
[Compendial Notices](#)

USP–NF Compendial Notices are designed to inform stakeholders of the changing status of *USP–NF* monographs and general chapters and other *USP–NF* standards-setting initiatives. Compendial Notices include General Announcements, Notices of Intent to Revise, and Publications Corrections.

Notices are generally posted at the end of the month, but can be posted at any time depending upon the urgency of the notice. USP posts Compendial Notices by general chapter (numerical order), then by monograph name (alphabetical order). The "New Notices" section includes the most recently posted Compendial Notices in chronological order.

Main Topics

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New Notices

- New Publication Announcement: [New USP–NF Online, USP 41–NF 36 and Supplements: Cross-reference to Chromatography <621>, Thin-Layer Chromatography](#) (posted 10–Aug–2018)
- New General Announcement: [Omission of Levodopa Capsules Monograph](#) (posted 01–Aug–2018)
- New Pending Notice of Intent to Revise: [Methylphenidate Hydrochloride Extended-Release Tablets](#) (posted 27–Jul–2018)
- New Notice of Intent to Revise: [<191> Identification Tests— General](#) (posted 27–Jul–2018)
- New Notice of Intent to Revise: [<797> Pharmaceutical Compounding— Sterile Preparations](#) (posted 27–Jul–2018)
- New Notice of Intent to Revise: [<825> Radiopharmaceuticals— Preparation, Compounding, Dispensing, and Repackaging](#) (posted 27–Jul–2018)
- New Notices of Intent to Revise: [Phytonadione](#) (posted 27–Jul–2018)
- Updated Notice of Intent to Revise: [Acetaminophen Tablets](#) (posted 27–Jul–2018)

General Announcements

General Announcements are posted on USP's website to provide *USP–NF* users with general information about the *USP–NF*, Supplements, Pharmacopeial Forum (PF), or other USP standards-setting activities.

- [<797> Pharmaceutical Compounding—Sterile Preparations to be Republished in Pharmacopeial Forum for Public Comment](#) (posted 27–Jan–2017)
- [Changes to Pending Monographs Program](#) (posted 29–May–2015)
- [Comment Deadline for Packaging General Chapters Appearing in Pharmacopeial Forum 43\(3\) Extended](#) (posted 28?Jul?2017)
- [Comment Deadline for Pharmacopeial Forum 43\(2\) Extended](#) (posted 23?May?2017, updated 18–Jul–2017)
- [Expanded Monograph Omission Initiative](#) (posted 17–Nov–2017)
- [General Chapters <232> Elemental Impurities- Limits and <2232> Elemental Contaminants in Dietary Supplements Applicable as of January 1, 2018](#) (posted 17–Nov–2017)
- [General Notices and Requirements Nomenclature of Biologics Proposal Will be Deferred](#) (posted 27–Apr–2018)
- [New USP-NF Online Launch and Delayed Implementation for Second Supplement to USP41-NF36](#) (posted 15–May–2018)
- [Notice of Publication Error: *USP 40?NF 35* Second Supplement: Timolol Maleate](#) (posted 30?Jun?2017)
- [Omission of Levodopa Capsules Monograph](#) (posted 01–Aug–2018)
- [Packaging Chapters Published in PF 44 \(3\) \[May–Jun. 2017\] to be Cancelled and Redeveloped](#) (posted 23–Feb–2018)
- [Pharmacopeial Discussion Group Working Procedure Changes](#) (posted 26–Jan–2018)
- [Publication Announcements for *USP 41–NF 36*: Reorganization of Content](#) (posted 27–Oct–2017)
- [Revision Bulletin Schedule Change](#) (posted 29?Sep?2017)
- [Stimuli Article- The Complexity of Setting Compendial Specifications for Excipient Composition and Impurities](#) (posted 27?Apr?2018)
- [*USP 40–NF 35*: General Chapter <191> Notice](#) (posted 01–Jun–2017)
- [USP Monographs Will No Longer Cite Reference Standards Required by a General Chapter as of *USP 41–NF 36*](#) (posted 18?Nov?2016)

Notices of Intent to Revise

USP provides Intent to Revise Announcements to notify users of official text that is under revision. Note: Intent to Revise notices for reference related changes are listed below in the [Reference Changes](#) section.

- [General Notices and Requirements](#) (posted 29?Sep?2017)
- [<191> Identification Tests— General](#) (posted 27–Jul–2018)
- [<476> Organic Impurities and <1086> Impurities in Drug Substances and Drug Products](#) (posted 29?Sep?2017)
- [<561> Articles of Botanical Origin](#) (posted 30–Jun–2017)
- [<795> Pharmaceutical Compounding– Nonsterile Preparations](#) (posted 30–Mar–2018)
- [<797> Pharmaceutical Compounding— Sterile Preparations](#) (posted 27–Jul–2018)
- [<825> Radiopharmaceuticals— Preparation, Compounding, Dispensing, and Repackaging](#)

(posted 27–Jul–2018)

- [<1160> Pharmaceutical Calculations in Prescription Compounding](#) (posted 25–Apr–2014)
- [<1168> Compounding for Phase I Investigational Studies](#) (posted 28?Apr?2017)
- [<2750> Manufacturing Practices for Dietary Supplements](#) (posted 29?Sep?2017)
- [Acetaminophen Oral Suspension](#) (posted 29–Jun–2018)
- [Acetaminophen Tablets](#) (posted 29–Jun–2018)
- [Amoxicillin Capsules](#) (posted 30–Mar–2018)
- [Amoxicillin Tablets](#) (posted 30–Mar–2018)
- [Cloxacillin Sodium](#) (posted 26–Feb–2016)
- [Cloxacillin Sodium Intramammary Infusion](#) (posted 23–Feb–2018)
- [Dicloxacillin Sodium](#) (posted 26–Feb–2016)
- [Diphenhydramine Hydrochloride Monographs](#) (posted 01–Feb–2016; updated 26–Feb–2016)
- [Glycine](#) (posted 01–Jun–2018)
- [Revision of Selected Insulin Family Monographs](#) (posted 27?Apr?2018)
- [Ketoconazole](#) (posted 17–Nov–2017)
- [Krill Oil](#) (posted 28?Apr?2017)
- [Methylcobalamin](#) (posted 31–Mar–2017)
- [Methylcobalamin Tablets](#) (posted 31–Mar–2017)
- [Naproxen Sodium and Pseudoephedrine Extended-Release Tablets](#) (posted 01–Jun–2018; revised 04–Jun–2018)
- [Phenylephrine Hydrochloride Monographs](#) (posted 01–Feb–2016)
- [Phytonadione](#) (posted 27–Jul–2018)
- [Theophylline Oral Solution](#) (posted 18–Nov–2016)
- [Trihexyphenidyl Hydrochloride Oral Solution](#) (posted 04–May–2016)
- [Trihexyphenidyl Hydrochloride Extended-Release Capsules](#) (posted 04–May–2016)
- [Topiramate](#) (posted 26–Aug–2016)
- [Witch Hazel](#) (posted 30–June–2017)

Notices of Intent to Revise: Pending Monograph Program

For more information please see the [Pending Monograph Program webpage](#)

- [Metoprolol Succinate Extended-Release Tablets](#) (posted 26–Jan–2018)
- [Metformin Hydrochloride Extended-Release Tablets](#) (posted 29–Jun–2018)
- [Methylphenidate Hydrochloride Extended-Release Tablets](#) (posted 27–Jul–2018)
- [Penacillamine Capsules](#) (posted 27?Apr?2018)
- [Propafenone Hydrochloride Extended-Release Capsules](#) (posted 27?Apr?2018)

General Chapter Prospectus

As part of a pilot process, USP Expert Committee members will develop a brief prospectus for new general chapters or major general chapter revisions prior to their publication in Pharmacopeial Forum (PF). The purpose of these is to solicit input during the early stages of general chapter development. The input received from the prospectus process will be considered as advisory only. Formal comments on subsequent PF proposals must be submitted separately at the time of publication in PF.

Below is a listing of the currently active general chapter prospectus notices:

- [New Proposed Chapter: <1085> Guidelines on Endotoxins Test](#) (posted 26–Jan–2018)
- [New Proposed Chapter: Evaluating Screening Technologies for Assessing Medicine Quality](#) (posted 29–Dec–2017)
- [New Proposed Chapter: Supplier Qualification by User of Upstream Supply Chain for Pharmaceutical Excipients](#) (posted 30–Mar–2018; deadline 30–Apr–2018)
- [<541> Titimetry](#) (posted 29?Sep?2017)
- [<825> Compounding—Radiopharmaceuticals](#) (posted 01–Jun–2017; deadline 31–Aug–2017)
- [<922> Water Activity](#) (posted 30–Mar–2018; deadline 30–Apr–2018)
- [<1711> Oral Solid Dosage Forms - Dissolution Testing](#) (posted 29?Sep?2017)
- [<1788> Methods for the Determination of Particulate Matter in Injections and Ophthalmic Solutions](#) (posted 30–Mar–2018; comment deadline 30–Apr–2018)
- [<2740> Manufacturing Practices for Dietary Ingredients](#) (posted 29?Sep?2017)

Reference Changes

USP and its Expert Committees periodically deem it necessary to modify general chapter titles or similar text that may be referenced in other standards throughout the *USP–NF*. When this occurs, USP staff undertakes a rigorous process for identifying and updating such references. These updates may occur through a routine revision, or, in cases in which an update appears to present no significant change in the affected standard, through a direct update of the reference in that standard without providing an opportunity for notice and comment. In all cases, USP will publish on its website a notice indicating the source change, any resulting references, and whether those references will be updated through a routine revision or a direct update. Below is a listing of these notices and related information. Updates made through direct publication in the *USP–NF* will be clearly identified by symbols and shading in the print and electronic publications.

- [Changes to General Chapter Format and General Chapter Reference Format](#) (posted 31–Jul–2015)
- [Clean-up of General Chapter References in *USP 39–NF 34*](#) (posted 31–Jul–2015; updated 28–Aug–2015)
- [Clean-up of General Chapter References in *USP 40–NF 35*](#) (posted 28–Oct–2016)
- [Monographs and GCs Affected by Revision to GC <1> Injections](#) (posted 31–Jul–2015)
- [Monographs Affected by Revision to General Chapter <191> Identification Tests – General](#) (posted 16–Mar–2015)
- [Monographs Affected by Revision to <191> Identification Tests– General](#) (posted 27–Oct–2017)
- [Monographs and GCs Affected by Revisions to GC <231> Heavy Metals Revision Bulletin](#) (posted 27–Mar–2015; official 01–Apr–2015; updated 12–May–2015)
- [Monographs Affected by Revision to Revision to <345> Assay for Citric Acid/Citrate and Phosphate](#) (posted 27–Oct–2017)
- [Monograph Affected by the Revision of <531> Thiamine Assay](#) (posted 28–Oct–2016)
- [Monographs Affected by Revision to <591> Zinc Determination](#) (posted 27–Oct–2017)
- [Monographs Affected by Revision to <659> Packaging and Storage](#) (posted 28–Oct–2016)
- [Monographs and GCs Affected by Revisions to GC <601>](#) (posted 25–Apr–2014)
- [Monographs and GCs Affected by Revision to GC <661> Containers—Plastics](#) (posted 31–Jul–2015)
- [Monographs and GCs Affected by Revision to General Chapter <659> Packaging and Storage Requirements](#) (posted 24–Apr–2015)
- [Monographs Affected by Revision to <659> Packaging and Storage](#) (posted 28–Oct–2016)
- [Monographs Affected by Revision to <821> Radioactivity](#) (posted 28–Oct–2016)

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- [Monographs Affected by Revision to <1211> Sterility Assurance](#) (posted 27–Oct–2017)
 - [Monographs and General Chapters Affected by Revision to General Notices](#) (posted 27–Oct–2017)
 - [New Revision Markup for Reference Changes in USP–NF](#) (posted 25–Jul–2014)

Publications Announcements

- [Addition of UNII Codes in USP 40–NF 35 Online](#) (posted 28–Oct–2016)
- [First Supplement to USP 39–NF 34 Online: Errata Icon for GC <661.1>](#) (posted 27–May–2016)
- [Integration of Accelerated Revisions into USP–NF Online](#) (posted 18–Jun–2018)
- [June 2016 and April 2016 USP–NF Errata Postings](#) (posted 10–Jun–2016)
- [June 2016 USP–NF Errata Posting](#) (posted 24–Jun–2016) [USAN 2016](#) (posted 19–Aug–2016)
- [New USP–NF Online Launch and Delayed Implementation for Second Supplement to USP41–NF36](#) (posted 15–May–2018)
- [New USP–NF Online, USP 41–NF 36 and Supplements: Cross-reference to Chromatography <621>, Thin-Layer Chromatography](#) (posted 10–Aug–2018)
- [Pharmacopeial Forum 43\(4\) \[Jul.–Aug. 2017\]: Climbazole](#) (posted 09–Nov–2017)
- [Pharmacopeial Forum 44\(2\) \[Mar.–Apr. 2018\] Phytonadione Compounded Oral Suspension and Pyridostigmine Bromide Extended-Release Tablets](#) (posted 23–Mar–2018)
- [Pharmacopeial Forum 44\(3\) \[May–Jun. 2018\]: Eriochrome Black T](#) (posted 6–Jul–2018)
- [Removal of 3D Chemical Structures in USP–NF Online](#) (posted 28–Oct–2016)
- [Second Supplement to USP 39–NF 34 Online: Greek Symbols](#) (posted 24–Jun–2016)
- [Stage 4 Harmonization \[April 2018\]: Methylcellulose](#) (posted 01–Jun–2018)
- [Update to Style for Latin Binomials for USP 40–NF 35](#) (posted 28–Oct–2016)
- [USP 41–NF 36 Online Table of Contents: Admissions](#) (posted 17–Nov–2017)
- [USP Compounding Compendium](#) (posted 05–Feb–2016)
- [USP–NF Errata Table Correction](#) (posted 04–Oct–2017)
- [USP–NF Revision Symbols](#) (posted 23–Feb–2018)

USP–NF Redesigned Monographs

The downloadable Excel file below lists titles of monographs appearing in an official publication (*USP–NF* or Supplement) in the redesigned format. Monographs are redesigned either through USP’s revision process in the Pharmacopeial Forum (PF), accelerated revision, or as part of USP’s ongoing redesign process. The list can be sorted by monograph type, Expert Committee designation, or publication vehicle in which the monograph initially appeared in the redesigned format. This list is updated with the publication of each new *USP–NF* and Supplement. Currently, some drug substance monographs do not include the chemical structure of the article or may incorrectly include a structure in a dosage form monograph. As part of the redesign effort, the chemical structure of the article is being deleted or added to these monographs as an editorial change.

For questions regarding the redesign process, email redesign@usp.org.

- [List of monographs appearing in redesigned format as of USP 41–NF 36 2S](#) (posted 18–Jun–2018)
- [List of monographs appearing in redesigned format as of USP 41–NF 36 1S](#) (posted 26–Jan–2018)
- [List of monographs appearing in redesigned format as of USP 41–NF 36](#) (posted

