

Federal Commission for the Protection against Sanitary Risks

Authorizations, Certificates and Visits

Homoclave of the format
FF-COFEPRIS-01
RUPA number

Exclusive use of COFEPRIS
Admission number

Before filling out this form, carefully read the instructions, the guide and the list of attached documents.
Fill out with legible print or typewriter or computer.
The format will not be valid if it contains any deletions or corrections to the information.

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

Homoclave:	Name:
Mode:	

2. Owner's data

Natural person
RFC:
CURP (optional):
Name(s):
First surname:
Second surname:
Pepper:
Telephone:
Extension:
Email:

Legal entity
RFC:
Name or corporate name:
Legal representative or attorney requesting the procedure
RFC:
CURP (optional):
Name(s):
First surname:
Second surname:
Pepper:
Telephone:
Extension:
Email:

Tax domicile of the owner

Postal code:	
Type and name of road:	
(For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)	
Exterior number:	Inner number:
Type and name of the colony or human settlement:	
(Type of human settlement for example: Condominium, hacienda, ranch, subdivision among others.)	

Locality:
Municipality or mayor's office:
Federative Entity:
Between roads (type and name):
And road (type and name):
Subsequent roads (type and name):
Pepper:
Telephone:
Extension:

"In accordance with articles 4 and 69-M, section V of the Federal Law of Administrative Procedure, the forms to request procedures and services must be published in the Official Gazette of the Federation (DOF)"

Federal Commission for the Protection against Sanitary Risks

3. Establishment data

RFC:	Name or corporate name:
Please indicate the code and description of the business that corresponds to the establishment according to the North American Industrial Classification System:	
Clave SCIAN	SCIAN Description
Health license number or indicate whether you submitted a notice of operation: Note: If there is insufficient space for the SCIAN codes, add the necessary lines.	

Health Officer	
RFC:	
CURP (optional):	
Name(s):	
First surname:	
Second surname:	

Only for health license registration			
Hours of operation:			
DLMMJVS from		HH : MM	a HH : MM
DLMMJVS from		HH : MM	a HH : MM
Start date of operations:	DD	MM	AAAA

Address of the establishment

Postal code:	
Type and name of road:	
(For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)	
Exterior number:	Inner number:
Type and name of the colony or human settlement:	
(Type of human settlement for example: Condominium, hacienda, ranch, subdivision among others.)	

Locality:
Municipality or mayor's office:
Federative Entity:
Between roads (type and name):
And road (type and name):
Subsequent roads (type and name):
Pepper:
Telephone:
Extension:

Legal representative(s) and authorized person(s)

Legal representative	
CURP (optional):	
Name(s):	
First surname:	
Second surname:	
Pepper:	
Telephone:	
Extension:	
Email:	

Authorized person	
CURP (optional):	
Name(s):	
First surname:	
Second surname:	
Pepper:	
Telephone:	
Extension:	
Email:	

Note: Reproduce the section on Legal Representative(s) and/or Authorized Person(s) as many times as necessary.

Federal Commission for the Protection against Sanitary Risks

Legal representative
CURP (optional):
Name(s):
First surname:
Second surname:
Pepper:
Telephone:
Extension:
Email:

Authorized person
CURP (optional):
Name(s):
First surname:
Second surname:
Pepper:
Telephone:
Extension:
Email:

Legal representative
CURP (optional):
Name(s):
First surname:
Second surname:
Pepper:
Telephone:
Extension:
Email:

Authorized person
CURP (optional):
Name(s):
First surname:
Second surname:
Pepper:
Telephone:
Extension:
Email:

Note: Reproduce the section on Legal Representative(s) and Authorized Person(s) as many times as necessary.

4. Modification and/or extension

Select an option:	<input type="checkbox"/> Modification	<input type="checkbox"/> Extension
-------------------	---------------------------------------	------------------------------------

Document number:

Dice / authorized condition	Must say / condition requested

5. Product data

Product
1) Name of the product or service classification:
2) Specify:
3) Specific name of the product:
4) Name (trademark) or distinctive name:

Product
1) Name of the product or service classification:
2) Specify:
3) Specific name of the product:
4) Name (trademark) or distinctive name:

Federal Commission for the Protection against Sanitary Risks

5) International Common Name (INN) or generic name or name scientific or OECD unique identifier:									
6) Pharmaceutical form or physical form:									
7) Product type:									
8) Tariff fraction:									
9) Number of lots:									
10) Unit of measurement:									
11) Total quantity or volume:									
12) Number of pieces to be manufactured:									
13) Kilograms or grams per batch:									
14) Import or export health permit number or alphanumeric code:									
15) Health registration number:									
16) Minutes number:									
17) Presentation:									
18) Specific use or process:									
19) Key of the lot(s):									
20) Indications for use:									
21) Concentration:									
22) Therapeutic indications:									
23) Date of manufacture:									
24) Expiration date:									
25) Storage temperature:									
26) Transport temperature:									
27) Means of transport or entry customs:									
28) Container identification:									
29) Primary packaging:									
30) Secondary packaging:									
31) Type of packaging and number of packaging units:									
32) Item number:									

5) International Common Name (INN) or generic name or name scientific or OECD unique identifier:									
6) Pharmaceutical form or physical form:									
7) Product type:									
8) Tariff fraction:									
9) Number of lots:									
10) Unit of measurement:									
11) Total quantity or volume:									
12) Number of pieces to be manufactured:									
13) Kilograms or grams per batch:									
14) Import or export health permit number or alphanumeric code:									
15) Health registration number:									
16) Minutes number:									
17) Presentation:									
18) Specific use or process:									
19) Key of the lot(s):									
20) Indications for use:									
21) Concentration:									
22) Therapeutic indications:									
23) Date of manufacture:									
24) Expiration date:									
25) Storage temperature:									
26) Transport temperature:									
27) Means of transport or entry customs:									
28) Container identification:									
29) Primary packaging:									
30) Secondary packaging:									
31) Type of packaging and number of packaging units:									
32) Item number:									

Federal Commission for the Protection against Sanitary Risks

33) Key to the basic table or catalogue of the health sector (CBSS):

34) Presentation intended for:

 Export Generic Health Sector Sale

35) Product manufacturing:

 National Foreign

36) TIGIE application measurement unit (UMT):

37) Quantity of unit of measure of application of the TIGIE:

38) Type of genetically modified organism (GMO) only one product per application:

39) IMMEX program number (only for companies that are part of the program for the manufacturing, maquiladora and export services industry):

33) Key to the basic table or catalogue of the health sector (CBSS):

34) Presentation intended for:

 Export Generic Health Sector Sale

35) Product manufacturing:

 National Foreign

36) TIGIE application measurement unit (UMT):

37) Quantity of unit of measure of application of the TIGIE:

38) Type of genetically modified organism (GMO) only one product per application:

39) IMMEX program number (only for companies that are part of the program for the manufacturing, maquiladora and export services industry):

Note: Reproduce product data as many times as necessary in accordance with the provisions of each type of procedure.

6. Information for certificates

Use of the certificate (for export, registration, extension and others):

Destination country:

Specify features:

7. Information for research protocol

Mark the type of protocol to be performed:

 New

 Modification or amendment

Title of the protocol:

Route of administration (medicines or medical devices):

Name of principal investigator:

Name(s) of the institution(s) where the research will be conducted:

Federal Commission for the Protection against Sanitary Risks

8. Information for health registration of health supplies

8.A. For manufactured product

Natural person

RFC: ()

CURP (optional):

Name(s):

First surname:

Second surname:

(a) Only when the establishment is national.

Legal entity

RFC: ()

Name or corporate name:

(a) Only when the establishment is national.

Data of the health officer

RFC:

CURP (optional):

Name(s):

First surname:

Second surname:

Pepper:

Telephone:

Extension:

Email:

Stage of the manufacturing process:

Health license number or operating notice:

Address for manufactured product

Postal code:

Type and name of road:

(For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)

Exterior number:

Inner number:

Type and name of the colony or human settlement:

(Type of human settlement for example: Condominium, hacienda, ranch, subdivision among others.)

Locality:

Municipality or mayor's office:

Federative Entity:

Between roads (type and name):

And road (type and name):

Subsequent roads (type and name):

8.B. Manufacturer data abroad for imported or domestic products

Natural person

RFC: ()

CURP (optional):

Name(s):

First surname:

Second surname:

(a) Only when the establishment is national.

Legal entity

RFC: ()

Name or corporate name:

Contact:

Oklahoma Street No. 14, Nápoles neighborhood;
Benito Juárez Delegation, Mexico City, CP 03810.

Telephone 01-800-033-5050

contacto@cofepris.gob.mx

Federal Commission for the Protection against Sanitary Risks

Manufacturer's domicile abroad for imported or domestic products

Postal code:

Type and name of road:

(For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)

Exterior number:

Inner number:

Type and name of the colony or human settlement:

(Type of human settlement for example: Condominium, hacienda, ranch, subdivision among others.)

Note: If there is more than one manufacturer, you may reproduce this section as many times as necessary.

Locality:

Municipality or mayor's office:

Federative Entity:

Between roads (type and name):

And road (type and name):

Subsequent roads (type and name):

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

Natural person

RFC: ()

CURP (optional):

Name(s):

First surname:

Second surname: (a)

Only when the establishment is national.

Legal entity

RFC: ()

Name or corporate name:

Address of the supplier or distributor (for health supplies)

Postal code:

Type and name of road:

(For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)

Exterior number:

Inner number:

Type and name of the colony or human settlement:

(Type of human settlement for example: Condominium, hacienda, ranch, subdivision among others.)

Note: If there is more than one manufacturer or distributor, you may reproduce this section as many times as necessary.

Locality:

Municipality or mayor's office:

Federative Entity:

Between roads (type and name):

And road (type and name):

Subsequent roads (type and name):

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

Natural person

RFC: ()

CURP (optional):

Name(s):

First surname:

Second surname: (a)

Only when the establishment is national.

Legal entity

RFC: ()

Name or corporate name:

Contact:

Oklahoma Street No. 14, Nápoles neighborhood;
Benito Juárez Delegation, Mexico City, CP 03810.Telephone 01-800-033-5050
contacto@cofepris.gob.mx

Federal Commission for the Protection against Sanitary Risks

Address of the establishment that will condition or store health supplies

Postal code:	Locality:
Type and name of road: (For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)	Municipality or mayor's office:
Exterior number:	Inner number:
Type and name of the colony or human settlement: (Type of human settlement for example: Condominium, hacienda, ranch, subdivision among others.)	Federative Entity:
(a) Only when the establishment is national.	Between roads (type and name):
	And road (type and name):
	Subsequent roads (type and name):

9. Information for import, export and other authorizations

Import regime (only for importers)	<input type="radio"/> Temporal	<input type="radio"/> Definitive	<input type="radio"/> Bonded warehouse
Country of origin:	Country of origin:		
Country of destination:	Customs of entry or exit: (Specify only one)		

9.A. Manufacturer's data

Natural person	Legal entity
RFC: ()	RFC: ()
CURP (optional):	Name or corporate name:
Name(s):	
First surname:	
Second surname: (a)	
Only when the establishment is national.	

Manufacturer's address

Postal code:	Locality:
Type and name of road: (For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)	Municipality or mayor's office:
Exterior number:	Inner number:
Type and name of the colony or human settlement: (Type of human settlement for example: Condominium, hacienda, ranch, subdivision among others.)	Federative Entity:
(a) Only when the establishment is national.	Between roads (type and name):
	And road (type and name):
	Subsequent roads (type and name):

Federal Commission for the Protection against Sanitary Risks

9.B. Supplier or distributor data

Natural person	Legal entity
RFC: ()	RFC: ()
CURP (optional):	Name or corporate name:
Name(s):	
First surname:	
Second surname: (a)	
Only when the establishment is national.	

Address of the supplier or distributor

Postal code:	Locality:
Type and name of road: (For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)	Municipality or mayor's office:
Exterior number: Inner number:	Federative Entity:
Type and name of the colony or human settlement: (Type of human settlement, for example: Condominium, hacienda, ranch, subdivision, among others.)	Between roads (type and name):
(a) Only when the establishment is national.	And road (type and name):
	Subsequent roads (type and name):

9.C. Recipient details (final destination)

Natural person	Legal entity
RFC:	RFC:
CURP (optional):	Name or corporate name:
Name(s):	
First surname:	
Second surname:	

Recipient's address (final destination)

Postal code:	Locality:
Type and name of road: (For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)	Municipality or mayor's office:
Exterior number: Inner number:	Federative Entity:
Type and name of the colony or human settlement: (Type of human settlement for example: Condominium, hacienda, ranch, subdivision among others.)	Between roads (type and name):
(a) Only when the establishment is national.	And road (type and name):
	Subsequent roads (type and name):

Federal Commission for the Protection against Sanitary Risks

9.D Biller data

Natural person

RFC:

CURP (optional):

Name(s): ()

First surname:

Second surname: (b)

Only for health supplies.

Legal entity

RFC:

Name or corporate name: ()

Biller's address

Postal code:

Type and name of road:

(For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)

Exterior number:

Inner number:

Type and name of the colony or human settlement:

(Type of human settlement for example: Condominium, hacienda, ranch, subdivision among others.)

(a) Only

when the establishment is national.

Locality:

Municipality or mayor's office:

Federative Entity:

Between roads (type and name):

And road (type and name):

Subsequent roads (type and name):

10. Information for third party authorization

10.A. Testing Laboratory

- Analysis of food, beverages, dietary supplements, perfumery and beauty products.
- Analysis of drugs and medical devices
- Analysis of pesticides, fertilizers and plant nutrients
- Other (please specify): _____

10.B. Verification units

- Verification of establishments
- Sampling
- Other (please specify): _____

10.C. Interchangeability testing for interchangeable generic drugs

- Clinical unit for carrying out bioavailability and/or bioequivalence studies
- Analytical unit for carrying out bioavailability and/or bioequivalence studies
- Analytical unit for dissolution profile studies

Contact:

Oklahoma Street No. 14, Nápoles neighborhood;
Benito Juárez Delegation, Mexico City, CP 03810.Telephone 01-800-033-5050
contacto@cofepris.gob.mx

Federal Commission for the Protection against Sanitary Risks

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

Natural person

RFC:

CURP (optional):

Name(s):

First surname:

Second surname:

Pepper:

Telephone:

Extension:

Email:

PHOTO

Hours of operation:

DLMMJVS from

--	--	--	--	--	--	--	--	--	--

 HH : MM a HH : MMDLMMJVS from

--	--	--	--	--	--	--	--	--	--

 HH : MM a HH : MM

In case of extension, indicate the health control card number:

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

Postal code:

Type and name of road:

(For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)

Exterior number:

Inner number:

Type and name of the colony or human settlement:

(Type of human settlement for example: Condominium, hacienda, ranch, subdivision among others.)

Locality:

Municipality or mayor's office:

Federative Entity:

Country:

Between roads (type and name):

And road (type and name):

Subsequent roads (type and name):

I declare under protest that I comply with the applicable requirements and regulations, without exempting me from having to verify compliance by the health authority, 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 be carried out through the Comprehensive Service Center or offices in the states corresponding to the Federal Health 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

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

Contact:

Oklahoma Street No. 14, Nápoles neighborhood;
Benito Juárez Delegation, Mexico City, CP 03810.Telephone 01-800-033-5050
contacto@cofepris.gob.mx