



Commentary

Interim Revision Announcements

August 9, 2022

In accordance with USP's *Rules and Procedures of the Council of Experts* ("Rules"), and except as provided in Section 9.02 *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 re-published in *PF* for further notice and comment, in accordance with the Rules. In cases when proposals advance to official status, a summary of comments received and the appropriate Expert Committee's responses, as well as Expert Committee-initiated changes, are published in the Proposal Status/Commentary section of *USPNF.com* 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 or conflict between the contents of the *Commentary* and the official text, the official text prevails.

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

Starch TS
<89.2> Collagenase II
Salmeterol Inhalation Powder

No comments were received from the following proposals:

Fluticasone Propionate Inhalation Aerosol
Fluticasone Propionate Inhalation Powder
Fluticasone Propionate and Salmeterol Inhalation Aerosol
Fluticasone Propionate and Salmeterol Inhalation Powder
Mesalamine Delayed-Release Tablets

Revision/Section: Starch TS

Expert Committee: Headquarters

Number of Commenters: 2

Comment Summary #1: The commenter recommended adding sufficient boiling water to solubilize the starch. In addition, they recommended reducing the concentration of the iodine used in the Test for Sensitivity to facilitate the visualization of the endpoint.

Response: Comments incorporated. The preparation of all Starch TS solutions and the conditions of the Test for Sensitivity were revised.

Comment Summary #2: The commenter suggested to increase the amount of water used to prepare the paste from 5 mL to 50 mL.

Response: Comment not incorporated. The small volume of water is sufficient to prepare the paste. The solubilization will happen with the addition of the boiling water.

Chapter/Section: <89.2> Collagenase II/Assay

Expert Committee: Biologics 2- Proteins

Number of Commenters: 1

Comment Summary #1: Commenter recommended retaining dilution range under the Standard solution

Response: Comment partially incorporated. Dilution range will be incorporated in the USP certificate. Reference to the USP certificate added to the chapter as a note under Standard solution

Comment Summary #2: The commenter suggested revision of statement under impurities section to specify final volume of the substrate solution as:

“Transfer 0.5 mL of Substrate stock solution, 1.0 mL of Dithiothreitol solution, and 1.0 mL of Calcium chloride solution to a 25-mL volumetric flask and dilute with Potassium phosphate buffer to volume the 25-mL mark of the volumetric flask.”

Response: Comment not incorporated. Existing statement in the chapter is considered self-explanatory as it mentions 25-mL volumetric flask.

Monograph/Section: Salmeterol Inhalation Powder /Specific Tests

Expert Committee: Monographs – Small Molecules 5

No. of Commenters: 1

Comment Summary #1: The commenter recommended deleting Escherichia coli and Salmonella species tests under “Microbial Enumeration Tests 61 and Tests for Specified Microorganisms 62”, as recommended in USP General Chapter <1111>.

Response: Comment incorporated.