Guideline for Referencing *USP–NF* Documentary Standards

Introduction:

In the new *USP–NF Online* platform, USP is introducing a document-centric model for the version control and presentation of our documentary standards. Whether a document is official or not official will no longer be linked to when a specific publication such as the main *USP–NF* edition or one of the Supplements becomes official, but instead will be based on the individual document.

This leads to the question of how to reference the currently official documentary standard when you are using the new *USP–NF Online* platform. USP has created this guideline to help your organization transition to referencing documentary standards within the new platform.

Background:

Many organizations reference the *USP–NF* edition along with a page number as an indication that the method or specification listed is or was official at the time of testing, filing, or release (e.g. *USP41–NF36 1S page 8428* indicating an official date of August 1, 2018).

In addition, any Accelerated Revision (Erratum, Revision Bulletin [RB], Interim Revision Announcement [IRA]) published on www.uspnf.com would then be noted, as it supersedes the official text referenced in the publications (e.g. Revision Bulletin official on December 1, 2018).

Moving Forward:

Although USP will continue to publish the *USP–NF* standards on a set schedule, there are changes in the document-centric platform that affect the application of official date references.

As USP transitions to document-centric standards, the general publication reference (e.g. *USP41–NF36 1S* page 8428) will no longer be an indication of an official period. Each individual document within the new online publication has its own official date reference, which is linked to a unique permanent documentary identifier (Unique DocIDs) available in the new *USP–NF Online* platform. The Unique DocIDs will only change when there is a revision to a document. The Unique DocIDs do not change with each publication. Click **here** for more information on Unique DocIDs.

Scenario 1 below offers our recommendation for referencing standards in the new document-centric model. Recognizing that there are organizations still employing the print format of the compendia that will need time to transition to referencing the new *USP-NF Online,* we provide guidance in *Scenario 2*.

Please note, in the event of any disparity between the print or USB flash drive versions and the *USP–NF Online*, the *USP–NF Online* will be deemed to apply. See ***General Notices* 2.10.**

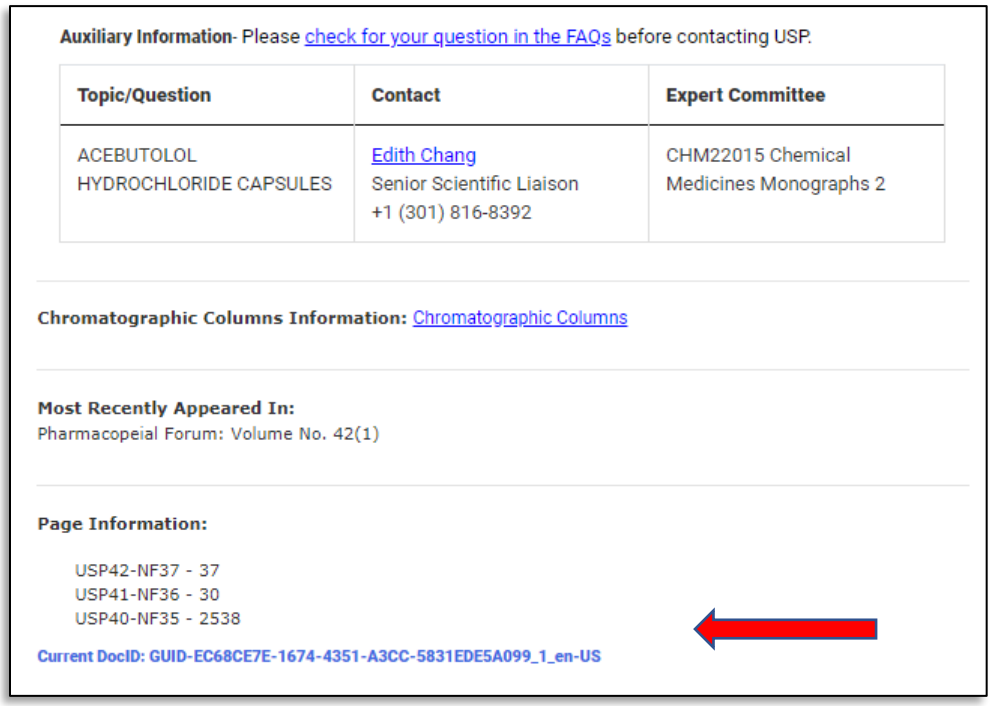
Please also note that *USP43-NF38* is the last edition that will be available in print or on a flash drive. Future supplements and editions will not be printed or on flash drives; only the online format will contain all current *USP-NF* content. Starting with the *USP43–NF38* Supplement 1 that publishes on February 1, 2020, print and flash drive formats will not be available. Click **here** for more information.

- **Scenario 1** describes how to reference documentary standards within the new platform.
- **Scenario 2** describes how to find corresponding information between the two different formats that you may use for referencing purposes.

Recommendations:

- **Scenario 1**: References found within the new *USP–NF Online* platform:
  - When referencing a documentary standard in the new online platform, USP's recommendations differ depending on whether the user seeks to make a general reference to a standard (e.g., seeks to reference the "currently official" version of a standard, without specific reference to the official period) or a specific reference (i.e., seeks to reference a specific standard associated with a specific official period).
  - For general references, USP recommends using the name/title of the standard, e.g., "Acebutolol Hydrochloride Capsules Monograph." This general reference is understood to refer to the currently official version of the standard and may be appropriate in certain circumstances (e.g., SOPs, policy documents) where it would be difficult or unnecessary to update the specific version of a standard to reflect each subsequent revision.
  - For specific references, USP recommends using the Unique DocID found after the "Auxiliary Information" section. This unique identifier, which is searchable and traceable, is linked to the official date for the particular *version* of a document. See *Figure 1* for an example of the Unique DocID for Acebutolol Hydrochloride.

Figure 1: DocIDs for Acebutolol Hydrochloride Capsules Monograph



  - The Unique DocID will also appear in the printout for a documentary standard in the main header on the first page (see *Figure 2a*) and in the footer on subsequent pages (see *Figure 2b*). Note: be sure to enable footers in your printer settings.

Figure 2a: DocID Print-Out (header)

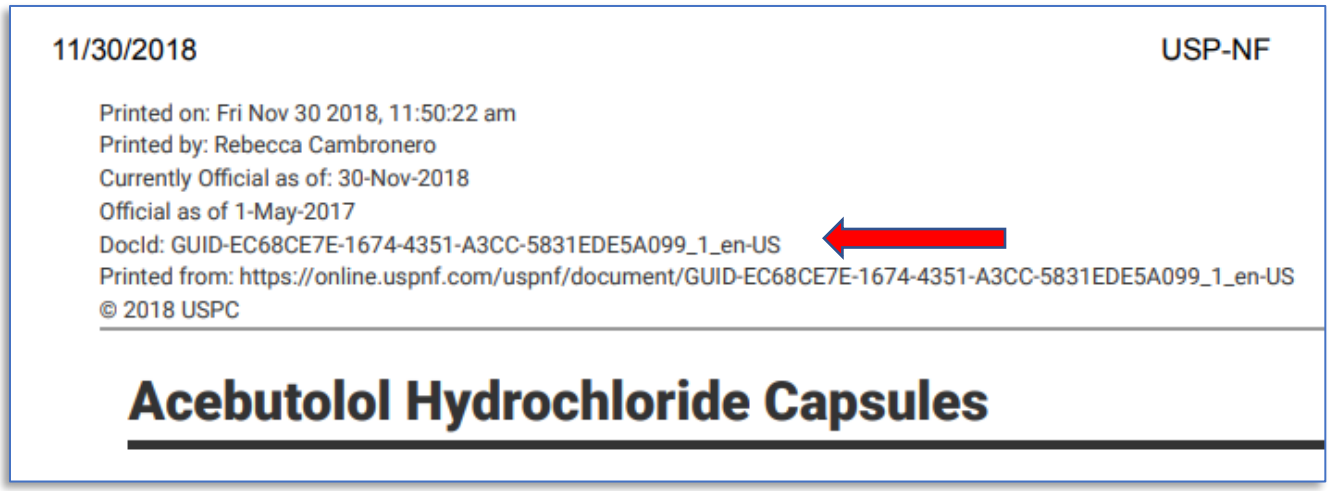
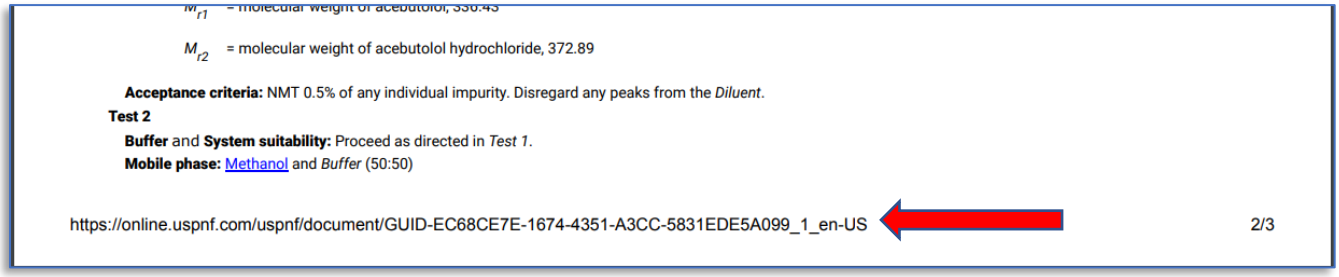
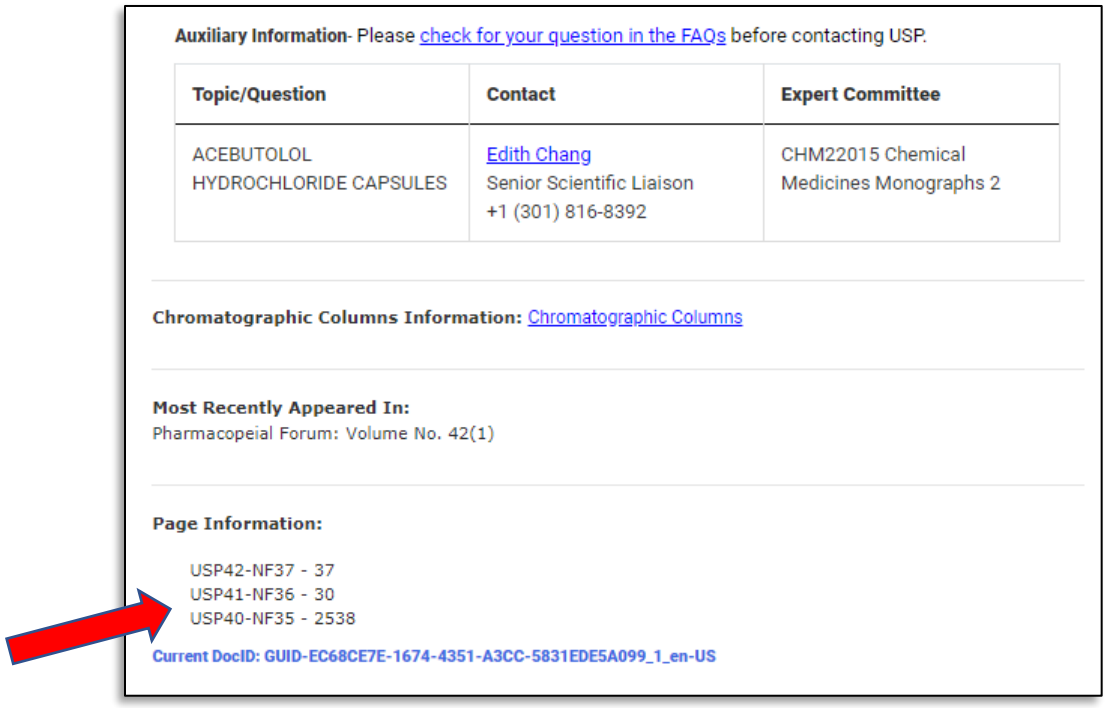


Figure 2b: DocID Print-Out (footer)



- **Scenario 2**: Tracing from the print *USP–NF* to the new *USP–NF Online*
  - When referencing a document in the print *USP–NF*, you may reference the edition number (e.g. *USP41–NF36*) and the page number.
    - When using the print *USP–NF*, check the official text information posted on www.uspnf.com to ensure the text has not been superseded by an Accelerated Revision. Click **here** for more information on Accelerated Revisions.
  - To find the corresponding information in the new online format, search for the document, scroll to the bottom of the document, "Auxiliary Information" section, for a list of current and previous editions in which this document appeared in print with relevant page numbers (see *Figure 3*). Please note that the page number information does not necessarily indicate when a file was last revised, just when it was last published in print.
    - Click **here** for more information on page numbers.

Figure 3: Page Information for Acebutolol Hydrochloride Capsules Monograph



Auxiliary Information- Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ACEBUTOLOL HYDROCHLORIDE CAPSULES	Edith Chang Senior Scientific Liaison +1 (301) 816-8392	CHM22015 Chemical Medicines Monographs 2

Chromatographic Columns Information: Chromatographic Columns

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 42(1)

Page Information:

USP42-NF37 - 37
USP41-NF36 - 30
USP40-NF35 - 2538

Current DocID: GUID-EC68CE7E-1674-4351-A3CC-5831EDE5A099_1_en-US

Important Notes:

- The icon at the top of the document will indicate if there is an Accelerated Revision (e.g. Errata, RB, IRA) or a Harmonization that superseded the print *USP–NF* indicated at the bottom (see *Figure 4*). Any text that has been revised through an Accelerated Revision or a Harmonization is integrated directly into the version of the standard displayed in the *USP–NF Online*.
  - Click **here** for more information on icons.

Figure 4: Bupropion Hydrochloride Extended-Release Tablets Monograph