

DIRECCIÓN NACIONAL DE FARMACIA Y DROGAS

Departamento de Registros Sanitarios de Medicamentos, Cosméticos y Otros productos para la
Salud Humana
Sección de Bioequivalencia

CONVERSATORIO INCLUSIÓN DE PRINCIPIOS ACTIVOS DIRIGIDO A INSTITUCIONES PÚBLICAS DE SALUD

Mgtra. Lorena Cruz
Licda. Karina Troya
Mgter. Uriel Pérez
Mgter. Rubens Donoso
Mgter. Nelson Rodríguez

Panamá, 22 de febrero de 2021

No. 28776-B

Gaceta Oficial Digital, viernes 17 de mayo de 2019

1



GACETA OFICIAL

DIGITAL

Año CXIII

Panamá, R. de Panamá viernes 17 de mayo de 2019

Nº 28776-B

CONTENIDO

MINISTERIO DE SALUD

Decreto Ejecutivo Nº 95
(De martes 14 de mayo de 2019)

QUE REGLAMENTA LA LEY 1 DE 10 DE ENERO DE 2001, SOBRE MEDICAMENTOS Y OTROS PRODUCTOS PARA LA SALUD HUMANA



GACETA OFICIAL

DIGITAL

Año CXIII

Panamá, R. de Panamá viernes 07 de junio de 2019

Nº 28791

CONTENIDO

MINISTERIO DE SALUD

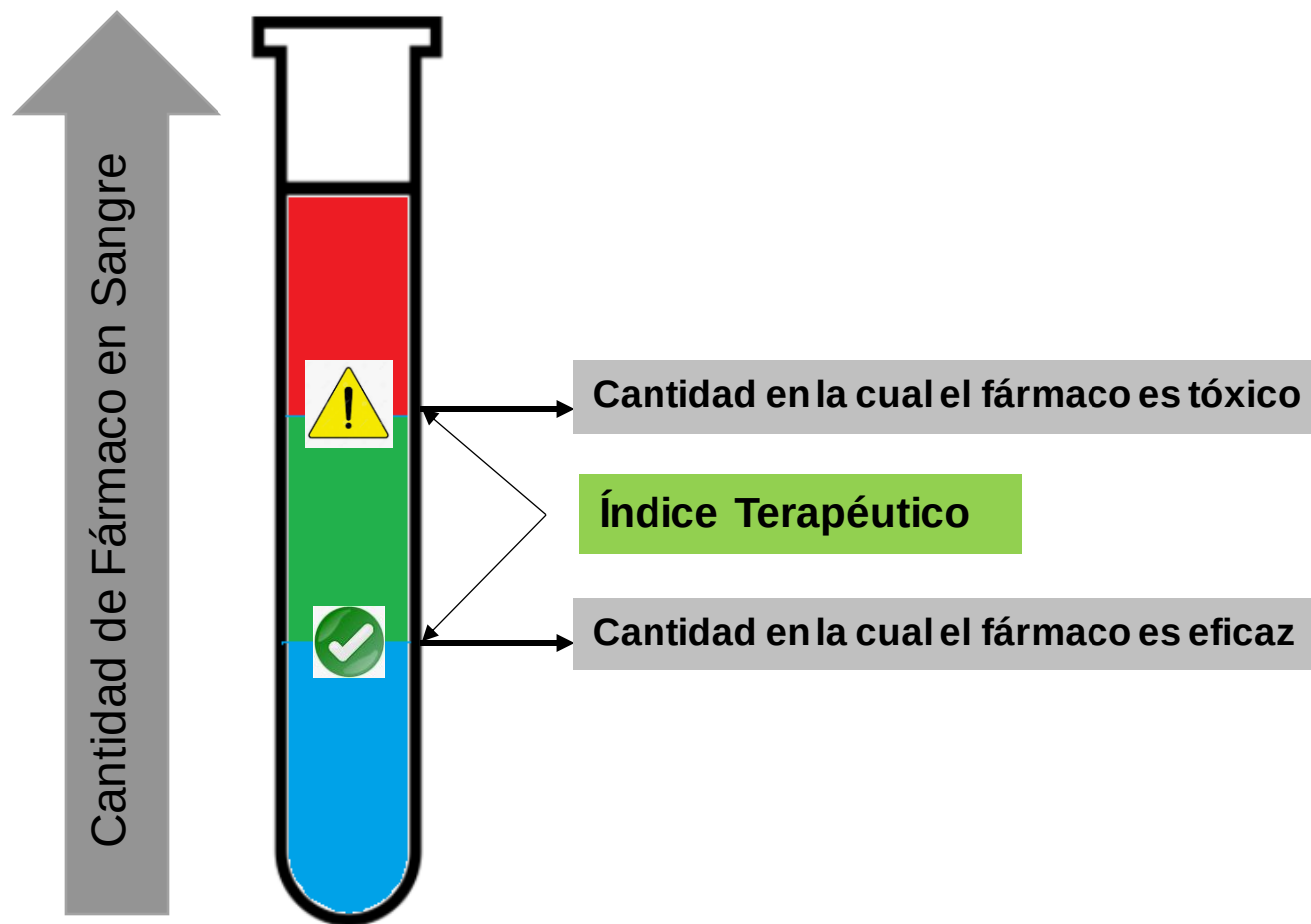
Resolución Nº 419-A
(De viernes 24 de mayo de 2019)

POR LA CUAL SE PRESENTA EL LISTADO DE PRODUCTOS QUE HAN CUMPLIDO CON LA PRESENTACIÓN DE LAS EVIDENCIAS SOLICITADAS SEGÚN LAS RECOMENDACIONES DE ORGANISMOS INTERNACIONALES DE MANERA SATISFACTORIA POR LO QUE SE PERMITE SU COMERCIALIZACIÓN EN EL PAÍS.

Resolución Nº 498
(De lunes 27 de mayo de 2019)

POR LA CUAL SE ESTABLECEN LOS PRINCIPIOS ACTIVOS QUE REQUIEREN DEMOSTRAR INTERCAMBIABILIDAD Y LOS MEDICAMENTOS DE REFERENCIA.

ÍNDICE TERAPÉUTICO

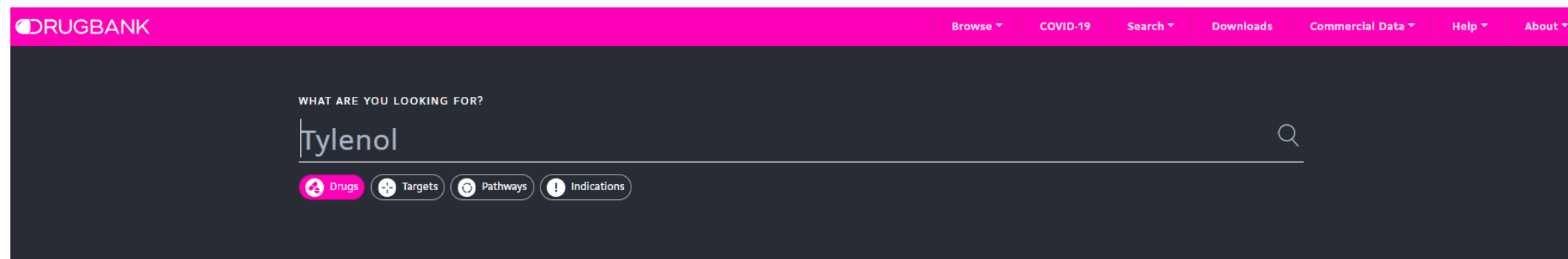


□*Cociente entre la dosis letal media, DL_{50} y la dosis eficaz media, DE_{50} . Cociente entre la concentración mínima tóxica y la concentración mínima eficaz.

*Decreto Ejecutivo No. 95 de 14 de mayo de 2019. "Que reglamenta la Ley 1 de 10 de enero de 2001, sobre medicamentos y otros productos para la salud humana". G.O. 28776-B de 17 de mayo de 2019.

ÍNDICE TERAPÉUTICO: FUENTES DE INFORMACION

- DRUG BANK: [Narrow Therapeutic Index Drugs](#) | [DrugBank Online](#)



DrugBank is a pharmaceutical knowledge base that is enabling major advances across the data-driven medicine industry.

The knowledge base consists of proprietary authored content describing clinical level information about drugs such as side effects and drug interactions, as well as molecular level data such as chemical structures and what proteins a drug interacts with. DrugBank offers a suite of products powered by the DrugBank Platform and has customers located around the world crossing multiple industries including precision medicine, electronic health records, drug development and regulatory agencies. DrugBank also provides DrugBank Online as a free-to-access resource for academic research and is used by millions of pharmacists, pharmacologists, health professionals and pharmaceutical researchers every year.

[DrugBank for Commercial Use](#) >

[Cite DrugBank](#) ⬇

[About DrugBank](#) >

ÍNDICE TERAPÉUTICO: FUENTES DE INFORMACION

DRUG BANK: Narrow Therapeutic Index Drugs | DrugBank Online

1

- **DRUG BANK**
- <https://go.drugbank.com/>



2

- **BROWSE: CATEGORIES**
- <https://go.drugbank.com/categories>



Drug Categories

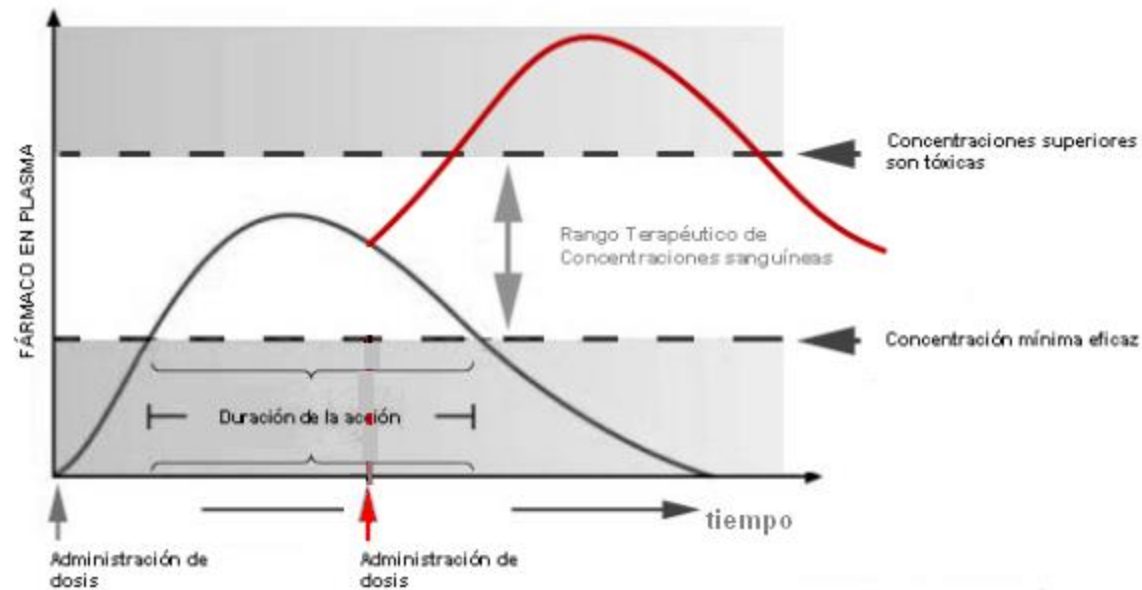
3

- **Narrow Therapeutic Index (Categoría 3221, pág. 129)**
- <https://go.drugbank.com/categories/DBCAT003972> 254 P.A.



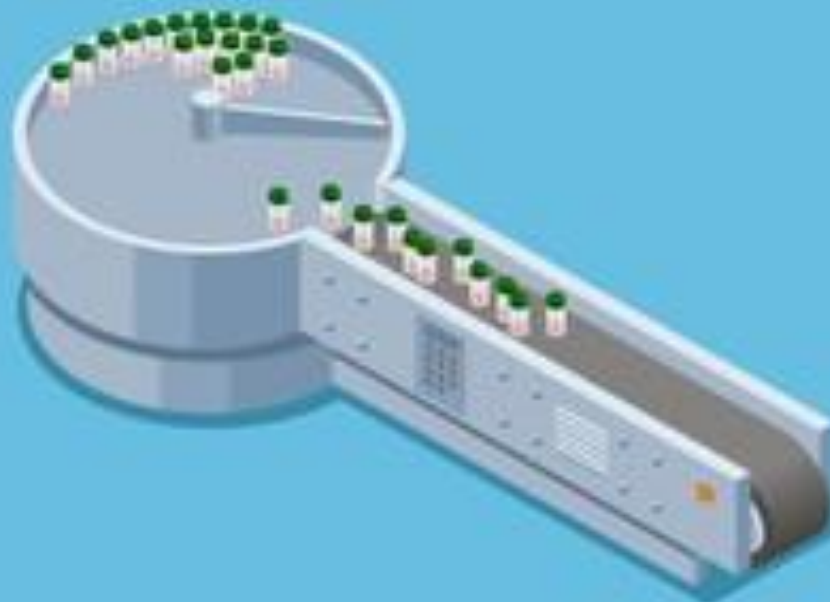
Narrow Therapeutic Index Drugs

ÍNDICE TERAPÉUTICO:





PROPIEDADES FISICOQUÍMICAS DEL FÁRMACO





PROPIEDADES FISICOQUÍMICAS DEL FÁRMACO

DRUGBANK

[Browse](#) [COVID-19](#) [Search](#) [Downloads](#) [Commercial Data](#) [Help](#) [About](#)

Drugs

Identification

Pharmacology

Interactions

Products

Categories

Chemical Identifiers

References

Clinical Trials

Pharmacoeconomics

Properties

Spectra

Targets (2)

Enzymes (6)

Carriers (2)

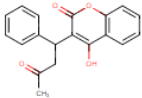
Warfarin

Targets (2)

Enzymes (6)

Carriers (2)

IDENTIFICATION

Name	Warfarin	Accession Number	DB00682
Description	Warfarin is an anticoagulant drug normally used to prevent blood clot formation as well as migration. Although originally marketed as a pesticide (d-Con, Rodex, among others), Warfarin has since become the most frequently prescribed oral anticoagulant in North America. Warfarin has several properties that should be noted when used medicinally, including its ability to cross the placental barrier during pregnancy which can result in fetal bleeding, spontaneous abortion, preterm birth, stillbirth, and neonatal death. Additional adverse effects such as necrosis, purple toe syndrome, osteoporosis, valve and artery calcification, and drug interactions have also been documented with warfarin use. Warfarin does not actually affect blood viscosity, rather, it inhibits vitamin-k dependent synthesis of biologically active forms of various clotting factors in addition to several regulatory factors.		
Type	Small Molecule	Groups	Approved
Structure	 3D Download Similar Structures		
Synonyms	Coumafene  Warfarin Warfarina  Zoocoumarin Show All Synonyms		

PROPIEDADES FISICOQUÍMICAS DEL FÁRMACO



[Browse](#) [COVID-19](#) [Search](#) [Downloads](#) [Commercial Data](#) [Help](#) [About](#)

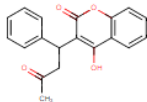
Drugs

Identification
Pharmacology
Indication
Associated Conditions
Contraindications & Blackbox Warnings
Pharmacodynamics
Mechanism of action
Absorption
Volume of distribution
Protein binding
Metabolism
Route of elimination
Half-life
Clearance
Adverse Effects
Toxicity
Affected organisms
Pathways
Pharmacogenomic Effects/ADRs
Interactions
Products
Categories
Chemical Identifiers

Warfarin

[Targets \(2\)](#) [Enzymes \(6\)](#) [Carriers \(2\)](#)

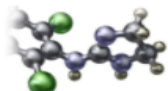
IDENTIFICATION

Name	Warfarin	Accession Number	DB00682
Description	Warfarin is an anticoagulant drug normally used to prevent blood clot formation as well as migration. Although originally marketed as a pesticide (d-Con, Rodex, among others), Warfarin has since become the most frequently prescribed oral anticoagulant in North America. Warfarin has several properties that should be noted when used medicinally, including its ability to cross the placental barrier during pregnancy which can result in fetal bleeding, spontaneous abortion, preterm birth, stillbirth, and neonatal death. Additional adverse effects such as necrosis, purple toe syndrome, osteoporosis, valve and artery calcification, and drug interactions have also been documented with warfarin use. Warfarin does not actually affect blood viscosity, rather, it inhibits vitamin-k dependent synthesis of biologically active forms of various clotting factors in addition to several regulatory factors.		
Type	Small Molecule	Groups	Approved
Structure	 3D Download Similar Structures		
Synonyms Show All Synonyms	Coumafene Warfarin Warfarina Zoocoumarin		

PROPIEDADES FISICOQUÍMICAS DEL FÁRMACO

 U.S. National Library of Medicine

[NLM Home](#) > [ChemIDplus Advanced](#)

 **ChemIDplus**
Lite • Browse • Advanced

[Search](#) [Clear](#) [History](#) [Help](#) [API Help](#)

Substance Identification

(automatic) (automatic)

Data is available for 425,797 records.

Toxicity

Test: (any) between (mg/kg or ppm)

Species: (any)

Route: (any)

Effect: (any)

Toxicity data is available for 112,444 records.

Physical Properties

Melting Point between

Either Measurement Type

Physical property data is available for 17,473 records and was provided by [SRC, Inc.](#)

Locator Codes

(any) AND (any)

Structure

[Draw](#)

Powered by [ChemAxon's Marvin](#)

Use: Marvin JS

[Import MOL](#)

Structure Search Options

☐ Substructure Search

☒ Similarity Search 80 %

☐ Exact (parent only)

☐ Flex (parent, salts, mixture)

☐ Flexplus (parent, all variations)

3D courtesy of [MN-AM's CORINA Classic](#).

Structure data is available for 345,248 records.

Molecular Weight

between

Molecular weight data is available for 345,248 records.

<http://www.chem.nlm.nih.gov>

PROPIEDADES FISICOQUIMICAS DEL FÁRMACO

Search and share chemistry

For medical information relating to Covid-19, please consult the [World Health Organisation](#) or local healthcare provision.

[Simple](#) [Structure](#) [Advanced](#) [History](#)

Search ChemSpider

Matches any text strings used to describe a molecule.

Systematic Name, Synonym, Trade Name, Registry Number, SMILES, InChI or CSID

What is ChemSpider?	Search by chemical names	Search by chemical structure	Find important data
ChemSpider is a free chemical structure database providing fast text and structure search access to over 100 million structures from hundreds of data sources.	• Systematic names • Synonyms • Trade names • Database identifiers	• Create structure-based queries • Draw structures in the web page • Use structure files from your computer	• Literature references • Physical properties • Interactive spectra • Chemical suppliers

Blog

[Subscribe](#)

[Royal Society of Chemistry Renews Partnership with ACD/Labs to Continue Providing Industry-Leading Data to Worldwide Research Community](#)

[Behind the Scenes at ChemSpider](#)

[Introduction to the new ChemSpider website](#)

VISIT OUR BLOG

103 Million
chemical structures

278

<http://www.chemspider.com/>

PROPIEDADES FISICOQUÍMICAS DEL FÁRMACO

 National Library of Medicine
National Center for Biotechnology Information

PubChem About Blog Submit Contact

Explore Chemistry

Quickly find chemical information from authoritative sources

Try covid-19 aspirin EGFR C9H8O4 57-27-2 C1=CC=C(C(=C1)C=O InChI=1S/C3H6O/c1-3[2]4/h1-2H3

☐ Use Entrez ☒ Compounds ☐ Substances ☐ BioAssays

 Draw Structure  Upload ID List  Browse Data  Periodic Table

110M Compounds 270M Substances 286M Bioactivities 32M Literature 25M Patents 771 Data Sources

<https://pubchem.ncbi.nlm.nih.gov/>

PROPIEDADES FARMACOLÓGICAS. FARMACOCINÉTICAS Y FARMACODINÁMICAS



FUENTES DE INFORMACIÓN

- AMDE
- MECANISMO DE ACCIÓN
- INDICACIONES
- DOSIS
- EFECTOS ADVERSOS
- TOXICIDAD
- PRECAUCIONES
- CONTRAINDICACIONES

1. European medicine Agency <http://www.ema.europa.eu/ema/>
2. Agencia Española de Medicamentos y Productos Sanitarios <https://www.aemps.gob.es/cima/inicial.do>
3. Health Products Regulatory Authority <http://www.hpra.ie/>
4. New Zealand Medicines and Medical Devices Safety Authority <http://medsafe.nz/Medicines/infoSearch.asp>
5. U.S. Food & Drug Administration <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>
6. Health Canada <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>
7. Regulating Medicines and Medical Devices Reino Unido <http://www.mhra.gov.uk/spc-pil/>
8. Agence nationale de sécurité du médicament et des produits de sante <http://ansm.sante.fr/Produits-de-sante/Medicaments>
9. Agencia Italiana del Farmaco <https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/home>
10. Therapeutics Goods Administration Australian Government <https://www.tga.gov.au/>
11. Agencia de Productos Farmacéuticos y Dispositivos Médicos de Japón. <http://www.pmda.go.jp/english/index.html>

¿Cómo Entregar los Documentos?

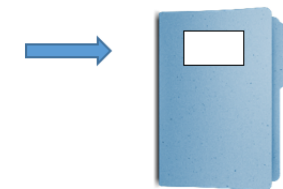


EXPEDIENTE



- La documentación debe ser presentada en carpeta con gancho en la parte superior. Dicho dossier debe estar identificado, mediante un rótulo en la parte superior frontal de la carpeta, con la siguiente información: nombre de la institución de salud pública, principio activo y fecha; en **letra Arial No. 14**.

Principio Activo:
Nombre de la Institución:
Fecha:



EXPEDIENTE



- Páginas numeradas

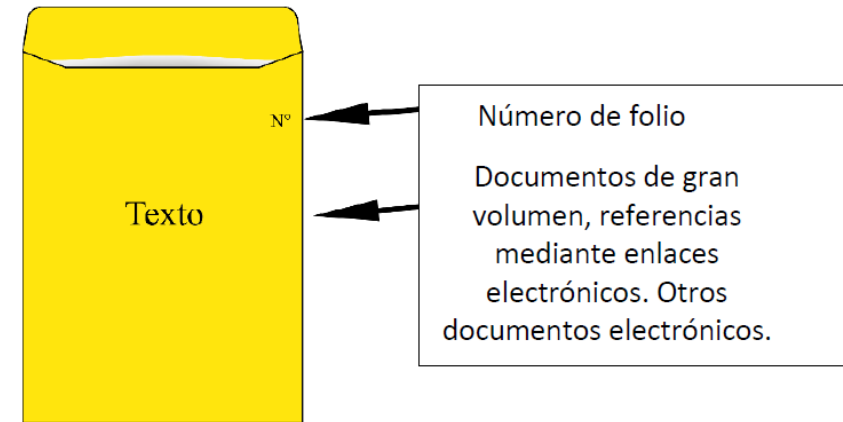


- Las hojas en blanco y separadores no deben ser numeradas
- Si existe errores en la foliación, está se anulará con una línea oblicua (/),

EXPEDIENTE



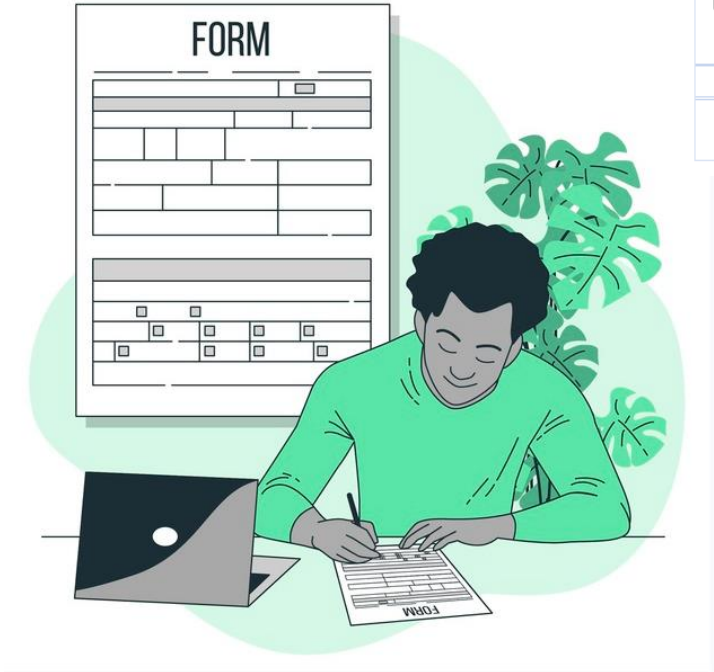
- La documentación presentada en dispositivos digitales (CD, USB, otros), deberán ser colocadas en sobre sobres



¿Qué Documentos Entregar?



FORMULARIO PARA LA SOLICITUD DE INCLUSIÓN DE PRINCIPIOS ACTIVOS EN LAS LISTAS DE MEDICAMENTOS QUE REQUIEREN DEMOSTRAR INTERCAMBIABILIDAD



 REPÚBLICA DE PANAMÁ GOBIERNO NACIONAL	MINISTERIO DE SALUD	DIRECCIÓN NACIONAL DE FARMACIA Y DROGAS DEPARTAMENTO DE REGISTROS SANITARIOS DE MEDICAMENTOS Y OTROS PRODUCTOS PARA LA SALUD HUMANA	
Código: GU-02-IA-RS	Versión: 01	Fecha de emisión: 12. marzo.2021	Página 3 de 5
GUÍA PARA LA SOLICITUD DE INCLUSIÓN DE PRINCIPIOS ACTIVOS QUE REQUIEREN PRESENTAR EVIDENCIAS DE EQUIVALENCIA TERAPÉUTICA			

DOCUMENTACIONES

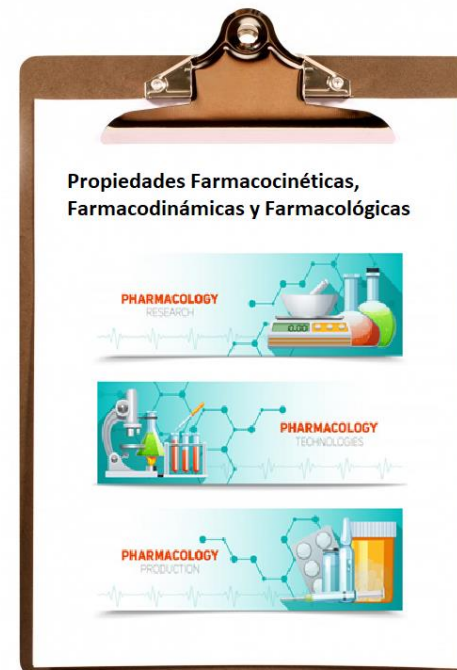
ÍNDICE TERAPÉUTICO



PROPIEDADES FISICOQUÍMICAS



PROPIEDADES FARMACOCINÉTICAS, FARMACODINÁMICAS Y FARMACOLÓGICAS



JUSTIFICACIÓN DE LA SOLICITUD DE INCLUSIÓN DEL PRINCIPIO ACTIVO



- NOTA FORMAL
- POR:
 - Comité de Farmacoterapia o
 - Centro Nacional de Farmacoterapia o
 - Dirección médica
- FARMACOVIGILANCIA

INCLUSIÓN EN LAS LISTAS OFICIALES DE MEDICAMENTOS



- NOTA FORMAL
- POR:
 - Comité de Farmacoterapia o
 - Centro Nacional de Farmacoterapia o
 - Dirección Médica
- VERSIÓN Y PÁGINA
- COPIA SIMPLE
- VÍNCULO ELECTRÓNICO



¿Cuándo Entregar?

- Segundo Cuatrimestre de cada año



¿QUÉ PRINCIPIOS ACTIVOS NO APLICAN?

MEDICAMENTOS
HUÉRFANOS O PARA
ENFERMEDADES
RARAS



- Medicamentos de Venta Libre



- Medicamentos Biológicos o Biotecnológicos



GRACIAS





REPÚBLICA DE PANAMÁ

— GOBIERNO NACIONAL —

**MINISTERIO
DE SALUD**

DIRECCIÓN NACIONAL DE FARMACIA Y DROGAS