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Compounded Preparation Monographs

What is a USP Compounded Preparation Monograph (CPM)?

A USP CPM is an official documentary standard which provides specific formulations for human and animal patients for whom there are no suitable conventionally manufactured products available.

USP Compounded Preparation Monographs include the following:

- Formuxlas (ingredients and quantities)
- Beyond-use dates based on stability studies
- Acceptable pH ranges
- Directions to correctly compound the preparation
- Packaging and storage information
- Stability-indicating assays

These monographs appear in the *USP–NF* and in the *USP Compounding Compendium*.

Process for Developing a Compounded Preparation Monograph for the *USP–NF*

The compounded preparation monograph development process begins with a request for the development of a new monograph or a revision to an existing compounded preparation monograph coupled with a submission of scientific data (raw data and summaries) supporting the request. The process culminates with approval by the USP Compounding Expert Committee and publication in the *USP–NF*.

- Data Review
- Monograph Draft Published in Pharmacopeial Forum
- Monograph Finalized
- Monograph Draft Written
- Public Comment Period (90 days)

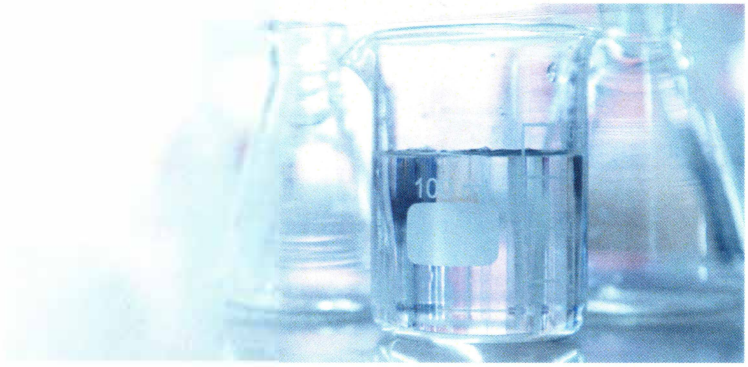
Criteria for Prioritizing USP Compounded Preparation Monographs

USP applies the following criteria to prioritize formulas for compounded preparation monograph development:

- Public health impact (i.e., affecting major population groups, disease states, access needs) or frequently on drug shortage
- Essential to treat pediatric, geriatric, and veterinary patients where there are unmet needs
- Need to be formulated to avoid allergic reactions and to be suitable for administration to patients with specific genetic anomalies

USP will **not** develop compounding monographs for:

- Preparations with insufficient information to support clinical use
- Preparations using bulk drug substances that do not have a *USP–NF* monograph and are not a component of an FDA-approved human drug product, if the drug substance does not appear on a list of bulk drug substances developed by FDA regulation
- Preparations for human use containing drugs on the FDA Do Not Compound List



How are Beyond-Use Dates (BUDs) in CPMs established?

The BUDs in USP CPMs are based on quality attributes (e.g., sterility, antimicrobial effectiveness) and a stability study supported by a stability-indicating assay specifically developed and validated for the compounded formulation using the criteria described in General Chapter Validation of Compendial Procedures.

The BUDs stated in USP Chapters and are often referred to as "BUD limits," meaning that these BUDs can be applied in the absence of stability information, unless otherwise indicated (e.g., drugs or chemicals known to be more liable to decomposition will require shorter BUDs). Where the requirements in a CPM differ from an applicable general chapter, the monograph requirements apply and supersede the general chapter (see General Notices 3.10. Applicability of Standards).

USP is requesting for **donations of scientific data** to develop compounded preparation monographs for the *USP–NF*.

Donate Today

To leverage existing science and support public health needs, USP invites interested parties to participate in the **donations of scientific data** to develop compounded preparation monographs for the *USP–NF*.

Compounded preparation monograph donations can be submitted to USP for consideration by contacting the program manager via email at CompoundingSL@usp.org.

Critical Information to Submit

- **Title:** proposed name of the monograph including the type of formulation. (*e.g.*, Metronidazole Benzoate Compounded Oral Suspension)
- **Formulas:** ingredients (including manufacturer) and their specific quantities
- **Compounding procedures**
- **Stability indicating assay:** validation based on the acceptance criteria described in General Chapter <1225> *Validation of Compendial Procedures*
- **Stability testing results:** to establish a beyond-use date
- **Specific tests such as:** <791> *pH;* <51> *Effective Testing;* <71> *Sterility Tests;* <85> *Bacterial Endotoxin Tests;* <788> *Particulate Matter in Injections;*
- *Packaging, Labeling and Store Instructions*

Confidentiality and Intellectual Property

USP has established policies and rules that provide safeguards to confidential information submitted by donors during the course of the monograph development or revision process. USP's confidentiality policies and the Council of Experts rules require both USP expert volunteers and staff involved in USP's standards-setting process to maintain the confidentiality of information submitted to USP by a third party. A copy of these rules is available on request.

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