Guideline for Referencing USP–NF Documentary Standards

Introduction:

The USP–NF Online platform introduced 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 three Issues of USP–NF – becomes official, but instead is based on the individual document.

USP has created this guideline to help your organization reference the currently official documentary standard when you are using the USP–NF Online.

Background:

As USP has transitioned the *USP-NF* from print to an online-only product <u>the general</u> <u>publication reference (e.g. *USP41–NF36 1S*) will no longer be an indication of an official <u>period</u>. 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. Each individual document within the new online publication has its own official date reference, which is linked to a unique permanent Digital Object Identifier (DOI) available in November 2021 with the launch of USP-NF 2022 Issue 1. The DOI will only change when there is a revision to a document.</u>

Click <u>here</u> for more information on DOI.

Recommendation:

- To make a general reference to a standard: USP recommends using the name/title of the standard, e.g., "Acebutolol Hydrochloride 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.
- To make a reference to a specific version of a standard: When referencing a version of a standard official during a specific time period, USP recommends using the Digital Object Identifier found below 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 DOI for Acebutolol Hydrochloride.

Topic/Question	Contact	Expert Committee
ACEBUTOLOL HYDROCHLORIDE	Yanyin Yang Associate Scientific Liaison	SM22020 Small Molecules 2
ost Recently Appeared In: armacopeial Forum: Volume	Information: <u>Chromatographic Database</u> No. 45(2)	
age Information:		
age Information: USPNF 2021 ISSUE 1 - onli USP43-NF38 - 33 USP42-NF37 - 35	ne	

Figure 1: DOI for Acebutolol Hydrochloride Monograph

• Note: *DOI ref* is a unique, compressed version of the DOI string that can be used for your convenience in your internal documentation as a shorthand reference to USP-NF content. It functions exactly like the full length DOI. However, when citing USP-NF content in journals or other publications, always use the full DOI.

• Citation Examples

- General Chapter: USP. Injections and Implanted Drug Products (Parenterals)—Product Quality Tests <1>. In: USP–NF. Rockville, MD: USP; Dec 1, 2020.
 DOI: <u>https://doi.org/10.31003/USPNF_M98730_03_01</u>.
- Monograph: USP. Acebutolol Hydrochloride. In: USP–NF. Rockville, MD: USP; May 1, 2021.
 DOI: <u>https://doi.org/10.31003/USPNF_M125_05_01</u>.

• The DOI and DOI ref will also appear in the printout for a documentary standard in the main header on the first page (see *Figure 2*).

Figure 2: DOI Print-Out (header)

10/9/21, 1:57 PM	USP-NF Acebutolol Hydrochloride
Printed on: Sat Oct 09 2021, 13:57:32 pm	
Printed by: Scott Bolgiano Official Status: Currently Official on 09-Oct-2021	
Official Date: Official as of 1-May-2021	
Document Type: USP DocId: 1_GUID-BF41B99E-B619-405D-8604-C8B6BB9E0E1D_5_en-US	
DOI: https://doi.org/10.31003/USPNF_M125_05_01	
DOI Ref: u3uae © 2021 USPC	
Acebutolol Hydrochloride	

 Note: The Page Information listed below the Auxiliary Information section is historical data as the USP-NF is no longer printed. The page information does not necessarily indicate when a file was last revised, just when it was last published. If page numbers are listed in this section, they should not be used to reference currently official content.

Topic/Question	Contact	Expert Committee
ACEBUTOLOL HYDROCHLORIDE	Yanyin Yang Associate Scientific Liaison	SM22020 Small Molecules 2
Chromatographic Database	Information: Chromatographic Database	1
Most Recently Appeared In: Pharmacopeial Forum: Volume		
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Page Information: USPNF 2021 ISSUE 1 - on USP43-NF38 - 33 USP42-NF37 - 35	line	
Page Information: USPNF 2021 ISSUE 1 - on USP43-NF38 - 33 USP42-NF37 - 35	line 519-405D-8604-C8B6BB9E0E1D_5_en-US	