



Commentary

USPNF 2026 ISSUE 4

January 30, 2026

In accordance with USP's *Rules and Procedures of the 2025-2030 Council of Experts (CoE Rules)*, and except as provided in Section 10.02 *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 (EC) deems appropriate, the proposal may advance to official status or be republished in *PF* for further notice and comment, in accordance with *CoE Rules*. In cases when proposals advance to official status, a summary of comments received and the appropriate Expert Committee's responses, as well as EC-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:
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Comments were received for the following monographs and chapters when they were proposed in Pharmacopeial Forum:

General Chapters

[<1152> ANIMAL DRUGS FOR USE IN ANIMAL FEEDS](#)

Monographs

[ALECTINIB CAPSULES](#)

[ALECTINIB HYDROCHLORIDE](#)

[DIPROPYLENE GLYCOL](#)

[EUROPEAN ELDER BERRY AQUEOUS DRY EXTRACT](#)

[EUROPEAN ELDER BERRY DRY EXTRACT](#)

[GAMMA-AMINOBUTYRIC ACID](#)

[GUAIFENESIN](#)

[INDIAN ELECAMpane ROOT](#)

[INDIAN ELECAMpane ROOT DRY EXTRACT](#)

[INDIAN ELECAMpane ROOT POWDER](#)

[POLYPROPYLENE GLYCOL 11 STEARYL ETHER](#)

[SOUTHERN SCHISANDRA FRUIT](#)

[SOUTHERN SCHISANDRA FRUIT POWDER](#)

[WHITE WAX](#)

No comments were received for the following proposals:

Monographs

AMBRISANTAN TABLETS

ANASTROZOLE TABLETS

CITALOPRAM TABLETS

CITRULLINE

CLIDINIUM BROMIDE

DEXTRAN 1

EUROPEAN ELDER BERRY DRY JUICE

EUROPEAN ELDER BERRY POWDER

FLUTICASONE PROPIONATE CREAM

FLUTICASONE PROPIONATE OINTMENT

INDOMETHACIN

MERCAPTOPYRINE

MERCAPTOPYRINE TABLETS

METHSCOPOLAMINE BROMIDE TABLETS

PERILLA FRUIT

PERILLA FRUIT POWDER

PRAMOXINE HYDROCHLORIDE

PRAMOXINE HYDROCHLORIDE CREAM

General Chapter

General Chapter/Section(s): <1152> ANIMAL DRUGS FOR USE IN ANIMAL FEEDS
Expert Committee: Dosage Forms
No. of Commenters: 1

Comment Summary #1: The commenter suggested certain editorial changes to the text of the general chapter.

Response: Comment incorporated. The suggested changes were carried out for clarity.

Monograph

Monograph/Section(s): ALECTINIB CAPSULES
Expert Committee: Small Molecules 3
No. of Commenters: 3

Comment Summary #1: The commenter requested confirmation on whether the proposed limit for any unspecified degradation product of 0.15% is based on toxicological justification, analytical feasibility, or other regulatory considerations. If not, they suggest revisiting this limit to align with ICH Q3B(R2) (i.e., NMT 0.167%) to ensure global regulatory harmonization.

Response: Comment not incorporated. The proposed limit for any unspecified degradation product is consistent with the sponsor's approved specifications. A future revision can be considered upon receipt of approved specifications and supporting data.

Comment Summary #2: The commenter requested widening the limit for any unspecified degradation product from 0.15% to 0.16% to better align with generic product labeling.

Response: Comment not incorporated. The proposed limit for any unspecified degradation product is consistent with the sponsor's approved specifications. A future revision can be considered upon receipt of approved specifications and supporting data.

EC-Initiated Change #1: The filter particle size of 0.45 µm is removed from the Sample solution in the Dissolution test.

Monograph/Section(s): ALECTINIB HYDROCHLORIDE
Expert Committee: Small Molecules Therapeutic Areas 3
No. of Commenters: 3

Comment Summary #1: The commenter requested clarification on drying the 2,2,2-trifluoroethanol reagent in the test for Water Determination.

Response: Comment incorporated. A note is added to the Sample solution in the test for Water Determination for additional clarity as follows: [Note: 2,2,2-trifluoroethanol can be dried using 0.3 nm molecular sieve].

Comment Summary #2: The commenter requested in the test for Organic Impurities to relax the limit of total impurities to NMT 1.0%.

Response: Comment not incorporated. The commenter's product is not currently approved. The proposed impurities and acceptance criteria for Organic Impurities are consistent with the sponsor's approved specifications. A future revision can be considered upon receipt of approved specifications and supporting data.

Comment Summary #3: The commenter indicated that they have additional impurities controlled at NMT 0.08% and recommended including them in the monograph.

Response: Comment not incorporated. The commenter's product is not currently approved. The proposed impurities and acceptance criteria for Organic Impurities are consistent with the

sponsor's approved specifications. A future revision can be considered upon receipt of approved specifications and supporting data.

Comment Summary #4: The commenter recommended including a test for chloride content.

Response: Comment not incorporated. The commenter's product is not currently approved. If needed, a future revision can be considered upon receipt of approved specifications and supporting data.

EC Initiated Change #1: In the calculation definition table, "nominal" is removed from the Sample solution concentration in the test for Organic Impurities.

Monograph/Section(s): DIPROPYLENE GLYCOL

Expert Committee: Excipient Monographs 1

No. of Commenters: 0

EC-Initiated Change #1: Change the formula weight from 134.174 to 134.18 in line with *USP-NF* format.

Monograph/Section(s): EUROPEAN ELDER BERRY AQUEOUS DRY EXTRACT

Expert Committee: Botanical Dietary Supplements & Herbal Medicines

No. of Commenters: 4

Definition /Content

Comment Summary #1: The commenter requested a change in the limit of total anthocyanosides from NLT 15% to NLT 14%.

Response: Comment incorporated. The total anthocyanosides limit was changed from NLT 15% to NLT 14% based on additional manufacturing information provided.

Identification

Comment Summary #2: In the test for "organic acids (ratio of malic acid to shikimic acid)", the commenter proposed removing this parameter because they do not see any significant differences between the two technologies (resin adsorption vs. ultrafiltration). In both technologies, the ratios are at the level of 0.5–0.6

Response: Comment incorporated. The organic acid test was deleted from the monograph.

Comment Summary #3: The commenter recommended including a new specification for total flavanol content with a limit of NLT 1.0% using the HPLC method at 365 nm, which is intended for ID purposes.

Response: Comment not incorporated. This method was not validated for quantitative purposes.

Comment Summary #4: The commenter suggested changing the detection wavelengths of the HPLC ID test from 365 nm to 350 nm, and from 535 nm to 520 nm.

Response: Comment not incorporated. This difference in detection wavelength (15 nm difference) does not affect the fitness for purpose of this identification method.

Specific Tests

Comment Summary #5: The commenter requested to expand the limits for Total Fiber from 5%–16% to 4%–16%.

Response: Comment incorporated. The limits were expanded to give greater flexibility to different manufacturers of this ingredient.

Comment Summary #6: The commenter proposed to replace the AOAC method for total fiber with the one in general chapter <561>.

Response: Comment not incorporated. This proposal will be considered upon the submission of data generated using the method in general chapter <561>.

Definition

Comment Summary #7: The commenter indicated that soluble solids could vary by 10% and that this parameter is not controlled during the manufacturing process.

Response: Comment incorporated. Removed the description of the content of soluble solids from the Definition.

Content

Comment Summary #8: The commenter indicated that the relative response factor (RRF) values used in their SOP for the HPLC quantification of anthocyanins are based on molecular weight calculations.

Response: Comment not incorporated. RRFs for this monograph were obtained by NMR and, therefore, are considered more accurate.

Monograph/Section(s): EUROPEAN ELDER BERRY DRY EXTRACT
Expert Committee: Botanical Dietary Supplements & Herbal Medicines
No. of Commenters: 1

Identity/Content

Comment Summary #1: The commenter proposed to include a new specification for total flavanol content using the HPLC method at 365 nm, which is intended for ID purposes.

Response: Comment not incorporated. This method has not been validated for quantitative purposes.

Monograph/Section(s): GAMMA-AMINOBUTYRIC ACID
Expert Committee: Non-botanical Dietary Supplements
No. of Commenters: 0

EC-Initiated change #1: Changed “peak response” to “peak area” in Assay and Related Compounds testing to align with the method validation report.

Monograph/Section(s): GUAIFENESIN
Expert Committee: Small Molecules 2
No. of Commenters: 1

Comment Summary #1: The commenter commented that they observed cloudiness when a stock solution of guaifenesin dimer was prepared at 150 µg/mL in water. The commenter was concerned that guaifenesin dimer may not be fully soluble in water.

Response: Comment not incorporated. The Expert Committee determined that the commenter did not provide any additional details regarding difficulties in performing the test procedure.

Monograph/Section(s): INDIAN ELECAMPANE ROOT
Expert Committee: Botanical Dietary Supplements & Herbal Medicines
No. of Commenters: 1

Identification

Comment Summary #1: The commenter suggested changing the concentration of Standard solution B for HPTLC to 50 mg/mL and using either glacial acetic acid or NaOH for the pH adjustment of Solution A in HPLC.

Response: Comment incorporated. For the HPLC solution preparation in Assay, the current version mentions that the pH of Solution A (ammonium acetate buffer) is adjusted with glacial acetic acid, which is from the sponsor, but early procedure evaluation in *USP* used 1 N NaOH. The line needs to be changed to “Adjust with either glacial acetic acid or 1 N NaOH”.

Assay

Comment Summary #2: The commenter suggested changing the concentration of Standard solution B for HPTLC to 50 mg/mL and using both glacial acetic acid and NaOH for the pH adjustment for Solution A in HPLC.

Response: Comment incorporated. For the HPLC solution preparation in Assay, the current version indicates that the pH of Solution A (ammonium acetate buffer) is adjusted with glacial acetic acid. This is from the sponsor, but early procedure evaluation in *USP* used 1 N NaOH. The line needs to be changed to “Adjust with either glacial acetic acid or 1 N NaOH”.

Monograph/Section(s): INDIAN ELECAMPANE ROOT DRY EXTRACT
Expert Committee: Botanical Dietary Supplements and Herbal Medicines
No. of Commenters: 1

Assay

Comment Summary #1: The commenter suggested changing the concentration of Standard solution B for HPTLC to 50 mg/mL and using both glacial acetic acid and NaOH for pH adjustment for Solution A in HPLC.

Response: Comment incorporated. For the HPLC solution preparation in Assay, the current version indicates the pH of Solution A (ammonium acetate buffer) is adjusted with glacial acetic acid, which is from the sponsor, but early procedure evaluation in *USP* used 1 N NaOH. The line needs to be changed to “Adjust with either glacial acetic acid or 1 N NaOH”.

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Monograph/Section(s): INDIAN ELECAMPANE ROOT POWDER
Expert Committee: Botanical Dietary Supplements and Herbal Medicines
No. of Commenters: 1

Identification

Comment Summary #1: The commenter suggested changing the concentration of Standard solution B for HPTLC to 50 mg/mL and using either glacial acetic acid or NaOH for the pH adjustment of Solution A in HPLC.

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Assay

Comment Summary #2: The commenter suggested changing the concentration of Standard solution B for HPTLC to 50 mg/mL and using both glacial acetic acid and NaOH for the pH adjustment for Solution A in HPLC.

Response: Comment incorporated. For the HPLC solution preparation in Assay, the current version indicates that the pH of Solution A (ammonium acetate buffer) is adjusted with glacial acetic acid, which is from the sponsor, but early procedure evaluation in *USP* used 1 N NaOH. The line needs to be changed to “Adjust with either glacial acetic acid or 1 N NaOH”.

Monograph/Section(s): POLYPROPYLENE GLYCOL 11 STEARYL ETHER
Expert Committee: Excipient Monographs 2
No. of Commenters: 1

Impurities

Comment Summary #1: The commenter suggested using the SI unit, which is µg/g or mg/kg, instead of ppm.

Response: Comment not incorporated. The unit ppm is a universally recognized unit in contaminant testing. It is also frequently used in residual monomer and residual solvent tests in *USP–NF*.

Monograph/Section(s): SOUTHERN SCHISANDRA FRUIT
Expert Committee: Botanical Dietary Supplements and Herbal Medicines
No. of Commenters: 1

Comment Summary #1: The commenter suggested using Karl Fischer Direct Titration with Extraction (KF DTE) method to replace LOD because LOD will lose both water and volatile components.

Response: Comment incorporated. Lab tests have been conducted to confirm the suggestion.

Monograph/Section(s): SOUTHERN SCHISANDRA FRUIT POWDER
Expert Committee: Botanical Dietary Supplements and Herbal Medicines
No. of Commenters: 1

Comment Summary #1: The commenter indicated that lab test results confirmed KF DTE is suitable for water determination of Southern schisandra fruit powder. The azeotropic-toluene distillation (ATD) method should be replaced by KF DTE because the ATD method is complicated and an environmental hazard.

Response: Comment incorporated. The ATD method is replaced by KF DTE method to determine water content.

Monograph/Section(s): WHITE WAX
Expert Committee: Complex Excipients
No. of Commenters: 1

COMPOSITION

Comment Summary #1: The commenter indicated that the specified column has a maximum temperature of 380 °C, lower than the detector temperature of 390 °C.

Response: Comment not incorporated. The Avantor Hichrom Hi-5 HT column specified in the procedure has a maximum temperature of 400 °C, which meets the procedure requirements.

Comment Summary #2: The commenter requested additional time for implementation for instrument upgrade.

Response: Comment incorporated. The Expert Committee acknowledged the commenter's concern and agreed to extend the implementation date by one year (1-Aug-2027) after publication.

Comment Summary #3: The commenter indicated that the on-column mode is not a common GC inlet type and therefore may not be easily adopted by many companies.

Response: Comment incorporated. The Expert Committee acknowledged the commenter's concern and agreed to extend the implementation date by one year (1-Aug-2027) after publication.