Mexican Official Standard NOM-176-SSA1-1998, Sanitary requirements that must be met by manufacturers, distributors and suppliers of drugs used in the production of medicines for human use.

On the margin a seal with the National Coat of Arms, which says: United Mexican States.- Ministry of Health.

OFFICIAL MEXICAN STANDARD NOM-176-SSA1-1998, SANITARY REQUIREMENTS THAT MUST BE COMPLIED WITH BY MANUFACTURERS, DISTRIBUTORS AND SUPPLIERS OF DRUGS USED IN THE MANUFACTURE OF MEDICINES FOR HUMAN USE.

ENRIQUE RUELAS BARAJAS, President of the National Advisory Committee on Standardization, Regulation and Health Promotion, based on articles 39 of the Organic Law of the Federal Public Administration; 4th and 69-H of the Federal Law of Administrative Procedure; 3rd. section XXII, 13 Section A section I, 194, 195, 210, 212, 214 and 256 of the General Health Law; 38 section II, 40 sections I, VII and XII and 47 of the Federal Law on Metrology and Standardization; 28 and 34 of the Regulations of the Federal Law on Metrology and Standardization; 10, 24, 26 and other applicable articles of the Health Supplies Regulations; 7 sections V and XIX of the Internal Regulations of the Ministry of Health, and 2 section III and 10 sections I and II of the Decree creating the Federal Commission for Protection against Sanitary Risks, and

CONSIDERING

That on December 11, 1997, in compliance with the provisions of article 46 section I of the Federal Law on Metrology and Standardization, the General Directorate of Health Supplies presented to the Subcommittee on Standardization of Regulation of Health Supplies, the preliminary draft of this Official Mexican Standard.

That on January 20, 1999, in compliance with the agreement of the Subcommittee and the provisions of article 47, section I of the Federal Law on Metrology and Standardization, the draft of this Mexican Official Standard was published in the **Official Gazette of the Federation ,** so that within the following sixty calendar days after said publication, interested parties could present their comments to the National Advisory Committee on Standardization and Health Promotion.

Which were published in the **Official Gazette of the Federation** prior to the issuance of this Standard the responses to the comments received by the aforementioned Committee, in accordance with Article 47, Section III of the Federal Law on Metrology and Standardization.

That in light of the above considerations and with the approval of the National Advisory Committee for Standardization, Regulation and Health Promotion, the following is issued:

MEXICAN OFFICIAL STANDARD NOM-176-SSA1-1998, SANITARY REQUIREMENTS THAT MUST BE COMPLIED WITH MANUFACTURERS, DISTRIBUTORS AND SUPPLIERS OF DRUGS USED IN THE MANUFACTURE OF MEDICINES FOR HUMAN USE

PREFACE

The following administrative units and institutions participated in the preparation of this Standard:

SECRETARY OF HEALTH

FEDERAL COMMISSION FOR PROTECTION AGAINST HEALTH RISKS

GENERAL DIRECTORATE OF MEDICINES AND HEALTH TECHNOLOGIES

MEXICAN INSTITUTE OF SOCIAL SECURITY

TECHNICAL CONTROL UNIT OF INPUTS

NATIONAL ACADEMY OF PHARMACEUTICAL SCIENCES

ASOCIACION FARMACEUTICA MEXICANA, AC

NATIONAL CHAMBER OF THE PROCESSING INDUSTRY

SECTION 89

NATIONAL CHAMBER OF THE PHARMACEUTICAL INDUSTRY

NATIONAL COLLEGE OF PHARMACEUTICAL CHEMISTS AND BIOLOGISTS OF MEXICO, AC

INTERINSTITUTIONAL COMMISSION ON GOOD MANUFACTURING PRACTICES

CHEMICAL PHARMACEUTICAL PRODUCTION, AC

HELM DE MEXICO, S.A. DE C.V.

WARNER LAMBERT MEXICO, DIVISION CAPSUGEL

INDEX

1. Objective

This Mexican Official Standard establishes the minimum health requirements that must be met by manufacturers, distributors and suppliers of drugs of national or foreign manufacture, used for the production of medicines for human use.

2. Field of application

This Mexican Official Standard is mandatory for all establishments dedicated to the manufacture, purchase, sale, import, export, storage and distribution of drugs used in the manufacture of medicines for human use, as well as for establishments dedicated to the manufacture of medicines for human use.

3. References

For the correct application of this Mexican Official Standard, the following standards must be consulted:

3.1. NOM-059-SSA1-1993, Good manufacturing practices for chemical pharmaceutical industry establishments dedicated to the manufacture of medicines.

3.2. NOM-164-SSA1-1998, Good manufacturing practices for drugs.

4. Terms and definitions

For the purposes of this Standard, the following definitions apply:

4.1. Additive, a substance included in the formulation of medicines and which acts as a vehicle, preservative or modifier of some of their characteristics to improve their efficacy, safety, stability, appearance or acceptability.

4.2. Faithful copy, a copy of the original document, preserving the same content, wording and with the handwritten signature of the issuer.

4.3. Distributor, the natural or legal person dedicated to the purchase, storage and sale of drugs, to other participants in the process of medicines for human use.

4.4. Distributor-transferor, the distributor that carries out transfer operations.

4.5. Manufacturing, the operations involved in the production of a drug or medicine from the receipt of materials to its release as a finished product.

4.6. Manufacturer, the natural or legal person dedicated to the manufacture of medicines, drugs or any of them.

4.7. Drug (pharmaceutical): any natural, synthetic or biotechnological substance that has some pharmacological activity and is identified by its physical, chemical or biological properties, that is not presented in pharmaceutical form and that meets the conditions to be used as a medicine or ingredient of a medicine.

4.8. Supplier, the natural or legal person dedicated to the purchase, sale, storage or distribution of drugs used in the manufacture of medicines for human use, whether or not they are a manufacturer.

4.9. Transfer to the product fractionation and repackaging operation.

5. Abbreviations

The meaning of the abbreviations used in this Standard is as follows:

NEED	Pharmacopoeia of the United Mexican States
SSA	Ministry of Health
NAME	Mexican Official Standard
Regulation	Health Supplies Regulation

6. Drug suppliers

6.1. Manufacturers

In addition to complying with applicable legal provisions, drug manufacturers must:

6.1.1. Issue the corresponding certificate of analysis, signed by the health officer, to verify that the quality of the drugs they manufacture meets the specifications established in the current edition of the FEUM and its supplements. When the information does not appear in the FEUM, pharmacopoeias from other countries may be used, whose analysis procedures are carried out in accordance with specifications from specialized organizations or other internationally recognized scientific literature.

6.1.2. Comply with Good Manufacturing Practices for Drugs, in accordance with the provisions of NOM-164-SSA1-1998, Good manufacturing practices for drugs.

6.1.3. Have documentary evidence of the analyses, tests and evaluations that have been carried out for each batch at the different stages of the process.

6.1.4. Keep identification documentation for the operations you perform.

6.1.5. Label the packaging of products sold with the name and address of the manufacturer, the batch number and the name of the product.

6.2. When requested by the buyer, the corresponding certificate of analysis must be issued.

7. Importers

7.1. For drugs of foreign origin, the importer must demonstrate:

7.1.1. That the manufacturer of the product being marketed complies with the health regulations of the country of origin.

7.1.2. That it has the original certificate of analysis from the manufacturer.

7.1.3. That the manufacturer complies with Good Manufacturing Practices for Drugs.

8. Distributors

In addition to complying with applicable legal provisions, drug distributors must:

8.1. Ensure that the product being marketed has been manufactured in compliance with the requirements established in sections 6.1. and 7.1. of this Standard, as appropriate to the origin of the product.

8.2. Have the technical documentation for the release of each batch for the products you sell.

8.3. Have documentary evidence of the studies carried out in accordance with your own quality control process.

8.4. When requested by a buyer, he must issue a true copy of the original certificates and, where applicable, the certificate of the analysis he performs.

8.5. Keep identification documentation for the operations you carry out.

8.6. Maintain the origin identification elements in the containers if transfer operations are not carried out.

8.7. Carry out transfer operations under appropriate sanitary conditions, as well as identify and document them; the transferred products must contain information on their labels regarding the origin and the distributor.

8.8. Label the packaging of products sold with the name and address of the manufacturing establishment, the batch number and the name of the product.

9. Drug manufacturers

9.1. In addition to complying with applicable legal provisions, drug manufacturers must:

9.1.1. Have a quality assurance system to demonstrate that the drugs purchased comply with applicable health regulations.

9.1.2. Conduct quality control studies of its suppliers to ensure uniformity in the quality of its drugs.

9.1.3. Keep documentary evidence of the studies, analyses and evaluations carried out on the drugs used, in accordance with its internal quality control process, for at least one year after the expiration date of the medication.

9.1.4. Acquire drugs for the production of medicines that have been produced with Good Manufacturing Practices for Drugs and have an original certificate of analysis from the manufacturer that meets the quality specifications indicated in the current edition of the Pharmacopoeia of the United Mexican States and its supplements. When the information does not appear in this edition, pharmacopoeias from other countries may be used.

9.1.5. Notify the Secretariat of any change in supplier, origin of the drug, or raw materials, prior to marketing the products.

10. Compliance with international and Mexican standards

This Standard is not equivalent to any international standard, but is partially equivalent to the following Mexican standards:

10.1. NMX-016-1993-SCFI. Quality Systems - Quality Management and Elements of a Quality System
Quality.

10.2. NMX-CC-001: 1995 IMNC ISO 8402: 1994. Quality Management and Assurance
Quality. Vocabulary.

10.3. NMX-CC-004: 1995 IMNC ISO 9002: 1994. Quality Systems - Model for Quality Assurance
Quality in Production, Installation and Service.

10.4. NMX-CC-005: 1995 IMNC ISO 9003: 1994. Quality Systems - Model for Quality Assurance in Inspection and Final Testing.

10.5. NMX-CC-006/1: 1995 IMNC ISO 9004-1: 1994. Quality Management and Quality System Elements Part 1. Guidelines.

10.6. NMX-CC-006/2: 1995 IMNC ISO 9002-2: 1994. Quality management and elements of the quality system part 2. Guidelines for services.

10.7. NMX-CC-006/4: 1995 IMNC ISO 9004/4: 1994. Quality management and Quality System Elements part 4. Guidelines for quality improvement.

10.8. NMX-CC-017/1:1995 IMNC ISO 10012-1:1992 - Quality assurance requirements for measuring equipment - Part 1 - Metrological confirmation system for measuring equipment.

10.9. NMX-CC-7-1-1993/ISO-10011-1. Guidelines for auditing quality systems - Part 1 - Audits.

10.10. NMX-CC-7-2-1993/ISO-10011-3. Guidelines for auditing quality systems - Part 2 - Administration of the audit program.

10.11. NMX-CC-8-1993/ISO-10011-2. Qualification criteria for quality systems auditors.

11. Bibliography

11.1. General Health Law.

11.2. Health Supplies Regulation, February 4, 1998.

11.3. Federal Law on Metrology and Standardization, January 7, 1992.

11.4. NMX-CC-001: 1995 IMNC ISO 8402: 1994. Quality Management and Quality Assurance. Vocabulary.

11.5. NMX-CC-002/1: 1995 IMNC ISO 9000-1: 1994. Quality Management and Quality Assurance Part 1: Selection and Use Guidelines.

11.6. NMX-CC-003: 1995 IMNC ISO 9001: 1994. Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation and Service.

11.7. NMX-CC-004: 1995 IMNC ISO 9002: 1994. Quality Systems - Model for Quality Assurance in Production, Installation and Service.

11.8. NMX-CC-005: 1995 IMNC ISO 9003: 1994. Quality Systems - Model for Quality Assurance in Inspection and Final Testing.

11.9. NMX-CC-006/1: 1995 IMNC ISO 9004-1: 1994. Quality Management and Quality System Elements Part 1. Guidelines.

11.10. NMX-CC-006/2: 1995 IMNC ISO 9002-2: 1994. Quality Management and Quality System Elements Part 2. Guidelines for Services.

11.11. NMX-CC-006/4: 1995 IMNC ISO 9004/4: 1994. Quality Management and Quality System Elements Part 4. Guidelines for quality improvement.

11.12. NMX-CC-017/1:1995 IMNC ISO 10012-1:1992 - Quality assurance requirements for measuring equipment - Part 1 - Metrological confirmation system for measuring equipment.

11.13. NMX-CC-018/1:1995 IMNC ISO 10013-1:1995 - Guidelines for developing quality manuals.

11.14. NMX-CC-7-1-1993/ISO-10011-1. Guidelines for auditing quality systems - Part 1 - Audits.

11.15. NMX-CC-7-2-1993/ISO-10011-3. Guidelines for auditing quality systems - Part 2 - Administration of the audit program.

11.16. NMX-CC-8-1993/ISO-10011-2. Qualification criteria for quality systems auditors.

11.17. CIPAM. Guide to Good Manufacturing Practices for the Manufacture of Pharmachemicals. Second Edition.

11.18. Good Manufacturing Practices Guide for the Manufacture of Pharmachemicals. Mexican Pharmaceutical Association - Ministry of Health. Part One.

11.19. Supplier validation guide, General Directorate of Health Supplies, Ministry of Health. 1990.

11.20. Approved Validation and Certification Process for Suppliers to the Pharmaceutical Industry. 1998.

12. Compliance with the Standard

Monitoring compliance with this Standard is the responsibility of the Ministry of Health, whose staff will carry out the necessary verification and monitoring.

13. Validity

This Mexican Official Standard will enter into force thirty days after its publication in the **Official Gazette of the Federation.**

Kind regards

Mexico City, October 17, 2001.- The President of the National Advisory Committee on Standardization, Regulation and Health Promotion, **Enrique Ruelas Barajas.-** Signature.