The Mexican Pharmacopeia (FEUM) as standard of pharmaceutical products

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Pharmacopoeias in the world

There are currently 192 countries participating in the WHO 45 countries have a national pharmacopoeia.
Farmacopea Mexicana
Academia Farmacéutica de la Capital de la República

Nueva Farmacopea Mexicana

1874 1884 1896 1904 1925 1952

Sociedad Farmacéutica Mexicana

Oficial

Farmacopea Nacional de los Estados Unidos Mexicanos

1930 1952 1962 1974
Since 1984 it was defined a new structure to allow a quick and timely update.

**Farmacopea de los Estados Unidos Mexicanos**

- **1988**: Fifth edition
- **1994**: Sixth edition
- **2000**: Seventh edition
- **2004**: Eighth edition
- **2008**: Ninth edition
- **2011**: Tenth edition
- **2014**: Eleventh edition

**Supplements:**
- **Mexican Herbal Pharmacopoeia**
- **Mexican Homeopathic Pharmacopoeia**
- **Pharmacies Supplement**
- **Medical devices Supplement**
- **Supplement 2015**
- **Supplement 2016**
Mexican Pharmacopoeia is referred in national legislation:

- **General Law of Health (LGS):** It states that drugs and other health products are regulated by the Mexican Pharmacopoeia; Articles 195, 200, 224, 258 and 370.

- **Regulation of Health Supplies (RIS),** articles on the 2\textsuperscript{nd}, 7\textsuperscript{th}, 8\textsuperscript{th}, 13\textsuperscript{th}, 17\textsuperscript{th}, 21\textsuperscript{st}, 75\textsuperscript{th} and 167\textsuperscript{th}.

- **Mexican Official Standards:** Mexican Official Standard NOM-001-SSA1-2010, which establishes the procedure by which is reviewed, updated and edited the Pharmacopoeia of the United Mexican States. The Mexican pharmacopoeia is also referred to other Mexican standards.
Definition

The document is issued by the Ministry of Health to establish the general methods of analysis and the requirements for identity, purity and quality of drugs, additives, medicines, biologicals and other health supplies.
National legislation includes reference to other.

- *Regulation of Health Supplies in Mexico* states that:

  The quality specifications of medicine additives, drugs and medicines are those indicated in the current edition of the Mexican Pharmacopoeia. When it does not contain the information, the pharmacopoeias of other countries may be used (Or other internationally recognized scientific literature.)
FEUM as mandatory document

Articles 200 and 258 of General Law of Health indicated which establishments require possess, use and be implemented the latest edition of the FEUM and its supplements.
Administrative sanctions by LGS

Not possess or not go into effect the latest edition of the FEUM and its supplements. It entails a fine of 6,000 to 12,000 times the daily minimum wage, according to art. 421 of the LGS.
In order to get the health registration for medicines it require that specifications for identity and purity is consistent are as indicated in FEUM

Collaborators

Government 39%

Industry 24%

Universities 37%
Technical council divided in 24 committees integrated by 215 professionals.


- 138 General methods of analysis.
- 178 Monographs of additives.
- 527 Drug monographs.
- 662 Monographs for Medicines.
- 7 Monographs of medical gases.
- 39 Monographs of biological products.
- 64 Biological product methods.
- 11 Monographs of biotechnological products.
- 27 Monographs of hemoderivative products.
- 16 Monographs of dissolution profiles, among other chapters.
- 10 Critic Systems monographs.
- 45 Radiopharmaceuticals monographs.
- 73 Basic Tests for drugs.
- 13 Bioequivalence Guide for studies.
Reference Substances

- Reference substances are high purity materials without impurities and excipients. Those are stored in adequate conditions to decrease the degradation kinetic activity.

- Reference substances are established with approval from Reference substance Committee from Mexican Pharmacopoeia Permanent Commission and following their recommendations.

- Those are used in identity physic-chemical tests and essays explained in the monographs from Mexican Pharmacopoeia and supplies.

- Currently, the Mexican Pharmacopoeia has a program of work for the establishment of pharmaceutical reference substances.
International collaboration and harmonization

Collaboration with and/or being part of a (different) national/regional pharmacopoeia.
  ◦ The Mexican pharmacopoeia has signed a collaboration agreement with USP.

Publication of harmonized pharmacopoeia texts within the pharmacopoeia.

Collaboration with World Health Organization.
  ◦ Good pharmacopoeial practices
Interaction with stakeholders, including regulators

- Although FEUM has always had into account the opinions of its users. Since 2005 it has been established a procedure that allows greater interaction with users and others interested in its contents.

- We have four periods per year of consultation through a website open to the public: www.farmacopea.org.mx

- When it’s necessary, we develop forums in order to discuss specific topics.
Goals for FEUM

Increase the monographs considering the following priorities:

- Cover the basic tables and catalogue of consumables used in the health sector in Mexico
- Include the generic list
- Biotechnological products
Thanks

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