

# USP Updates

## Preview of the upcoming USP- NF/PF integrated platform

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Senior Director, Digital Platforms & Delivery



# Today's Agenda



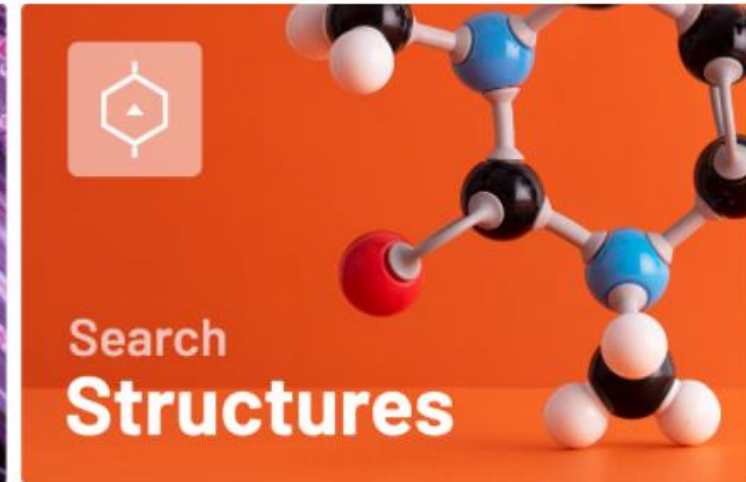
- ▶ Recent Updates
  - Updated USAN Launch
  - DOIs in the USP-NF Online
  - Updates to USP-NF Online contact information
- ▶ Preview of USP-NF/PF Integration

# A Trusted Resource for the Pharmaceutical Community



## The USP Dictionary helps to:

- ✓ Ensure compliance in labeling to obtain new drug approval
- ✓ Reference generic drug names for use in advertising and labeling
- ✓ Preserve trademarks to drug brand names by using proper generic names
- ✓ Filing accurate INDs, NDAs, and ANDAs
- ✓ Avoid verbal and written medication errors in reports, correspondence, articles, and package inserts
- ✓ Group drug products into families
- ✓ Verify names, chemical structures, and compositions



# USP Dictionary Redesign and Launch Goals

- ❑ Bolster USP strategic role in nomenclature science and solutions to include:
  - ❑ USP Dictionary Online
  - ❑ USAN / INN institutional data / services
  - ❑ Nomenclature services (e.g., POCA) and other cheminformatics offerings
- ❑ Meet customer needs with modernized cheminformatics platform
  - ❑ Current platform is > 15 years old and is not on par with other competitive offerings

The screenshot shows the USP Dictionary Online interface for the entry 'LEUCOVORIN'. The header is orange with the USP logo and navigation links: 'Browse Substances', 'Structure Search', 'Sequence Search', 'Guided Search', 'Help', and 'About'. The main content area is white and features the title 'LEUCOVORIN' in blue, followed by a red 'EPIMERIC' tag. A chemical structure of Leucovorin is displayed. To the right, there are sections for 'Names' (listing LEUCOVORIN with a checkmark, 5-FORMYLTETRAHYDROFOLATE, 5-FORMYLTETRAHYDROFOLIC ACID, and FOLINIC ACID), 'Codes' (listing CAS: 58-05-9, EVMPD: SUB13910MIG, ChEMBL: CHEMBL1679, DRUG BANK: DB00650, and DRUG CENTRAL: 1232), 'Relationships: 2', 'Mol. Weight: 473.4401', and 'Formula: C<sub>20</sub>H<sub>23</sub>N<sub>7</sub>O<sub>7</sub>'. At the bottom, there is a 'Substance Hierarchy' section with a blue button labeled '> LEUCOVORIN'.

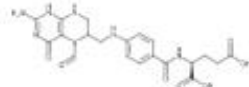
USP Dictionary Online

USP

Browse Substances Structure Search Sequence Search Guided Search Help About

## LEUCOVORIN

EPIMERIC



Names: LEUCOVORIN ✓  
5-FORMYLTETRAHYDROFOLATE  
5-FORMYLTETRAHYDROFOLIC ACID  
FOLINIC ACID

Codes: CAS: [58-05-9](#)  
EVMPD: SUB13910MIG  
ChEMBL: [CHEMBL1679](#)  
DRUG BANK: [DB00650](#)  
DRUG CENTRAL: [1232](#)

Relationships: 2

Mol. Weight: 473.4401

Formula: C<sub>20</sub>H<sub>23</sub>N<sub>7</sub>O<sub>7</sub>

Substance Hierarchy

> [LEUCOVORIN](#)

# Change Summary and FAQs



Feature	Current Platform	New Platform
# of compounds	~ 13,000	~40,000
Search by Name	✓	✓
Search Facets <ul style="list-style-type: none"><li>• USAN / INN Stems</li><li>• USAN Adoption Dates</li><li>• Mol Weights</li><li>• Stereochemistry</li><li>• Substance class (proteins, polymers, mixtures, etc.)</li></ul>		✓
Search by UNII / CAS-RN	✓	
Search by Pubchem, ATC Class, CHEBI, RxNorm, USAN ID, INN, RS Catalog #		✓
Search by Structure or Structure Similarity	✓	✓
Search by SMILES / InCHI Key		✓
Dynamic Addition of Content (e.g. Excipients, USP Drug Classes, links to monographs)		✓
Volume Pricing		✓
Access Point account integration		✓



Latest *USP-NF* Online Features



# Digital Object Identifiers (DOIs)



## What are Digital Object Identifiers (DOIs)?

A Digital Object Identifier (DOI) is a unique alphanumeric string assigned by a registration agency to identify content and provide a persistent link to its location on the Internet.

### ▶ How is USP implementing DOI in USP-NF Documentary Standard content?

Beginning with USP-NF 2022 Issue 1, USP will assign a DOI to all new and revised content in the USP-NF when it is made available electronically.

### ▶ Is the DOI system a Standard?

Yes. The DOI system was created by the International DOI Foundation and was adopted as International Standard ISO 26324 in 2012.

## What are the benefits of using DOI?

- ▶ DOIs provide a robust mechanism for sharing and citation of scientific content, including the USP-NF. Additionally, DOI implementation in the USP-NF means that current Documentary Standard content will, for the first time, be indexed by public search engines and data providers, making it easier to find on the Internet.

# Example of DOI



ACS ACS Publications C&EN CAS Find my institution Log In

ACS Publications Most Trusted. Most Cited. Most Read.

Search text, DOI, authors, etc.

My Activity Publications

ADVERTISEMENT

RETURN TO ARTICLES ASAP < PREV COMMUNICATION NEXT >

## Late-Stage $\beta$ -C(sp<sup>3</sup>)-H Deuteration of Carboxylic Acids

Alexander Uttry, Sourjya Mal, and Manuel van Gemmeren\*

Cite this: *J. Am. Chem. Soc.* 2021, XXXX, XXX, XXX-XXX  
Publication Date: July 19, 2021  
<https://doi.org/10.1021/jacs.1c06474>  
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Article Views | Altmetric | Citations

- | 2 | -

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RIGHTS & PERMISSIONS



# DOI: Standard Form and Abbreviated Form



## How DOI is displayed within a document:

Current DocID: GUID-33AD0880-7404-4169-BDD5-F74D808EE77F\_4\_en-US

DOI: [https://doi.org/10.31003/USPNF\\_M150\\_04\\_01](https://doi.org/10.31003/USPNF_M150_04_01) ⓘ

DOI ref: [dsv5r](#) ⓘ

## How DOI is displayed within a PDF:

Printed on: Wed Oct 27 2021, 05:16:05 AM(EST)

Printed by: Rebecca Cambroner

Official Status: Currently Official on 27-Oct-2021

Official Date: Official as of 01-May-2020

DOI Ref: dsv5r

DocId: 1\_GUID-33AD0880-7404-4169-BDD5-F74D808EE77F\_4\_en-US

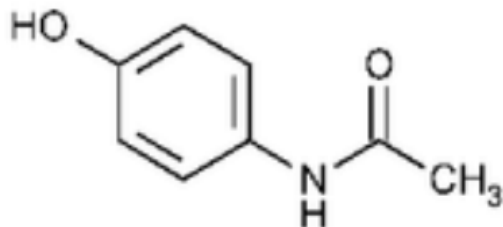
Document Type: USP

DOI: [https://doi.org/10.31003/USPNF\\_M150\\_04\\_01](https://doi.org/10.31003/USPNF_M150_04_01)

@2021 USPC

1

### Acetaminophen



$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

- $r_u$  = peak response from the *Sample solution*
- $r_s$  = peak response from the *Standard solution*
- $C_s$  = concentration of USP Acetaminophen RS in the *Standard solution* (mg/mL)
- $C_u$  = concentration of Acetaminophen in the *Sample solution* (mg/mL)

10/27/21, 6:16 AM

USP-NF Acetaminophen

Printed on: Wed Oct 27 2021, 06:16:05 am

Printed by: Rebecca Cambroner

Official Status: Currently Official on 27-Oct-2021

Official Date: Official as of 1-May-2020

Document Type: USP

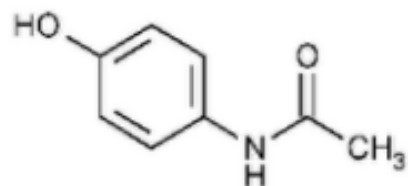
DocId: 1\_GUID-33AD0880-7404-4169-BDD5-F74D808EE77F\_4\_en-US

DOI: [https://doi.org/10.31003/USPNF\\_M150\\_04\\_01](https://doi.org/10.31003/USPNF_M150_04_01)

DOI Ref: dsv5r

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## Acetaminophen



$C_8H_9NO_2$

151.16

Acetamide, *N*-(4-hydroxyphenyl)-;

4'-Hydroxyacetanilide [103-90-2]; UNII: 36209ITL9D.

# DOI Landing Page – Google Searchable!



This is a preview of  
**USP-NF** content.

Subscriber?  
Full access here!

Not a subscriber?  
Learn more!

## Aspirin, Caffeine, and Dihydrocodeine Bitartrate Capsules

» Aspirin, Caffeine, and Dihydrocodeine Bitartrate Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of aspirin ( $C_9H_8O_4$ ), caffeine ( $C_8H_{10}N_4O_2$ ), and dihydrocodeine bitartrate ( $C_{18}H_{23}NO_3 \cdot C_4H_6O_6$ ).

### USP Reference Standards for Purchase

[USP Dihydrocodeine Bitartrate RS](#)  
[USP Aspirin RS](#)  
[USP Caffeine RS](#)  
[USP Salicylic Acid RS](#)

United States Pharmacopeia (2022). *USP Monographs, Aspirin, Caffeine, and Dihydrocodeine Bitartrate Capsules*. USP-NF, Rockville, MD: United States Pharmacopeia.

DOI: [https://doi.org/10.31003/USPNF\\_M6312\\_03\\_01](https://doi.org/10.31003/USPNF_M6312_03_01)  
Doc ID: GUID-9B6F9EFB-F1E6-4149-AE59-991F2E7CCAFO\_3\_en-US

[Privacy policy](#)

© The United States Pharmacopeial Convention

# USP-NF Contact Information Updates



## Currently . . .

### Contact Information Updates

Stakeholders contact SM liaisons listed at the bottom of monographs in USP and the questions are forwarded to Technical Services to be answered.

## Coming Soon!

Technical Services / Scientific Support ([stdsmonographs@usp.org](mailto:stdsmonographs@usp.org)) will be added to the bottom of the SM monographs.

# PF Contact Information Updates



## Currently . . .

### Contact Information Updates

Stakeholders contact SM liaisons listed at the bottom of proposals in PF instead of the using the Comment Form and the comments are forwarded to other Scientists to be addressed.

## Coming Soon!

Single address for PF Comments (PFComments@usp.org) will be added to the bottom of the SM PF proposals.

# Why Are We Making These Changes?



- ▶ For over 2 years USP has been moving toward a single point of contact for scientific support.
  - More efficient
  - Promotes consistency in our responses to stakeholders
  - Improved quality assurance tracking
  - SM Scientists still consulted if needed



*Sneak-peek into the Upcoming USP-NF Online + PF*



# How We Got Here...



- ▶ **Goal: To improve the user experience, particularly for “less experienced users,” and to update the UI to current industry standards.**
- ▶ Design done by *Atomic Object*, which has extensive UX expertise, and has worked on the USP-NF Online since 2017.
- ▶ Inputs included:
  - Almost 4 years of feedback from users, including emails with comments, suggestions, and complaints from users in many different roles at a wide range of companies inside and outside the US
  - Analysis of navigation and usage patterns from the Nabu platform
  - Multiple surveys, with responses from >2500 individuals
  - Focus groups and one-on-one “live usage” interviews from more than 30 users



# DISCLAIMER



- ▶ The following images are design mock-ups – **NOT the actual pages**
- ▶ The final look and feel may be slightly different
- ▶ Please disregard dates and document status – these are examples only, NOT actual USP-NF documents

# USP-NF Online Home Page- Current











The screenshot shows the USP-NF Online Home Page. At the top is a dark red navigation bar with the USP-NF logo, a search bar containing the text "Search for General Chapter, Monograph here!", and user information including "Hi," "Bookmarks", "EN", and a "Help" link. Below the navigation bar is a white header with a home icon and menu items: "START HERE", "GENERAL NOTICES", "GENERAL CHAPTERS", "MONOGRAPHS", "REAGENTS AND REFERENCE TABLES", and "RESOURCES". The main content area features a "USP-NF Online Dashboard" section with a heading and a help icon. Below this is a paragraph: "Get the most out of your USP-NF Online! Explore this area for helpful video tutorials and links to USP resources." The dashboard is titled "USP-NF ONLINE DASHBOARD" and contains eight promotional tiles arranged in two rows of four. Each tile includes an icon, a title, a brief description, and a call to action. The tiles are: 1. Supporting COVID-19 health response (yellow background, virus icon); 2. Improved Search Tutorial (dark red background, play icon); 3. Navigation Basics Tutorial (dark red background, play icon); 4. COVID-19 Vaccine Handling Toolkit (yellow background, virus icon); 5. USP-NF Mobile App (dark red background, app icon); 6. Please Read: Release Notes (dark red background, warning icon); 7. Spanish USP-NF Online (dark red background, computer icon); 8. Understanding Official Status Tutorial (dark red background, play icon). A circular arrow icon is located at the bottom right of the dashboard area.

## USP-NF Online Dashboard

Get the most out of your USP-NF Online! Explore this area for helpful video tutorials and links to USP resources.

### USP-NF ONLINE DASHBOARD

 <b>Supporting COVID-19 health response</b>	 <b>Improved Search Tutorial</b> Get relevant contextual results much faster.	 <b>Navigation Basics Tutorial</b> Browse smartly with information arranged relevantly.	 <b>COVID-19 Vaccine Handling Toolkit</b>
<b>STAY CONNECTED DURING COVID-19</b> Click here for latest updates to services	<b>IMPROVED SEARCH TUTORIAL</b> Watch a video tutorial on the improved search tool!	<b>NAVIGATION BASICS TUTORIAL</b> Learn how to navigate the new USP-NF Online	<b>COVID-19 VACCINE HANDLING TOOLKIT</b> Click here to download the toolkit
 <b>USP-NF Mobile App</b> Download this app to have access to the USP-NF Online on your device.	 <b>Please Read: Release Notes</b> Please read for known issues on this release.	 <b>Spanish USP-NF Online</b> The Spanish USP-NF Online will be launched in 2020! Click here for FAQs.	 <b>Understanding Official Status Tutorial</b> What you need to know about USP-NF versions and official status
<b>USP-NF MOBILE APP</b> USP-NF Mobile App is here! Click here for the latest info	<b>PLEASE READ: RELEASE NOTES</b> Please read for known issues on this release	<b>SPANISH USP-NF ONLINE</b> Click here for details	<b>OFFICIAL STATUS TUTORIAL</b> Understand official dates for monographs and general chapters

# Dashboard View: USP-NF + PF



USP-NF

## My Dashboard

**Currently Official** [USPNF 2021 Issue 3](#) [Published June 01, 2021](#)

**PF 47(6)** [Commenting closed](#)

**PF 48(1)** [Commenting open for 55 more days](#) [January 3, 2022 to March 31, 2022](#)

## My Resources

MY VIEWING ACTIVITY   BOOKMARKS   COMMENTS

DATE ▾	PAGE ▾	SECTION ▾	PUBLICATION ▾
04-Feb-2022	<a href="#">Test Solutions</a>	Reagents	Forum USP41-NF36
03-Feb-2022	<a href="#">Isopropyl Alcohol</a>	Monographs	Forum USPNF 2021 Issue 3
01-Feb-2022	<a href="#">〈17〉 Prescription Container Labeling</a>	General Chapters	Forum USPNF 2021 Issue 3

# Dashboard View: A Closer Look



Dashboard navigation bar containing a menu icon, USP-NF logo, a search bar with the placeholder text "Search for General Chapter, Monograph here!", and icons for home, bookmarks, and user profile.

## My Dashboard

- Currently Official** *USPNF 2021 Issue 3* *Published June 01, 2021*
- PF 47(6)** *Commenting closed*
- PF 48(1)** *Commenting open for 55 more days* *January 3, 2022 to March 31, 2022*

# Dashboard View: Bookmarks



MENU USP-NF  [Advanced Search](#) [Home](#) [Bookmarks](#) [User](#) EN

### My Dashboard

- Currently Official** [USPNF 2021 Issue 3](#) *Published June 01, 2021*
- PF 47(6)** *Commenting closed*
- PF 48(1)** *Commenting open for 55 more days* *January 3, 2022*

#### YOUR BOOKMARKS

- [Acetaminophen Tablets, Monograph](#)
- [Acetaminophen Capsules, Monograph](#)
- [\(227\) 4-Aminophenol in Acetaminophen-Containing Drugs, General Chapter](#)
- [USP Admissions List, Front Matter](#)

[View All Bookmarks](#)

### My Resources

MY VIEWING ACTIVITY **BOOKMARKS** COMMENTS

DATE ▾	PAGE ▾	SECTION ▾	PUBLICATION ▾
04-Feb-2022	<a href="#">Test Solutions</a>	Reagents	Forum USP41-NF36
03-Feb-2022	<a href="#">Isopropyl Alcohol</a>	Monographs	Forum USPNF 2021 Issue 3
01-Feb-2022	<a href="#">(17) Prescription Container Labeling</a>	General Chapters	Forum USPNF 2021 Issue 3

# Dashboard View: New Look for Navigation



✕
 USP-NF

🏠
📖
👤

- Dashboard
- Start Here ▶
- General Notices ▶
- General Chapters ▶
- Monographs ▶
- Reagents & Reference Tables ▶
- Resources ▶

**GENERAL CHAPTERS**  
*Guidelines on activities related to tests and procedures in monographs, descriptions of tests and procedures, general information on the interpretation of compendial requirements, and general guidance on official substances or official products.*

- General Tests & Assays (1 to 999) ▶**
- General Information (1000 to 1999)
- Dietary Supplements (2000 to 2999)
- Chapter Charts

**GENERAL TESTS & ASSAYS**

- General Requirements for Tests and Assays (1 to 20)
- Apparatus for Tests & Assays (21 to 50)
- Microbiological Tests (51 to 80)
- Biological Tests & Assays (81 to 180)
- Chemical Tests & Assays ▶**
- Physical Tests & Determinations (601 to 999)

**CHEMICAL TESTS & ASSAYS**

- Identification Tests (181 to 203)
- Limit Tests (204 to 300)
- Other Tests & Assays (301 to 600)

MY VIEWING ACTIVITY
BOOKMARKS
COMMENTS

DATE ▾	PAGE ▾	SECTION ▾	PUBLICATION ▾
04-Feb-2022	<a href="#">Test Solutions</a>	Reagents	Forum USP41-NF36

# Document View - Current



**usp** USP-NF  Hi, [Bookmarks](#) [EN](#) [Help](#)

[START HERE](#) [GENERAL NOTICES](#) [GENERAL CHAPTERS](#) [MONOGRAPHS](#) [REAGENTS AND REFERENCE TABLES](#) [RESOURCES](#)

**CURRENTLY OFFICIAL**  
Official as of 1-May-2020

**Document Tools**

[HISTORY](#) [CONTENTS](#) [SUPPORT](#)

**CURRENTLY OFFICIAL**  
Official as of 1-May-2020

**OLDER VERSION**  
Official 1-Jan-2018 to 30-Apr-2020

BOOKMARKED

MONOGRAPHS > [USP](#) > [ACETAMINOPHEN](#) **REFERENCE STANDARDS**

## Acetaminophen

$C_8H_9NO_2$  151.16

# Document View: Currently Official

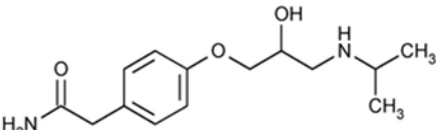


**USP-NF**  Search Filters EN ? 🔖 👤

**CURRENTLY OFFICIAL** Official as of 01-May-2021 ? Revisions  Off ◀ Prev Next ▶ Reference Standards ☰ Document Info

[Monographs](#) ▶ [USP](#) ▶ [Atenolol](#)

## Atenolol ?



[CLICK IMAGE TO ENLARGE](#)

$C_{14}H_{22}N_2O_3$  266.34  
Benzeneacetamide, 4-[2-hydroxy-3-[(1-methylethyl) amino]propoxy]-;  
2-[p-[2-Hydroxy-3-(isopropylamino)propoxy]-phenyl] acetamide [29122-68-7]; UNII: 50VV3VW0T1.

**DEFINITION**  
Atenolol contains NLT 98.0% and NMT 102.0% of  $C_{14}H_{22}N_2O_3$ , calculated on the dried basis.

**IDENTIFICATION**  
**Change to read:**

- A. [SPECTROSCOPIC IDENTIFICATION TESTS <197>](#), [Infrared Spectroscopy: 197K](#) (CN 1-May-2020)

**Change to read:**

- B. [SPECTROSCOPIC IDENTIFICATION TESTS <197>](#), [Ultraviolet-Visible Spectroscopy: 197U](#) (CN 1-May-2020)

**Sample solution:** 20 µg/mL in methanol

**ASSAY**

**Tools**

- Print
- Email
- PDF
- Set Alert
- Bookmark
- Search Term



# Document View: Status Comparisons



USP-NF

Search: Type a General Chapter, Monograph, or text search

Search Filters

EN

Revisions: Off

Reference Standards

Document Info

**CURRENTLY OFFICIAL** Official as of 01-May-2021

USP-NF

Search: Type a General Chapter, Monograph, or text search

Search Filters

EN

Revisions: Off

Reference Standards

Document Info

**NOT YET OFFICIAL** To be Official on 1-Dec-2022

USP-NF

Search: Type a General Chapter, Monograph, or text search

Search Filters

EN

Revisions: Off

Reference Standards

Document Info

**OLDER VERSION** Official on 01-May-2021

USP-NF

Search: Type a General Chapter, Monograph, or text search

Search Filters

EN

Revisions: Off

Reference Standards

Document Info

**FORUM PF 47(6)** 01-Nov-2021 to 31-Jan-2022

# Full Documents with Watermarks



USP-NF | Type a General Chapter, Monograph, or text search | Search Filters | EN | Revisions: OFF | Prev | Next | Reference Standards | Document Info

FORUM PF 47(6) 01-Nov-2021 to 31-Jan-2022  
CURRENTLY OFFICIAL Official as of 01-May-2021  
OLDER VERSION Effective 01-Nov-2021 to 30-Apr-2022  
FORUM PF 46(2) 02-Mar-2020 to 31-May-2020

### (1469) Nitrosamine Impurities

1. INTRODUCTION  
The presence of nitrosamine impurities has been detected recently in several drug substances and drug products. In 2016, nitrosodimethylamine (NDMA) in some valproate drug substances and the drug products manufactured from drug substances using specific synthetic routes. The development of analytical procedures to quantify these two nitrosamine impurities. As additional pharmaceuticals were evaluated, added as impurities of concern. Given the potentially broad implications of the presence of carcinogenic members of this class of based approach for the control of nitrosamine impurities to ensure that the potential presence of nitrosamines in drug substances. Recommendations are provided regarding: a) the establishment of controls of nitrosamine levels in order to ensure their elimination procedures used to monitor nitrosamine levels.

2. NITROSAMINE IMPURITIES  
Nitrosamines addressed in this general chapter are listed in Table 1 by their common names and chemical names. This list is a compilation of the information additional nitrosamines are identified as potential concerns, the principles described herein should be applied for the assessment of the appropriate regulatory authority should be contacted for determining appropriate limits. The potential presence of any one or more of these impurities. The list of nitrosamines is not intended to be exhaustive but represents those that have been observed and communicated. Nitrosamine compounds are among the structural groups of high potency mutagenic carcinogens in several animal species, and to the "hotspot of concern" in ICH M7. Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (2016) recommendation to control the impurities at or below the acceptable cancer risk. As a result of the potential toxicity associated with presence in pharmaceutical materials.

Common Name and Chemical Name	Acronym	CAS #	Structure
Nitrosodimethylamine N-Methyl-N-nitrosomethanamine	NDMA	62-75-9	
Nitrosodimethylamine N-Ethyl-N-nitrosoethanamine	NEEA	55-18-5	
Nitrosodipropylamine N-Isopropyl-N-nitrosodipropylamine	NDIPA	601-77-4	
Nitrosoethylpropylamine N-Ethyl-N-nitroso-2-propanamine	NEIPA	16329-04-1	
Nitrosobutylamine N-Butyl-N-nitroso-1-butanamine	NDBA	924-18-3	
Nitrosophenethylamine N-Methyl-N-nitrosophenethylamine	NMPEA	614-05-6	
Nitrosomethylaminobutyric acid 4-Methyl(nitrosamino)butanoic acid	NMBA	61445-55-5	

IMPURITIES  
Inorganic Iodides

Standard solution: 0.01 mg/mL of USP Atenolol RS in Mobile phase  
Sample solution: 0.01 mg/mL of Atenolol in Mobile phase. Sifted for 5 min

Chromatographic system  
(See Chromatography <621> System Suitability)

Mode: LC  
Detector: UV 226 nm  
Column: 3.9 mm x 30 cm; packing L1  
Flow rate: 0.6 mL/min  
Injection size: 10 µL

System suitability  
Sample: Standard solution  
Suitability requirements  
Column efficiency: NLT 5000 theoretical plates  
Tailing factor: NMT 2.0  
Relative standard deviation: NMT 2.0%

Analysis  
Samples: Standard solution and Sample solution  
Calculate the percentage of C<sub>17</sub>H<sub>19</sub>N<sub>3</sub>O<sub>2</sub> in the portion of Atenolol taken

t<sub>r</sub> = peak response from the Sample solution  
t<sub>r</sub> = peak response from the Standard solution  
C<sub>s</sub> = concentration of USP Atenolol RS in the Standard solution  
C<sub>p</sub> = concentration of Atenolol in the Sample solution (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

USP-NF | Type a General Chapter, Monograph, or text search | Search Filters | EN | Revisions: OFF | Prev | Next | Reference Standards | Document Info

NOT YET OFFICIAL To Be Official on 1-Nov-2022

### (1469) Nitrosamine Impurities

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Common Name and Chemical Name	Acronym	CAS #	Structure	Chemical Name
Nitrosodimethylamine N-Methyl-N-nitrosomethanamine	NDMA	62-75-9		C <sub>2</sub> H <sub>5</sub> N <sub>2</sub> O
Nitrosodimethylamine N-Ethyl-N-nitrosoethanamine	NEEA	55-18-5		C <sub>4</sub> H <sub>9</sub> N <sub>2</sub> O
Nitrosodipropylamine N-Isopropyl-N-nitrosodipropylamine	NDIPA	601-77-4		C <sub>12</sub> H <sub>23</sub> N <sub>2</sub> O
Nitrosoethylpropylamine N-Ethyl-N-nitroso-2-propanamine	NEIPA	16329-04-1		C <sub>7</sub> H <sub>15</sub> N <sub>2</sub> O
Nitrosobutylamine N-Butyl-N-nitroso-1-butanamine	NDBA	924-18-3		C <sub>8</sub> H <sub>17</sub> N <sub>2</sub> O
Nitrosophenethylamine N-Methyl-N-nitrosophenethylamine	NMPEA	614-05-6		C <sub>11</sub> H <sub>17</sub> N <sub>2</sub> O
Nitrosomethylaminobutyric acid 4-Methyl(nitrosamino)butanoic acid	NMBA	61445-55-5		C <sub>5</sub> H <sub>9</sub> N <sub>2</sub> O <sub>2</sub>

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### (1469) Nitrosamine Impurities

1. INTRODUCTION  
The presence of nitrosamine impurities has been detected recently in several drug substances and drug products. In 2016, nitrosodimethylamine (NDMA) in some valproate drug substances and the drug products manufactured from drug substances using specific synthetic routes. The development of analytical procedures to quantify these two nitrosamine impurities. As additional pharmaceuticals were evaluated, added as impurities of concern. Given the potentially broad implications of the presence of carcinogenic members of this class of based approach for the control of nitrosamine impurities to ensure that the potential presence of nitrosamines in drug substances and drug products is identified. Recommendations are provided regarding: a) the establishment of controls of nitrosamine levels in order to ensure their elimination or reduction; and b) procedures used to monitor nitrosamine levels.

2. NITROSAMINE IMPURITIES  
Nitrosamines addressed in this general chapter are listed in Table 1 by their common names and chemical names. This list is a compilation of the information additional nitrosamines are identified as potential concerns, the principles described herein should be applied for the assessment of these nitrosamines. If a regulatory authority should be contacted for determining appropriate limits. The potential presence of any one or more of these impurities. The list of nitrosamines is not intended to be exhaustive but represents those that have been observed and communicated by regulators and industry. Nitrosamine compounds are among the structural groups of high potency mutagenic carcinogens in several animal species, and some are classified as a "hotspot of concern" in ICH M7. Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (2016) recommendation to control the impurities at or below the acceptable cancer risk. As a result of the potential toxicity associated with these impurities, it is recommended to control the impurities at or below the acceptable cancer risk. As a result of the potential toxicity associated with these impurities, it is recommended to control the impurities at or below the acceptable cancer risk.

Common Name and Chemical Name	Acronym	CAS #	Structure	Chemical Name
Nitrosodimethylamine N-Methyl-N-nitrosomethanamine	NDMA	62-75-9		C <sub>2</sub> H <sub>5</sub> N <sub>2</sub> O
Nitrosodimethylamine N-Ethyl-N-nitrosoethanamine	NEEA	55-18-5		C <sub>4</sub> H <sub>9</sub> N <sub>2</sub> O
Nitrosodipropylamine N-Isopropyl-N-nitrosodipropylamine	NDIPA	601-77-4		C <sub>12</sub> H <sub>23</sub> N <sub>2</sub> O
Nitrosoethylpropylamine N-Ethyl-N-nitroso-2-propanamine	NEIPA	16329-04-1		C <sub>7</sub> H <sub>15</sub> N <sub>2</sub> O
Nitrosobutylamine N-Butyl-N-nitroso-1-butanamine	NDBA	924-18-3		C <sub>8</sub> H <sub>17</sub> N <sub>2</sub> O
Nitrosophenethylamine N-Methyl-N-nitrosophenethylamine	NMPEA	614-05-6		C <sub>11</sub> H <sub>17</sub> N <sub>2</sub> O
Nitrosomethylaminobutyric acid 4-Methyl(nitrosamino)butanoic acid	NMBA	61445-55-5		C <sub>5</sub> H <sub>9</sub> N <sub>2</sub> O <sub>2</sub>

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Common Name and Chemical Name	Acronym	CAS #	Structure	Chemical Name
Nitrosodimethylamine N-Methyl-N-nitrosomethanamine	NDMA	62-75-9		C <sub>2</sub> H <sub>5</sub> N <sub>2</sub> O
Nitrosodimethylamine N-Ethyl-N-nitrosoethanamine	NEEA	55-18-5		C <sub>4</sub> H <sub>9</sub> N <sub>2</sub> O
Nitrosodipropylamine N-Isopropyl-N-nitrosodipropylamine	NDIPA	601-77-4		C <sub>12</sub> H <sub>23</sub> N <sub>2</sub> O
Nitrosoethylpropylamine N-Ethyl-N-nitroso-2-propanamine	NEIPA	16329-04-1		C <sub>7</sub> H <sub>15</sub> N <sub>2</sub> O
Nitrosobutylamine N-Butyl-N-nitroso-1-butanamine	NDBA	924-18-3		C <sub>8</sub> H <sub>17</sub> N <sub>2</sub> O
Nitrosophenethylamine N-Methyl-N-nitrosophenethylamine	NMPEA	614-05-6		C <sub>11</sub> H <sub>17</sub> N <sub>2</sub> O
Nitrosomethylaminobutyric acid 4-Methyl(nitrosamino)butanoic acid	NMBA	61445-55-5		C <sub>5</sub> H <sub>9</sub> N <sub>2</sub> O <sub>2</sub>

3. SOURCES OF NITROSAMINES  
There are a number of pathways by which nitrosamines can be introduced into pharmaceutical drug products. Specifically, nitrosamines are formed in a chemical reaction of secondary or tertiary amines with nitrites (the latter via intermediate degradation) under acidic conditions (see 3.1. Nitrosamine Formation Reaction). Some examples of the reported sources or pathways leading to the generation of nitrosamines identified empirically or reported in the literature (2.2) include (but are not limited to) the following:

- Drug substance processing under specific conditions and in the presence of certain reagents, solvents, raw materials, and processing aids. There is evidence that multiple processing and purification steps, reactive species, whether intentionally added to or formed during the process/reaction sequence (e.g., nitrites and secondary amines in the presence of acidic conditions), can carry over to subsequent steps (see 3.1. Nitrosamine Formation Reaction). Special attention should be given to the formation of nitrosamines containing heterocycles by employing acids followed by quenching with nitrous acid to remove excess acids.
- The drug substance itself, which may degrade under some conditions resulting in the formation of nitrosamines (e.g., valmidine).
- Degradation of solvents (e.g., dimethylformamide (DMF) leading to the formation of dialyl amines).
- Impurities in raw materials, solvents (including recycled solvents), reagents, or analytes.
- Impurities in materials and intermediates, reagents, and solvents used to prepare the starting materials or intermediates.
- Impurities in water, excipients, or processing aids used in the production of the finished drug product.
- During drug product manufacture under certain reaction conditions and in the presence of requisite process reagents for the formation of nitrosamines.
- Impurities in the container/closure system for the finished drug product, which may include impurities capable of forming nitrosamines, especially if associated with materials containing amines and potential sources of a nitrating agent (e.g., nitrite, nitrocellulose).

A risk assessment should be conducted to determine the materials that contribute to the potential for inclusion of nitrosamines in the drug product. All potential sources for the introduction of nitrosamines should be considered in a risk assessment including, for example, the drug substance, excipients, water, solvents, the manufacturing process, packaging components, and formation on stability. See Figure 1 for a diagram of some potential sources to be considered.

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## <1469> Nitrosamine Impurities

**1. INTRODUCTION**

The presence of nitrosamine impurities has been detected recently in several drug substances and drug products. In 2018, *N*-nitrosodimethylamine (NDMA) and *N*-nitrosodiethylamine (NDEA) were detected in some valsartan drug substances and the drug products manufactured from drug substances using specific synthetic routes. This observation triggered extensive synthetic route assessments and development of analytical procedures to quantify these two nitrosamine impurities. As additional pharmaceuticals were evaluated and, in some cases tested, other nitrosamines beyond NDMA and NDEA were added as impurities of concern. Given the potentially broad implications of the presence of carcinogenic members of this class of chemicals, this chapter has been developed to provide a science- and risk-based approach for the control of nitrosamine impurities to ensure that the potential presence of nitrosamines in drug substances and drug products is identified, assessed, and controlled.

Recommendations are provided regarding: a) the establishment of controls of nitrosamine levels in order to ensure their elimination or reduction; and b) analytical procedure performance characteristics for procedures used to monitor nitrosamine levels.

**2. NITROSAMINE IMPURITIES**

Nitrosamines addressed in this general chapter are listed in [Table 1](#) by their common names and chemical names. This list is a compilation of the information shared by multiple global health authorities. As additional nitrosamines are identified as potential concerns, the principles described herein should be applied for the assessment of these nitrosamines. If a manufacturer finds a nitrosamine not listed in [Table 1](#), the appropriate regulatory authority should be contacted for determining appropriate AI limits. The potential presence of any one or more of these impurities is dependent on the reaction chemistries and processes. The list of nitrosamines is not intended to be exhaustive but represents those that have been observed and communicated by regulators and manufacturers as being potentially present or observed.

*N*-nitroso compounds are among the structural groups of high potency mutagenic carcinogens in several animal species, and some are classified as probable or possible human carcinogens referred to as the "cohort of concern" in ICH M7: *Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (1)*, a designation that carries with it a recommendation to control the impurities at or below the acceptable cancer risk. As a result of the potential toxicity associated with these impurities, it is recommended to take steps to control and limit their presence in pharmaceutical materials.

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CLICK IMAGE TO ENLARGE

$C_{14}H_{22}N_2O_3$  266.34  
Benzeneacetamide, 4-[2-hydroxy-3-[(1-methylethyl) amino]propoxy]-;  
2-[p-[2-Hydroxy-3-(isopropylamino)propoxy]-phenyl] acetamide [29122-68-7]; UNII: 50VV3VW0T1.

**DEFINITION**  
Atenolol contains NLT 98.0% and NMT 102.0% of  $C_{14}H_{22}N_2O_3$ , calculated on the dried basis.

**IDENTIFICATION**  
**Change to read:**

- A. **SPECTROSCOPIC IDENTIFICATION TESTS** <197>, **Infrared Spectroscopy: 197K** (CN 1-MAY-2020)

**Change to read:**

- B. **SPECTROSCOPIC IDENTIFICATION TESTS** <197>, **Ultraviolet-Visible Spectroscopy: 197U** (CN 1-MAY-2020)

**Sample solution:** 20 µg/mL in methanol

Tools

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Nitrosodimethylamine <i>N</i> -Methyl- <i>N</i> -nitrosomethanamine	NDMA	62-75-9	 CLICK IMAGE TO ENLARGE	C <sub>2</sub> H <sub>5</sub> N <sub>2</sub> O
Nitrosodiethylamine <i>N</i> -Ethyl- <i>N</i> -nitrosoethanamine	NDEA	55-18-5	 CLICK IMAGE TO ENLARGE	C <sub>4</sub> H <sub>9</sub> N <sub>2</sub> O
Nitrosodiisopropylamine <i>N</i> -Isopropyl- <i>N</i> -nitrosoisopropylamine	NDIPA	601-77-4	 CLICK IMAGE TO ENLARGE	C <sub>6</sub> H <sub>13</sub> N <sub>2</sub> O
Nitrosoethylisopropylamine <i>N</i> -Ethyl- <i>N</i> -nitroso-2-propanamine	NEIPA	16339-04-1	 CLICK IMAGE TO ENLARGE	C <sub>7</sub> H <sub>15</sub> N <sub>2</sub> O
Nitrosodibutylamine <i>N</i> -Butyl- <i>N</i> -nitroso-1-butanamine	NDBA	924-16-3	 CLICK IMAGE TO ENLARGE	C <sub>10</sub> H <sub>21</sub> N <sub>2</sub> O
Nitrosomethylphenylamine			 CLICK IMAGE TO ENLARGE	C <sub>7</sub> H <sub>9</sub> N <sub>2</sub> O

### Document Info

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  - Testosterone Propionate
  - Bromodiphenhydramine Hydrochloride
  - Sulfisoxazole Acetyl
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  - Chapter Charts
  - (2) Oral Drug Products—Product Quality Tests
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- REAGENTS** (9 results)
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- 📄 Acetaminophen Suppositories, Monograph
- 📖 (227) 4-Aminophenol in Acetaminophen-Containing Drugs, General Chapter
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 E *Monographs Official as of 1-May-2020*  
**Acetaminophen.** C<sub>8</sub>H<sub>9</sub>N<sub>2</sub>O<sub>2</sub> 151.16 Acetamide, N-(4-hydroxyphenyl)-; 4'-Hydroxyacetanilide 103-90-2

---

**Acetaminophen Tablets**  
 E *Monographs Official as of 1-Oct-2021*  
**Acetaminophen** Tablets. 4-Aminophenol. C<sub>6</sub>H<sub>7</sub>N<sub>2</sub>O 109.13. Detector: UV 272 nm. Column temperature: 40

---

**Acetaminophen Capsules**  
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<711> **Dissolution. Dissolution** medium: Proceed as directed for Immediate-Release Dosage Forms

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 General Chapters To be Official on 1-May-2022  
<711> **Dissolution. Dissolution** medium: Prepare as directed for Immediate-Release Dosage Forms

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 General Chapters Official as of 1-Dec-2020  
<1087> Intrinsic **Dissolution—Dissolution** Testing Procedures for Rotating Disk and Stationary Disk

**ICON KEY** ?  
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**ORIGIN OF CHANGE KEY** ?  
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**IRA:** Interim Revision Announcements  
**RB:** Revision Bulletin  
**H:** Harmonization

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<711> Dissolution  
✔ General Chapters Official as of 1-May-2016  
<711> **Dissolution. Dissolution** medium: Proceed as directed for Immediate-Release Dosage Forms

<711> Dissolution  
🕒 General Chapters To be Official on 1-May-2022  
<711> **Dissolution. Dissolution** medium: Prepare as directed for Immediate-Release Dosage Forms

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