

# What are UNIs and How Do You Get Them?

**Frank L Switzer, PhD**

Chemist

US FDA

Office of the Commissioner/ODT/ODAR/Health Informatics Staff

SBIA DMF Workshop: GDUFA III Enhancements and Structured Data Submissions

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# Disclaimer



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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. For example, Unique Ingredient Identifiers (UNIs) used in electronic listing and other regulatory activities.

Search Substances

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[Browse Substances](#)

[Browse Applications](#)

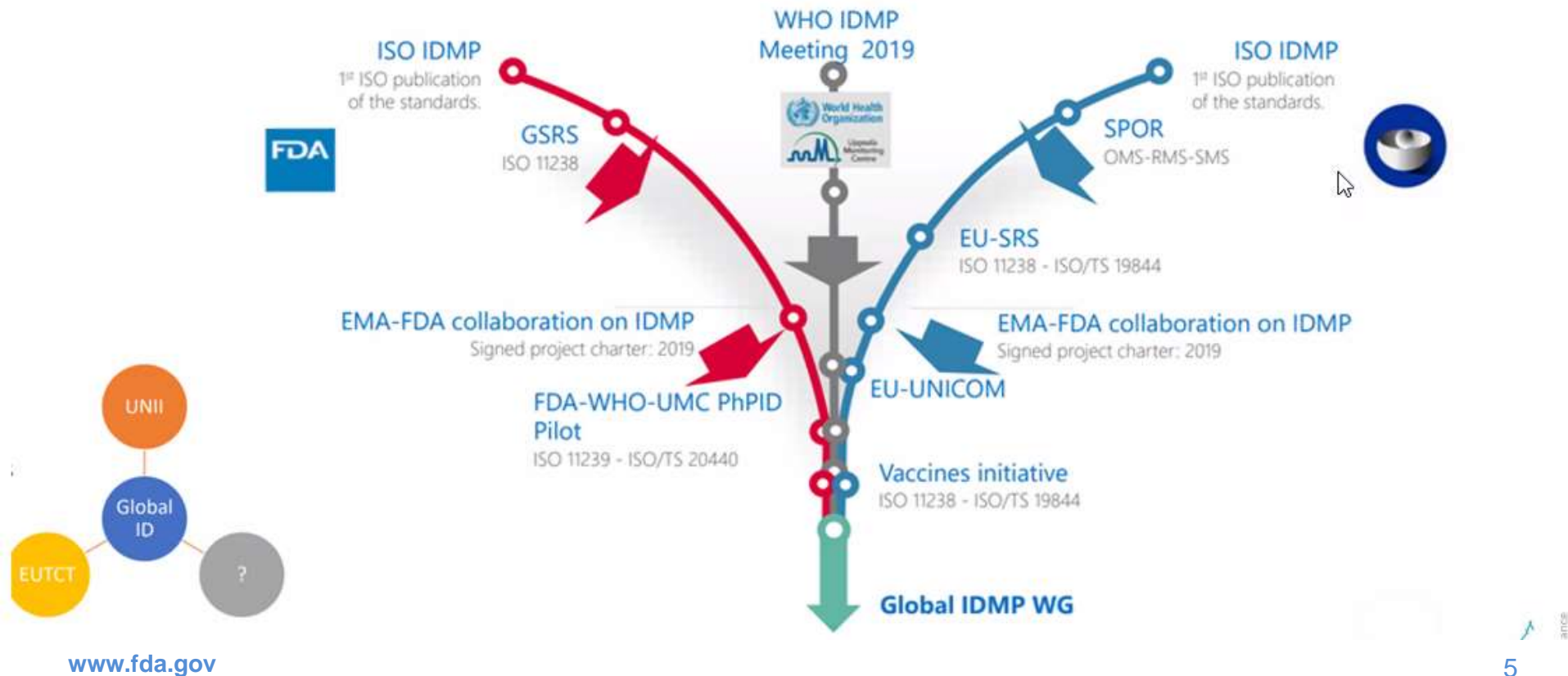
[Structure Search](#)

## Why GSRS?

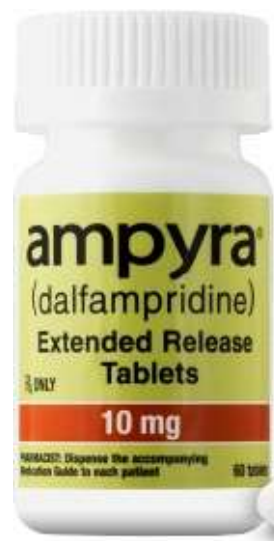
- Manage Regulatory Substance Information
- Facilitate Global Monitoring (ISO 11238)
- Provide Unique Identifiers (UNII)
- Support Regulatory Activities (e.g., DailyMed)

# 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**

Generic Name (USAN)

**DALFAMPRIDINE**

Brand Name (US)

**AMPYRA**

Chemical Name

**4-Aminopyridine**

Generic Name (INN)

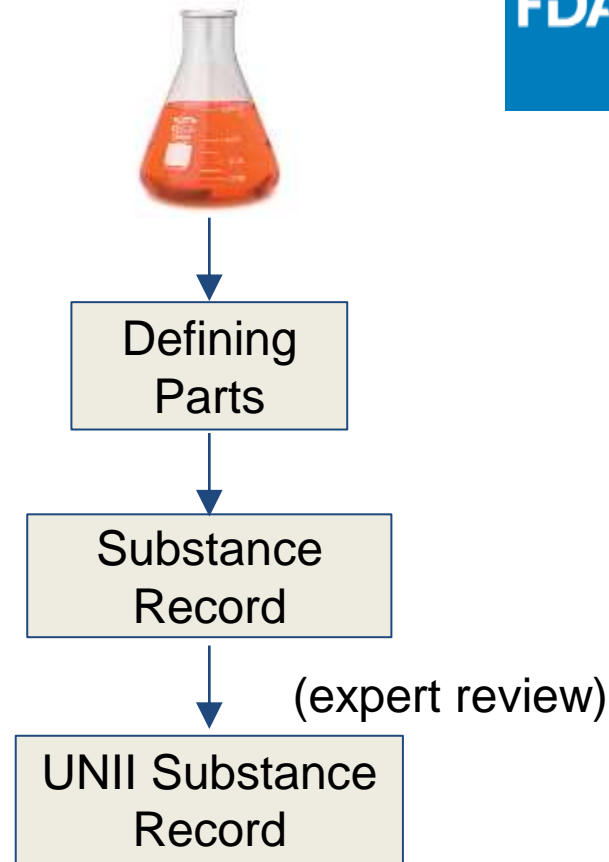
**FAMPRIDINE**

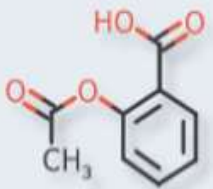

Brand Name (US)

**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

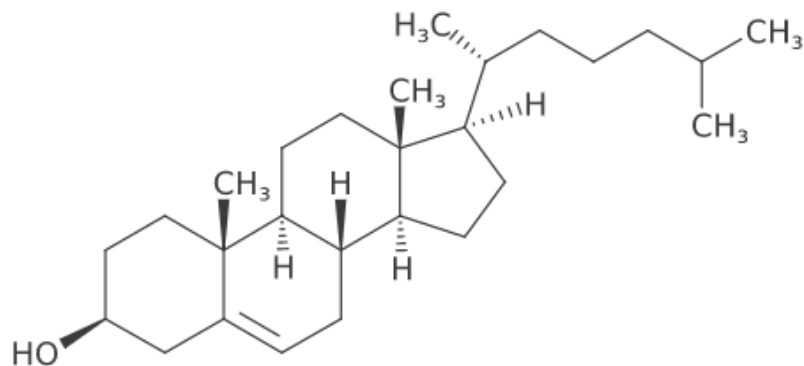


Substance Type	Chemical	Polymer	Protein	Nucleic Acid	Structurally Diverse
Defined by	Chemical Structure	Structural Repeats	Amino Acid Sequence	Nucleotide Sequence	Taxonomic Information
Example			<pre>&gt;A35X00TA2K RCPGCGQGVQAGCPGG CVEEDGGSPAEGCAE AEGCLRREGQECGVYT PNCAPGLQCHPP...</pre>	<pre>&gt;303159CVH9 TAAACGTTATAACGTT ATGACGTCAT</pre>	<div> Organism Family <a href="#">Asteraceae</a>  Organism Genus <a href="#">Echinacea</a>  Organism Species <a href="#">purpurea</a>  Organism Author <a href="#">(L.) Moench</a>  Part <a href="#">WHOLE</a> </div>

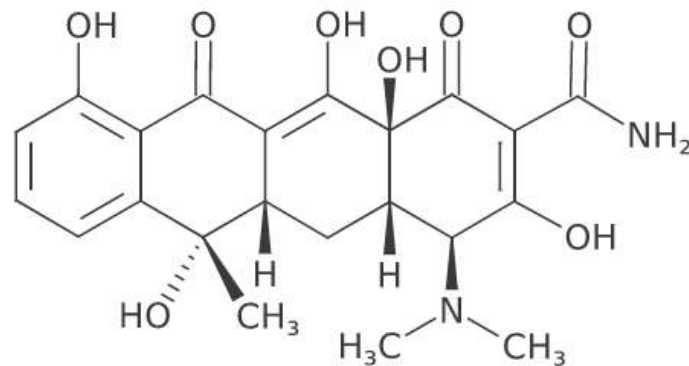


# Fully Define Stereochemistry

## Cholesterol



## Tetracycline



# UNII on Wikipedia

[https://en.wikipedia.org/wiki/Unique\\_Ingredient\\_Identifier](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](mailto: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:** C<sub>5</sub>H<sub>6</sub>N<sub>2</sub>

**Preferred Substance Name:**

DALFAMPRIDINE

**InChIKey:** NUKYPUAOHBNCYP-

UHFFFAOYSA-N

[Common Chemistry](#)

[Inxight Drugs](#)

[DailyMed Regulated Products](#)

[NCATS GSRS Full Record](#)

[NCI Thesaurus](#)

[PubChem](#)

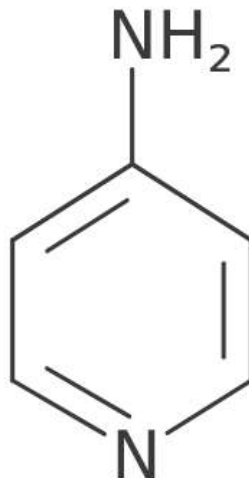
## Chemical Structure

Stereochemistry	ACHIRAL
Molecular Formula	C <sub>5</sub> H <sub>6</sub> N <sub>2</sub>
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:

NUKYPUAOHBNCYP-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

**DAILYMED**



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

  **DRUG IMAGE NOT AVAILABLE**

**DALFAMPRIDINE TABLET, FILM COATED, EXTENDED RELEASE**

**NDC Code(s):** 51407-246-60

**Packager:** GOLDEN STATE MEDICAL SUPPLY, INC.

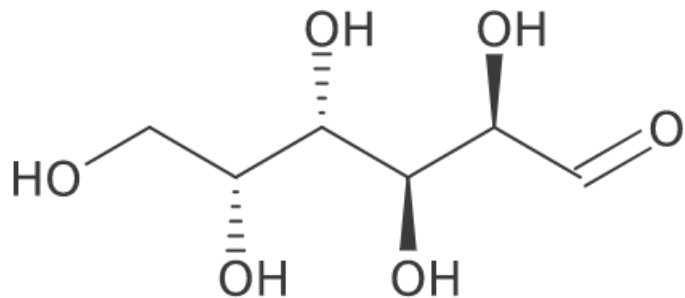
**This is a repackaged label.**

**Source NDC Code(s):** 16729-292

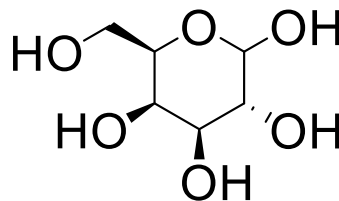
<https://dailymed.nlm.nih.gov/dailymed/search.cfm?adv=1&query=BH3B64OKL9>

# Use Forms That Allow Full Definition

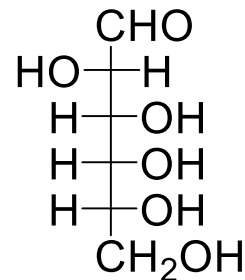
## D-Galactose



**Preferred  
drawing**

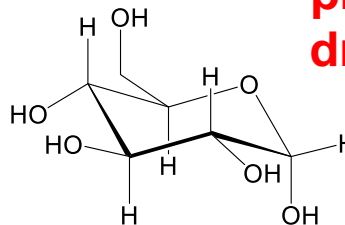


Haworth



Fischer

**NOT  
preferred  
drawings**



Chair



# Alternative Definitions

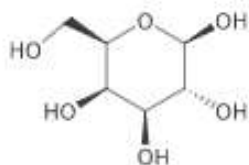
ALTERNATIVE DEFINITION for [GALACTOSE]



## Mixture Components

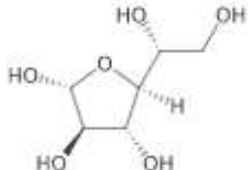
All of the following components *must* be present:

RQ6K52J67A



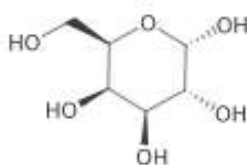
[β-D-Galactopyranose](#)

TC2Q4G87B7



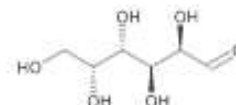
[β-D-Galactofuranose](#)

7I0F6H4H77



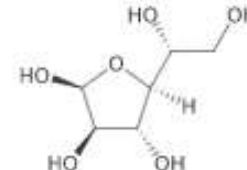
[α-D-Galactopyranose](#)

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		<a href="#">Export All Products</a>				

<	pe (12)	Adverse Event PT (481)	Adverse Event DME (13)	Adverse Event CVM (0)	Impurities Specs (0)	>
HEALTH CANADA		SPL				
SPL		<a href="#">Export All Products</a>				

# Thank you!



## **GSRS Scientists**

Frank Switzer

Larry Callahan

Marlene Kim

Tyler Peryea

Dammika Amugoda

Marian Nkeng

Siba Bhattacharyya

## **GSRS Developers**

Tyler Peryea

Archana Newatia

Ramez Ghazzaoui

Lihui Hu

Niko Anderson

Mitchell Miller

Alex Welch

Egor Puzanov

## **GSRS Collaborators**

US Pharmacopeia

USAN Council

Herman Dieterik

WHO INN

WHO UMC

EMA

EDQM

Health Canada

# Questions



