Commentary – *Pharmacopeial Forum 34(3)* May-June 2008
Interim Revision Announcements to *USP 31-NF 26*
Revised June 30, 2008

Revision proposals published in *Pharmacopeial Forum* often elicit public comments that are forwarded to the appropriate Expert Committee for review and response. In accordance with the Rules and Procedures of the 2005-2010 Council of Experts, revision proposals can advance to official status with minor modifications, as needed, without requiring further public review. In such cases 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 becomes official. For those proposals that require further revision and republication in *Pharmacopeial Forum*, a summary of the comments and the Expert Committee's responses will be included in the briefing that accompanies each article.

The *Commentary* section is not part of the official text of the monograph 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* section and the official monograph, the text of the official monograph prevails. In case of a dispute or question of interpretation, the language of the official text, alone and independent of the *Commentary* section, shall prevail.

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Monograph/Section(s): Alendronate Sodium Tablets/Labeling, Dissolution
Expert Committee(s): Biopharmaceutics
No. of Commenters: 0
Reason for Revision: The *Dissolution* test is revised to add a second procedure. The previous procedure is changed to indicate it is “TEST 1” and the new procedure is titled “TEST 2”. In addition, the *Labeling* section has been revised to indicate that users must indicate which *Dissolution* test they use if they are not using Test 1.

Monograph/Section(s): Cefotetan Disodium/Water
Expert Committee(s): Monograph Development – Antibiotics
No. of Commenters: 0
Reason for Revision: The limit in the test for *Water* was revised from not more than “1.5%’’ to ‘‘2.5%’’. This limit is representative of current marketed product.

Monograph/Section(s): Cefotetan for Injection/Water
Expert Committee(s): Monograph Development – Antibiotics
No. of Commenters: 0
Reason for Revision: The *Other requirements* section was revised to remove reference to the drug substance monograph. A test for *Water* was added with a limit of ‘‘not more than 2.8%’’. This limit is representative of current marketed product.

Monograph/Section(s): Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets/Labeling, Dissolution
Expert Committee(s): Biopharmaceutics
No. of Commenters: 0
Reason for Revision: The *Dissolution* test is revised to add a second procedure. The previous procedure is changed to indicate it is “TEST 1” and the new procedure is titled “TEST 2”. In addition, the *Labeling* section has been revised to indicate that users must indicate which *Dissolution* test they use if they are not using Test 1.

Monograph/Section(s): Indium In 111 Chloride Solution/Radiochemical purity
Expert Committee(s): Radiopharmaceuticals and Medical Imaging Agents
No. of Commenters: 0
Reason for Revision: The monograph revision modernized the test for *Radiochemical purity* by replacing the paper chromatography method with an instant thin-layer chromatography method.

Monograph/Section(s): Meloxicam Tablets/Dissolution
Expert Committee(s): Biopharmaceutics
No. of Commenters: 0
Reason for Revision: *Dissolution* was added to the monograph requirements and is based on current approved marketed product conditions.

Monograph/Section(s): Nystatin Oral Suspension/Uniformity of dosage units
Expert Committee(s): Monograph Development – Antibiotics
No. of Commenters: 0
Reason for Revision: The monograph was changed because there was a discrepancy between the text in the Nystatin Oral Suspension monograph and General Chapter <905> Uniformity of Dosage Units. The reference in the monograph to section (B)(3) of the General Chapter was deleted as this section does not exist in the currently official version of <905>.

Monograph/Section(s): Pantoprazole Sodium/New Monograph
Expert Committee(s): Monograph Development – Gastrointestinal, Renal, and Endocrine
No. of Commenters: 4
Reason for Revision: This new monograph previously appeared for public comment as both a Pending Standard and Proposed IRA. Based on comments received the following changes were made to reflect the requirements for all approved marketed product:

1. The *Water* test limit was changed from between "6.0% and 8.0%" to "5.0% and 8.0%".
2. A second test for *Related compounds* was added. A Hypersil ODS brand of L1 column was used in method validation. The pantoprazole peak displayed a typical retention time of about 11 minutes.
3. The *Labeling* section has been revised to indicate that users must indicate the *Related compounds* test they use if they are not using Test 1.
4. The limit of Related compound A under *Test 1* of *Related compounds* was changed from not more than "0.15%" to "0.20%"

Monograph/Section(s): Pantoprazole Sodium Delayed-Release Tablets/New Monograph
Expert Committee(s): Monograph Development – Gastrointestinal, Renal, and Endocrine
No. of Commenters: 4
Reason for Revision: This new monograph previously appeared for public comment as both a Pending Standard and Proposed IRA. Based on comments received the following changes were made to reflect the requirements for all approved marketed product:

1. The *Dissolution* test is revised to add 2 additional procedures. The original proposed procedure is changed to indicate it is "TEST 1" and the new procedures are titled "TEST 2" and "Test 3", respectively. A Hypersil BDS C18 brand of L1 column was used in Test 3 method validation with the pantoprazole peak having a typical retention time of about 22 minutes.
2. The *Labeling* section has been revised to indicate that users must indicate which *Dissolution* test they use if they are not using Test 1.
3. Test 1 under *Dissolution* has been corrected to indicate that the analyst should follow the instruction in *Method B* under *Apparatus 1 and Apparatus 2* as indicated in General Test Chapter <711> Dissolution; Procedure; Apparatus 3 (Reciprocating Cylinder); Delayed-Release Dosage Forms.
4. The *Chromatographic purity* test limits were revised based on the current approved marketed products' conditions. The limit for Related compound A is changed from not more than "0.3%" to "0.5%", the total impurities limit is increased from not more than "0.7%" to "1.0%", and a 0.5% limit was added for Pantoprazole Related compounds D and F.