

USP Excipients Stakeholder Forum
Wednesday, November 13, 2019

USP NF Online Updates: Progress Towards a Digital Future

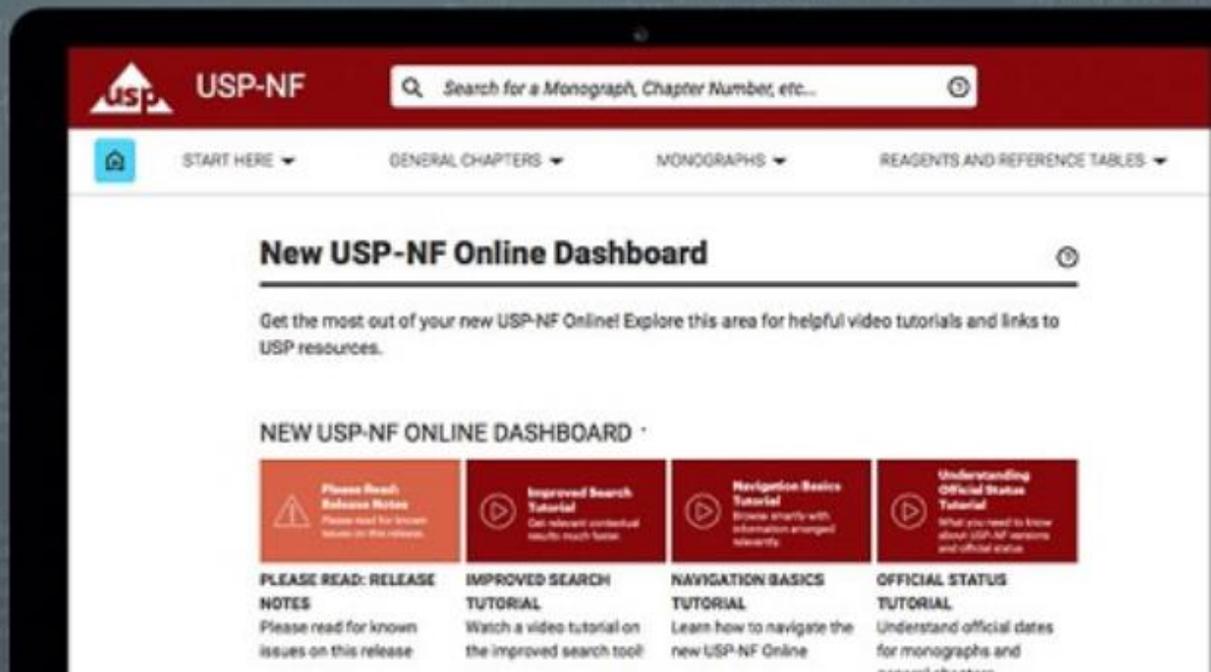
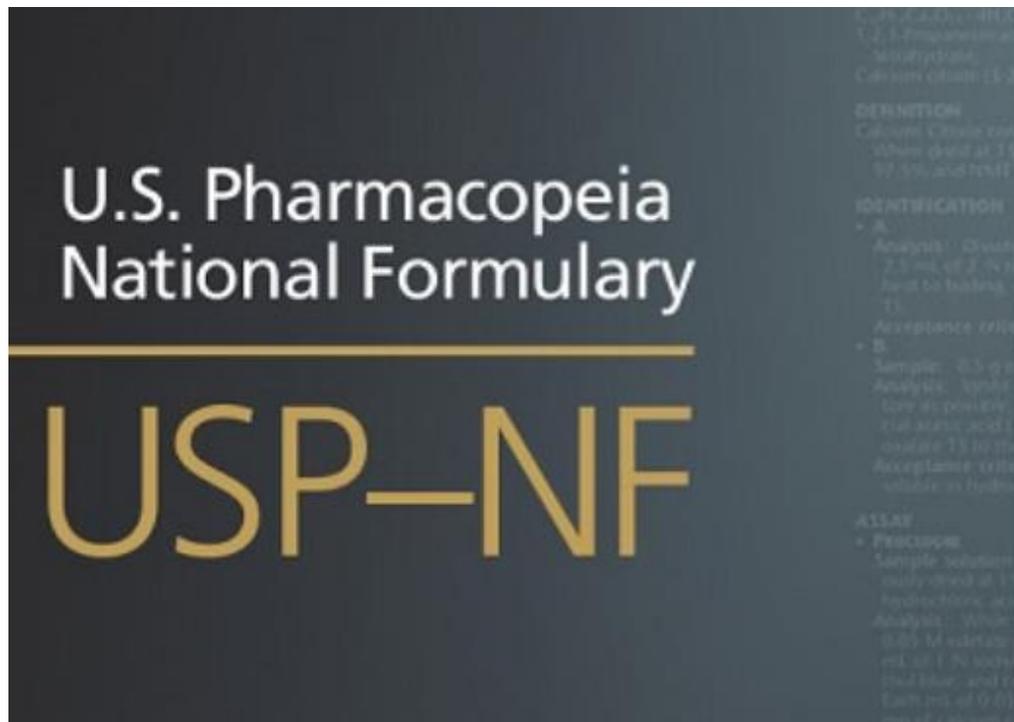
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Director, SMPO Documentary Standards



Updates for *USP–NF Online*



- **Upcoming Enhancements**
- Future of print & USB formats
- Upcoming *USP–NF Online* products



Upcoming Enhancements* (New & Changed)



- 508 Compliance
 - Implemented September 16, 2019

- New & Changed
 - “Extract List” feature
 - Default “New & Changed” list to “Currently Official”
 - Add “Compendial Notice” revisions to the “New & Changed” List
 - Add the following search facets
 - “CN” and normal “Compendial Revisions”
 - Type of Revision (elimination, addition, change)
 - Category (only applies to monographs)
 - Optimize “sorting” of in “New & Changed” list
 - General Chapters first (in correct number sequence)
 - Monographs
 - then Reagents and Front matter documents
 - General Notices to “float” to top of the “New & Changed” list when revised
 - Add “up arrow” to the “New & Changed” list
 - “Collapse all” and “Select all” for filters

*Expected enhancements – entire list may not be launched at the same time

Upcoming Enhancements* (Printing)



■ Printing

- Allow for PDF generation and printing (not using web browser)
- PDF generation will be in a 2-column format
- Printout has header on each page
- Printout in 12 point font: font sizes in PDFs too small
- Clarify printout dates in the header
- Book section will be included in the header
- Printout contains watermark indicative of that document's status, e.g. official, not yet official, or no longer official
- For any reagent section, be able to print all items to one PDF, instead of all individual titles (i.e.. Solutions, Indicators, Reagents, etc.)

*Expected enhancements – entire list may not be launched at the same time

Upcoming Enhancements* (Search & Other)



- Search
 - Add “x” feature to search box to quickly delete a term
 - Change search term highlighting to a blue color since revision text is in yellow.
 - Toggle on/off button for search highlighting feature
- Other
 - General Notices to appear on main navigation bar
 - For files that have a “postponed indefinitely” official date, will appear as “Not yet official”
 - For files that are omitted, they will appear as “No longer official”
 - Enhance the text on the search results page with the number of results
 - Extend login sessions to 90 minutes
 - Remove “All Versions” banner
 - Rename "Chromatographic Columns" to "Chromatographic Database" so as to avoid confusion with the use of "Chromatographic Columns" under "Reagents and Reference Tables"
 - Add link to FAQs under "Resources"

*Expected enhancements – entire list may not be launched at the same time

508 Compliance Updates



The screenshot shows the USP-NF Online Dashboard. At the top, there is a dark red navigation bar with the USP logo, 'USP-NF', a search bar, and user information. Below this is a white navigation bar with a home icon and several menu items. The main content area is titled 'USP-NF Online Dashboard' and contains a grid of eight promotional tiles for various resources.

Navigation Bar: Dashboard, Activity and Bookmarks, Event and Training

Search Bar: Search for a Monograph, Chapter Number, etc...

Navigation Menu: START HERE, GENERAL CHAPTERS, MONOGRAPHS, REAGENTS AND REFERENCE TABLES, RESOURCES

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

Please Read: Release Notes Please read for known issues on this release.	Improved Search Tutorial Get relevant contextual results much faster.	Navigation Basics Tutorial Browse smartly with information arranged relevantly.	Understanding Official Status Tutorial What you need to know about USP-NF versions and official status.
PLEASE READ: RELEASE NOTES Please read for known issues on this release	IMPROVED SEARCH TUTORIAL Watch a video tutorial on the improved search tool!	NAVIGATION BASICS TUTORIAL Learn how to navigate the new USP-NF Online	OFFICIAL STATUS TUTORIAL Understand official dates for monographs and general chapters
DSC Online Click here for more information	Reference Standard Mobile App Stay notified. USP compliance made easy. Download the USP Reference Standard App today!	USP <800> HazRX™ Mobile App Download the app to know your exposure to hazardous drugs!	Referencing Guideline Click here for FAQs
DIETARY SUPPLEMENTS COMPENDIUM DSC Online is here! Click here for the latest info	REFERENCE STANDARD APP Download the free USP Reference Standards App today.	USP <800> HAZRX APP Download this app to know your drug exposure	REFERENCING GUIDELINE Click here for guidance on how to reference documentary standards

New & Changed list



usp USP-NF Hi, Rebecca

GENERAL CHAPTERS MONOGRAPHS REAGENTS AND REFERENCE TABLES RESOURCES

New and Changed

ALL VERSIONS

Filters

PUBLICATION

- USP41-NF36 (423)
- USP41-NF36 1S (535)
- USP41-NF36 2S (636)
- USP42-NF37 (775)
- USP42-NF37 1S (908)

MONTHLY POSTING

- 25-Jan-2019 - USP42-NF37 (13)
- 28-Dec-2018 - USP42-NF37 (10)
- 30-Nov-2018 - USP42-NF37 (30)
- 26-Oct-2018 - USP41-NF36 2S (24)
- 28-Sep-2018 - USP41-NF36 2S (26)
- 31-Aug-2018 - USP41-NF36 2S (11)

OFFICIAL STATUS

- Official (584)

(±)-1-(9-Fluorenyl)ethanol

Reagents Official as of 1-Aug-2018

(±)-1-(9-Fluorenyl)ethyl Chloroformate Solution

Reagents Official as of 1-Aug-2018

0.002 M Edetate Disodium VS

Reagents To be Official on 1-May-2019

0.002 N Sodium Thiosulfate VS

Reagents To be Official on 1-May-2019

0.01 M Edetate Disodium VS

Reagents To be Official on 1-May-2019

0.01 M Lead Nitrate VS

Reagents To be Official on 1-May-2019

0.01 M Phosphoric Acid TS

Reagents Official as of 1-May-2018

D

E

Sample of Extracted List



- Sample list extracted from New & Changed list
- Extracted list will be an Excel worksheet

#	Title	Document Type	Official Status	Official Date	Official Date Range*
1	Acetaminophen Oral Suspension	Monograph	Official	1-Jul-2019	
2	Alosetron Hydrochloride	Monograph	To Be Official	2-Dec-2019	
3	Acamprosate Calcium	Monograph	No Longer Official	1-Aug-2018	1-Aug-2018 to 30-Nov-2018
4	Azithromycin Tablets	Monograph	No Longer Official	Official Prior to 2013	
5	6Z-Retinoic Acid	Reagents	Never Official		

- List pre-populated with headers (as seen above) for filtering and sorting
- Feature will extract out what you have displayed
 - Example: with search filters applied, if you have 10 results, you will see a list of 10 items

Example of Extracted List



Filters [Clear All](#) 🔍

PUBLICATION

USP42-NF37 1S (7)

USP42-NF37 2S (8)

MONTHLY POSTING

26-Jul-2019 - USP42-NF37 2S (2)

OFFICIAL STATUS

Official (9)

Never Official (1)

DOCUMENT TYPE

USP Monographs (142)

NF Monographs (6)

Dietary Supplement Monographs (14)

Global Health (1)

General Chapter (9)

Reagents (19)

[Show More](#)

OFFICIAL DATE

01-Aug-2019 (9)

REVISION DATE

01-Aug-2019 (9)

01-May-2019 (2)

ERRATA

USP42-NF37 2S (2)

Document Results

(1057) Biotechnology-Derived Articles—Total Protein Assay

General Tests & Assays Official as of 1-Aug-2019

(1151) Pharmaceutical Dosage Forms

General Tests & Assays Official as of 1-Aug-2019

(123) Glucagon Bioidentity Tests

E **General Tests & Assays** Official as of 1-Aug-2019

(2) Oral Drug Products—Product Quality Tests

General Tests & Assays Official as of 1-Aug-2019

(41) Balances

E **General Tests & Assays** Official as of 1-Aug-2019

(644) Conductivity of Solutions

H **General Tests & Assays** Official as of 1-Aug-2019

(64) Probiotic Tests

General Tests & Assays Official as of 1-Aug-2019

(701) Disintegration

General Tests & Assays Official as of 1-Aug-2019

(729) Globule Size Distribution in Lipid Injectable Emulsions

General Tests & Assays Official as of 1-Aug-2019

- Based on filters, I have 9 results, all general chapters
- Extracted list will display only these 9 results

Default view of New & Changed



usp USP-NF Hi, Rebecca ▼ Bookmarks ▼ [Help](#)

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

New and Changed

ALL VERSIONS ?

Filters [Clear All](#) ?

PUBLICATION

- USP42-NF37 (1)
- USP42-NF37 1S (272)
- USP42-NF37 2S (266)

MONTHLY POSTING

- 31-May-2019 - USP42-NF37 1S (32)
- 26-Apr-2019 - USP42-NF37 1S (27)
- 29-Mar-2019 - USP42-NF37 1S (20)
- 22-Feb-2019 - USP42-NF37 1S (26)

OFFICIAL STATUS

Document Results

- [0.01 M Edetate Disodium VS](#)
 E Reagents Official as of 1-Jun-2019
- [0.01 N Sodium Hydroxide VS](#)
 E Reagents Official as of 1-Mar-2019
- [0.02 M Edetate Disodium VS](#)
 E Reagents Official as of 1-Jun-2019
- [0.02 M Zinc Sulfate VS](#)
 E Reagents Official as of 1-Aug-2019

“Up” Arrow for New & Changed



ERRATA

- USP41-NF36 (39)
- USP41-NF36 1S (32)
- USP41-NF36 2S (62)
- USP42-NF37 (26)
- USP42-NF37 1S (66)
- USP42-NF37 2S (39)

RB

- USP41-NF36 (7)
- USP41-NF36 1S (13)
- USP41-NF36 2S (9)
- USP42-NF37 (9)
- USP42-NF37 1S (28)
- USP42-NF37 2S (12)

IRA

- USP41-NF36 (3)
- USP42-NF37 (5)
- USP42-NF37 2S (2)

HARM

- USP41-NF36 (1)
- USP41-NF36 1S (5)
- USP42-NF37 1S (1)

0.05 M Monobasic Sodium Phosphate TS

✓ Reagents Official as of 1-Aug-2018

0.05 N Silver Nitrate VS

✓ Reagents Official as of 1-May-2019

0.05 N Sulfuric Acid VS

✓ Reagents Official as of 1-May-2019

0.06 M Phosphoric Acid TS

✓ E Reagents Official as of 1-Jan-2018

0.1 M Monobasic Sodium Phosphate TS

✓ Reagents Official as of 1-Aug-2018

0.1 N Ammonium Thiocyanate VS

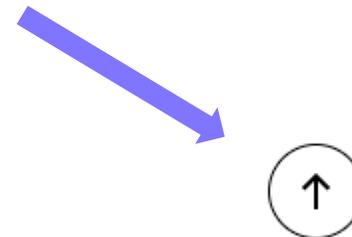
✓ Reagents Official as of 1-Aug-2019

0.1 N Ceric Sulfate VS

✓ Reagents Official as of 1-Aug-2018

0.1 N Potassium Arsenite VS

✓ Reagents Official as of 1-Aug-2019

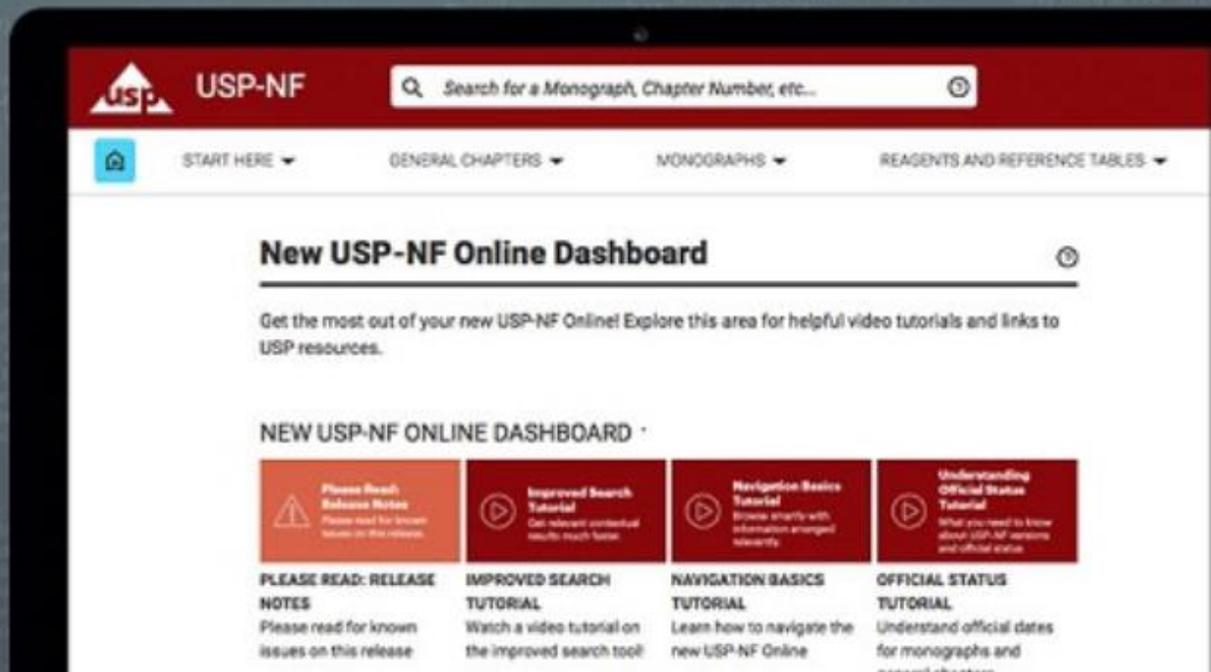
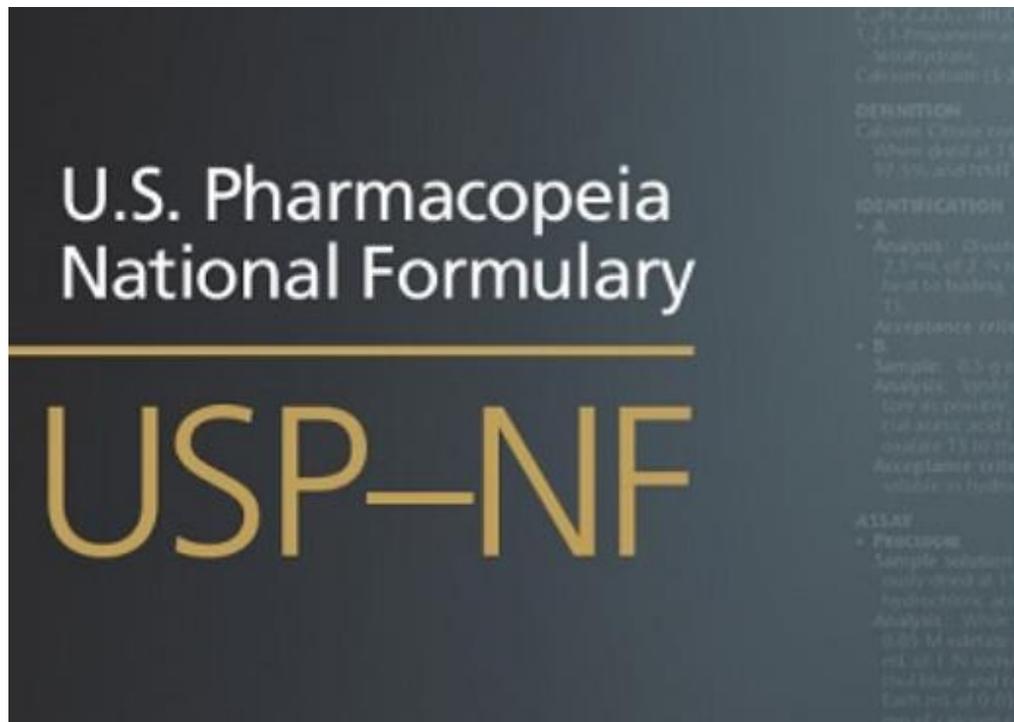


- “Up” arrow will be added

Updates for *USP–NF Online*



- Upcoming Enhancements
- **Future of print & USB formats**
- Upcoming *USP–NF Online* products



Future of Print & USB Formats



- *USP43-NF38* will be the last edition that has a print or flash drive (USB) format
 - There will be no print or USB formats for the Supplements to *USP43-NF38*
 - All current print and USB customers transitioning over to the online platform
 - Created “Referencing Guideline” along with FAQs
- Access to Archive content; planned future archive subscription

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.

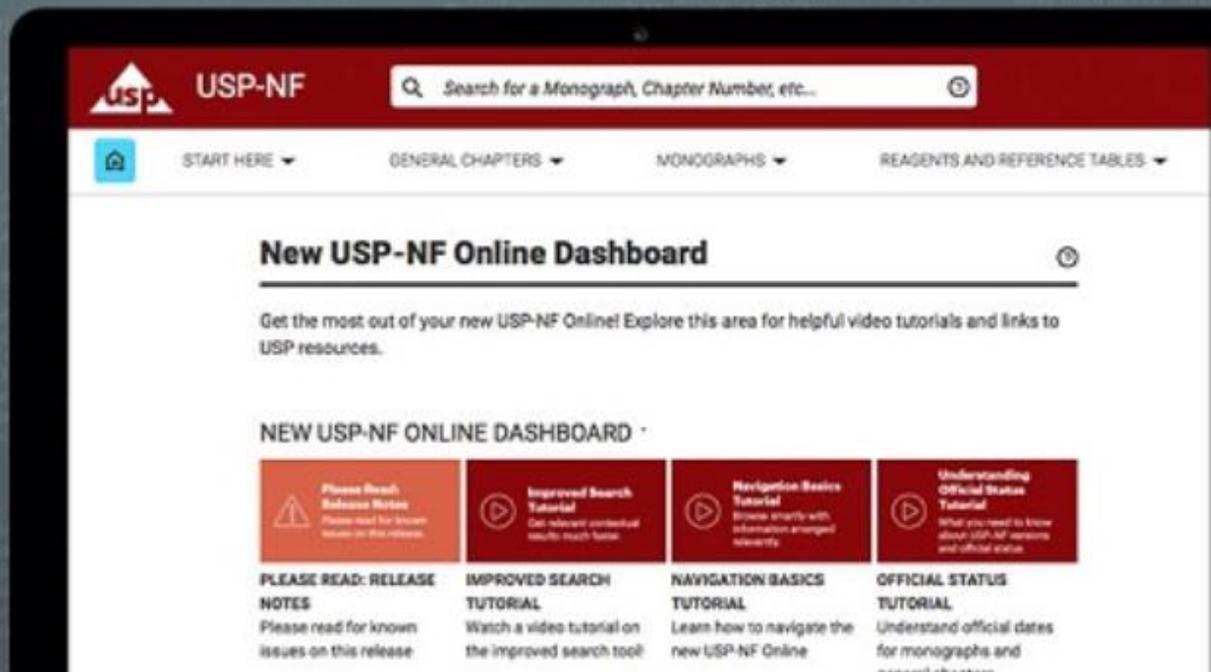
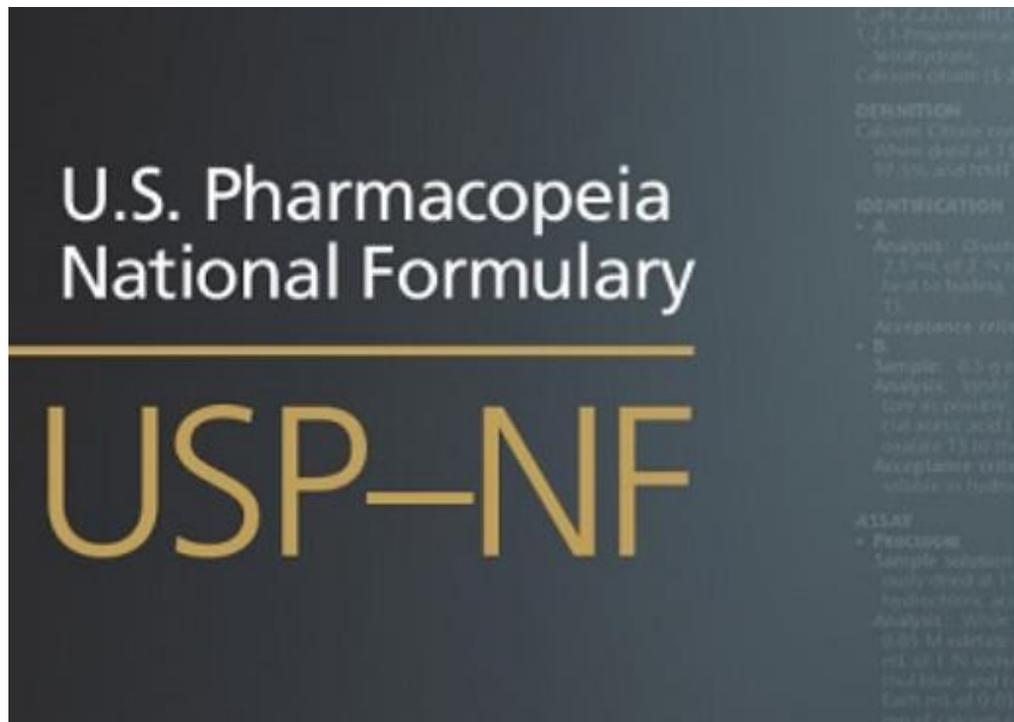
Background:

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).

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Offline Version & Mobile Interface



- Offline Version: to be launched Feb 2020
 - Will have streamlined functionality
 - Linked to a specific device
- Mobile Interface: to be launched Feb 2020
 - Will have full functionality

Launch of *Spanish USP–NF Online* in 2020



Lanzamiento de la Edición en Español de USP-NF En Línea:

Próximamente en 2020

Haga clic para más información



Thank You



Empowering a healthy tomorrow