Formula and/or composition, if applicable.
» Stability, if applicable.
» Sterility period, if applicable.
» Primary and secondary packaging, if applicable.

ÿ Original Certificate of Free Sale with code and issued no more than a year ago translated into Spanish by an expert translator and legalized. ÿ Technovigilance report in Mexico for the last 5 years. ÿ Letter of representation, if not affiliated, translated by an expert translator and legalized.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Label project for commercialization in Mexico in accordance with the applicable and current legal provisions. ÿ Instructions for use for marketing in Mexico in accordance with the applicable and current legal provisions.

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

Upon notification of the resolution corresponding to the extension request, the holder of the record must deliver to the notifier the original of the sanitary authorization and, where appropriate, its modifications. If you do not have the original of the registration, you must present the original of the complaint made to the Public Ministry of the loss or theft.

Requests for extensions must be submitted no later than **one hundred and fifty calendar days** before the date on which the validity of the corresponding registration ends.

The Secretariat will resolve the requests for Extension of Registrations of Medical Devices granted under the Japan Equivalence Agreement as established therein.

When the last day of the period is a non-business day, it will be understood as extended until the next business day. In the event that the Secretariat does not issue the respective resolution within the periods indicated in this article, the request shall be deemed appropriate.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-021-G** Request for Extension of the Sanitary Registry of Medical Devices.
Modality G.- Nationally Manufactured Products Considered Low Risk

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|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 34, and 35} national product |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ The label project in Spanish, in the terms of the corresponding standard. ÿ Simple copy of the "Notice of Operation and Health Responsible of the Establishment of Supplies for Health" or its modification more recent.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-021-H** Request for Extension of the Sanitary Registry of Medical Devices.
Modality H.- Import Products (Foreign Manufacture) Considered Low Risk

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|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 34, and 35} | ÿ | **8.B** Imported product | ÿ | **8.C** {Do not fill in the RFC data} | ÿ | **8.D** {Do not fill in the RFC data} |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ The label project in Spanish, in the terms of the corresponding standard. ÿ Simple copy of the "Notice of Operation and Health Responsible of the Establishment of Supplies for Health" or its modification more recent.

ÿ The letter of representation from the manufacturer, if the product is not manufactured by the parent company or factory or laboratory that requests registration in Mexico.

**NOTE:** The letter of representation must be presented in Spanish, or otherwise, its respective translation into Spanish by an expert translator must be attached, likewise it must be apostilled or legalized (Art. 153 of the Health Supplies Regulation).

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-021-I** Request for Extension of the Sanitary Registry of Medical Devices.
Modality I.- Nationally Manufactured Products Considered Low Risk that are Manufactured by Another Establishment

**1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | **5** {Fields: 1, 2, 3, 4, 5, 6, 7, 17, 20, 34, and 35} ÿ **8.A** manufactured product

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ The label project in Spanish,
in the terms of the corresponding standard. ÿ Simple copy of the "Notice of Operation and
Health Responsible of the Establishment of Supplies for Health" or its modification
more recent.

## 4.2. Sanitary registry medicines

### 4.2.1. By high or new

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-004-A** Sanitary Registry of Allopathic Medications, Vaccines and Blood Products.
Modality A.- Sanitary Registration of Nationally Manufactured Allopathic Medications, Vaccines and Blood Products (New Molecule).

**1** ÿ **2** ÿ **3** ÿ | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} National manufacturing product ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | |

Documentary requirements
**For the entry of the application, you must have the corresponding conclusions derived from the meeting with the New Molecules Committee of the Federal Commission for the Protection against Sanitary Risks.**

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ **Technical and scientific information that demonstrates:**

» The stability of the finished product in accordance with the Official Mexican Standards.
» The therapeutic efficacy and safety according to the scientific information published in prestigious journals and references bibliographic, in case of not having, preclinical and clinical studies indicated by the Secretariat.
» The information to prescribe in its broad and reduced versions.
» Documentation that shows that you are the owner of the patent, of the substance or active ingredient or that you have the license corresponding, both registered in the Mexican Institute of Industrial Property.
» The label project for primary and/or secondary packaging in accordance with the corresponding Official Mexican Standard.
» Identification of the origin and certificate of good manufacturing practices of the drug issued by the Secretariat or by the competent authority of the country of origin.
» In the event that the applicant presents the certificate of the competent authority of the country of origin, and this comes from countries with which the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat may verify compliance with good manufacturing practices. In this case, the authority will set the date on which the verification visit will be carried out within a period of no more than twenty business days, in accordance with the procedure established by the Secretariat and published in the Official Gazette of the Federation. If this visit is not carried out on the scheduled date for reasons attributable to the Secretariat, it will be rescheduled as a priority.
» The certification of good manufacturing practices will be valid for thirty months. ÿ **The technical and scientific information that demonstrates the identity and purity of its components:** » **For raw materials:**



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Monograph of the raw material and its bibliographical references. ÿ
Control methods, their validation and bibliographical references. ÿ
Certificates of analysis carried out in the laboratory, spectra or chromatograms obtained.

» **Of the finished product:** ÿ
Monograph and its bibliographical references. ÿ
Control methods, their validation and bibliographical references. ÿ
Certificates of analysis carried out in the laboratory, spectra or chromatograms obtained. ÿ Copy of the production orders of the lots used for the stability tests.

» **Of the packaging materials:**
ÿ Description and capacity of primary and secondary packaging materials. ÿ
Leakage test of the finished product in the primary container, results and bibliographical reference.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-004-B** | Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products.<br>Modality B.- Sanitary Registry of Nationally Manufactured Allopathic Medications, Vaccines and Blood Products. (Generic) |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5**<br>**{Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35}**<br>**National manufacturing product** | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ **Technical and scientific information that demonstrates:**

» The stability of the finished product in accordance with the Official Mexican Standards.
» For generics, interchangeability tests in accordance with the corresponding official Mexican standards and other provisions applicable.
» The information to prescribe in its broad and reduced versions.
» Documentation that shows that you are the owner of the patent, of the substance or active ingredient or that you have the license corresponding, both registered in the Mexican Institute of Industrial Property.
» The label project for primary and/or secondary packaging in accordance with the corresponding Official Mexican Standard.
» Identification of the origin and certificate of good manufacturing practices of the drug issued by the Secretariat or by the competent authority of the country of origin.
» In the event that the applicant presents the certificate of the competent authority of the country of origin, and this comes from countries with which the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat may verify compliance with good manufacturing practices. In this case, the authority will set the date on which the verification visit will be carried out within a period of no more than twenty business days, in accordance with the procedure established by the Secretariat and published in the Official Gazette of the Federation. If this visit is not carried out on the scheduled date for reasons attributable to the Secretariat, it will be rescheduled as a priority.
» The certification of good manufacturing practices will be valid for thirty months.
» For generics, interchangeability tests in accordance with the corresponding official Mexican standards and other provisions applicable.

ÿ **The technical and scientific information that demonstrates the identity and purity of its components:**

» **For raw materials:**
ÿ Monograph of the raw material and its bibliographical references. ÿ
Control methods, their validation and bibliographical references. Certificates of analysis carried out in the laboratory, spectra or obtained chromatograms.

» **Of the finished product:** ÿ
Monograph and its bibliographical references. ÿ
Control methods, their validation and bibliographical references. ÿ
Certificates of analysis carried out in the laboratory, spectra or chromatograms obtained. ÿ Copy of the production orders of the lots used for the stability tests.

» **Of the packaging materials:**
ÿ Description and capacity of primary and secondary packaging materials. ÿ
Leakage test of the finished product in the primary container, results and bibliographical reference.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-004-C** Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products Modality C.-
Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products of Foreign Manufacture.
(New Molecule)

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| **1** ÿ **2** ÿ **3** ÿ | | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35}** **Foreign manufacturing product** | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | | |

Documentary requirements

**For the entry of the application, you must have the corresponding conclusions derived from the meeting with the New Molecules Committee of the Federal Commission for the Protection against Sanitary Risks.**

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ **Technical and scientific information that demonstrates:**

» The stability of the finished product in accordance with the Official Mexican Standards corresponding to the standards of the country of origin.
» The therapeutic efficacy and safety according to the scientific information published in prestigious journals and references bibliographic, in case of not having, preclinical and clinical studies indicated by the Secretariat.
» The information to prescribe in its broad and reduced versions.
» Documentation that shows that you are the owner of the patent, of the substance or active ingredient or that you have the license corresponding, both registered in the Mexican Institute of Industrial Property.
» The label project for primary and/or secondary packaging in accordance with the corresponding Official Mexican Standard.
» Identification of the origin and certificate of good manufacturing practices of the drug issued by the Secretariat or by the competent authority of the country of origin.
» In the event that the applicant presents the certificate of the competent authority of the country of origin, and this comes from countries with which the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat may verify compliance with good manufacturing practices. In this case, the authority will set the date on which the verification visit will be carried out within a period of no more than twenty business days, in accordance with the procedure established by the Secretariat and published in the Official Gazette of the Federation. If this visit is not carried out on the scheduled date for reasons attributable to the Secretariat, it will be rescheduled as a priority.

» The certification of good manufacturing practices will be valid for thirty months. ÿ **The technical and scientific information that demonstrates the identity and purity of its components:** » **For raw materials:**

ÿ Monograph of the raw material and its bibliographical references. ÿ Control methods, their validation and bibliographical references. Certificates of analysis carried out in the laboratory, spectra or obtained chromatograms.

» **Of the finished product:** ÿ
Monograph and its bibliographical references. ÿ
Control methods, their validation and bibliographical references. ÿ
Certificates of analysis carried out in the laboratory, spectra or chromatograms obtained. ÿ Copy of the production orders of the lots used for the stability tests.

» **Of the packaging materials:**
ÿ Description and capacity of primary and secondary packaging materials. ÿ Leakage test of the finished product in the primary container, results and bibliographical reference.

ÿ Original certificate of free sale issued by the health authority of the country of origin.

**NOTE:** In the case of medicines that contain new molecular entities that have not been marketed in any other country because they do not have the corresponding sanitary registry and that are intended to be registered in Mexico, the aforementioned Certificate of Free Sale may be replaced by the report of clinical studies that have the participation of the Mexican population and that demonstrate the safety, quality, and efficacy of the product, as well as the document that describes the activities and interventions designed to characterize and prevent previously identified potential risks related to medications, including measuring the effectiveness of such interventions.

ÿ Certificate of good manufacturing practices for the drug and medication issued by the Secretariat or by the competent authority of the country of origin.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ In the event that the applicant presents the certificate of the competent authority of the country of origin, and this comes from countries with which the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat may verify compliance with good manufacturing practices. In this case, the authority will set the date on which the verification visit will be carried out within a period of no more than twenty business days, in accordance with the procedure established by the Secretariat and published in the Official Gazette of the Federation. If this visit is not carried out on the scheduled date for reasons attributable to the Secretariat, it will be rescheduled as a priority. ÿ The certification of good manufacturing practices will be valid for thirty months. ÿ Original of the letter of representation authenticated by the legal procedure that exists in the country of origin, in Spanish or in another language, with its respective translation into Spanish made by an expert translator, when the laboratory that manufactures it abroad is not a subsidiary or parent company of the laboratory requesting the Sanitary Registry.

| homoclave | Name, modality and quick filling guide |
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| **COFEPRIS-04-004-D** | Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products Modality D.- Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products of Foreign Manufacture. (Generic). |

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| **1** ÿ **2** ÿ **3** ÿ | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} Foreign manufacturing product | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | | |

documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ **Technical and scientific information that demonstrates:**

» The stability of the finished product in accordance with the Official Mexican Standards corresponding to the standards of the country of origin.
» For generics, interchangeability tests in accordance with the corresponding official Mexican standards and other provisions applicable.
» The information to prescribe in its broad and reduced versions.
» Documentation that shows that you are the owner of the patent, of the substance or active ingredient or that you have the license corresponding, both registered in the Mexican Institute of Industrial Property.
» The label project for primary and/or secondary packaging in accordance with the corresponding Official Mexican Standard.
» Identification of the origin and certificate of good manufacturing practices of the drug issued by the Secretariat or by the competent authority of the country of origin.
» In the event that the applicant presents the certificate of the competent authority of the country of origin, and this comes from countries with which the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat may verify compliance with good manufacturing practices. In this case, the authority will set the date on which the verification visit will be carried out within a period of no more than twenty business days, in accordance with the procedure established by the Secretariat and published in the Official Gazette of the Federation. If this visit is not carried out on the scheduled date for reasons attributable to the Secretariat, it will be rescheduled as a priority.

» The certification of good manufacturing practices will be valid for thirty months. ÿ **The technical and scientific information that demonstrates the identity and purity of its components:** » **For raw materials:**

ÿ Monograph of the raw material and its bibliographical references. ÿ Control methods, their validation and bibliographical references. Certificates of analysis carried out in the laboratory, spectra or obtained chromatograms.

» **Of the finished product:** ÿ Monograph and its bibliographical references. ÿ Control methods, their validation and bibliographical references. ÿ Certificates of analysis carried out in the laboratory, spectra or chromatograms obtained. ÿ Copy of the production orders of the lots used for the stability tests.

» **Of the packaging materials:** ÿ Description and capacity of primary and secondary packaging materials. ÿ Leakage test of the finished product in the primary container, results and bibliographical reference.

ÿ Original certificate of free sale issued by the health authority of the country of origin. ÿ Certificate of good manufacturing practices for the drug and medication issued by the Secretariat or by the competent authority of the country of origin.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ In the event that the applicant presents the certificate of the competent authority of the country of origin, and this comes from countries with which the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat may verify compliance with good manufacturing practices. In this case, the authority will set the date on which the verification visit will be carried out within a period of no more than twenty business days, in accordance with the procedure established by the Secretariat and published in the Official Gazette of the Federation. If this visit is not carried out on the scheduled date for reasons attributable to the Secretariat, it will be rescheduled as a priority. ÿ The certification of good manufacturing practices will be valid for thirty months. ÿ Original of the letter of representation authenticated by the legal procedure that exists in the country of origin, in Spanish or in another language, with its respective translation into Spanish made by an expert translator, when the laboratory that manufactures it abroad is not a subsidiary or parent company of the laboratory requesting the Sanitary Registry.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-004-E** Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products.
Modality E.- Sanitary Registration of Nationally Manufactured Innovative Biotechnological Medicine.

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| **1** ÿ **2** ÿ **3** ÿ | | | **5**<br>**{Fields: 1, 2, 4, 6, 17, 21, 22, 29, 30, 34, and 35}**<br>**National manufacturing product** | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | | | |

Documentary requirements

**All innovative biotechnological medicines must be submitted for evaluation before the New Molecules Committee and must be studied by the Biotechnological Products Evaluation Subcommittee prior to submitting the application for Sanitary Registration, to determine if the clinical tests are effective for demonstrate its safety, quality and efficacy.**

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Certificate of Good Manufacturing Practices of the biopharmaceutical issued by the Secretariat or by the competent authority of the country of origin. In the event that the Secretariat has not entered into Recognition Agreements on good manufacturing practices, the Secretariat may verify compliance with good manufacturing practices.

ÿ Certificate of Good Manufacturing Practices issued by the Secretariat, from the manufacturer(s) of the biotechnological medicine and, when applicable, from the manufacturer of the diluent. ÿ Simple copy of the Sanitary License and the Notice of Sanitary Responsible of the manufacturer(s) of the biotechnological drug and of the applicant for the Sanitary Registry.

ÿ Simple copy of the Sanitary License and the Notice of Sanitary Responsible of the conditioning site, when applicable. ÿ Simple copy of the Notice of Operation and the Notice of Sanitary Responsible of the deposit and distribution warehouse, when applicable. ÿ The biopharmaceutical monograph, composition and formula; which should contain:

» International Nonproprietary Name, structural, molecular formula and when applicable the relative molecular mass.

» Characterization of the biopharmaceutical: present data that allows determining the structure and physicochemical, immunological and biological characteristics of the biopharmaceutical depending on the method used with the analytical evidence generated (amino acid sequencing, peptide mapping, carbohydrate structure, oligosaccharide pattern, glycosylation sites). , electrophoretic pattern, chromatograms, isoform pattern, spectroscopic profiles [UV, IR, NMR, etc.], and others, depending on new analytical technologies or modifications to existing ones).

ÿ The origin and history of the master cell bank, the gene, the construction of the vector-host expression system for the protein of interest and relevant characterization of the genotype and phenotype; that includes the following information: » Starting materials: microorganisms (strains), seed lots, cell lines, Master Cell Bank and Work Cell Bank system, relevant characterization of the genotype and phenotype, viral markers or those that apply; attaching the analytical evidence generated. ÿ Origin, identification, biological and molecular characterization. ÿ Controls: summary of genetic stability, adventitious agents, endogenous viruses, number of passages, among others. ÿ For starting materials from biological sources, submit a summary on viral safety. ÿ Analytical certificates attaching the analytical evidence generated.

» Identity of the gene, summary of the construction of the vector-host for the protein of interest, summary of the stability of the expression of the gene; attaching the analytical evidence generated.

ÿ The summary of the manufacturing process of the biopharmaceutical: strain or cell line, fermentation, separation and purification, as well as the flowchart corresponding to said process; according to the following:

» List of raw materials used in the manufacture of the biopharmaceutical: culture media, fetal serum, diluting solutions, buffer solutions, antibiotics, etc.

» Certificate of sera of animal origin.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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» In the case of inputs of animal origin, present the document stating that the requirements on the minimization of the risk of transmission of the agents of animal spongiform encephalopathy.

» Description of the process, flowchart including all production steps and summary of the inactivation process, purification and when applicable, conjugation; indicating their quality controls.

ÿ Analytical methods: physical, chemical and biological for raw materials and biopharmaceuticals, as well as the validation report of their results, made by the manufacturer, for cases in which they are not pharmacopoeial methods;

» For the biopharmaceutical:

ÿ Specifications and bibliographical references. ÿ Protocol and report or report on the validation of non-pharmacopoeial analysis methods. ÿ Certificate of analysis carried out by the manufacturer, attaching the analytical evidence generated. ÿ Description and specifications of the container-closure system. ÿ Stability study report in accordance with the Official Mexican Standard and International Guidelines.

» For additives:

ÿ Common name and description, whether or not they are in the final product.

ÿ Specifications and monograph with bibliographical references. ÿ Analytical certificate of each additive issued by their manufacturers and by the drug manufacturer, with spectra or corresponding chromatograms. ÿ

The validation report of the manufacturing process, carried out by the manufacturer; ÿ The drug monograph that includes the International Nonproprietary Name, pharmaceutical form, qualitative specifications and quantitative;

» For the medicine:

ÿ Justification of the pharmaceutical form, consideration of use and formulation indicating the function of its components. ÿ Specifications and certificate of analysis of the standard or reference materials. ÿ Methods of analysis, in the case of non-pharmacopoeial methods, the validation report must be included. ÿ Certificate of analysis carried out by the manufacturer, corresponding to the batches or control number used in the studies of stability and clinical studies, endorsed by the registrant and the manufacturer (when applicable). ÿ Protocol and report of the stability study according to the Official Mexican Standard and International Guidelines. ÿ Report on the validation of the network or cold chain.

» For the diluent (when applicable):

ÿ Description, common name of each of the components; as well as its function in the formulation. ÿ Certificate of analysis carried out by the manufacturer. ÿ Simple copy of the Sanitary Registry before the Secretariat (when applicable). ÿ The manufacturing, formulation, filling and conditioning processes, as well as their process controls;

» For the medicine:

ÿ Qualitative-quantitative formula, signed by the Sanitary Manager. ÿ Summary and flowchart of the manufacturing process indicating the controls during the process and their results. ÿ Protocol and validation report of the manufacturing process. ÿ Type, justification and controls of the sterilization process(es). ÿ Protocol and report of the validation of the sterilization process and, when applicable, aseptic filling and depyrogenation. ÿ Copy of the title page of the production order or summary manufacturing protocol of the batches submitted to the stability studies, where the raw materials used are specified. The batches of the drug must be produced using different batches of the biopharmaceutical; as well as the batches reported in the clinical study. ÿ Copy of the cover of the conditioning order, where the materials used are specified.

» For the diluent, when applicable: ÿ Qualitative-quantitative formula, signed by the Sanitary Manager. ÿ Copy of the title page of the production and conditioning order that contains the assortment of raw materials and materials. ÿ Type, justification and controls of the sterilization process(es). ÿ Protocol and report on the validation of the sterilization process, and when applicable, aseptic filling and depyrogenation. ÿ The label projects and the corresponding instructions, as well as the specifications of the primary and secondary packaging, of in accordance with the General Health Law, the Health Supplies Regulations and other applicable provisions;

» For the primary and secondary packaging of the drug and, when applicable, its components, submit the following information:

ÿ Description, specifications and methods of analysis. ÿ Certificates of analysis issued by their manufacturers and by the drug manufacturer, for each of the materials of the container-closure system.

ÿ Primary packaging: Biological tests, including non-toxicity tests if applicable. ÿ Test for the evaluation of the container-closure system in the primary container, with results and bibliographical references. ÿ Medical device: description, composition, function and when applying the registration before the Secretariat.

» For the primary and secondary packaging of the diluent and its components (if applicable):



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Description, specifications and methods of analysis. ÿ
Certificates of analysis carried out by the manufacturer and by the diluent manufacturer.
ÿ Primary packaging: Biological tests, including non-toxicity tests if applicable. ÿ Test for
the evaluation of the container-closure system in the primary container, with results and bibliographical reference.
ÿ Information to prewrite in broad and reduced version. ÿ
Documentation that shows that you are the owner of the patent, of the substance or active ingredient or that you have the license corresponding, both registered in the Mexican Institute of Industrial Property;
ÿ Intensive pharmacovigilance program, in accordance with the provisions that are applicable, and ÿ The
preclinical and clinical studies indicated by the Secretariat as necessary to demonstrate the safety, efficacy and quality of the product, in accordance with the provisions of the General Health Law. , the Health Supplies Regulations and other applicable legal provisions, including the reporting of adverse events and immunogenicity, characterizing the immune response and evaluating the correlation between neutralizing antibodies, the pharmacokinetics and pharmacodynamics of the product. ÿ Clinical studies of innovative
biotechnological drugs must be carried out in Mexico:
» When the medicine is manufactured in the national territory, so determined by the Secretariat, based on the opinion of the Committee of New Molecules, after consulting the latter with the Subcommittee for the Evaluation of Biotechnological Products.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-004-F** Sanitary Registry of Allopathic Medications, Vaccines and Blood Products.
Modality F.- Sanitary Registration of Innovative Biotechnological Medicine of Foreign Manufacture.

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| **1** ÿ **2** ÿ **3** ÿ | | | **5**<br>**{Fields: 1, 2, 4, 6, 17, 21, 22, 29, 30, 34, and 35}**<br>**Foreign manufacturing product** | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ In the case of foreign-manufactured biotechnological drugs, in addition to the documents requested for the Registry of Nationally Manufactured Innovative Biotechnological Medicine, must be attached: »
Certificate of Free Sale or equivalent issued by the corresponding authority of the country of origin.
» Certificate of Good Manufacturing Practices from the manufacturer(s) of the biotech drug and, when applicable, from the manufacturer of the diluent; issued by the Secretariat or by the competent authority of the country of origin. In the event that the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat may verify compliance with good manufacturing practices.

» Letter of representation authenticated by the procedure of the country of origin, in accordance with the provisions of article 170 of the Regulation of health products.
» Document that accredits a legal representative domiciled in the United States of Mexico.
» Clinical studies of innovative biotechnological medicines must be carried out in Mexico: ÿ When the manufacture and the aforementioned studies have been carried out abroad and so determined by the Secretariat, based on the opinion of the New Molecules Committee, after consulting the this is carried out by the Subcommittee for the Evaluation of Biotechnological Products.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-004-G** Sanitary Registry of Allopathic Medicines, Vaccines and Blood Products.
Modality G.- Sanitary Registry of Nationally Manufactured Biocomparable Biotechnological Medicines.

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| **1** ÿ **2** ÿ **3** ÿ | | | **5**<br>**{Fields: 1, 2, 4, 6, 17, 21, 22, 29, 30, 34, and 35}**<br>**National manufacturing product** | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Certificate of Good Manufacturing Practices of the biopharmaceutical issued by the Secretariat or by the competent authority of the country of origin. In the event that the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat may verify compliance with good manufacturing practices. ÿ Certificate of Good Manufacturing
Practices issued by the Secretariat, of the manufacturer(s) of the biotechnological medicine and when thinner manufacturer's applique.
ÿ Simple copy of the Sanitary License and the Notice of Sanitary Responsible of the manufacturer(s) of the biotechnological drug and of the applicant for the Sanitary Registry.
ÿ Simple copy of the Sanitary License and the Notice of Sanitary Responsible of the conditioning site, when applicable. ÿ Simple copy of the Notice of Operation and the Notice of Sanitary Responsible of the deposit and distribution warehouse, when applicable. ÿ The biopharmaceutical monograph, composition and formula; which should contain:

» International Nonproprietary Name, structural, molecular formula and when applicable the relative molecular mass.
» Characterization of the biopharmaceutical: present data that allows determining the structure and physicochemical, immunological and biological characteristics of the biopharmaceutical depending on the method used with the analytical evidence generated (amino acid sequencing, peptide mapping, carbohydrate structure, oligosaccharide pattern, glycosylation sites). , electrophoretic pattern, chromatograms, isoform pattern, spectroscopic profiles [UV, IR, NMR, etc.], and others, depending on new analytical technologies or modifications to existing ones).

ÿ The origin and history of the master cell bank, the gene, the construction of the vector-host expression system for the protein of interest and relevant characterization of the genotype and phenotype; that includes the following information: » Starting materials: microorganisms (strains), seed lots, cell lines, Master Cell Bank and Work Cell Bank system, relevant characterization of the genotype and phenotype, viral markers or those that apply; attaching the analytical evidence generated. ÿ Origin, identification, biological and molecular characterization. ÿ Controls: summary of genetic stability, adventitious agents, endogenous viruses, number of passages, among others. ÿ For starting materials from biological sources, submit a summary on viral safety. ÿ Analytical certificates attaching the analytical evidence generated.

» Identity of the gene, summary of the construction of the vector-host for the protein of interest, summary of the stability of the expression of the gene; attaching the analytical evidence generated.
ÿ The summary of the manufacturing process of the biopharmaceutical: strain or cell line, fermentation, separation and purification, as well as the flowchart corresponding to said process; according to the following:

» List of raw materials used in the manufacture of the biopharmaceutical: culture media, fetal serum, diluting solutions, buffer solutions, antibiotics, etc.
» Certificate of sera of animal origin.
» In the case of inputs of animal origin, present the document stating that the requirements on the minimization of the risk of transmission of the agents of animal spongiform encephalopathy.
» Description of the process, flowchart including all production steps and summary of the inactivation process, purification and when applicable, conjugation; indicating their quality controls.

ÿ Analytical methods: physical, chemical and biological for raw materials and biopharmaceuticals, as well as the validation report of their results, made by the manufacturer, for cases in which they are not pharmacopoeial methods;

» For the biopharmaceutical:

ÿ Specifications and bibliographical references. ÿ Protocol and report or report on the validation of non-pharmacopoeial analysis methods. ÿ Certificate of analysis carried out by the manufacturer, attaching the analytical evidence generated. ÿ Description and specifications of the container-closure system. ÿ Stability study report in accordance with the Official Mexican Standard and International Guidelines.

» For additives:

ÿ Common name and description, whether or not they are in the final product.
ÿ Specifications and monograph with bibliographical references. ÿ Analytical certificate of each additive issued by their manufacturers and by the drug manufacturer, with spectra or corresponding chromatograms. ÿ
The validation report of the manufacturing process, carried out by the manufacturer; ÿ The drug monograph that includes the International Nonproprietary Name, pharmaceutical form, qualitative specifications and quantitative;

» For the medicine:

ÿ Justification of the pharmaceutical form, consideration of use and formulation indicating the function of its components. ÿ Specifications and certificate of analysis of the standard or reference materials. ÿ Methods of analysis, in the case of non-pharmacopoeial methods, the validation report must be included. ÿ Certificate of analysis carried out by the manufacturer, corresponding to the batches or control number used in the studies of stability and clinical studies, endorsed by the registrant and the manufacturer (when applicable). ÿ Protocol and report of the stability study according to the Official Mexican Standard and International Guidelines.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Report on the validation of the network or cold chain.

» For the diluent (when applicable):

ÿ Description, common name of each of the components; as well as its function in the formulation. ÿ Certificate of analysis carried out by the manufacturer. ÿ Simple copy of the Sanitary Registry before the Secretariat (when applicable). ÿ The manufacturing, formulation, filling and conditioning processes, as well as their process controls;

» For the medicine:

ÿ Qualitative-quantitative formula, signed by the Sanitary Manager. ÿ Summary and flowchart of the manufacturing process indicating the controls during the process and their results. ÿ Protocol and validation report of the manufacturing process. ÿ Type, justification and controls of the sterilization process(es). ÿ Protocol and report of the validation of the sterilization process and, when applicable, aseptic filling and depyrogenation. ÿ Copy of the title page of the production order or summary manufacturing protocol of the batches submitted to the stability studies, where the raw materials used are specified. The batches of the drug must be produced using different batches of the biopharmaceutical; as well as the batches reported in the clinical study.

ÿ Copy of the cover of the conditioning order, where the materials used are specified.

» For the diluent, when applicable: ÿ Qualitative-quantitative formula, signed by the Sanitary Manager. ÿ Copy of the title page of the production and conditioning order that contains the assortment of raw materials and materials. ÿ Type, justification and controls of the sterilization process(es). ÿ Protocol and report on the validation of the sterilization process, and when applicable, aseptic filling and depyrogenation. ÿ The label projects and the corresponding instructions, as well as the specifications of the primary and secondary packaging, of

in accordance with the General Health Law, the Health Supplies Regulations and other applicable provisions; » For the primary and secondary packaging of the drug and, when applicable, its components, submit the following information: ÿ Description, specifications and methods of analysis. ÿ Certificates of analysis issued by their manufacturers and by the drug manufacturer, for each of the

materials of the container-closure system.

ÿ Primary packaging: Biological tests, including non-toxicity tests if applicable. ÿ Test for the evaluation of the container-closure system in the primary container, with results and bibliographical references. ÿ Medical device: description, composition, function and when applying the registration before the Secretariat.

» For the primary and secondary packaging of the diluent and its components (if applicable):

ÿ Description, specifications and methods of analysis. ÿ Certificates of analysis carried out by the manufacturer and by the diluent manufacturer. ÿ Primary packaging: Biological tests, including non-toxicity tests if applicable. ÿ Test for the evaluation of the container-closure system in the primary container, with results and bibliographical reference.

ÿ Information to prewrite in broad and reduced version. ÿ Documentation that shows that you are the owner of the patent, of the substance or active ingredient or that you have the license corresponding, both registered in the Mexican Institute of Industrial Property;

ÿ Intensive pharmacovigilance program, in accordance with the provisions that are applicable, and ÿ Protocol authorized by the Secretariat and report of the biocomparability studies, in accordance with the Regulation of Inputs for Health and other applicable provisions.

**NOTE 1:** The specific requirements of the *in vitro,* preclinical and clinical studies for the approval of each biocomparable biotechnological medicine will be determined by the Secretariat, considering the opinion of the New Molecules Committee, after consulting the Subcommittee for the Evaluation of Biotechnological Products. .

**NOTE 2:** In the case of biocomparability studies in relation to a reference biotechnological drug, it must be used throughout the development of the biocomparable biotechnological drug, to compare the quality and preclinical and clinical studies.
The posology, dose and route of administration of the biocomparable biotech medicinal product should be the same as the reference biotech medicinal product.

**NOTE 3:** Clinical studies of biocomparable biotechnological drugs must be carried out in Mexico, when so determined by the Secretariat based on the opinion of the New Molecules Committee, after consulting the Subcommittee for the Evaluation of Biotechnological Products.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-004-H** Sanitary Registry of Allopathic Medications, Vaccines and Blood Products.
Modality H - Sanitary Registry of Biocomparable Biotechnological Medicines of Foreign Manufacture.

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| **1** ÿ **2** ÿ **3** ÿ | | | **5** {Fields: 1, 2, 4, 6, 17, 21, 22, 29, 30, 34, and 35} Foreign manufacturing product | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ In the case of foreign-
manufactured biotechnological drugs, in addition to the documents requested for the Nationally Manufactured Biocomparable Biotechnological Drug Registry, the following must be submitted: ÿ Certificate of Free Sale or equivalent issued by
the corresponding authority of the country of origin. ÿ Letter of representation authenticated by the procedure
of the country of origin, in accordance with the provisions of article 170 of the Regulation of Supplies for health. ÿ
Document that accredits a legal representative domiciled in the United States of Mexico. ÿ Certificate of
Good Manufacturing Practices from the manufacturer(s) of the biotech drug and, when applicable, from the manufacturer of the diluent; issued by the Secretariat or by the competent authority of the country of origin. In the event that the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat may verify compliance with good manufacturing practices.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-004-I** Sanitary Registry of Allopathic Medicines, Vaccines and Hemoderivatives Modality
I.- Sanitary Registry of Biological Product whose Active Ingredient is not Registered in the United Mexican States, but is Authorized for Sale in the European Union, Switzerland , United States of America, Canada or Australia (Under the Equivalence Agreements).

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| **1** ÿ **2** ÿ **3** ÿ | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} Foreign manufacturing product | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Informative note: With the
opinions generated from the evaluation of the New Molecules Committee, prior to the submission of the application for sanitary registration, to determine if the analytical, preclinical and clinical studies are adequate and sufficient to demonstrate their safety, quality and efficacy. As well as the requirements indicated therein.
ÿ Sanitary License or Notice of Operation of the establishment in the United Mexican States, as appropriate for the Holder of the Registry and/or distributor, according to articles 257 and 258 of the Law. In the case of foreign manufacturers, it is required to have a license , certificate or document that proves that the company has the permit to manufacture medicines, issued by the competent authority of the country of origin, in accordance with article 168 of the Regulation;
ÿ Notice of Sanitary Responsible of the establishment in the United Mexican States according to article 259 of the Law; ÿ The
document that accredits a legal representative domiciled in the United Mexican States; ÿ Simple copy of the
Sanitary License and the Notice of Sanitary Responsible of the conditioning site, when applicable. ÿ Simple copy of the Notice of
Operation and the Notice of Sanitary Responsible of the storage and distribution warehouse, when applicable. ÿ The technical and scientific
information that demonstrates: » The identity and purity
of its components in accordance with the provisions of the Pharmacopoeia of the United Mexican States and its supplements;
- **For raw materials:**
  - Monograph of the raw material and its bibliographical references.
  - Control methods, their validation and bibliographical references. Certificates of analysis carried out in the laboratory, spectra or obtained chromatograms.
- **Of the finished product:**



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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• Monograph and its bibliographical references. •
Control methods, their validation and bibliographical references. •
Certificates of analysis carried out in the laboratory, spectra or chromatograms obtained. • Copy of the production orders of the lots used for the stability tests.

- **Of the materials and specifications of the primary and secondary packaging:**
  • Description and capacity of primary and secondary packaging materials. • Leakage test of the finished product in the primary container, results and bibliographical reference.

» The stability of the finished product in accordance with the corresponding Standards (Official Mexican Standard and the standards of the country of origin)

» The therapeutic efficacy and safety according to the corresponding scientific information. ÿ Prescribing information, in its broad and reduced versions. ÿ The label projects and the corresponding instructions, in accordance with the General Health Law, Regulation of Supplies for the Health and the corresponding official Mexican standard.

ÿ In the case of a patent, the documentation that demonstrates that it is the holder of the patent of the substance or active ingredient or that it has the corresponding license, both registered with the Mexican Institute of Industrial Property.

ÿ Original certificate of free sale issued by the health authority of the country of origin. ÿ Certificate of good manufacturing practices of the drug(s) and medication(s) issued by the Secretariat or by the authority of origin and, when applicable, that of the manufacturer of the diluent(s). ), issued by the Secretariat or by the competent authority of the country of origin. In the event that the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat may verify compliance with good manufacturing practices. ÿ The certification of good manufacturing practices will be valid for thirty months. ÿ Original of the letter of representation authenticated by the legal procedure that exists in the country of origin, in Spanish or in another language, with its respective translation into Spanish made by an expert translator, when the laboratory that manufactures it abroad is not a subsidiary or parent company of the laboratory requesting the Sanitary Registry.

ÿ The technical information of the drug manufacturer must be submitted with a translation into Spanish and signed by the person in charge health or legal representative in Mexico; with the following information and documentation:

| Regulatory Agency | documentation |
|---|---|
| **European Medicines Agency (EMA)** | • Notarized copy of the Marketing Authorization • Notarized copy of the Marketing Authorization |
| **Swiss Agency for Therapeutic Products - Swissmedic** | |
| **Food and Drug Administration (Food and Drug Administration - FDA)** | • Notarized copy of the FDA Approval Letter in accordance with 21 CFR 314.<br>• Certificate for Foreign Government, CPP or EIR. • Notarized copy of the Registered Drug Establishment document (Registration of Drug Establishment Form FDA-2656) in accordance with 21 CFR 207.35(a) or equivalent determined by FDA. |
| **Health Canada Office - Office of Therapeutic Products (TPD)** | • Notice of Compliance. • Certificate of Pharmaceutical Product or EIR. • Establishment License Number issued by Health Canada (Establishment License Number). |
| **Therapeutic Products Administration of Australia (Therapeutic Goods Administration - TGA)** | • Notarized copy of the Letter of Approval for Registration. |



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-004-J** Sanitary Registry of Allopathic Medications, Vaccines and Blood Products.
Modality J.- Sanitary Registration of Biotechnological Medication whose Active Ingredient is not Registered in the United Mexican States, but is Authorized for Sale in the European Union, Switzerland, the United States of America, Canada or Australia (Under the Agreements of Equivalence).

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|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35}** **Foreign manufacturing product** | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | | | |

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Informative note: With the opinions generated from the evaluation of the New Molecules Committee, prior to the submission of the application for sanitary registration, to determine if the analytical, preclinical and clinical studies are adequate and sufficient to demonstrate their safety, quality and efficacy. As well as the requirements indicated therein.

ÿ Sanitary License or Notice of Operation of the establishment in the United Mexican States, as appropriate for the Holder of the Registry and/or distributor, according to articles 257 and 258 of the Law. In the case of foreign manufacturers, it is required to have a license , certificate or document that proves that the company has the permit to manufacture medicines, issued by the competent authority of the country of origin, in accordance with article 168 of the Regulation;

ÿ Notice of Sanitary Responsible of the establishment in the United Mexican States according to article 259 of the Law; ÿ The document that accredits a legal representative domiciled in the United Mexican States; ÿ Simple copy of the Sanitary License and the Notice of Sanitary Responsible of the conditioning site, when applicable. ÿ Simple copy of the Notice of Operation and the Notice of Sanitary Responsible of the deposit and distribution warehouse, when applicable. ÿ The biopharmaceutical monograph, composition and formula. (If there is no monograph, you must attach specifications of organisms

specialized or other internationally recognized scientific bibliography).
» International Nonproprietary Name, structural, molecular formula and when applicable the relative molecular mass.
» Characterization of the biopharmaceutical: present data that allows determining the structure and physicochemical, immunological and biological characteristics of the biopharmaceutical depending on the method used with the analytical evidence generated (amino acid sequencing, peptide mapping, carbohydrate structure, oligosaccharide pattern, glycosylation sites). , electrophoretic pattern, chromatograms, isoform pattern, spectroscopic profiles [UV, IR, NMR, etc.], and others, depending on new analytical technologies or modifications to existing ones).

ÿ The origin and history of the master cell bank, the gene, the construction of the vector-host expression system for the protein of interest and relevant characterization of the genotype and phenotype; that includes the following information: » Starting materials: microorganisms (strains), seed lots, cell lines, Master Cell Bank and Work Cell Bank system, relevant characterization of the genotype and phenotype, viral markers or those that apply; attaching the analytical evidence generated. ÿ Origin, identification, biological and molecular characterization. ÿ Controls: summary of genetic stability, adventitious agents, endogenous viruses, number of passages, among others. ÿ For starting materials from biological sources, submit a summary on viral safety. ÿ Analytical certificates attaching the analytical evidence generated.

» Identity of the gene, summary of the construction of the vector-host for the protein of interest, summary of the stability of the expression of the gene; attaching the analytical evidence generated.

ÿ The summary of the manufacturing process of the biopharmaceutical: strain or cell line, fermentation, separation and purification, as well as the flowchart corresponding to said process; according to the following: » List of raw materials used in the manufacture of the biopharmaceutical: culture media, fetal serum, diluting solutions, buffer solutions, antibiotics, etc.

» Certificate of sera of animal origin.
» In the case of inputs of animal origin, present the document stating that the requirements on the minimization of the risk of transmission of the agents of animal spongiform encephalopathy.
» Description of the process, flowchart including all production steps and summary of the inactivation process, purification and when applicable, conjugation; indicating their quality controls.

ÿ Analytical methods: physical, chemical and biological for raw materials and biopharmaceuticals, as well as the validation report of their results, made by the manufacturer, for cases in which they are not pharmacopoeial methods.

ÿ The validation report of the manufacturing process, made by the manufacturer. ÿ The drug monograph that includes the International Nonproprietary Name, pharmaceutical form, qualitative specifications and quantitative.

» For the medicine:



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Justification of the pharmaceutical form, consideration of use and formulation indicating the function of its components. ÿ Specifications and certificate of analysis of the standard or reference materials. ÿ Methods of analysis, in the case of non-pharmacopoeial methods, the validation report must be included. ÿ Certificate of analysis carried out by the manufacturer, corresponding to the batches or control number used in the studies of stability and clinical studies, endorsed by the registrant and the manufacturer (when applicable).

» For the diluent (when applicable):

ÿ Description, common name of each of the components; as well as its function in the formulation. ÿ Certificate of analysis carried out by the manufacturer. ÿ Simple copy of the Sanitary Registry before the Secretariat (when applicable). ÿ The manufacturing, formulation, filling and conditioning processes, as well as their process controls:

» For the medicine:

ÿ Qualitative-quantitative formula, signed by the Sanitary Manager. ÿ Summary and flowchart of the manufacturing process indicating the controls during the process and their results. ÿ Protocol and validation report of the manufacturing process. ÿ Type, justification and controls of the sterilization process(es). ÿ Protocol and report of the validation of the sterilization process and, when applicable, aseptic filling and depyrogenation. ÿ Copy of the title page of the production order or summary manufacturing protocol of the batches submitted to the stability studies, where the raw materials used are specified. The batches of the drug must be produced using different batches of the biopharmaceutical; as well as the batches reported in the clinical study. ÿ Copy of the cover of the conditioning order, where the materials used are specified.

» For the diluent, when applicable: ÿ Qualitative-quantitative formula, signed by the Sanitary Manager. ÿ Copy of the title page of the production and conditioning order that contains the assortment of raw materials and materials. ÿ Type, justification and controls of the sterilization process(es). ÿ Protocol and report on the validation of the sterilization process, and when applicable, aseptic filling and depyrogenation. ÿ Certificate of good manufacturing practices from the manufacturer(s) of the biopharmaceutical and from the manufacturer of the medication and, when applicable, that of the manufacturer of the diluent, issued by the Secretariat or by the competent authority of the country of origin. In the event that the Secretariat has not entered into recognition agreements on good manufacturing practices, the Secretariat will verify compliance with good manufacturing practices. ÿ Drug stability studies. Submit protocol and stability study report in accordance with Official Mexican Standard NOM-073-SSA1-2005. Stability of drugs and medicines, and for cases not provided for in the standard, according to the recommendations of the International Guidelines (WHO, ICH, FDA/CDER/CBER).

» For the primary and secondary packaging of the drug and, when applicable, its components, submit the following information:

ÿ Description, specifications and methods of analysis. ÿ Certificates of analysis issued by their manufacturers and by the drug manufacturer, for each of the materials of the container-closure system.

ÿ Primary packaging: Biological tests, including non-toxicity tests if applicable. ÿ Test for the evaluation of the container-closure system in the primary container, with results and bibliographical references. ÿ Medical device: description, composition, function and when applying the registration before the Secretariat.

» For the primary and secondary packaging of the diluent and its components (if applicable):

ÿ Description, specifications and methods of analysis. ÿ Certificates of analysis carried out by the manufacturer and by the diluent manufacturer. ÿ Primary packaging: Biological tests, including non-toxicity tests if applicable. ÿ Test for the evaluation of the container-closure system in the primary container, with results and bibliographical reference.

ÿ Protocol and report of the validation of the network or cold chain. ÿ Intensive pharmacovigilance program, in accordance with the applicable provisions. ÿ Prescribing information in broad and reduced version. ÿ In the case of a patent, the documentation that demonstrates that it is the owner of the patent, of the substance or active ingredient or that has the corresponding license, both registered with the Mexican Institute of Industrial Property.

ÿ The preclinical and clinical studies indicated by the Secretariat as necessary to demonstrate the safety, efficacy and quality of the product, in accordance with the provisions of the Law, the Regulations and other applicable legal provisions, including the report of adverse events and immunogenicity, characterizing the immune response and the evaluation of the correlation between neutralizing antibodies of the pharmacokinetics and pharmacodynamics of the product.

ÿ Clinical studies must be carried out in Mexico when so determined by the Secretariat, based on the opinion of the Molecules Committee. New, after consulting the latter with the Subcommittee for the Evaluation of Biotechnological Products.

ÿ The label projects and the corresponding instructions, as well as the specifications of the primary and secondary packaging, of in accordance with the General Health Law, the Health Supplies Regulations and other applicable provisions.

ÿ The technical information of the drug manufacturer must be submitted with a translation into Spanish and signed by the person in charge health or legal representative in Mexico; with the following information and documentation:



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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| Regulatory Agency | documentation |
|---|---|
| **European Medicines Agency (EMA)** | • Notarized copy of the Marketing Authorization • Notarized |
| **Swiss Agency for Therapeutic Products - Swissmedic** | copy of the Marketing Authorization |
| **Food and Drug Administration (Food and Drug Administration - FDA)** | • Notarized copy of the FDA Approval Letter in accordance with 21 CFR 314. • Certificate for Foreign Government, CPP or EIR. • Notarized copy of the Registered Drug Establishment document (Registration of Drug Establishment Form FDA-2656) in accordance with 21 CFR 207.35(a) or equivalent determined by FDA. |
| **Health Canada Office - Office of Therapeutic Products (TPD)** | • Notice of Compliance. • Certificate of Pharmaceutical Product or EIR. • Establishment License Number issued by Health Canada (Establishment License Number). |
| **Therapeutic Products Administration of Australia (Therapeutic Goods Administration - TGA)** | • Notarized copy of the Letter of Approval for Registration. |

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-004-K** Sanitary Registry of Allopathic Medications, Vaccines and Blood Products.
Modality K.- Sanitary Registration of Allopathic Medication whose Active Ingredient is not Registered in the United Mexican States, but is Registered for Sale in the European Union, Switzerland, the United States of America, Canada or Australia (Under the Agreements of Equivalence)

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| **1** ÿ | **2** ÿ | **3** ÿ | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} Foreign manufacturing product | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Informative note: With the opinions generated from the evaluation of the New Molecules Committee, prior to the submission of the application for sanitary registration, to determine if the analytical, preclinical and clinical studies are adequate and sufficient to demonstrate their safety, quality and efficacy. As well as the requirements indicated therein.
ÿ Sanitary License or Notice of Operation of the establishment in the United Mexican States, as appropriate for the Holder of the Registry and/or distributor, according to articles 257 and 258 of the Law. In the case of foreign manufacturers, it is required to have a license , certificate or document that proves that the company has the permit to manufacture medicines, issued by the competent authority of the country of origin, in accordance with article 168 of the Regulation;
ÿ Notice of Sanitary Responsible of the establishment in the United Mexican States according to article 259 of the Law; ÿ The document that accredits a legal representative domiciled in the United Mexican States; ÿ Simple copy of the Sanitary License and the Notice of Sanitary Responsible of the conditioning site, when applicable. ÿ Simple copy of the Notice of Operation and the Notice of Sanitary Responsible of the deposit and distribution warehouse, when applicable. ÿ The technical and scientific information that demonstrates: » The identity and purity of its components in accordance with the provisions of the Pharmacopoeia of the United Mexican States and its supplements;
- **For raw materials:**
  • Monograph of the raw material and its bibliographical references.
  • Control methods, their validation and bibliographical references. Certificates of analysis carried out in the laboratory, spectra or obtained chromatograms.
- **Of the finished product:** • Monograph and its bibliographical references.
  • Control methods, their validation and bibliographical references.
  • Certificates of analysis carried out in the laboratory, spectra or chromatograms obtained. • Copy of the production orders of the lots used for the stability tests.
- **Of the materials and specifications of the primary and secondary packaging:** • Description and capacity of the primary and secondary packaging materials.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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• Leakage test of the finished product in the primary container, results and bibliographical reference.
» The stability of the finished product in accordance with the corresponding Standards (Official Mexican Standard and the standards of the country of origin)
» The therapeutic efficacy and safety according to the corresponding scientific information. ÿ Prescribing information, in its broad and reduced versions. ÿ The label projects and the corresponding instructions, in accordance with the General Health Law, Regulation of Supplies for the Health and the corresponding official Mexican standard.
ÿ Documentation that shows that you are the owner of the patent, of the active substance or ingredient or that you have the corresponding license, both registered with the Mexican Institute of Industrial Property in accordance with article 167 Bis of the Regulations, and ÿ Certificate of Good Manufacturing Practices of the manufacturer of the drug, of the medication, of the conditioner of the primary container and/or secondary (when applicable) or the documents mentioned in the following cases:

| Regulatory Agency | Documents Equivalent to the Certificate of Good Manufacturing Practices in Mexico |
|---|---|
| **Food and Drug Administration (Food and Drug Administration - FDA)** | For the drug manufacturer to present CPP, Certificate for Foreign Government<br>For the drug manufacturer to present CPP, Certificate for Foreign Government<br>For conditioner of the primary container present CPP, Certificate for the Government Foreign<br>For conditioner of the secondary packaging present EIR |
| **Health Canada Office - Office of Therapeutic Products (TPD)** | Pharmaceutical Product Certificate |

ÿ The technical information of the drug manufacturer must be submitted with a translation into Spanish and signed by the person in charge health or legal representative in Mexico; with the following information and documentation:

| Regulatory Agency | documentation |
|---|---|
| **European Medicines Agency (EMA)** | • Notarized copy of the Marketing Authorization • Notarized copy of the Medicinal Products Authorization |
| **Swiss Agency products for Therapeutics - Swissmedic** | |
| **Administration Food and Medicines (Food and Drug Administration - FDA)** | • Notarized copy of the FDA Approval Letter pursuant to 21 CFR 314;<br>• Certificate for Foreign Government, CPP or EIR; • Notarized copy of the Medication Establishment document Registered (Registration of Drug Establishment – Form FDA-2656) in accordance with 21 CFR 207.35(a) or equivalent determined by FDA |
| **Health Canada Office - Office of Therapeutic Products (TPD)** | • Notice of Compliance; • Certificate of Pharmaceutical Product, and • Establishment License Number issued by Health Canada (Establishment License Number). • Letter of Approval for Registration |
| **Australian Therapeutic Goods Administration (Therapeutic Goods Administration - TGA)** | |

ÿ At the discretion of the applicant and optionally, the pre-opinion by an authorized third party may be included.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-005** Sanitary Registry of Specialized Enteral Feeding Formulas of National or Foreign Manufacture.

**1** ÿ **2** ÿ **3** ÿ | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} National manufacturing product | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ **Product description.**



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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» Qualitative-quantitative formula (must be signed by the health officer).
» Label project with precautionary legends and handling, conservation and storage conditions.
» Instructions for use (if applicable).
» Stability tests.
» Original of the certificate of analysis of raw materials and finished product, their control methods and bibliographical references.
» Finished product specifications.
» Original of the certificate of free sale issued by the health authority or competent body of the country of origin, if the product is of import.
» Original of the letter of representation of the product, if applicable, authenticated by the legal procedure that exists in the country of origin, in Spanish or another language, with their respective Spanish translation performed by expert translator.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-006-A** Sanitary Registry of Herbal Medicines.
Modality A.- Sanitary Registration of Nationally Manufactured Herbal Medicines

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| **1** ÿ **2** ÿ **3** ÿ | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ **The technical and scientific information that demonstrates the identity and purity of its components in accordance with what is established by the special pharmacopoeias, or failing that, the sources of international scientific information: » Description of the primary and secondary packaging .**
» Method of identification of the active principle or principles. ÿ
**Technical and scientific information that demonstrates the stability of the finished product.**
» Taxonomic identification certificate of each of the plants used or the document in which the information on the identity of the components is recorded. ÿ Therapeutic indications. ÿ Label projects. ÿ Instructions for its use (if applicable). ÿ Description of the manufacturing process of the drug to be registered. ÿ Information to prescribe in its extended and reduced versions.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-006-B** Sanitary Registry of Herbal Medicines.
Modality B.- Sanitary Registration of Foreign Manufactured Herbal Medicines

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| **1** ÿ **2** ÿ **3** ÿ | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ **The technical and scientific information that demonstrates the identity and purity of its components in accordance with what is established by the special pharmacopoeias, or failing that, the sources of international scientific information: » Description of the primary and secondary packaging .**
» Method of identification of the active principle or principles. ÿ
**The technical and scientific information that demonstrates the stability of the finished product:** »
Taxonomic identification certificate of each of the plants used or the document that contains the information on the identity of the components. ÿ Therapeutic indications. ÿ Label projects. ÿ Instructions for its use (if applicable).



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Description of the manufacturing process of the drug to be registered. ÿ
Information to prescribe in its extended and reduced versions. ÿ
Certificate of free sale issued by the competent authority of the country of origin. ÿ Letter
of representation from the manufacturer, authenticated by the legal procedure that exists in the country of origin, in Spanish or in another language, with its respective translation into Spanish by an expert translator, when the laboratory that manufactures it abroad is not a subsidiary or parent company of the laboratory requesting the Sanitary Registry.
ÿ Certificate of analysis issued by the manufacturer of the drug on letterhead and endorsed by the health officials of foreign and national companies.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-007-A** Sanitary Registry of Homeopathic Medicines.
Modality A.- Sanitary Registration of Nationally Manufactured Homeopathic Medicines

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| **1** ÿ **2** ÿ **3** ÿ | | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ **Technical and scientific information that demonstrates:**
» The identity and purity of its components according to what is established by the homeopathic pharmacopoeia of the United States Mexicanos and their supplements or, failing that, the homeopathic pharmacopoeias of other countries or sources of scientific information International.
» The stability of the finished product in accordance with the corresponding Official Mexican Standard.
ÿ Therapeutic indications. ÿ
Label projects. ÿ
Pathogenesis of active ingredients in extensive prescribing information. ÿ
Instructions for its use, if applicable. ÿ
Description of the drug manufacturing process. ÿ Text of the
extended and reduced version of the information to prescribe in the case of medications referred to in sections I to IV of article 226 of the General Health Law.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-007-B** Sanitary Registry of Homeopathic Medicines.
Modality B.- Sanitary Registration of Foreign Manufactured Homeopathic Medicines

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ **Technical and scientific information that demonstrates:**
» The identity and purity of its components in accordance with what is established by the Homeopathic Pharmacopoeia of the United States Mexicans and their supplements or, failing that, the homeopathic pharmacopoeias of other countries or sources of scientific information International.
» The stability of the finished product in accordance with the corresponding Official Mexican Standard.
ÿ Therapeutic indications. ÿ
Label projects. ÿ
Pathogenesis of active ingredients in extensive prescribing information. ÿ
Instructions for its use, if applicable. ÿ
Description of the drug manufacturing process. ÿ Text of the
extended and reduced version of the information to prescribe in the case of medications referred to in sections I to IV of article 226 of the General Health Law.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Copy of the certificate of free sale issued by the competent authority of the country of origin. ÿ Copy of the Letter of Representation of the manufacturer, authenticated by the legal procedure that exists in the country of origin, in Spanish or in another language, with its respective translation into Spanish by an expert translator, when the laboratory that manufactures it abroad does not is a subsidiary or parent company of the laboratory requesting the Sanitary Registry.
ÿ Certificate of analysis issued by the manufacturer of the drug on letterhead and endorsed by the health officials of foreign and national companies.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-008-A** Sanitary Registry of Vitamin Medications.
Modality A.- Sanitary Registry of Nationally Manufactured Vitamin Medications.

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Monograph of the finished product with qualitative and quantitative control methods of all components. ÿ Conditions of handling, conservation and storage. ÿ Description of primary and secondary packaging and toxicity tests. ÿ Label projects with precautionary legends. ÿ Instructions for use, if applicable. ÿ Stability tests, according to the Official Mexican Standard. ÿ Certificate of analysis of raw material and finished product, containing the physical, chemical and microbiological specifications. ÿ Information to prescribe in its extended and reduced versions.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-008-B** Sanitary Registry of Vitamin Medications.
Modality B.- Sanitary Registration of Foreign Manufactured Vitamin Medications.

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|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Monograph of the finished product with qualitative and quantitative control methods of all components. ÿ Conditions of handling, conservation and storage. ÿ Description of primary and secondary packaging and toxicity tests. ÿ Label projects with precautionary legends. ÿ Instructions for use, if applicable. ÿ Stability tests, according to the Official Mexican Standard. ÿ Certificate of analysis of raw material and finished product, containing the physical, chemical and microbiological specifications. ÿ Information to prescribe in its extended and reduced versions. ÿ Certificate of free sale or equivalent if the product is imported, issued by the health authority or competent body of the country originally.
ÿ Letter of representation from the supplier.

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-014-A** Request for Modification to the Sanitary Registry of Medications, due to a Change from National to Foreign Manufacture and from Foreign to National.
Modality A.- Change from Foreign to National Manufacture of Homeopathic Medicines.

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ **For change from foreign to national manufacture of homeopathic medicines:**

» Technical and scientific information that demonstrates:

ÿ The identity and purity of its components in accordance with what is established by the Homeopathic Pharmacopoeia of the United States Mexicanos and their supplements or, failing that, the Homeopathic Pharmacopoeias of other countries or sources of scientific information International.

ÿ The stability of the finished product in accordance with the corresponding Official Mexican Standard.

- Therapeutic indications. ÿ

Pathogenesis of active principles. -

Instructions for its use. ÿ

Description of the drug manufacturing process.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-014-B** Request for Modification to the Sanitary Registration of Medications, due to a Change from National to Foreign Manufacture and from Foreign to National.
Modality B.- Change from Foreign to National Manufacture of Allopathic and Vitamin Medicines.

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ **For change from foreign to national manufacture of allopathic medicines and vitamins:**

» Technical and scientific information that

demonstrates: ÿ The identity and purity of its components in accordance with the provisions of the Pharmacopoeia of the United Mexican States and your supplements.

ÿ The stability of the finished product in accordance with the corresponding Official Mexican Standard.

ÿ The therapeutic efficacy and safety according to the corresponding scientific information.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-014-C** Request for Modification of the Sanitary Registration of Medicines, due to a Change from National to Foreign Manufacture and from Foreign to National
Modality C.- Change from National to Foreign Manufacture of Medicines

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ | **2** ÿ | **3** ÿ | **4** ÿ | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ | **8.A** ÿ | **8.B** ÿ | **8.C** ÿ | **8.D** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ **For change from national manufacturing to foreign:**
» Copy of the last authorized labels.

» Stability tests in accordance with the corresponding Official Mexican Standard.
» Control method and specifications of drugs and additives and finished product and its validation, signed by the person in charge establishment toilet
» Certificate of free sale issued by the competent authority of the country of origin.
» Certificate of analysis issued by the manufacturer of the drug on letterhead and endorsed by the health officials of foreign and national companies.

» Letter of representation from the manufacturer authenticated by the legal procedure that exists in the country of origin, in Spanish or in another language, with its respective translation into Spanish by an expert translator, when the laboratory is not a subsidiary or parent company of the laboratory requesting the modification of the Sanitary Registry.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-014-D** Request for Modification to the Sanitary Registry of Medications, due to a Change from National to Foreign Manufacture and from Foreign to National.
Modality D.- Change from Foreign to National Manufacture of Herbal Medicines.

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ | **2** ÿ | **3** ÿ | **4** ÿ | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ | **8.A** ÿ | **8.B** ÿ | **8.C** ÿ | **8.D** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ **For change from foreign to national manufacture of herbal medicines:** » The technical and scientific information that demonstrates:

ÿ The identity and purity of its components in accordance with the provisions of the Special Pharmacopoeias or, failing that, the international scientific information sources.

- The stability of the finished product. -
Taxonomic identification.

" Therapeutic indications.
» Instructions for use.
» Description of the drug manufacturing process.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-015-A** Modification to the Conditions of Sanitary Registration of Medications Without Change in the Manufacturing Process.
Modality A.- Modification of the Name or Address of the Holder of the Registry or of the National Maquiladora.

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35}** | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ **For modifications of the name and/or address of the holder of the registry or of the national maquiladora without change in the process of production:** »
Copy of the last authorized labels.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-015-B** Modification to the Conditions of Sanitary Registration of Medications Without Change in the Manufacturing Process.
Modality B.- Modification of the Trade Name of the Medication.

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|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35}** | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ Copy of the last authorized labels.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-015-C** Modification to the Conditions of Sanitary Registration of Medications Without Change in the Manufacturing Process.
Modality C.- Modification of the Secondary Packaging.

| | | | | | | | | | | |
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| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35}** | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ Copy of the last authorized labels.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-015-D** Modification to the Conditions of Sanitary Registration of Medications Without Change in the Manufacturing Process.
Modality D.- Modification to the Information Texts to Prescribe in its Extended and Reduced Version.

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|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ Copy of the latest version of the information to prescribe in its broad and reduced authorized versions. ÿ Bibliographic information that supports the proposed modification.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-015-E** Modification to the Conditions of Sanitary Registration of Medications Without Change in the Manufacturing Process.
Modality E.- Modification to the Conditions of Sale and Supply to the Public.

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ Copy of the last authorized labels. ÿ Bibliographic justification that supports the requested change. ÿ If applicable, certificate of free sale from the country of origin issued by the competent health authority.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-015-F** Modification to the Conditions of Sanitary Registration of Medications Without Change in the Manufacturing Process.
Modality F.- Modification to the Presentation and Content of Containers.

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ Copy of the last authorized labels. ÿ Pharmacological justification of the therapeutic scheme(s) with the corresponding bibliographic support.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-015-G** Modification to the Conditions of Sanitary Registration of Medications Without Change in the Manufacturing Process.
Modality G.- Modification by Change of Additives or Excipients Without Changes in the Dosage Form or Principles Assets.

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|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35}** | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ For change of additives or excipients without change in the pharmaceutical form, drug or active principle: » Stability tests according to the corresponding Official Mexican Standard.

» Monograph of additives and excipients and their bibliographic references for changes of said ingredients.
» Control method and specifications of drugs and additives and finished product and its validation, signed by the person in charge facility toilet.
" Analysis certificate.
» Technical justification that supports the requested change

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-015-H** Modification to the Conditions of Sanitary Registration of Medications Without Change in the Manufacturing Process.
Modality H.- Modification due to Change of Primary Packaging.

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35}** | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ Stability tests in accordance with the corresponding Official Mexican Standard. ÿ Control method and specifications of drugs and additives and finished product and its validation, signed by the health officer

of the establishment.
ÿ Written technical justification that supports the need or convenience of changing the primary packaging.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-015-I** Modification to the Conditions of Sanitary Registration of Medications Without Change in the Manufacturing Process.
Modality I.- Modification of the Expiration Term.

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|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35}** | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ Stability tests in accordance with the corresponding Official Mexican Standard. ÿ Control method and specifications of drugs and additives and finished product and its validation.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Original Certificate of Analysis. ÿ
Technical justification that supports the requested change.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-015-J** | Modification to the Conditions of Sanitary Registration of Medications Without Change in the Manufacturing Process. Modality J.- Modification due to Change of Therapeutic Indication. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ Scientific information or final results of the investigation that demonstrate safety and therapeutic efficacy.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-015-K** | Modification to the Conditions of Sanitary Registration of Medications Without Change in the Manufacturing Process. Modality K.- Modification of Generic Drugs. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ Submit the corresponding technical tests published on March 10, 1998 in the Official Gazette of the Federation by the Council of General Health and the SSA.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-016** | Modification to the Conditions of the Sanitary Registry of Medicines with Change in the Manufacturing Processes. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ Copy of the last authorized labels. ÿ Copy of the notice that supports the change of name and/or address of the owner of the registry due to assignment of rights. ÿ Stability tests in accordance with the corresponding Official Mexican Standard. ÿ Monograph of drugs and additives and their bibliographical references. ÿ Control method and specifications of drugs and additives and finished product and its validation, signed by the health officer of the establishment.
ÿ Certificate of analysis. ÿ
Copy of the medication maquila notice.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-10-001** | Assignment of Rights of the Sanitary Registration of Medicines |

**1** ÿ **2** ÿ **3** ÿ **4** ÿ | | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 29, 30, 34, and 35} ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Label projects in accordance with the corresponding standard. ÿ Where appropriate, draft texts of the broad and reduced versions of the information to prescribe. ÿ Original or certified copy and simple copy for comparison of the public deed stating the assignment. ÿ Copy of the Sanitary Registry of each one of the products. ÿ Copy of the authorized tag projects of each one of the products. ÿ Copy of the sanitary licenses of the assignee and assignor.

4.2.3. by extension

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-022-A** | Request for Extension of the Sanitary Registry of Herbal, Vitamin and Homeopathic Medicines. Modality A.- Extension of the Sanitary Registration of Nationally Manufactured Herbal, Vitamin and Homeopathic Medicines. |

**1** ÿ **2** ÿ **3** ÿ | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 24, 29, 30, 34, and 35} ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Number or simple copy of the Sanitary Registry of which the extension is requested. ÿ Technical report of the interchangeability tests, when there are changes that may modify the pharmacokinetics of the drug, either in the production equipment, in the quality of the components, in the acceptance criteria or in the production process.
ÿ Labels in use, instructions, as well as information to prescribe in its broad and reduced forms, previously authorized. ÿ Drug pharmacovigilance report, under the terms of the applicable regulations. ÿ Certificate of good manufacturing practices of the drug, issued by the Secretariat or by the competent authority of the country of origin. origin.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-022-B** | Request for Extension of the Sanitary Registry of Herbal, Vitamin and Homeopathic Medicines. Modality B.- Extension of the Sanitary Registration of Herbal, Vitaminic, Homeopathic Medicines of Foreign Manufacture. |

**1** ÿ **2** ÿ **3** ÿ | | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 24, 29, 30, 34, and 35} ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** | | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Number or simple copy of the Sanitary Registry of which the extension is requested.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Technical report of the interchangeability tests, when there are changes that may modify the pharmacokinetics of the drug, either in the production equipment, in the quality of the components, in the acceptance criteria or in the production process.
ÿ Labels in use, instructions, as well as information to prescribe in its broad and reduced forms, previously authorized. ÿ Drug pharmacovigilance report, under the terms of the applicable regulations. ÿ The document that accredits a legal representative domiciled in the United States of Mexico. ÿ Certificate of good manufacturing practices of the drug, issued by the Secretariat or by the competent authority of the country of origin.
origin.
ÿ

**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulation).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-023-A** Request for Extension of the Sanitary Registry of Allopathic Medicines, Vaccines, Blood Products and Biomedicine
Modality A.- Extension of the Sanitary Registration of Allopathic Medications, Vaccines, Blood Products and Nationally Manufactured Biomedicine

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 24, 29, 30, 34, and 35}** | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Number or simple copy of the Sanitary Registry of which the extension is requested. ÿ Technical report of the interchangeability tests, when there are changes that may modify the pharmacokinetics of the drug, either in the production equipment, in the quality of the components, in the acceptance criteria or in the production process.

ÿ Labels in use, instructions, as well as information to prescribe in its broad and reduced forms, previously authorized. ÿ Drug pharmacovigilance report, under the terms of the applicable regulations. ÿ Certificate of good manufacturing practices for the drug and medication, issued by the Secretariat or by the competent authority of the country of origin.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-023-B** Request for Extension of the Sanitary Registry of Allopathic Medicines, Vaccines, Blood Products and Biomedicine.
Modality B.- Extension of the Sanitary Registration of Allopathic Medicines, Vaccines, Blood Products and Foreign Manufactured Biomedicine.

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|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5** **{Fields: 1, 2, 4, 5, 6, 7, 17, 21, 22, 24, 29, 30, 34, and 35}** | ÿ **8.A** | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | | |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Number or simple copy of the Sanitary Registry of which the extension is requested. ÿ Technical report of the interchangeability tests, when there are changes that may modify the pharmacokinetics of the drug, either in the production equipment, in the quality of the components, in the acceptance criteria or in the production process.

ÿ Labels in use, instructions, as well as information to prescribe in its broad and reduced forms, previously authorized. ÿ Drug pharmacovigilance report, under the terms of the applicable regulations. ÿ The document that accredits a legal representative domiciled in the United States of Mexico. ÿ Certificate of good manufacturing practices for the drug and medication, issued by the Secretariat or by the competent authority of the country of origin.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**NOTE:** All the documents that accompany the applications must be submitted in Spanish, or otherwise, their respective translation into Spanish must be attached to them, endorsed with the signature of the health officer. Documents issued by authorities of other countries must be apostilled or legalized and translated by an expert translator (Art. 153 of the Health Supplies Regulations)

4.3. by revocation

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-012** Request for Revocation of the Sanitary Registry and Other Authorizations. | |

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5**<br>**{Fields: 1, 3, 5, 6, 7, 14, 15, 17, 21, 29, 30, 34, 35} For herbal remedies**<br>**{Fields: 1, 3, 5, 6, 7, 15, 17, 20, 21, 29, 30, 34, 35} For medical devices**<br>**{Fields: 1, 3, 5, 6, 7, 15, 17, 21, 22, 29, 30, 34, 35} For drugs**<br>**{Fields: 1, 4, 7, 15, 17, 21 and 35 } Pesticides**<br>**{Fields: 1, 4, 7, 15, 17 and 35} Plant nutrients** |

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ By revocation of the registry at the request of a party: » Sanitary Registry and in its original case of modifications to the conditions of the registry with its corresponding annexes. If you do not have the original of the registration or the corresponding modifications, you must present the original of the complaint made before the Public Ministry for the loss or theft.

5. Authorization request

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-009-A** Request for Alphanumeric Code of Herbal Remedies.<br>Modality A.- Request for Alphanumeric Code of Herbal Remedies of National Manufacture | |

| | | | | | |
|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5**<br>**{Fields: 1, 2, 4, 5, 6, 7, 17, 20, 34, and 35}** | ÿ **9.A** ÿ **9.C** | |

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Certificate of analysis of finished product of organoleptic, physical and microbiological aspects and absence of toxic residues. ÿ Description of the manufacturing process. ÿ Taxonomic authentication certificate for each component or the document in which the information on the identity of the

components. ÿ
Scientific and popular denomination of the plant(s) used. ÿ Indications and time for use.
ÿ Label or label projects. ÿ Qualitative-quantitative formula of the components and additives. (must be signed by the health officer)

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-009-B** Application for Alphanumeric Code of Herbal Remedies
Modality B.- Request for Alphanumeric Code of Herbal Remedies of Foreign Manufacture

**1** ÿ **2** ÿ **3** ÿ | **5** {Fields: 1, 2, 4, 5, 6, 7, 17, 20, 34, and 35} | ÿ **8.A** ÿ **8.B** ÿ **8.C** ÿ **8.D** ÿ **9.A** ÿ **9.C**

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Certificate of analysis of finished product of organoleptic, physical and microbiological aspects and absence of toxic residues. ÿ Description of the manufacturing process. ÿ Taxonomic authentication certificate for each component or the document in which the information on the identity of the components. ÿ
Scientific and popular denomination of the plant(s) used. ÿ Indications and time for use. ÿ Label or tag projects. ÿ Qualitative-quantitative formula of the components and additives. (must be signed by the health officer) ÿ Certificate of free sale issued by the health authority of the country of origin. ÿ Certificate of analysis issued by the company that manufactures the herbal remedy, with the letterhead of its Denomination or company name and endorsed by the chemists responsible for the foreign and national company.
ÿ Certificate of good manufacturing practices. ÿ Letter of representation (If the product is manufactured by the parent company or subsidiary of the applicant laboratory in Mexico, the representation letter). ÿ Label projects in Spanish and counter-label, if applicable.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-04-010-A** Request for Authorization of Research Protocol in Human Beings.
Modality A.- Medicines, Biologicals and Biotechnologicals.

**COFEPRIS-04-010-B** Request for Authorization of Research Protocol in Human Beings.
Modality B.- Medications (Bioequivalence studies).

**COFEPRIS-04-010-C** Request for Authorization of Research Protocol in Human Beings.
Modality C.- New Resources (study of materials, grafts, transplants, prostheses, physical, chemical and surgical procedures) and other methods of prevention, diagnosis, treatment and rehabilitation carried out on human beings or their biological products, except pharmacological ones .

**1** ÿ **2** ÿ **3** ÿ **7**

Documentary requirements
**The information must be presented in print and preferably in electronic format (RTF) in the order listed below:** ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ **Initial Protocol.**

» Favorable opinion of the investigation, ethics and, where appropriate, biosafety commissions. Research protocol that must contain an objective and complete analysis of the risks involved compared with the risks of the established diagnostic and treatment methods and the expectation of the subject's living conditions with and without the proposed procedure or treatment.
» Informed consent of the research subject or, where appropriate, their legal representative Summary of the preclinical information and information previously obtained (Investigator's Manual or equivalent document): ÿ Modality A.- Preclinical and clinical information previously obtained, justifying the use of the drug, dose, form pharmaceutical, route of administration, speed of administration, study population, etc.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Modality B.- Information previously obtained from the study drug that justifies its use, dose, pharmaceutical form, route of administration, speed of administration, study population, etc.

ÿ Modality C.- Technical-scientific foundations, information on previous experimentation carried out on animals, in the laboratory and previous clinical research studies, when any.

» Letter of authorization from the head of the unit or institution where the investigation will be carried out.

» Description of available resources of the unit or institution where the investigation will be carried out, including areas, equipment, services laboratory assistants and cabinets.

» Description of available resources of the unit or institution where the investigation will be carried out for the management of medical emergencies. Confidentiality letter for reporting adverse events from the principal investigator.

» Professional history of the principal investigator (who must be a health professional and have adequate academic training and experience for the direction of the work to be carried out), which includes his academic preparation, representative scientific production and clinical practice, as well as a simple copy of the documentation legally issued and registered by the competent educational authorities.

» Academic preparation and experience of the medical, paramedical and other experts who will participate in the activities of the investigation.

» Study schedule.

» Amount of import inputs required at each stage of the study. Information that will be considered as acknowledgment of knowledge but not authorization.

» Others indicated by the Sanitary Regulation in force in the field of Research for Health in Human Beings.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-04-010-D** | Request for Authorization of Research Protocol in Human Beings. Modality D - Risk-free Research (observational studies that use documentary research techniques and methods and those in which no intentional intervention or modification is made to the physiological, psychological and social variables of the research subjects). |

**1** ÿ **2** ÿ **3** ÿ **7**

Documentary requirements **The information must be presented in print and preferably in electronic format (RTF) in the order listed below:** ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Favorable opinion of the commissions of investigation, ethics and, where appropriate, biosafety. ÿ Investigation protocol that must contain an objective and complete analysis of the procedures that will be carried out. ÿ Letter of authorization from the head of the unit or institution responsible for the study. ÿ Letter of acceptance and confidentiality from the principal investigator. ÿ Professional history of the principal investigator. ÿ Study schedule. ÿ Others indicated by the Sanitary Regulation in force in Research for Health in Human Beings.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-07-001** | Third Party Authorization Request. |

**1** ÿ **2** ÿ **3** ÿ **10.A** | If this is the case | ÿ **10.B** If this is the case | ÿ **10.C** If this is the case

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Documents that demonstrate the technical, material, human and financial capacity, as well as the facilities, equipment and technology for carry out the tests, studies, verifications and other activities necessary to issue the opinions (original).

ÿ Procedures that show that the applicant has standard operating procedures that guarantee quality in the performance of their duties (original).



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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ÿ Proposals for activities to be ruled on (original). ÿ
Description of the services it intends to provide and the procedures to be used (original).

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-07-005** Request for Extension of the Validity of Third Party Authorization. | |

**1** ÿ **2** ÿ **3** ÿ **4** ÿ **10.A** [ ] [ ] [ ] If this is the case ÿ **10.B** [ ] If this is the case ÿ **10.C** [ ] If this is the case

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-09-012** Request for Modification or Amendment to the Investigation Protocol Authorization. | |

**1** ÿ **2** ÿ **3** ÿ **4** ÿ **7** [ ] [ ] [ ]

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and
two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Original of the authorization
of the research protocol that is requested to be modified. ÿ Documentation that
supports the requested modification in accordance with article 62 of the Regulations of the General Health Law in Material of Research for Health. ÿ

**Subsequent Protocol** (Inclusion of centers).

» Favorable opinion of the investigation, ethics and, where appropriate, biosafety commissions. Letter of authorization from the owner of the unit or institution where the research will be carried out.
» Description of available resources of the unit or institution where the investigation will be carried out, including areas, equipment, services laboratory assistants and cabinets.
» Description of available resources of the unit or institution where the investigation will be carried out for the management of medical emergencies. In the case of research centers that enter into agreements for medical emergencies with other institutions, a simple copy of the current agreement must be included, as well as a description of said institution's resources.
» Letter of acceptance, confidentiality and commitment to report adverse events from the principal investigator.
» Professional history of the principal investigator (who must be a health professional and have adequate academic training and experience for the direction of the work to be carried out), which includes his academic preparation, representative scientific production and clinical practice, as well as a simple copy of the documentation legally issued and registered by the competent educational authorities.
» Academic preparation and experience of the medical, paramedical and other experts who will participate in the activities of the investigation.
» Study schedule.
» Others indicated by the Sanitary Regulation in force in the field of Research for Health in Human Beings. ÿ **Amendment to the protocol** (any change to a document that is part of the protocol, derived from variations to the methodological structure, substitution of the principal investigator or before the identification of risks in the research subjects. The documents are: protocol, letter of informed consent , investigator's manual, patient documents, measurement scales, and schedule).
» Form of Authorizations, Certificates and Visits, Modality A or C. duly completed.
» Proof of payment of rights in terms of the Federal Law of Rights.
» Favorable opinion of the research, ethics and, where appropriate, biosafety commissions, including a detailed description of the approved documents, corresponding to the requested amendment.
» Amended document, brief description of the changes made with respect to the previous document.
» Others indicated by the Sanitary Regulation in force in the field of Research for Health in Human Beings.
ÿ **In the case of a change in the principal investigator of the protocol,** in addition to the aforementioned points, it must include the following: following:
• Letter of authorization for the change of principal investigator issued by the corresponding Ethics and Research Committee. • Letter of acceptance, confidentiality and commitment to report adverse events from the new principal investigator.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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• Professional history of the principal investigator (who must be a health professional and have adequate academic training and experience for the direction of the work to be carried out), including his academic preparation, representative scientific production and clinical practice, as well as a simple copy of the documentation legally issued and registered by the competent educational authorities.

• Academic preparation and experience of the medical, paramedical and other experts who will participate in the activities of the investigation.

ÿ **Modification to the official document** (any administrative change that does not alter the protocol or research project, such as: change of domicile, name or company name, team or work group of the researcher, among others).

» Form of Authorizations, Certificates and Visits, Modality A, B, C or D duly completed.
» Proof of payment of rights in terms of the Federal Law of Rights.
» Copy of health license, Notice of Operation or, where appropriate, updated Federal Taxpayer Registry for authorized third parties in the matter of investigation.
» Official letter of authorization in original with autograph signature, to which the modification is requested.
» Others indicated by the Sanitary Regulation in force in the field of Research for Health in Human Beings.

ÿ **In the case of a change of name or business name of the holder of the protocol,** in addition to the aforementioned points, it must Include the following: • Copy of health license, Notice of Operation or, where appropriate, Federal Taxpayer Registry of the new Denomination or social reason.

ÿ **In the case of a change of address (change of geographic location of the research center),** in addition to the aforementioned points, it must include: • Letter of authorization from the head of the unit or institution where the research will be carried out. • Description of available resources of the unit or institution where the investigation will be carried out, including areas, equipment, auxiliary services of laboratory and cabinets.

• Description of available resources of the unit or institution where the investigation will be carried out for the management of medical emergencies. In the case of research centers that enter into agreements for medical emergencies with other institutions, a simple copy of the current agreement must be included, as well as a description of said institution's resources. • Copy of health license, Notice of Operation or, where appropriate, Federal Taxpayer Registry of the new location of the center.

ÿ **In the event of a change in the Holder of the research protocol (only in the event that the holder of the protocol in Mexico is not the sponsor),** in addition to the aforementioned points, it must include: • Notification of the change in the holder of the research protocol to the Ethics and Research Committee.

ÿ **In the case of inclusion of the principal investigator's work team,** in addition to the aforementioned points, it must include: • Letter of acceptance, confidentiality and commitment to report adverse events of the personnel included in the research team. principal investigator.

• Professional history of the main researcher's work team (who must be a health professional and have the appropriate academic training and experience for the work to be carried out), including their academic preparation and clinical practice, as well as a simple copy of the documentation legally issued and registered by the competent educational authorities.

ARTICLE 17, Section I of the REGULATION OF THE GENERAL HEALTH LAW ON RESEARCH FOR HEALTH

## 5.1. From genetically modified organisms

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-09-013** | Request for Authorization for Commercialization and Import for its Commercialization of Genetically Modified Organisms. |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | **5** {Fields: 1, 2, 3, 4, 5, 8, 11, 13, 18, 19, 23, 24, 27, 28, 29, 30, 31, 35, and 38} | ÿ **8.B** | ÿ **8.C** | ÿ **8.D** | ÿ **9.A** | ÿ **9.B** | ÿ **9.C** | ÿ **9.D** | | |

Documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Study of possible risks that the use or human consumption of the GMO in question could represent to human health, in which It will include the scientific and technical information related to its safety, consisting of:

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» Recipient organism, be it plant, animal or microorganism:
ÿ Identification, ÿ
Most recent taxonomic designation, ÿ
Origin, history of safe use in food, previous experience of use or consumption, ÿ
Pathogenicity associated with genera and species, any relevant evidence of the potential for production of compounds toxic or antinutrients, and
ÿ Indication of the presence of plasmids, transposons and integrons containing antimicrobial resistance genes.
» On each gene donor organism: ÿ Most recent
taxonomic classification, ÿ History of use, ÿ
Origin, and ÿ
Indication of
the presence of plasmids, transposons and integrons containing antimicrobial resistance genes.
» In the case of genetically modified microorganisms, whether recipients or gene donors:
ÿ Genus, species, subspecies, strain and common name of the recipient,
ÿ Genetic stability, potential immunological and human health impact, ability to form spores or other structures of survival, and
ÿ Infectivity, virulence factors and range of receptors potentially susceptible to being infected.
» On the introduction of genetic material: ÿ
Function of the introduced DNA.
ÿ Location and orientation of genetic material. ÿ For
all introduced DNA, the DNA sequence or restriction map must be described, characterization of all genetic components including marker genes, regulatory elements, promoters, terminators and others that affect DNA function.

ÿ Detailed description of the transformation method and number of coding sequences. ÿ Regulation
of gene expression, identification of any open reading frames within the inserted DNA or created by the contiguous DNA modifications in the chromosome. ÿ
Stability of the modification, and ÿ
Intermediate host organisms.
» When a marker gene was used as a selection element for modified organisms: ÿ Reasons for choosing
said marker, and ÿ If it were a gene that confers
antimicrobial resistance, its use must be justified and the reason for not choosing another marker gene.
» Regarding the GMO:
ÿ Organization of the inserted genetic material and the methods used for its characterization. ÿ In the
event that truncated portions have been inserted, their size, mechanism of action of the product of expression of the inserted genes.
ÿ Gene products or analysis of transcripts or expressed products to identify any new substance that may be present in the food or, in the case of organisms used for the purpose of bioremediation in the environment or public health, any secondary effect on the biochemistry, physiology and metabolism of the GMO.
ÿ Stability of the genetic construct under different processing conditions and the expression of new materials or modification of native materials, and
ÿ Characterization, sensitivity and specificity of the designated action on the expression products of the inserted transgenes.
» When genetic modifications alter the expression of natural constituents or metabolites, information must be provided on the possible side effects on related metabolic pathways.
» On the expression of transgenes: ÿ
Kinetics of gene expression in the modified organism. ÿ In the case
of vegetables, level of expression in the different structures of the plant. ÿ Demonstrate if the
desired effects have been achieved with the modification and if all the characteristics expressed are inherited in a stable way in the amount of propagation necessary for its use in food production, bioremediation or public health and in accordance with the laws of the inheritance.

ÿ Indicate if there are data that suggest that one or more genes of the recipient organism have been affected by the modifications or by the process of genetic exchange, and
ÿ Size and copy number of all detectable inserts, both fully inserted and truncated.
» GMO detection and identification methods, including the infrastructure required for its identification, reagents required for the extraction, purification and detection methodologies of its materials, sequences of event-specific primers and probes to detect transgenic DNA, at least 300 bp at a side of the insertion site, antibodies specific for the exogenous protein, and level of reliability of each method. Attach samples of the positive and negative controls used. In the case of microorganisms



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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genetically modified, the identification method that allows its unequivocal detection must be described in detail; basing their choice on their sensitivity, specificity and reproducibility.

» When the GMO is used as food or for food processing: ÿ Description of the product. ÿ Proposed use, specifying information about its processing. ÿ Any change introduced in the GMO that may alter the way in which it interacts with the food matrix and, when applicable, in the intestinal lumen and with the microorganisms that coexist in the intestinal lumen.

ÿ Development of transgene expression during the life cycle of the plant and parts where the insert is expressed, and ÿ Substantial equivalence studies applied to conditions of use or consumption in Mexico, including:

• True protein content, non-protein nitrogen, amino acid profile. If a new protein has been introduced: presence and level in the different parts of the plant and in the proposed feed, evidence of consumption in other foods, effects of processing, biological function, digestibility. • Qualitative and quantitative composition of total lipids. • Composition of the carbohydrate fraction. • Qualitative and quantitative composition of vitamins. • Presence of antinutritional components. • Stability during storage, especially nutrient degradation and nutrient bioavailability, and • For each case, the impact of changes in nutrient components that could affect the profile should be determined. overview of nutrients.

» In the case of genetically modified microorganisms, the process by which raw materials are transformed into the final product, step by step, with special emphasis on the most relevant parameters for the characterization of the final product in relation to safety and nutritional aspects. .

» Complete toxicity studies: ÿ Acute.

- Subchronic. ÿ Chronic in those cases where the subchronic study supposes or evidences some long-term health risk, of all the products of expression of the transgenes, according to whether their purpose is for human use or consumption, bioremediation or public health.

ÿ In the case of being used as food or for food processing, studies of the constituents of the food or specific components that were altered as a consequence of the genetic modification, and ÿ When used for the bioassay, transgenic protein obtained from crops bacteria, it must be shown that the protein expressed in the GMO has the same molecular weight and immunoreactivity as the microbial protein.

» Complete allergenicity studies. The pertinent criteria used must include aspects referring to:

- Origin of the transferred genetic material. ÿ Amino acid sequence homology between the new protein and known allergens. ÿ Effect of pH or enzymatic digestion. ÿ Stability against heat or processing. ÿ Post-translational modifications, and ÿ When, despite the fact that there is no homology between the transgenic protein and known allergens, but the aforementioned tests of enzymatic digestion, at pH and stability to heat or processing, demonstrate its allergenic potential, they must be provided. data from the analysis of IgE cross-reactivity between a newly expressed protein and a known allergen.

» In the case of events with a combination of genes, the parental events involved in the generation of said event must be previously authorized. The information that must be provided in this particular type of GMOs includes: ÿ Specification of the following categories: • Category 1. Parents with unrelated phenotypic characteristics. • Category 2. Parents that have related characteristics but their action derives from different routes or are included at different modes of action, and • Category 3. Parents with characteristics related to activity in the same metabolic or biosynthetic pathway. ÿ Procedure applied to obtain the event with a combination of genes, including the genotypic characteristics and phenotypic characteristics of their parental lines: • Metabolic pathways in which each of the transgenic proteins encoded in the event with combination of genes act. • Stability studies of inserted genes, and • Substantial equivalence studies, and

ÿ In the case of requests for authorization of a GMO to be able to import it for the purposes referred to in article 91 of the Law, the information and documentation that proves that the GMO is authorized in accordance with the legislation of the country of origin or, in failing that, statement by the interested party of the non-existence of said situation and presentation of the elements of consideration that support the fact that Ministry of Health can resolve the authorization request, and

ÿ Other requirements determined by the Ministry of Health in the NOMs derived from the Law.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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## 6. Application for export certificates

### 6.1. By high or new

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-007-A** Request for Export Support Certificate.
Modality A.- Request for Certificate for Free Export Sale. (Food, alcoholic, non-alcoholic beverages, etc.).

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ | **2** ÿ | **3** ÿ | | | **5** {Fields: 1, 2, 3, 4 and 8} | ÿ **6** ÿ | | **9** Only data from the destination country | ÿ | **9.A** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Labels with which the product is marketed in National Territory when the application is submitted for the first time, when one year has elapsed since the last submission, or when there are modifications to it. If due to the characteristics of the product it is not possible to present it, secondary packaging containing the labels may be presented, as long as it is not bulky, in which case there will be the option of submitting photographs, 20 by 25 centimeters, of the packaging for all their faces.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-007-B** Request for Export Support Certificate.
Modality B.- Request for Export Certificate.

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ | **2** ÿ | **3** ÿ | | | **5** {Fields: 1, 2, 3, 4 and 8} | ÿ **6** ÿ | | **9** Only data from the destination country | ÿ | **9.A** | |

documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-007-C** Request for Export Support Certificate.
Modality C.- Request for Certificate for Export of Conformity of Good Sanitary Practices.
a) For all cases

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | 5 {Fields: 1, 2, 3 and 4} | ÿ **6** ÿ | | 9 Only data from the country of destination | ÿ **9.A** | |

b) For applications to the European Union or at the request of users.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | 5 {Fields: 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 13, 19, 23, 24, 25, 26, 27, 28, 29, 30, and 31} | ÿ **6** ÿ | | 9 Only data from the country of destination | ÿ **9.A** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Legible and complete copy of the current certification notification letter.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-007-D** Request for Export Support Certificate.
Modality D.- Request for Certificate for Product Analysis Export.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | 5 {Fields: 1, 2, 3, 4, 9, 10, 11, 13, 19, 24, 25, 26, 27, 28, 29, 30, and 31} | ÿ **6** ÿ | | 9 Only data on the country of destination and customs office of entry or exit | ÿ **9.A** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Original laboratory results carried out on the products to be exported and a copy of the verification certificate

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-01-019** Certificate of Export of Health Supplies that Are Not or Contain Narcotic or Psychotropic Drugs.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | 5 {Fields: 1, 2, 4, 5, 6, 7 and 17} | ÿ **6** ÿ | | 9 Only data on the country of destination and customs office of entry or exit | ÿ **9.A** ÿ **9.C** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Letter of acceptance from the final importer on letterhead. ÿ Certificate of Good Manufacturing Practices (current). ÿ Notice of Sanitary Responsible or its last modification. ÿ Percentage composition formula, on letterhead with the signature of the health officer (only if the applicant so requests). require).



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Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-05-016-A** Certificate of Support for the Export of Health Supplies.
Modality A.- Certificate of Good Manufacturing Practices for Health Supplies.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | | 5 {Fields: 1, 2, 4, 15 and 17} | ÿ **6** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Notice of Operation or Sanitary License. ÿ In the case of renewal or new sanitary registrations and if the product is imported, you must present the written consent of the manufacturer of the asset and the finished product, which must be authorized and apostilled by the competent authority of the country of origin and translated by expert (both documents in original).

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-05-016-B** Certificate of Support for the Export of Health Supplies.
Modality B.- Certificate of Free Sale of Medicines.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | | 5 {Fields: 1, 2, 4, 5, 6, 15 and 17} | ÿ **6** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Sanitary Registry and the corresponding modification in its case, as well as its annexes. ÿ Formula in your case. ÿ Last production order.

**homoclave** **Name, modality and quick filling guide**

**COFEPRIS-05-016-C** Certificate of Support for the Export of Health Supplies.
Modality C.- Certificate of Free Sale of Medical Devices.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | | | 5 {Fields: 1, 2, 4, 15 and 17} | ÿ **6** | |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Copy of the Sanitary Registry and the corresponding modification in its case, as well as its annexes. ÿ Formula in your case. ÿ Last production order.



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Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
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Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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| homoclave | Name, modality and quick filling guide |
|---|---|
| COFEPRIS-07-002 | Sanitary Report on Bacteriological Effectiveness of Germicidal Equipment or Substances for Domestic Type Water Purification. |

**1** ÿ **2** ÿ **3** ÿ 5 [ ] [ ] **{Fields: 1 and 2}** ÿ **6** [ ]

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Product technical information package containing: instructions for use or operation, safety sheet of the Formulated product or of the substances that are part of the equipment, as well as the characteristics of said equipment. ÿ Report of bactericidal or germicidal efficiency tests of the product, carried out at the National Public Health Laboratory, in

accredited laboratories or by authorized third parties. ÿ

Commercial label of the product.

| homoclave | Name, modality and quick filling guide |
|---|---|
| COFEPRIS-07-004 | Application for Certificate of Accreditation of Bivalve Mollusk Processing Plants. |
| COFEPRIS-07-007 | Application for Certificate of Sanitary Quality of Water in the Area of Production and Cultivation of Bivalve Molluscs. |

**1** ÿ **2** ÿ **3** ÿ 5 [ ] [ ] **{Fields: 1 and 2}** ÿ **6** [ ]

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights.

6.2. by modification

| homoclave | Name, modality and quick filling guide |
|---|---|
| COFEPRIS-01-008 | Modification of Export Certificate. (Certificates for free sale export, products for export, product analysis and compliance with good sanitary practices) |

**1** ÿ **2** ÿ **3** ÿ **4** [ ] [ ]

Documentary requirements ÿ

Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Original of the corresponding current Certificate.



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Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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## 7. Health visit request

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-01-020** Request for Sanitary Verification Visit for Export. | |

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 **{Fields: 1, 2, 4, 5, 6, 7, 15, 17 and 22}** |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-01-029** Request for Sanitary Verification Visit for Certification of Good Pharmaceutical Manufacturing Practices, Medications and Other Health Supplies in Establishments Located in Mexico and Abroad for the Granting or Extension of the Sanitary Registry | |

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 **{Fields: 1, 2, 4, 5, 6, 7, 15, 17 and 22}** |

Documentary and information requirements The
request for sanitary verification visits for the certification of good manufacturing practices shall be accompanied by the following information: ÿ Authorizations, Certificates and Visits Form, duly
completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law
of Rights. ÿ Name and general data of the applicant establishment, which must have the equivalent of the sanitary license issued by the
competent authority of the country of origin; In the event that the applicant is not the manufacturer, he must submit the latter's authorization.

ÿ Name of the drug, medication or medical device, for which verification of good manufacturing practices is requested. ÿ Full name and address of the
establishment(s) involved in each stage of manufacturing the drug, medication or device
doctor.
ÿ Description of the process carried out in each of the establishments involved. ÿ In the case of medicines, medical devices
and other supplies, use, prophylactic or rehabilitative therapeutic action of the product for which verification of good manufacturing practices is requested. ÿ In the case of drugs, the
manufacturing process for which verification of good manufacturing practices is
requested, as well as a list and
description of products that are made in said line.
ÿ In the case of medicines, manufacturing line according to pharmaceutical form for which verification of good practices of
manufacturing, as well as a list and description of products that are made in said line.
ÿ In the case of devices and other inputs, manufacturing process according to line of business or family of products for which verification of good manufacturing practices is
requested, as well as a list and description of products that make up said line. ÿ Name of the legal representative, health manager
or person designated by the requesting establishment to attend to the
diligence.
ÿ Technical documentation of the manufacturing line to verify: » Organizational
charts (general, of the production and quality departments, indicating the reporting lines)
» Plans of the establishment and production areas.
» Block diagram of manufacturing processes.
» General summary of the Quality System including validation and qualification.
» In the case of drugs and medicines, information from the last two annual review reports of the products to be verified, specifically indicating: Manufactured batches, rejected batches (indicating reasons), released batches that were subject to investigation, conclusion and actions carried out, number of batches reprocessed, complaints, returns and withdrawal of products from the market, as well as conclusions of the report.

The documents that accompany the applications must be written in Spanish, otherwise, they must attach their respective translation into Spanish, endorsed with the signature of the health officer.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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Documents issued by authorities of other countries must be apostilled, legalized and translated by an expert translator.

**NOTE:** The sanitary verification for the certification of good manufacturing practices will be carried out under the following criteria:

I. The sanitary verification for the certification of good manufacturing practices of establishments located in Mexico or abroad that manufacture drugs, medicines and other health supplies, will be carried out at the request of the manufacturer or the companies to which it supplies; in the latter case prior authorization from the manufacturer.

II. The verification of good manufacturing practices of medicines will be carried out by manufacturing line, considering the number of establishments that intervene in it, from the preparation of the drug, the obtaining of the product, to its primary packaging.

III. In the case of viral or bacterial, biotechnological, blood derivatives, beta-lactam, cephalosporin, antineoplastic, immunosuppressant, non-synthetic hormonal vaccines; and those determined by the authority, the verification of good manufacturing practices will be by product.

IV. The sanitary verification visits must be carried out during the period of the operation process of the manufacturing lines.

| homoclave | Name, modality and quick filling guide | | | | |
|---|---|---|---|---|---|
| **COFEPRIS-03-001** | Verification Visit Request for Sampling and Release of Narcotic and Psychotropic Drugs. | **1** ÿ **2** ÿ **3** ÿ | | | 5 **{Fields: 1, 2, 4, 5, 6, 7, 9, 10, 11, 14, 15, and 27}** |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Attach a copy of the sanitary verification certificate carried out by personnel of the Federal Commission for the Protection against Sanitary Risks attached to customs.

| homoclave | Name, modality and quick filling guide | | | | |
|---|---|---|---|---|---|
| **COFEPRIS-03-018-A** | Request for Visit to Verify Raw Materials and Medications that Are or Contain Narcotic or Psychotropic Drugs. Modality A.- Destruction. | **1** ÿ **2** ÿ **3** ÿ | | | **5** **{Fields: 1, 2, 4, 5, 7, 11 and 15}** |

Documentary requirements ÿ
Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Standard operating procedure ÿ Copy of the SEMARNAT authorization issued to the incinerator company.



**Contacto:**
Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-03-018-B** | Request for Visit to Verify Raw Materials and Medications that Are or Contain Narcotic or Psychotropic Drugs Modality B.- Seal and Sealing Wax (Only Export of Psychotropic and Narcotic Drugs). |

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 **{Fields: 1, 2, 4, 7, 11 and 15}** |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Attach a copy or indicate the number of the corresponding export permit.

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-03-018-C** | Verification Visit Request for Raw Material and Medications that Are or Contain Narcotic or Psychotropic Drugs Modality C.- Balance |

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ | | | 5 **{Fields: 1, 2, 4, 5, 7, 11 and 15}** |

Documentary requirements
ÿ Authorizations, Certificates and Visits Format, duly completed ÿ Attached documents are not required

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-09-004** | Request for Advice on Sanitary Engineering. |

| | | | |
|---|---|---|---|
| **1** ÿ **2** ÿ **3** ÿ 5 | | | **{Fields: 1 and 2}** |

Documentary requirements
ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ No supporting documentation is required.



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Calle Oklahoma No. 14, colonia Nápoles;
Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx

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## 8. Application for health control card

### 8.1. By high or new

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-05-084** | Application for Sanitary Control Card for Tattoo Artists, Micropigmenters and Piercers |

**1** ÿ **2** ÿ **3** ÿ **11**

Documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Manual of procedures, which must indicate the following: » The tattooing, micropigmentation or perforation techniques that will be offered; » Detailed description of each procedure that you will use to present your services, and » The material and equipment that you will use in the provision of your services.

ÿ Curriculum vitae of the applicant that contains their general data, studies and work experience, related to the procedures to be accomplish;

ÿ Documentation that proves that the applicant has knowledge of first aid and mastery of hygiene techniques and asepsis;

ÿ Proof of vaccination against tetanus and hepatitis B; ÿ Two recent child-size photographs

### 8.2. by extension

| homoclave | Name, modality and quick filling guide |
|---|---|
| **COFEPRIS-05-087** | Request for Extension or Modification of the Sanitary Control Card for Tattoo Artists, Micropigmenters and Perforators |

**1** ÿ **2** ÿ **3** ÿ

**4**
**Only for change of address**

Documentary requirements

ÿ Form of Authorizations, Certificates and Visits, duly completed. ÿ Original and two copies of the proof of payment of rights, in terms of the Federal Law of Rights. ÿ Number or simple copy of the health control card for which the extension is requested.

**NOTE:** Upon delivery of the new card, the previous card will be requested.



**Contacto:**
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Delegación Benito Juárez, Ciudad de México,
C.P. 03810.
Teléfono 01-800-033-5050
contacto@cofepris.gob.mx