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Mission and Preface

This section provides background information on the United States Pharmacopeial Convention (USP), as well as general information about the *United States Pharmacopeia* and the *National Formulary (USP–NF)*. Whether a document is official or not official is not linked to when a specific publication becomes official, but is based on the individual document. USP publishes the *USP–NF* on a set schedule, and each individual document is associated with its indicated official date. Learn more about USP's document-centric official dates on our website (www.uspnf.com/new-uspnf-online-faqs/end-user#irg1).

MISSION STATEMENT

USP–NF is published in continuing pursuit of the mission of USP: *To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.*

HISTORY

USP has a rich history, dating back to 1820, when 11 physicians met in the Senate Chamber of the U.S. Capitol building to establish a pharmacopeia for the United States. Learn more about USP's history and major milestones on the USP website (<https://www.usp.org/about/usp-timeline>).

CONTENT OF USP–NF

USP–NF contains official substance (ingredient) and product monographs for official articles recognized in *USP–NF* (see [General Notices 2.20 Official Articles](#)). *USP–NF* also includes monographs for compounded preparations. With few exceptions, such as articles covered by *Global Health* monographs, the intent is that all articles for which monographs are provided in *USP–NF* are legally marketed in the United States or are contained in legally marketed articles. *Global Health* monographs are provided for articles that are not approved or legally marketed in the United States, but that have been approved by a stringent regulatory authority [as defined by the World Health Organization (WHO)] and are used for essential purposes in other parts of the world (see [General Notices 3.10.40 Applicability of Global Health Monographs](#)).

A *USP–NF* monograph for an official substance, product, or preparation may consist of various components, including the article's name; definition; packaging, storage, and other requirements; and a specification. General chapters provide frequently cited procedures, sometimes with acceptance criteria, in order to compile into one location repetitive information that is applicable to many monographs. See [General Notices 3.10 Applicability of Standards](#) for more information about standards contained in *USP–NF* monographs and general chapters.

The *USP Admissions List* section of the *USP–NF* indicates those new and revised monographs and general chapters as well as any omissions that published on a specific delivery date.

Revisions to *USP–NF*—*USP–NF* is continuously revised by an exceptional process of public involvement and substantial interaction between USP and its stakeholders, both domestically and internationally. Revisions are presented in the *USP–NF* three times per year in November, February, and June. *Accelerated Revisions* [including *Errata*, *Interim Revision Announcements (IRAs)*, and *Revision Bulletins*] are published periodically and with greater frequency.

Regular Revisions—USP's regular revision process calls for publication of a proposed revision in the *Pharmacopeial Forum (PF)* for a 90-day notice and comment period and, after the revision is approved by the relevant USP Expert Committee, publication in the *USP–NF*.

Accelerated Revisions—The *Accelerated Revision* process is used to make revisions to *USP–NF* official more quickly than through USP's *Regular Revision* process. Learn more about accelerated revisions and the criteria for and implementation thereof on the USP website (<http://www.uspnf.com/official-text>).

Modification of Compendial References—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 undertake a rigorous process for identifying and updating such references. These updates may occur through a regular 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 regular revision or a direct update.

Updating Chemical Information—Updates to the *Chemical Information* section at the beginning of monographs occur on an ongoing basis. Chemical names and molecular weights may also be reviewed and updated when a monograph undergoes revision to match the *United States Adopted Names (USAN)* or the original source of chemical information. Chemical structures are updated on a continuous basis. Chemical names typically reflect the naming conventions at the time of the monograph development or revision. If the nomenclature rules of CAS or IUPAC are significantly changed, the chemical names can be revised or added to implement those rules. Molecular weights are derived from the chemical formula and are based on the table of atomic weights as published by the IUPAC.

recommended values are changed to reflect the isotopic composition of normal terrestrial material, it is understood that the changes in molecular weights will be made in due course.

Graphical representation of the chemical compound structures is intended as a visual aid to help establish chemical identity and is understood to represent one of many possible ways to depict the molecule. Addition of a graphical representation or changes in such representation, that result in the same chemical information, e.g., a flipped chiral molecule or adding a molecule structure, may be introduced outside of the revision process. It is also understood that in the case of tautomerism, the molecule depicted may be one of the tautomers, but it is intended to represent all isomers in equilibrium. Stereogenic centers depicted with plain bonds imply mixtures of pertinent stereoisomers—enantiomer, diastereoisomers, epimers (anomers), etc. (see [General Notices 3.10 Applicability of Standards](#)).

Shading and Symbols—Shading is used to identify text that has been modified, added, or deleted since it was last published. Symbols identify the beginning and end of each revision or nonharmonized text. The following table summarizes the types of symbols and the associated subscripts used in USP publications:

Revision Type	Revision Symbol and Text
In Process Regular Revision	▲ (USP 1-May-2025)
	▲ (NF 1-May-2025)
	▲ (GH 1-May-2025)
Interim Revision Announcement	▲ (IRA 1-Jul-2025)
Revision Bulletin	▲ (RB 1-Jul-2025)
Harmonization	◆
Errata	▲ (ERR 1-Jul-2025)
Chapter References	▲ (CN 1-Jul-2025)
	▲ (Official 1-Jul-2025)
Pending	▲ (TBD)

Commentary—For revisions that are published for public review and comment in *PF*, the proposal may advance to official status or be republished in *PF* for further notice and comment. If comments are received, they are considered and incorporated as appropriate by the Expert Committee(s). In cases where proposals advance to official status without republication in *PF*, a summary of comments received and the appropriate Expert Committee's responses are published in the *Commentary* section of the USP website at the time the revision is published (see [Rules and Procedures of the 2020-2025 Council of Experts, Section 9.05 Publication in the Pharmacopeial Forum](#)).

The *Commentary* is not part of the official text and is not intended to be enforceable by regulatory authorities. Rather, it explains the basis of the Expert Committee's response to public comments. If there is a difference between the contents of the *Commentary* and the official text, the official text prevails. In case of a dispute or question of interpretation, the language of the official text, alone and independent of the *Commentary*, shall prevail.

USP-NF Presentations—See [General Notices 2.10 Official Text](#) for more information about USP-NF product formats. The USP-NF is available online. USP43–NF38 (published November 1, 2019) was the last publication made available in print or on a flash drive.

USP-NF Translations—Translations of the USP-NF are available in Spanish, Russian, and Chinese. The Spanish translation is current; other translations are based on previous revisions of the USP-NF.

USP Reference Standards—The use of USP Reference Standards promotes uniform quality of drugs and supports reliability and consistency by those performing compliance testing and other users of USP-NF, including manufacturers, buyers, and regulatory authorities. USP Reference Standards are referenced in specific procedures in both monographs and general chapters. USP advances this material via careful characterization studies and collaborative testing, followed by review and approval of the compendial use of the reference material by Expert Committees of the Council of Experts. This program benefits from the widespread voluntary contribution of suitable materials and test data from pharmaceutical manufacturers. The *USP Catalog*, which lists the collection of USP Reference Standards, and more information about use and storage, can be accessed on USP's website (<https://www.usp.org/reference-standards/reference-standards-catalog>).

USP GOVERNING, STANDARDS-SETTING, AND ADVISORY BODIES

USP's governing, standards-setting, and advisory bodies include the USP Convention, the Board of Trustees, the Council of Experts and its Expert Committees, Expert Panels, Subcommittees, Joint Standard-Setting Subcommittees, and staff. Learn about the composition and