



Compounded Preparation Monograph Donation Program

Program Overview

USP is soliciting donations of scientific data to develop compounded preparation monographs for the *USP–NF*. Compounded preparation monographs contain formulas, preparation procedures, assays, testing methods and stability data, which assist practitioners in compounding preparations for patients when there are no suitable alternatives.

USP has provided monographs for compounded medicines since 1820. Since 2012, USP has invested more than \$1,400,000 in developing monographs for compounded formulations to protect the public health. Today, compounding preparation monographs are based on extensive studies of the quality and stability of the formulations.

DONATE TODAY

To leverage existing science and support public health needs, USP invites interested parties to participate in the donation program.

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

What information should be submitted?

- 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 Storage Instructions

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*.

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.

Criteria for Prioritizing USP Compounded Preparation Monographs

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

- Medications with the highest public health impact (i.e., affecting major population groups, disease states, and access needs)
- Medications essential to treat pediatric and geriatric patients where there are unmet needs
- Medications that need to be formulated to avoid allergic reactions and to be suitable for administration to patients with specific genetic anomalies
- Medications for currently unmet clinical and therapeutic needs.

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