

What are UNIs and How Do You Get Them?

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SBIA DMF Workshop: GDUFA III Enhancements and Structured Data Submissions

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Global Substance Registration System - GSRS

GSRS has been developed to assist regulators in managing substance information. It was designed to facilitate global monitoring of food, tobacco, and cosmetic products. GSRS provides unique substance identifiers consistent with the ISO 11238 standard. These are Unique Ingredient Identifiers (UNII) used in electronic listing and other regulatory activities.

Search Substances

[Browse Substances](#)

[Browse Applications](#)

[Structure Search](#)

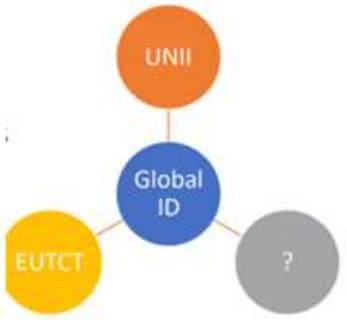
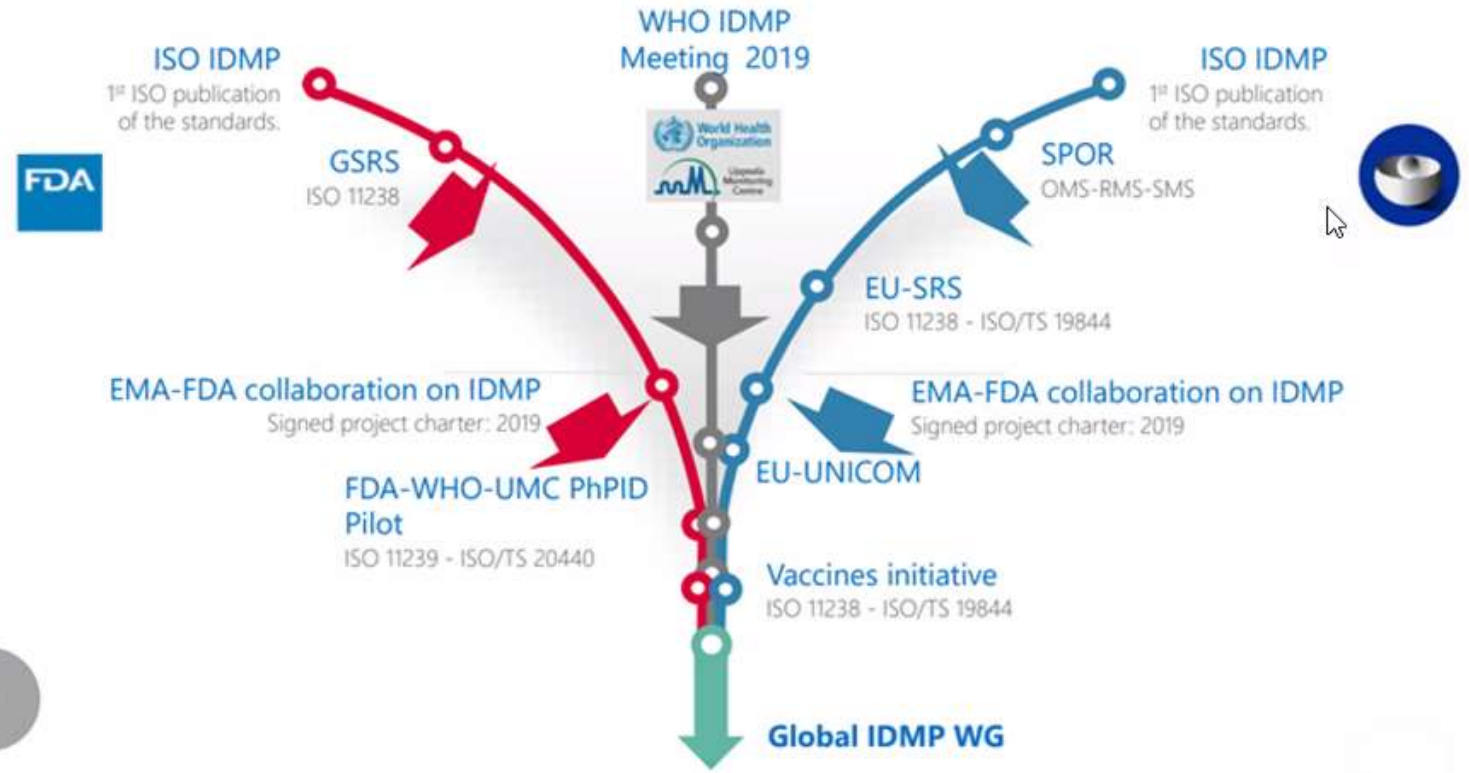


Why GSRs?

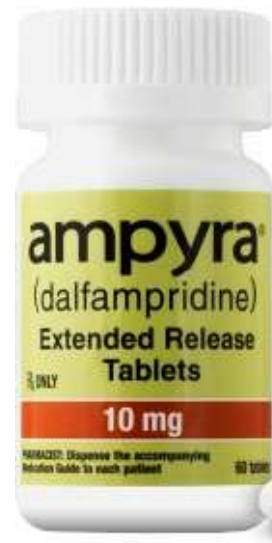
- Manage Regulatory Substance Information
- Facilitate Global Monitoring (ISO 11238)
- Provide Unique Identifiers (UNII)
- Support Regulatory Activities (e.g., DailyMed)

Global Collaboration for convergence rather than divergence

Convergence in Cross Region Collaboration



Substance *names* are good for tracking, but there are a lot of names which change based on **development phase** and **jurisdiction**, so we need standardization.



Company Code (IND)

EL-970

Chemical Name

4-Aminopyridine

Generic Name (USAN)

DALFAMPRIDINE

Generic Name (INN)

FAMPRIDINE

Brand Name (US)

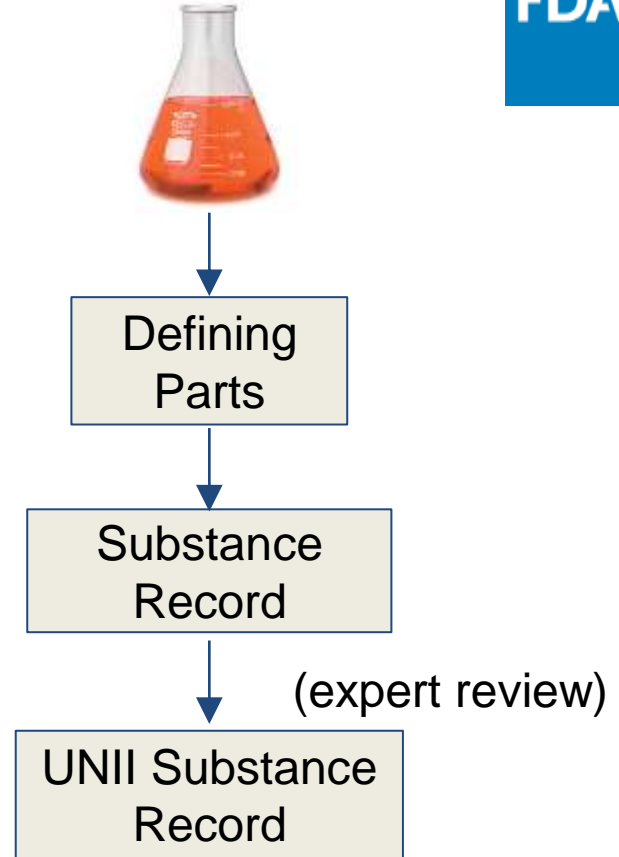
AMPYRA

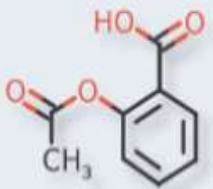

Brand Name (US)

FAMPYRA

UNII Process

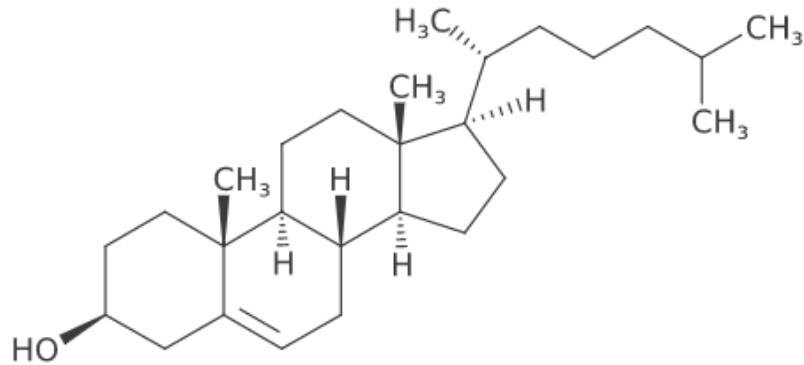
- Choose a substance type
- Define substance, following rules
- Convince an expert this definition is valid, unique, and descriptive of your substance
- Get a unique substance/ingredient identifier (UNII) which is later published



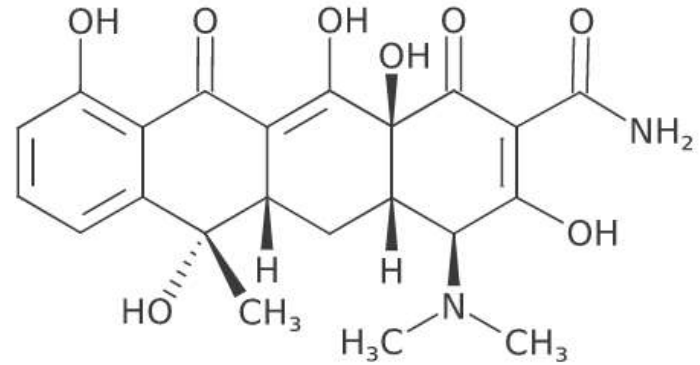
Substance Type	Chemical	Polymer	Protein	Nucleic Acid	Structurally Diverse
Defined by	Chemical Structure	Structural Repeats	Amino Acid Sequence	Nucleotide Sequence	Taxonomic Information
Example			<pre>>A35X00TA2K RCPGCGQGVQAGCPGG CVEEEDGGSPAEGCAE AEGCLRREGQECGVYT PNCAPGLQCHPP...</pre>	<pre>>303159CVH9 TAAACGTTATAACGTT ATGACGTCAT</pre>	<ul style="list-style-type: none"> Organism Family Asteraceae Organism Genus Echinacea Organism Species purpurea Organism Author (L.) Moench Part WHOLE

Fully Define Stereochemistry

Cholesterol



Tetracycline





UNII on Wikipedia

https://en.wikipedia.org/wiki/Unique_Ingredient_Identifier

- Ten character alphanumeric identifier
- Any substance from an atom to an organism
- Non-proprietary, unique, unambiguous and free

UNII Search



- Fuzzy Query Search (equals, starts with, contains)
- Direct URL Search

<https://precision.fda.gov/uniisearch/srs/unii/R16CO5Y76E>

- Data Downloads

<https://precision.fda.gov/uniisearch/archive>



Requesting a UNII

- FDA-SRS@fda.hhs.gov
- Data that leads to a chemical structure
- Safety Data Sheets (Ingredient Brand Name)
- Submit information securely through PrecisionFDA

UNII Data



<https://precision.fda.gov/uniisearch/srs/unii/BH3B64OKL9>

DALFAMPRIDINE

UNII: BH3B64OKL9

Formula: C₅H₆N₂

Preferred Substance Name:

DALFAMPRIDINE

InChIKey: NUKYPUAHOHBNCPY-

UHFFFAOYSA-N

[Common Chemistry](#)

[Inxight Drugs](#)

[DailyMed Regulated Products](#)

[NCATS GSRS Full Record](#)

[NCI Thesaurus](#)

[PubChem](#)

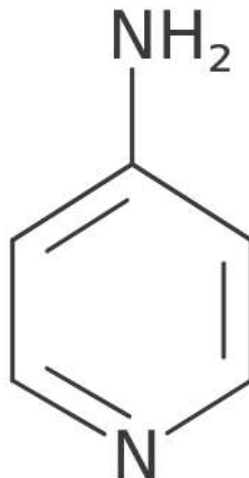
Chemical Structure

Stereochemistry	ACHIRAL
Molecular Formula	C ₅ H ₆ N ₂
Molecular Weight	94.11
Optical Activity	NONE
Defined Stereocenters	0 / 0
E/Z Centers	0
Charge	0
Additional stereochemistry	No

Show References ▾

Hide SMILES / InChi ▲

Show Systematic Names ▾



Show Stereo

SMILES:

NC1=CC=NC=C1

InChiKey:

NUKYPJUAOHBNCPPY-UHFFFAOYSA-N

InChi:

InChI=1S/C5H6N2/c6-5-1-3-7-4-2-5/h1-4H,(H2,6,7)

Public GSRS



<https://gsrs.ncats.nih.gov/ginas/app/beta/home>

UNIs in DailyMed

FDA

NIH NATIONAL LIBRARY OF MEDICINE



ALL DRUGS

HUMAN DRUGS

Enter drug, NDC code, drug class

HOME

+ NEWS

FDA RESOURCES

+ NLM SPL RESOURCES

SEARCH RESULTS FOR: **BH3B64OKL9** (10 results)

Sort By Relevance

< previous | page 1



DALFAMPRIDINE TABLET, FILM COATED, EXTENDED RELEASE

NDC Code(s): 51407-246-60

Packager: GOLDEN STATE MEDICAL SUPPLY, INC.

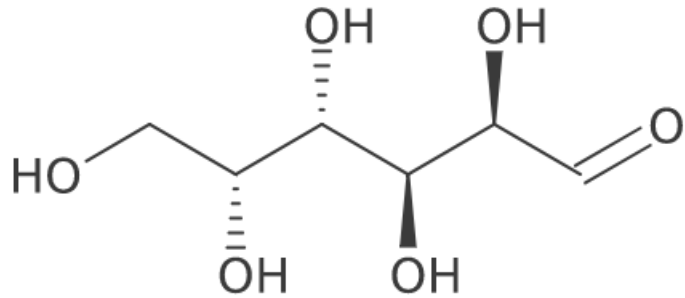
This is a repackaged label.

Source NDC Code(s): 16729-292

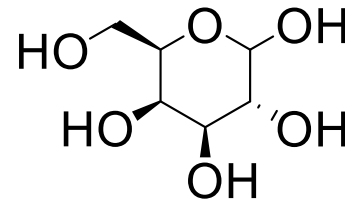
<https://dailymed.nlm.nih.gov/dailymed/search.cfm?adv=1&query=BH3B64OKL9>

Use Forms That Allow Full Definition

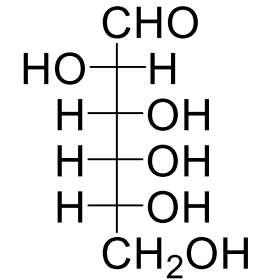
D-Galactose



**Preferred
drawing**

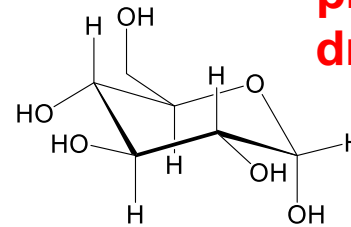


Haworth



Fischer

**NOT
preferred
drawings**



Chair

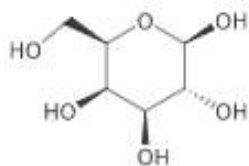
Alternative Definitions

ALTERNATIVE DEFINITION for [GALACTOSE]

Mixture Components

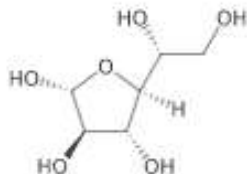
All of the following components *must* be present:

RQ6K52J67A



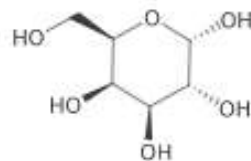
[β-D-Galactopyranose](#)

TC2Q4G87B7



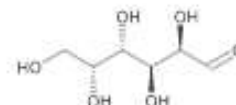
[β-D-Galactofuranose](#)

7I0F6H4H77



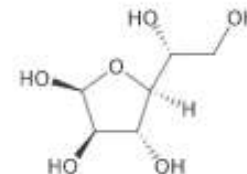
[α-D-Galactopyranose](#)

X2RN3Q8DNE



[GALACTOSE](#)

8DK6V668TJ



[α-D-Galactofuranose](#)

FDA Internal GSRS



Products, Applications, Clinical Trials, Adverse Events, Impurities Specs ^

< Product (534) Application (53) Clinical Trial (3) Clinical Trial Europe (12) Adverse Event PT (4) >

HEALTH CANADA SPL

SPL [↓ Export All Products](#)

< pe (12) Adverse Event PT (481) Adverse Event DME (13) Adverse Event CVM (0) Impurities Specs (0) >

HEALTH CANADA SPL

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Thank you!



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Mitchell Miller
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USAN Council
Herman Dieterik
WHO INN
WHO UMC
EMA
EDQM
Health Canada

Questions



