Commentary

Interim Revision Announcements

October 3, 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.

For further information, contact:
USP Executive Secretariat
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790 USA

Comments were received for the following when they were proposed in *Pharmacopeial Forum*:
<209> Low Molecular Weight Heparin Molecular Weight Determinations
<411> Folic Acid Assay

No comments were received from the following proposals:
Folic Acid Tablets
Levalbuterol Hydrochloride
Levalbuterol Inhalation Solution

Chapter/Section: <209> *Low Molecular Weight Heparin Molecular Weight Determinations*/Molecular Weight Measurements of Low Molecular Weight Heparins by Gel Permeation Chromatography
Expert Committee: Biologics Monographs 3 - Complex Biologics and Vaccines
Number of Commenters: 1

Comment Summary #1: The commenter recommended inserting the proposed deletion of how to prepare the System suitability solution in the Note as: [Note–In the cases where no product monograph is available, 5 mg/mL of USP Dalteparin Sodium RS, in Mobile phase and filtered using a nylon membrane of 0.45 μm pore size, can be applied as the system suitability solution.].
Response: Comment incorporated. The preparation procedure is added to *System suitability* solution.

Comment Summary #2: The commenter suggested clearly defining "Standard" in the Note of the Analysis subsection.
Response: Comment incorporated. The Note is revised from "The calibrant, Standard, or sample of low molecular weight heparin will…" to "The Calibration solution, System suitability solution, or Sample solution will…]".

Monograph/Section(s): <411> Folic Acid Assay/ Procedure 4
Expert Committee: Non-Botanical Dietary Supplements
No. of Commenters: 1

Comment Summary #1: The commenter recommended that specific information be provided on which procedure is best used for a particular dosage form, as either *Procedure 1* or *Procedure 2* of the chapter can be used to determine folic acid in the same finished products.
Response: Comment not incorporated. The comment was not related to the revision subject and can therefore be addressed through the regular revision in the future if necessary.
Comment Summary #2: The commenter recommended to review the RSD limit of *Procedure 1* for the *System suitability*, since the current RSD requirement for *Procedure 1* is NMT 3.0%, which is differ from the NMT 2.0% RSD requirements for the other three procedures.
Response: Comment not incorporated. The comment was not related to the revision subject and can therefore be addressed through the regular revision in the future if necessary.