Future of Commenting Forum
USP-NF Online Update

Trey White, Ph.D.
March 29, 2022
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

Late-Stage β-C(sp³)−H Deuteration of Carboxylic Acids
Alexander Uttry, Sourija Mal, and Manuel van Gemmeren*

Cite this: J. Am. Chem. Soc. 2021, XXXX, XXX, XXX-XXX

Publication Date: July 13, 2021
https://doi.org/10.1021/jacs.1c06474

© 2021 The Authors. Published by American Chemical Society

RIS

Read Online
PDF (2 MB)
Supporting Info (1)
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
DOI ref: dsv5r

How DOI is displayed within a PDF:

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

Acetaminophen

\[
\text{Result} = \left( \frac{r_u}{r_s} \right) \times \left( \frac{C_s}{C_u} \right) \times 100
\]

- \( r_u \) = 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)
Acetaminophen

C₉H₈NO₂  151.16
Acetamide, N-(4-hydroxyphenyl)-;
4'-Hydroxyacetanilide  [103-90-2]; UNII: 362091TL9D.
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$_8$H$_7$O$_4$), caffeine (C$_8$H$_10$N$_4$O$_2$), and dihydrocodeine bitartrate (C$_{19}$H$_{23}$NO$_5$C$_4$H$_6$O$_9$).

USP Reference Standards for Purchase
- USP Dihydrocodeine Bitartrate RS
- USP Aspirin RS
- USP Caffeine RS
- USP Salicylic Acid RS
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
The following images are design mock-ups – NOT the actual pages

The final look and feel may be slightly different than shown in these mock-ups

– There are multiple iterations of some of these views and some are still evolving – please disregard small inconsistencies between screens

Please disregard dates and document status – these are examples only, NOT actual USP-NF documents
USP-NF Online Home Page - Current
### 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

<table>
<thead>
<tr>
<th>DATE</th>
<th>PAGE</th>
<th>SECTION</th>
<th>PUBLICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>04-Feb-2022</td>
<td><em>Test Solutions</em></td>
<td>Reagents</td>
<td>Forum USP41-NF36</td>
</tr>
<tr>
<td>03-Feb-2022</td>
<td><em>Isopropyl Alcohol</em></td>
<td>Monographs</td>
<td>Forum USPNF 2021 Issue 3</td>
</tr>
<tr>
<td>01-Feb-2022</td>
<td><em>17) Prescription Container Labeling</em></td>
<td>General Chapters</td>
<td>Forum USPNF 2021 Issue 3</td>
</tr>
</tbody>
</table>
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
Updated USP-NF + PF: Bookmarks

My Dashboard

- Currently Official: USPNE 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

<table>
<thead>
<tr>
<th>DATE</th>
<th>PAGE</th>
<th>SECTION</th>
<th>PUBLICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>04-Feb-2022</td>
<td>Test Solutions</td>
<td>Reagents</td>
<td>Forum USP41-NF36</td>
</tr>
<tr>
<td>03-Feb-2022</td>
<td>Isopropyl Alcohol</td>
<td>Monographs</td>
<td>Forum USPNF 2021 Issue 3</td>
</tr>
<tr>
<td>01-Feb-2022</td>
<td>(17) Prescription Container Labeling</td>
<td>General Chapters</td>
<td>Forum USPNF 2021 Issue 3</td>
</tr>
</tbody>
</table>
Navigation - Current

Monographs
This section contains a complete list of monographs associated with the USP-NF edition you selected. Monographs contain tests, procedures, and acceptance criteria to ensure the identity, strength, quality, and purity of an article. A monograph also contains the article's name, definition, specification, and other requirements related to packaging, storage, and labeling. Refer to the General Notices under the "Start Here" tab for more information.
Acetaminophen

![Chemical Structure of Acetaminophen](image)

**Formula:** C₇H₉NO₂

**Molecular Weight:** 151.16
Atenolol

![Chemical Structure of Atenolol]

**DEFINITION**
Atenolol contains NLT 98.0% and NMT 102.0% of C₁₄H₂₂N₂O₂, calculated on the dried basis.

**IDENTIFICATION**
Change to read:

**ASSAY**
Sample solution: 20 µg/ml in methanol
Updated USP-NF + PF: Doc Status Comparisons

1. CURRENTLY OFFICIAL: Official as of 01-May-2021
2. NOT YET OFFICIAL: To be Official on 1-Oct-2022
3. OLDER VERSION: Official on 01-May-2021
4. FORUM PF 47(6): 01-Nov-2021 to 31-Jan-2022
(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 nitrosamines 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. Nitrosamines 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. 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.
**Updated USP-NF + PF: Document Versions Menu**

The image shows a screenshot of a webpage with a focus on the document versions menu. The page contains a search bar at the top, followed by a list of document versions:

- **Currently Official**: Official as of 01-May-2021
- **Older Version**: Effective 01-Nov-2020 to 30-Apr-2021
- **Older Version**: Effective 12-Mar-2020 to 31-May-2020

Below the versions list, there is a chemical structure with a molecular formula: 

\[ C_{11}H_{22}N_2O_3 \] \[ MW = 266.34 \]

**Definition**: Atenolol contains NLT 98.0% and NMT 102.0% of \( C_{11}H_{22}N_2O_3 \) calculated on the dried basis.

**Identification**: Change to read:

- A. Spectroscopic Identification Tests (2.17) Infrared Spectroscopy: 197K
  Change to read:
  - B. Spectroscopic Identification Tests (2.17) Ultraviolet-Visible Spectroscopy: 197K
  Sample solution: 20 \( \mu \)g/mL in methanol.
Updated USP-NF + PF: Recent Searches
Updated USP-NF + PF: Search Auto-Suggest
Results for “acetaminophen” (45 results)  ☐

Filters
- Clear All
- Expand All
- Collapse All
- Search by document title only
- PUBLICATION
- MONTHLY POSTING
- OFFICIAL STATUS
  - Official (43)
  - To Be Official (2)
  - No Longer Official (66)
  - Never Official (7)

Document Results (Scroll for more results)

**Acetaminophen**
- Monographs: Official as of 1-May-2020
- Acetaminophen. C8H9NO2. 151.16 Acetamide, N-(4-hydroxyphenyl); 4-Hydroxyacetanilide 103-90-2

**Acetaminophen Tablets**
- Monographs: Official as of 1-Oct-2021

**Acetaminophen Capsules**
- Monographs: Official as of 1-Dec-2014
- Acetaminophen Capsules. USP Reference Standards 11 USP Acetaminophen RS. B. Thin-Layer
Updated USP-NF + PF: Updated Results

Results for "Dissolution"

- **(711) Dissolution**
  - General Chapters, Official as of 1-May-2016
  - **Dissolution, Dissolution** medium: Proceed as directed for Immediate-Release Dosage Forms

- **(711) Dissolution**
  - To be Official on 1-May-2022
  - **Dissolution, Dissolution** medium: Prepare as directed for Immediate-Release Dosage Forms

- **(1087) Intrinsic Dissolution—Dissolution Testing Procedures for Rotating Disk and Sta**
  - General Chapters, Official as of 1-Dec-2020
  - **Intrinsic Dissolution—Dissolution Testing Procedures for Rotating Disk and Stationary Disk**
Updated USP-NF + PF: Search - Advanced Filters
Updated USP-NF + PF: Search - Advanced Filters
Updated USP-NF + PF: Search - Advanced Filters
Questions

Empowering a healthy tomorrow