INTERNATIONAL MEETING OF WORLD PHARMACOPOEIAS

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WHO, Geneva, Executive Board Room

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1. Name of pharmacopoeia

Farmacopea de los Estados Unidos Mexicanos

(Mexican Pharmacopoeia)
2. Pharmacopoeia referred to in national/regional legislations

**Mexican Pharmacopoeia is referred in national legislation:**

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

- **Regulation of health products**, articles on the 2\(^{nd}\), 7\(^{th}\), 8\(^{th}\), 13\(^{th}\), 17\(^{th}\), 21\(^{st}\), 75\(^{th}\) and 167\(^{th}\)

- **Mexican Official Standards**: Mexican Official Standard NOM-001-SSA1-93, which establishes the procedure by which the review, update and edit the Pharmacopoeia of the United Mexican States. The Mexican pharmacopoeia is also referred to other Mexican standards.
3. National/regional legislation includes reference to other

- General Health Act. 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.)
(Annual Update)

- 191 General methods of analysis
- 164 Monographs of additives
- 485 drug monographs
- 626 Monographs for Medicines
- 6 Monographs of medical gases
- 75 Monographs of biological products
- 16 Monographs of dissolution profiles, among other chapters.
2. Supplement for medical devices, second edition; 2011. (Updating every 5 years)

- 58 General Methods of Analysis
- 171 Monographs of Medical Devices
(Updating every 6 years)

- 74 Official Monographs
- 19 Monographs in extra- Pharmacopoeia (mexican plants)
- 20 General Methods of Analysis
(Updating every 5 years)

- Professional responsibility of the pharmacist on the premises
- Management and conservation of health products
- Pharmacovigilance and Tecnovigilance
- Hospital Pharmacy
- Requirements for the Operation of Pharmacies and distribution warehouses.
- Controlled drugs
- Officinal drugs
- Destruction of outdated or damaged drugs
- Inappropriate activities in establishments
- Manual of Standard Operating Procedures (SOP)
- inter alia
(Updating every 6 years) 

- General information 
- 469 Monographs of homeopathic active ingredients 
- 89 Monographs of homeopathic tinctures 
- One Chapter for homeopathic pharmacies
REFERENCE SUBSTANCES:

• Currently, the Mexican Pharmacopoeia has a work program for the establishment of pharmaceutical reference substances.

• Our main goal is to have the 100 substances most used in Mexico.
The Mexican pharmacopoeia has signed a collaboration agreement with USP.
• Although we do not have a formal process for the harmonization of information with other pharmacopoeias, our drug monographs are consistent in their specifications with the USP, EP, BP in 60 to 100%.
• 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.
11. Strategy for the future

• Stay tuned to the needs of the health authority and users, to maintain current pharmacopoeia.

• Continue promoting the approach of users to participate in the development of the monographs.

• Establish a closer communication with our colleagues in other parts of the world.
Headquarters
Thanks!

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