Commentary

Interim Revision Announcements proposed in:
***Pharmacopeial Forum* 41(4) [Jul.–Aug. 2015]**

November 20, 2015

In accordance with USP's Rules and Procedures of the Council of Experts ("Rules") and except as provided in Section 7.02 Accelerated Revision Processes, USP publishes proposed revisions to the United States Pharmacopeia and the National Formulary (USP–NF) for public review and comment in the Pharmacopeial Forum (PF), USP's free bimonthly journal for public notice and comment. After comments are considered and incorporated as the Expert Committee deems appropriate, the proposal may advance to official status or be republished in PF for further notice and comment, in accordance with the Rules. In cases when proposals advance to official status without republication in PF, a summary of comments received and the appropriate Expert Committee's responses are published in the Revisions and Commentary section of the USP Web site at the time the official revision is published.

The Commentary is not part of the official text and is not intended to be enforceable by regulatory authorities. Rather, it explains the basis of Expert Committees' responses to public comments on proposed revisions. If there is a difference between the contents of the Commentary and the official text, the official text prevails. In case of a dispute or question of interpretation, the language of the official text, alone and independent of the Commentary, shall prevail.

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Comments were received for the following IRAs, when they were proposed in *Pharmacopeial Forum*

Monograph/Sections: Methocarbamol/Impurities
Expert Committee: Monographs—Chemical Medicines 4
No. of Commenters: 1
Comment Summary #1: The commenter indicated that the proposal limits for the impurities are not consistent with what has been approved by FDA.
Response: Comment not incorporated. The Expert Committee will consider revising the monograph in future upon receipt of supporting data

Monograph/Section(s): Protamine Sulfate Injection/pH
Expert Committee: Biologics Monographs 3–Complex Biologics
Number of commenter: 1
Comment Summary #1: The commenter requested the new proposed pH range be widened to 6.0–7.3 to address variability between pH measuring device following initial pH adjustment between manufacturing and final release testing.
Response: Comment not incorporated. The proposed pH range reflects FDA approved specifications.