Registration of Vitamins in Mexico

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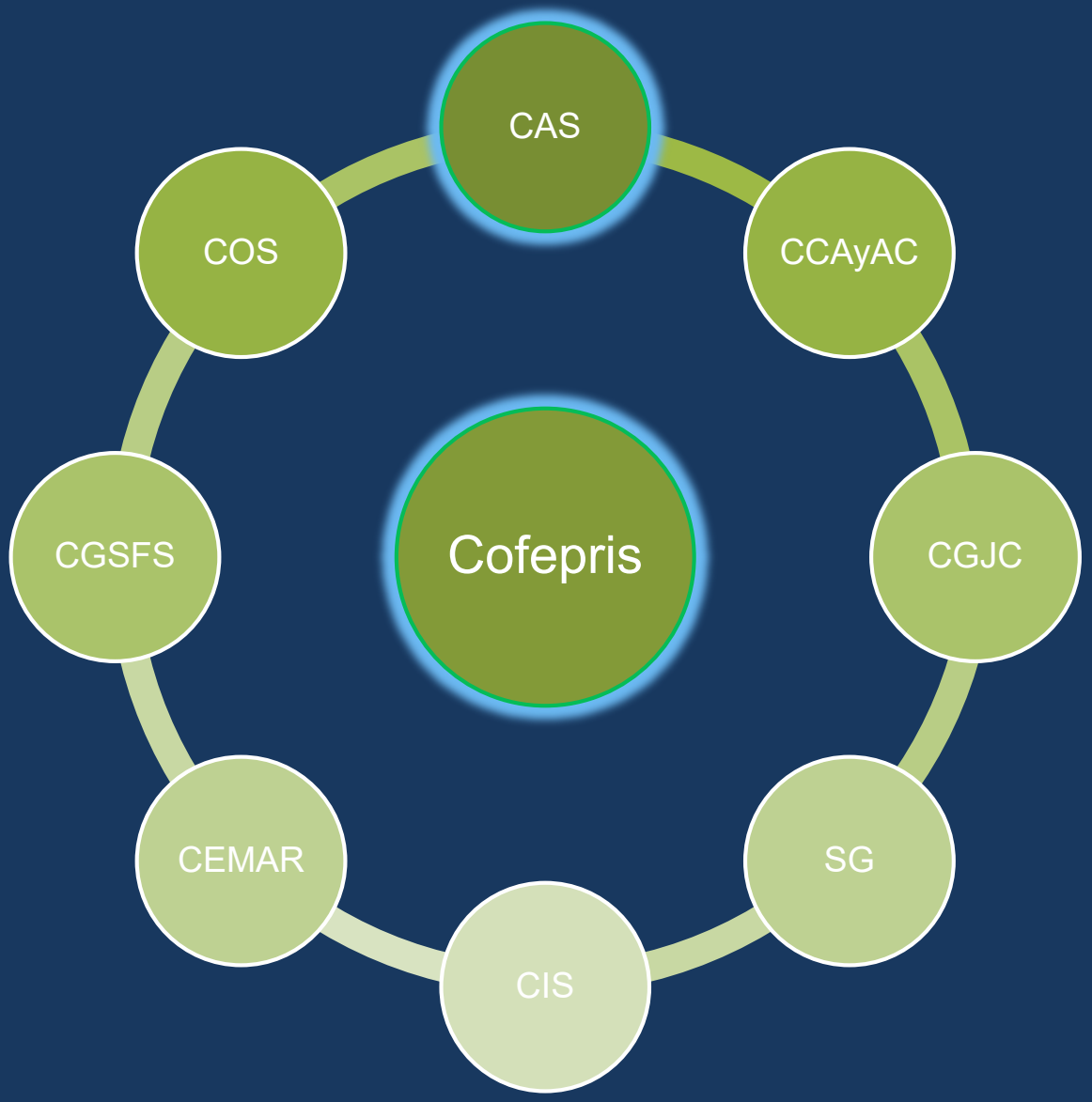
Mexico's Health Authority



The Federal Commission for Protection against Health Risks (COFEPRIS) is a decentralized body of the Ministry of Health, that is, it has technical, administrative and operational autonomy, its purpose is to protect the health of the population.

COFEPRIS evaluates vitamins submissions through the Sanitary Authorization Commission (CAS).

*Abbreviation

- CFS- Comisión de Fomento Sanitario.
- COS- Comisión de Operación Sanitaria
- CCAyAC- Comisión de Control Analítico y Ampliación de Cobertura
- CAS- Comisión de Autorización Sanitaria
- CEMAR- Comisión de Evidencia y Manejo de Riesgo
- CGSFS- Coordinación General del Sistema Federal Sanitario
- CGJC- Coordinación General Jurídica y Consultiva
- CIS-Centro Integral de Servicios

Definition od Vitamins

Cofepris defines Vitamins as:

“Products that contains only vitamins or minerals, alone or in association, that are indicated to prevent or treat conditions due to deficiencies thereof, and that are presented in pharmaceutical dosage forms.”

-Article 61 of the Health Supplies Regulation.

Registration Process of Vitamins in Mexico

1. Check the conformity of product formulation
2. Complete administrative Form (**COFEPRIS-04-022-A/B)**
3. Payment of registration fee to COFEPRIS
4. Compilation of Technical File
5. Sending the technical file to authorized third party for review*
6. Receive report of evaluation from Third party
7. Submit completed application form, receipt of Payment and third party evaluation report to Cofepris for review.

Registration Requirements

General requirements

- All registration documents must be submitted in Spanish to Cofepris.
- Documents issued by foreign health authorities must be apostilled or legalized and translated by an expert translator (Art.153 of the Health Supplies Regulation)

Checking the Conformity of Product Formulation

Vitamin should not include vitamins and or minerals in a concentration exceeding the maximum daily dose as shown here below. Otherwise they need to be subject to prescription .

Vitamin	Max Daily Dose
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Vitamin A / Retinol	2400 µg
Folic acid	2000 µg
Beta carotene	150 mg
Biotin	1000 µg
Vit. B1 / Thiamine	150 mg
Vit. B2 / Riboflavin	170 mg
Vit. B3 / Niacin	500 mg
Vit. B5 / Pantothenic Acid	550 mg
Vit B6 / Pyridoxine	250 mg
Vit B12 / Cyanocobalamin	1000 µg
Vit C / Ascorbic Acid	2000 mg
Vit D	50 µg
Vit E / d- a-Tocopherol	1000 mg
Vit K	65 µg

Minerals	Max Daily Dose
Calcium	2000 mg
Copper	10 mg
Chrome	500 µg
Fluorine	5.0 mg
Phosphorus	2000 mg
Iron	75 mg
Magnesium	1000 mg
Manganese	10 mg
Molybdenum	350 µg
Selenium	200 µg
Iodine	500 µg
Zinc	50 mg

Content of the Registration Dossier

1. Monograph of the finished product with qualitative control methods with qualitative and quantitative control methods of all the components
2. Conditions of handling, conservation and storage
3. Description of the primary and secondary packaging and toxicity tests
4. Label projects with cautionary legends
5. Instructions for use, if applicable.
6. Stability tests
7. Certificate of analysis of raw material and finished product, containing the physical, chemical and microbiological specifications.
8. Information to prescribe in its wide and reduced versions
9. Certificate of free sale or equivalent if the product is imported, issued by the health authority or country of origin

Registration Timelines and Fees

Registration Pathway	Cofepris review timelines	Fees (Mexican Pesos)
Without opinion from an authorized third party	45 business days	$19,501.87
With opinion from an authorized third party	15 business days	$19,501.87 *Fees to obtain opinión from third party may vary

References

- Ley General de Salud. Diario Oficial de la Federacion. Mexico
- Health Secretary NOM-059-SSA1-2015, Good Manufacturing Practices for Medicines. Published September 9th 2015. Consulted April 8th 2020. Available at http://dof.gob.mx/nota_detalle.php?codigo=5424575&fecha=05/02/2016
- Health Secretary NOM-072-SSA1-2012, Labeling of Medicines and Herbal Remedies. Published February 9th 2012. Consulted April 8th 2020. Available at https://www.dof.gob.mx/nota_detalle.php?codigo=5278341&fecha=21/11/2012
- Health Secretary NOM-073-SSA1-2015, Stability of drugs and medicines, as well as herbal remedies. Published February 26th 2015. Consulted April 8th 2020. Available at http://www.dof.gob.mx/nota_detalle_popup.php?codigo=5440183
- Health Secretary NOM-220-SSA1-2016, Installation and Operation of Pharmacovigilance. Published September 23rd 2016 . Consulted April 8th 2020. Available at http://dof.gob.mx/nota_detalle.php?codigo=5490830&fecha=19/07/2017
- Reglamento de la Ley General de Salud en Materia de Investigacion para la Salud. Diario Oficial de la Federacion. Mexico.

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Thank You

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