



## MEET THE WORLD PHARMACOPOEIAS SYMPOSIUM

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Strasburg, France

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## Name of pharmacopoeia



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



Mexican Pharmacopoeia



## Pharmacopoeia referred in national 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<sup>nd</sup>, 7<sup>th</sup>, 8<sup>th</sup>, 13<sup>th</sup>, 17<sup>th</sup>, 21<sup>st</sup>, 75<sup>th</sup> and 167<sup>th</sup>
- *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.**

Art. 167, 173, 174 y 178 of RIS. *DOF 04/feb/1998*

## 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.



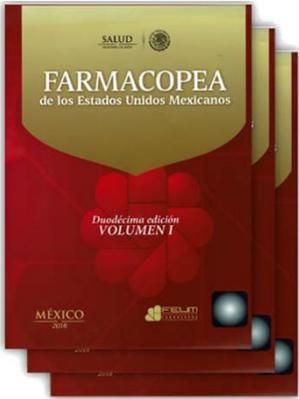
FEUM	12 <sup>o</sup> Ed.
General methods of analysis	139
Excipients	188
API	559
Pharmaceutical preparations	735
Gases for medicinal use	11
Biological products	41
Biological product methods	64
Biotechnological products	16
Blood-derived medicines	29
Disolution profile	16
Critical systems	24
Radiopharmaceuticals	Is excluded
Basic tests	73
Bioequivalence Guides	13





**New publications and advances**

# Online





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## Pharmacopoeia Herbal of the United Mexican States 2nd ed, 2013.



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



### Homeopathic Pharmacopoeia of the United Mexican States 3th ed, 2015.



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



### Supplement for medical devices 4th ed., 2017.



- General information
- 330 Solutions and reagents
- 60 General Methods of Analysis
- 171 Medical Device Monographs
- 53 Radiopharmaceutical monographs
- 10 Appendices

The screenshot displays the FEUM (FARMACOPÉA de los Estados Unidos Mexicanos) website. The main navigation menu on the left includes sections like 'VIII. Procedimientos Normalizados de Operación', 'IX. Control de inventarios', 'X. Manejo y almacenamiento de los insumos para la salud', 'XI. Receta médica', 'XII. Medicamentos estupefacientes y psicotrópicos', and 'XIII. Medicamentos genéricos y bioequivalentes'. The 'XI. Receta médica' section is expanded, showing sub-items: 'A. Elementos que constituyen una receta', 'B. Recomendaciones en una receta', 'C. Recetas de instituciones públicas', 'D. Revisión, surtido y dispensación de la receta médica', 'E. Tipos de recetas', and 'F. Formato del recetario especial', which is currently selected.

The main content area is titled 'Capítulo: XI. Receta médica' and contains the following text:

**F. Formato del recetario especial**

Los médicos pueden obtener la autorización para prescribir estupefacientes, así como los recetarios autorizados de manera electrónica, en el portal para médicos de <COFEPRIS/> <http://www.gob.mx/COFEPRIS/>, en el cual se encuentran las instrucciones para el trámite.

Estas recetas especiales obtenidas cumplen con los requisitos siguientes (figura 2):

Figure 2 shows a sample of a special prescription form with the following fields:

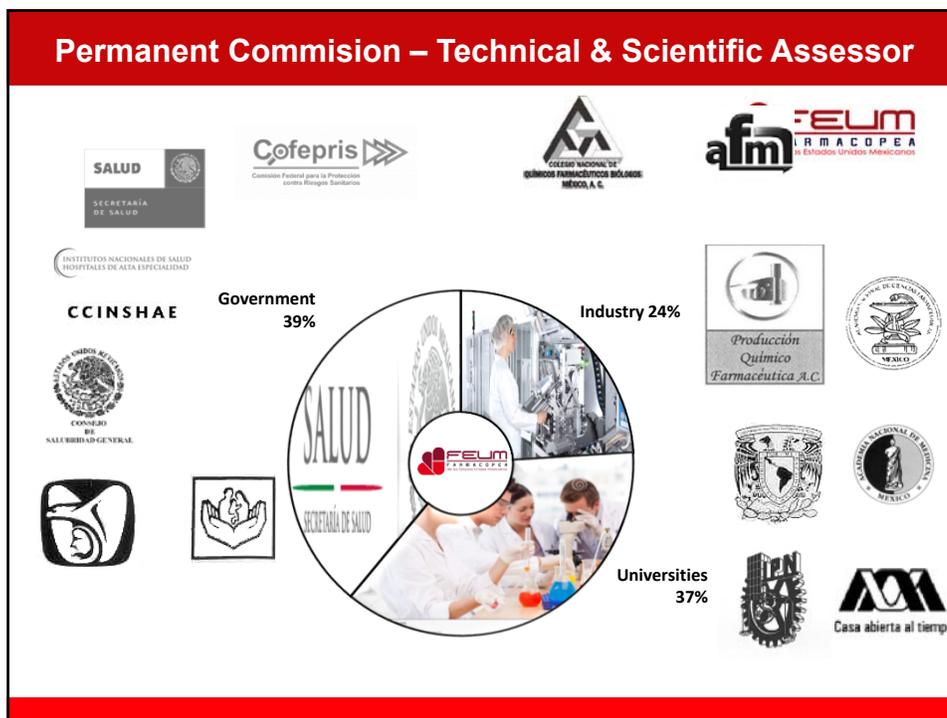
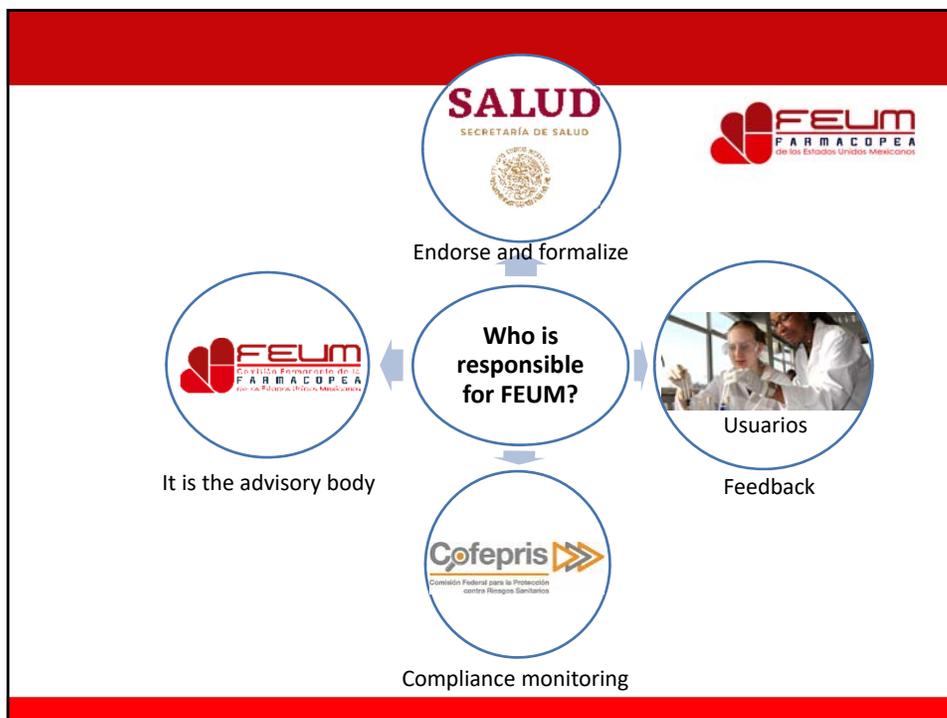
Folio XXXX		
Di	Mes	Año
Nombre del Paciente		
CURP		
Dirección del paciente		
Diagnóstico		
Nombre comercial y genérico del medicamento		
Cantidad	Presentación	
Dosificación	Via de administración	
No. de días de prescripción		
Firma y sello del médico		

At the bottom of the page, it says: 'Licencia Prueba - Farmacopea Online Versión v.0.1 Usuario de Prueba - Número Interno:'

## REFERENCE SUBSTANCES FEUM

- 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.

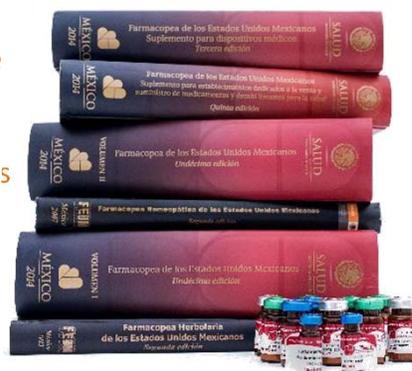




## Stakeholder interaction



- 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



PROSPECTIVO 2019-2028

PUBLICACIONES

	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
FEUM (Alopática)	Suplemento FEUM 2019	Suplemento FEUM 2020	13a edición	Suplemento FEUM 2022	Suplemento FEUM 2023	14a edición	Suplemento FEUM 2025	Suplemento FEUM 2026	15a edición	Suplemento FEUM 2028
Suplemento Farmacias	6a edición				7a edición				8a edición	
Farmacopea Homeopática		4a edición					5a edición			
Farmacopea Herbolaria	3a edición					4a edición				
Supt. Disp. Médicos				5a edición					6a edición	
Sustancias de referencia										
Encuentro científico FEUM-USP	EC FEUM/USP		EC FEUM/USP		EC FEUM/USP		EC FEUM/USP		EC FEUM/USP	



¡GRACIAS!

[www.farmacopea.org.mx](http://www.farmacopea.org.mx)

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