Commentary

Interim Revision Announcements proposed in:
***Pharmacopeial Forum* 42(1) [Jan.–Feb. 2016]**

May 27, 2016, updated June 24, 2016[1]

In accordance with USP's Rules and Procedures of the 2015-2020 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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[1] The PF 42(1) commentary was updated on June 24, 2016 to include the comments for Ceftriaxone Sodium and Ceftriaxone Sodium Injection, which were previously deferred

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

Monograph/Sections: Ceftriaxone Sodium/Multiple Sections
Expert Committee: Chemical Medicines Monographs 1
No. of Commenters: 1
Comment Summary #1: The commenter recommended revising the impurity profile to be consistent with what has been approved by the agency.
Response: Comment not incorporated. The impurity profile is consistent with FDA approved acceptance criteria. The Expert Committee will consider revising the monograph in future upon receipt of supporting data.

Monograph/Sections: Ceftriaxone for Injection/Multiple Sections
Expert Committee: Chemical Medicines Monographs 1
No. of Commenters: 1
Comment Summary #1: The commenter requested revising the limit of Total impurities from NMT 2.5% to NMT 5.0% based on FDA approved limits and to include the relative retention time for 7-Aminocephalosporanic acid in the impurities table with a note indicating that this is a process impurity.
Response: Comment incorporated.

Monograph/Sections: Cisatracurium Besylate/Multiple sections
Expert Committee: Chemical Medicines Monographs 4
No. of Commenters: 1
Comment Summary #1: The commenter requested revising the acceptance criteria within the test for *Organic Impurities.*
Response: Comment not incorporated. The Expert Committee will consider future revisions to the proposal.
Expert Committee-initiated Change #1: The reference to the counterion as “Besylate” was replaced with the alternate name “Benzenesulfonic acid”, and the counterions (benzenesulfonate and dibenzenesulfonate) were removed from the chemical names provided in Table 1 within the test for *Organic Impurities*.
Expert Committee-initiated Change #2: The counterion was added to the trivial names of the impurities present within the USP Cisatracurium Besylate System Suitability Mixture RS described in the *USP Reference Standards* section to reflect that the compounds are provided in the salt form.

No comments were received for the following IRAs, when they were proposed in *Pharmacopeial Forum*:

Corticotropin Injection
Corticotropin for Injection
Repository Corticotropin Injection

Protamine Sulfate
Protamine Sulfate Injection
Glyceryl Tristearate