Commentary – *Pharmacopeial Forum 34(4)* July-August 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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Pharmacopeial Forum 34(4)

Monograph/Section(s): Diclofenac Potassium Tablets/Dissolution, Assay, Limit of Potassium
Expert Committee(s): Biopharmaceutics**,** Monograph Development – Cough, Cold, and Analgesics
No. of Commenters: 0
Reason for Revision: Monograph revisions were made to reflect the current approved marketed product requirements and are as follows:

1. The concentration of the *Standard preparation* in the *Assay* procedure was changed from “50 µg per mL” to “0.5 mg per mL”.
2. The Loss on drying test was deleted because the result was demonstrated to be formulation specific.

3. The *Limit of potassium* test was deleted because the weight percentage requirements in the test were formulation specific and the requirement is not applicable to all marketed product. In addition, some products may have potassium in the excipient matrix that could interfere with the test results.
4. The impurity limits in the *Related compounds* test were revised. The diclofenac related compound A limit was changed from not more than “0.1%” to “0.5%”, the total impurities limit was changed from not more than “0.3%” to “1.5%”, and the individual impurities limit was changed from not more than “0.1%” to “0.5%”. In addition, the *Standard solution* concentration was changed from “50 µg per mL” to 2.5 µg per mL” to be consistent with the revised impurity limits.
5. The Dissolution test Tolerances were revised from not less than “80%” to “75%” to be consistent with the current approved marketed products.

Monograph/Section(s): Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets/Related compounds, Identification test C
Expert Committee(s): Monograph Development – Pulmonary and Steroids
No. of Commenters: 0
Reason for Revision: The limit for "any other impurity" is being revised from not more than “0.1%” to “0.2%” and the limit provided for "total other impurities" is being deleted from the *Related compounds* test. The notation ‘‘For Nonbilayer Tablets’’ under *Identification test C* is deleted because the test is applicable to both bilayer and nonbilayer tablets.

Monograph/Section(s): Fludeoxyglucose F 18 Injection/Chemical purity
Expert Committee(s): Radiopharmaceuticals and Medical Imaging Agents
No. of Commenters: 0
Reason for Revision: The expression of the limit of fludeoxyglucose related compound B was changed to be consistent with technological changes that allow for multi-dose batches of product.

Monograph/Section(s): Valproate Sodium Injection/Title
Expert Committee(s): Monograph Development – Psychiatrics and Psychoactives
No. of Commenters: 0
Rationale for IRA: The IRA was initiated to revise the title of the monograph from “Valproic Acid Injection” to “Valproate Sodium Injection” to be consistent with the USP *Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations*.