MEET THE WORLD PHARMACOPOEIAS SYMPOSIUM

20 February, 2020

Strasburg, France

UBALDO JUAREZ SEVILLA. Deputy Director
RAFAEL HERNANDEZ MEDINA. Technical and Publications Manager

Address:
Río Rhin 57, Col. Cuauhtémoc.
CP 06500, Ciudad de México, México.
Tel.: +52 55 5207-6887
http://www.farmacopea.org.mx
cpfeum@farmacopea.org.mx

Name of pharmacopoeia

Farmacopea de los Estados Unidos Mexicanos
(FEUM by its acronym in Spanish)

Mexican Pharmacopoeia
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\textsuperscript{nd}, 7\textsuperscript{th}, 8\textsuperscript{th}, 13\textsuperscript{th}, 17\textsuperscript{th}, 21\textsuperscript{st}, 75\textsuperscript{th} and 167\textsuperscript{th}

- **Technical Regulation**: Mexican Official Standard NOM-001-SSA1-2010, that establishes the procedure by which the review, update and edit of the Pharmacopoeia of the United Mexican States. The Mexican pharmacopoeia is also referred to other Mexican standards.
National legislation includes different reference

General Health Act. in Mexico states that:

The quality specifications of medicines, excipients, active pharmaceutical ingredient 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 by scientific literature)

Regulation of Health Supplies

In order to get the health registration for medicines, it requires that specifications for identity and purity are consistent as indicated in FEUM.

Scope

- The Mexican Pharmacopoeia has a wide scope, since it has publications for: allopathic, homeopathic, herbal medicines, medical devices and for storage and distribution activities for health supplies.

<table>
<thead>
<tr>
<th>FEUM</th>
<th>12 Ed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>General methods of analysis</td>
<td>139</td>
</tr>
<tr>
<td>Excipients</td>
<td>188</td>
</tr>
<tr>
<td>API</td>
<td>559</td>
</tr>
<tr>
<td>Pharmaceutical preparations</td>
<td>735</td>
</tr>
<tr>
<td>Gases for medicinal use</td>
<td>11</td>
</tr>
<tr>
<td>Biological products</td>
<td>41</td>
</tr>
<tr>
<td>Biological product methods</td>
<td>64</td>
</tr>
<tr>
<td>Biotechnological products</td>
<td>16</td>
</tr>
<tr>
<td>Blood-derived medicines</td>
<td>29</td>
</tr>
<tr>
<td>Dissolution profile</td>
<td>16</td>
</tr>
<tr>
<td>Crytical systems</td>
<td>24</td>
</tr>
<tr>
<td>Radiopharmaceuticals</td>
<td>Is excluded</td>
</tr>
<tr>
<td>Basic tests</td>
<td>73</td>
</tr>
<tr>
<td>Bioequivalence Guides</td>
<td>13</td>
</tr>
</tbody>
</table>
New publications and advances

Online


- 119 Official monographs.
- 16 Extra monographs - Pharmacopoeia.
- 46 General Methods of Analysis.

- 468 Monographs of excipients for homeopathic medicines.
- 105 Monographs of tinctures and homeopathic trituration.
- 1 chapter of homeopathic pharmacy.


- General information
- 330 Solutions and reagents
- 60 General Methods of Analysis
- 171 Medical Device Monographs
- 53 Radiopharmaceutical monographs
- 10 Appendices
Currently, the Mexican Pharmacopoeia is working in a program for the establishment of pharmaceutical reference substances.

Our main goal is to have the 100 substances most used in Mexico.
Who is responsible for FEUM?

Endorse and formalize

It is the advisory body

Usarios

Feedback

Compliance monitoring

Permanent Commision – Technical & Scientific Assessor

Government 39%

Industry 24%

Universities 37%
Stakeholder interaction

- Permanent representation of professionals in the various committees of the CPFEUM.
- Everyone can comment on what has already been published.
- Everyone can comment during the periods of consultation of FEUM users.
- Everyone can propose monographs for inclusion and review (technical justification)

EXPECTATIONS

1. The Mexican Pharmacopoeia is recognized as an official reference in some countries of the Americas such as: El Salvador, Guatemala, Costa Rica, Chile, Colombia, Peru, among others. It is in the interest of FEUM to work together with PAHO / WHO so that the Mexican Pharmacopoeia is increasingly useful in Spanish-speaking countries and promote the development of the Americas.

2. Establish collaboration agreements with PAHO / WHO for the development of reference substances that are necessary in Latin America (e.g. reference substances for neglected diseases such as Chagas).

3. Strengthen the development of standards for biological and biotechnology of interest to Mexico and the region.
Goals for MxPh

Increase the monographs considering the following priorities:
• Cover the essential medicines list used in Mexico.
• Include the generic list
• Biotechnological products

STRATEGY FOR THE FUTURE

• Identify 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.
**Expectations**

- Exchange of information to respond in time to the needs.
- Closer collaboration with the world's leading pharmacopoeias.
- Be the bridge between Spanish-speaking countries and the world's leading pharmacopoeias.
- Access to consultations to the main pharmacopoeias.

**UPDATE OF PUBLICATIONS OF THE MEXICAN PHARMACOPOEIA**

<table>
<thead>
<tr>
<th>PROSPECTIVO 2019-2028</th>
<th>PUBLICACIONES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td>FEUM (Agripáltica)</td>
<td>Suplemento</td>
</tr>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td></td>
<td>FEUM</td>
</tr>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td></td>
<td>FEUM</td>
</tr>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td></td>
<td>FEUM</td>
</tr>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td></td>
<td>FEUM</td>
</tr>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td></td>
<td>FEUM</td>
</tr>
<tr>
<td></td>
<td>2019</td>
</tr>
</tbody>
</table>
¡GRACIAS!

www.farmacopea.org.mx