



Checklist for Submitting Requests for Revision to the *USP-NF*

This checklist can be used to prepare submission packages for new monographs and requests for revisions to existing monographs. For detailed information, please consult the *Guideline for Submitting Requests for Revision to the USP-NF* available on our website at <http://www.usp.org/USPNF/submitMonograph/subGuide.html>.

Approval Status

- Finished Dosage Form Monograph: indicate approval status (e.g., approved or tentatively approved ANDA, pending approval, etc)
- Drug Substance Monograph: indicate if it has been included in an approved application or an application seeking/planning to seek FDA approval
- Excipient Monograph: indicate if it is included in the FDA Inactive Ingredient Database or if it has a GRAS designation
- If the product is not approved by the US FDA but is approved in other countries, please indicate in which countries the product is approved

Monograph Content

- Include the list of proposed tests, procedures and acceptance criteria
Note: It is not a requirement to submit a draft monograph or revision written in the USP style.

Chemical Information

For the proposed article (e.g., drug substances, excipients) and each related compound.

- Chemical names
- Chemical structure
- Molecular formula
- Molecular weight
- CAS No. (if known)

Supporting Data.

- Include validation data/report(s). This is required for any procedure developed and validated by the sponsor company. Typically includes chromatographic procedures for *Assay* and *Related compounds* tests validated per <1225> *Validation of Compendial Methods* and current FDA/ICH guidelines.
- If validation or verification data are available for general chapter tests (e.g., Residue on Ignition, Water, Heavy Metals, etc), then please include in the submission.
- Include representative spectra (e.g, IR, UV) for spectrophotometric procedures
- For chromatographic procedures:
 - Include representative chromatograms (e.g., standard solution, test solution, system suitability solution, related compounds, etc)
 - Include the brand name of the chromatographic column used for the validation
 - Include forced degradation/stability data to support stability-indicating procedures

- **Certificates of Analysis (COA)** Include COAs for at least three production-scale lots/batches. If COAs are not available, data can be submitted in a summary table or other convenient format.

Packaging and Storage

- Include packaging and storage recommendations (e.g., preserve in tight containers and store at controlled room temperature)
- Include any special handling instructions (e.g. store under nitrogen, do not freeze, etc.)
- Proposed finished dosage form monographs: include a copy of the approved package insert.

Labeling Information

- Include monograph-specific labeling requirements regarding safety and handling of the product (e.g., must be diluted before use, must be shaken before use, indicate if it is of plant or animal origin, etc)

Description and Solubility Information/NF Category.

- Proposed drug substance or excipient monographs: include a description and solubility entry (e.g, white to off-white powder freely soluble in methanol).
- Proposed excipient monograph: include an NF Category (e.g., acidifying agent, antioxidant, tablet binder, etc). More than one category may be assigned.

Reference Standards

- Please indicate if willing to donate the reference standard material(s) to support the proposed procedure(s). See *USP Guidelines for RS Suppliers Aug 21, 2004* for additional information
- Please indicate the name and lot number of any USP Reference Standard(s) used in the development and validation of any the proposed procedures.