

**USP Guideline for Submitting Requests for Revision to *USP-NF***  
***V3.1 April 2007***

**REVISION HISTORY**

**Version 3.1 April 2007**  
**Summary of Changes Made From Version 3 January 2007**

**TEMPLATES**

- A new template for Metered Dose Inhalers was added.

**Version 3 January 2007**  
**Summary of Changes Made From Version 2 September 2005**

**INTRODUCTION**

- Reference to the *Rules and Procedures of the 2005-2010 Council of Experts* was added
- Reference to the USP Intellectual Property Policy was added
- Explanation of SAPFA (Standards for Articles Pending FDA Approval) monographs was added
- Explanation of the USP Flexible Monograph policy was added

**GLOSSARY**

- Minor changes were made to some of the terms

**CHAPTER TITLES**

- “Noncomplex” was replaced by “Small Molecules” throughout the Guideline
- “Biologicals/Biotechnologicals” was replaced by “Biologics and Biotechnology” throughout the Guideline

**CHAPTER 1 SMALL MOLECULES SUBSTANCES AND PRODUCTS**

The following major revisions were made and apply to both drug substances and drug products:

**Labeling**

- New information regarding the flexible monograph policy was added

**Impurities**

- ICH reporting format (e.g., the number of decimal places) and terminology were added

**Organic Impurities**

- A reference to the USP policy of Relative Response Factors was added

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- Possible inclusion of a Quantitative Limit Solution was added

**Residual Solvents**

- An explanation that all drug substances and products are subject to the relevant control of residual solvents even when no test is specified in the monograph was added.

**New Monographs for a Drug Product**

**Official Title**

- An explanation that the title of a dosage form formulated with the salt of an acid or base shall be the same as that used in the expressing the strength of the article in the *Assay* was added.

**Microbial Limits Test**

- A reference to ICH Q6A was added

**TEMPLATES**

**Revised Templates**

- The templates for Drug Substance, Excipient, and Tablet and Capsule monographs were revised to include tables for gradient elution and presentation of data for impurities such as relative retention time and relative response factors. Minor editorial changes were made.

**New Templates**

- Cream and Ointment
- Injection and For Injection
- Oral Solution and Suspension
- Topical Lotion and Suspension
- Transdermal Delivery System