Commentary

***PF 46(2), PF* 46(6)**

Comments were received for the following when they were proposed in Pharmacopeial Forum:

Monographs:
Gemfibrozil Tablets
Ioversol Injection
Paroxetine Hydrochloride

No comments were received for the following proposals:

Monographs:
Ioversol

Monographs

Monograph/Section: Gemfibrozil Tablets /Organic Impurities
Expert Committee: Small Molecules 2
No. of Commenters: 1
Comment Summary #1: The commenter requested removing the 'reporting threshold' from the test for *Organic Impurities* as the appropriate value varies.
Response: Comment not incorporated. A general policy regarding reporting thresholds in monographs is still under discussion. The Expert Committee will consider future revisions to the monograph upon receipt of supporting data.
Expert Committee-initiated Change #1: In *Identification A* within the *Analysis* section, the reagent 0.1 N sodium hydroxide will be reinstated to align with the current official text. The forum proposal indicated 1 N sodium hydroxide due to an inadvertent publication error.

Monograph/Sections: Ioversol Injection/Multiple sections
Expert Committee: Small Molecules 4
No. of Commenters: 1
Comment #1: The commenter requested deleting the text "single-dose" from the *Packaging and Storage* section to accommodate additional packaging configurations.
EC Response: Comment not incorporated. This request is outside the scope of the proposed revisions to the monograph. The Expert Committee will consider future revisions to the monograph upon receipt of supporting data.

Comment #2: The commenter requested deleting the *Labeling* section to accommodate additional packaging configurations.
EC Response: Comment not incorporated. This request is outside the scope of the proposed revisions to the monograph. The Expert Committee will consider future revisions to the monograph upon receipt of supporting data.

Monograph/Sections: Paroxetine Hydrochloride
Expert Committee: Small Molecules 4
No. of Commenters: 2
Comment Summary #1: The commenter requested replacing the *Assay* with a more rugged procedure to address chromatographic issues, such as rapid column aging, variable retention times and difficulty meeting *Suitability requirements*.
Response: Comment not incorporated. The request is outside of the scope of the proposed revisions for the monograph. The Expert Committee will consider future revisions to the monograph upon receipt of supporting data.
Comment Summary #2: The commenter requested reducing the *Standard solution* concentration in the *Limit of Paroxetine Related Compound C* test to align it with the acceptance criterion.
Response: Comment not incorporated. The request is outside of the scope of the proposed revisions for the monograph. The Expert Committee will consider future revisions to the monograph upon receipt of supporting data.
Comment Summary #3: The commenter requested removing the column particle size from the *Chromatographic system* in the *Limit of Paroxetine Related Compound C* test, noting that a smaller particle size provided improved separation and peak shape.
Response: Comment not incorporated. The request is outside of the scope of the proposed revisions for the monograph. The Expert Committee will consider future revisions to the monograph upon receipt of supporting data.
Comment Summary #4: The commenter requested replacing the proposed *Limit of Paroxetine Related Compound E* test procedure with a different analytical technique, such as LC-MS, to improve method sensitivity and selectivity.
Response: Comment not incorporated. The proposed test procedure met all analytical method validation requirements appropriate for the analysis. The Expert Committee will consider future revisions to the monograph upon receipt of supporting data.
Comment Summary #5: The commenter requested incorporating the proposed *Limit of Paroxetine Related Compound E* test procedure as an alternative method.
Response: Comment not incorporated. The USP Paroxetine Related Compound E Mixture RS, which is needed to conduct the currently official procedure for the *Limit of 1-Methyl-4-(p-fluoro phenyl)1,2,3,6-tetrahydro pyridine* test, is targeted to be removed from the USP RS catalog; therefore, the currently official procedure will no longer be supported.
Expert Committee-initiated Change #1: Under Identification Test C, the proposals to replace "*Standard solution*" with "paroxetine peak of the *System suitability solution" and to replace "Assay"* with "test for *Limit of Paroxetine Related Compound* C" were not accepted.

Monograph/Section(s): Sulfamethoxazole/ Organic Impurities

Expert Committee(s): Small Molecules Monographs 1
No. of Commenters: 1

Comment Summary #1: The commenter requested removing the ‘reporting threshold’ from the test for *Organic Impurities*.
Response: Comment not incorporated. The comment is outside of the scope of the revision. A general position regarding the inclusion or absence of reporting thresholds in monographs is still under discussion. The Expert Committee will consider future revisions to the monograph upon receipt of further supporting data.