

**Commentary – *Pharmacopeial Forum* 34(5) September-October 2008
Interim Revision Announcements to USP 31-NF 26
Revised August 1, 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): Bupropion Hydrochloride Extended-Release Tablets
Expert Committee(s): Biopharmaceutics, Monograph Development – Psychiatric and Psychoactives
No. of Commenter(s): 0
Comment Summary: No comments received.
Reason for Revision: Revisions were made as follows:
1. To replace bupropion related compound E with the actual chemical name, l(3-chlorophenyl)-1,2-propanedione.
2. Add a *Dissolution test* to this monograph for a generic product approved by the FDA.

Monograph/Section(s): Carvedilol / Related compounds -Test 2
Expert Committee: Monograph Development - Cardiovascular
No. of Commenters: 1
Comment Summary: The commenter requested to clarify the type of the chromatographic column used in the *Related compounds Test 2* as the chromatographic reagents section has not been updated with a suitable description to this new column.

Response: Comment incorporated and the chromatographic system under *Test 2* is revised where the “L##” is replaced with “an appropriate column designation”. A footnote is also added to provide the source of an appropriate column and is stated as follows: “A suitable column is Suplex pKb-100 manufactured by Suplex (www.sigma-aldrich.com).”

Reason for Revision: Monograph revisions were made to reflect the comments from other manufacturers and are as follows:

1. The percentage of assay limits stated in the definitions was changed from 99.0%-101.0% to 98.0%-102.0% to represent the marketed products.
2. The use of a flexible monograph approach to enable manufacturers to perform either *Test 1 or Test 2* for related compounds based on the labeling instructions and impurity profile.
3. The addition of a labeling statement due to the flexible monograph approach.
4. Addition of *Test 2* in the Related compounds test to indicate the use of a new reference standard.
5. The addition of a test for the Limit of Carvedilol related compound F to quantify the carvedilol related compound F.

Monograph/Section(s): Carvedilol Tablets / Identification test B

Expert Committee(s): Biopharmaceutics, Monograph Development -Cardiovascular

No. of Commenter(s): 1

Comment Summary: The commenter requested the addition of a *Note* to indicate that a 0.2 cm cell is used to measure the UV absorbance since this is not a commonly used cell dimension.

Response: Comment incorporated.

Reason for Revision: Monograph revisions were made to correct the following:

1. The label claim (mg) of 6.5 in Table 1 is corrected to 6.25 based on FDA’s comments.
2. The column type in PF 33(5) briefing is revised to indicate the correct and full name for the column.

Monograph/Section(s): Dactinomycin

Expert Committee(s): Monograph Development - Antibiotics

No. of Commenter(s): 0

Comment Summary: No comments received.

Reason for Revision: Revisions were made to correct the limits in the test for *Specific rotation*.

Monograph/Section(s): Fexofenadine Hydrochloride

Expert Committee(s): Monograph Development – Pulmonary and Steroids

No. of Commenter(s): 0

Comment Summary: No comments received.

Reason for Revision: The limit of water for the anhydrous material was revised from not more than 0.5% to not more than 2.0%.

Monograph/Section(s): Nifedipine Extended-Release Tablets
Expert Committee(s): Biopharmaceutics
No. of Commenter(s): 0
Comment Summary: No comments received.
Reason for Revision: Revision to add a *Dissolution test 6* for a generic product approved by FDA.