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Powdered Forskohlii Extract

DEFINITION

Powdered Forskohlii Extract is prepared from Forskohlii using suitable solvents such as methanol, ethyl acetate, hexane or a mixture of these solvents. The ratio of plant material to extract is between 65:1 and 35:1. It contains NLT 90.0% and NMT 110.0% of the labeled amount of forskolin, calculated on the dried basis. It contains suitable added substances as carriers.

IDENTIFICATION

• **A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#).**

Standard solution A: 50 µg/mL of [USP Forskolin RS](#) in acetonitrile. Sonicate for about 10 min.

Standard solution B: 5 mg/mL of [USP Powdered Forskohlii Extract RS](#) in acetonitrile. Sonicate for about 15 min, centrifuge, and use the supernatant.

Sample solution: 5 mg/mL of Powdered Forskohlii Extract in acetonitrile. Sonicate for about 15 min, centrifuge, and use the supernatant.

Adsorbent: Chromatographic silica gel with an average particle size of 10–15 µm (TLC plates)

Application volume: 10 µL, as 4-mm bands

Developing solvent system: A mixture of toluene and ethyl acetate (85:15)

Spray reagent: A mixture of 5% vanillin in glacial acetic acid and 10% sulfuric acid in water (1:1)

Analysis

Samples: *Standard solution A, Standard solution B, and Sample solution*

Apply the samples as bands to a suitable thin-layer chromatographic plate (see [Chromatography \(621\)](#)). Use saturated chamber. Develop the chromatograms until the solvent front has moved up about 90% of the plate. Remove the plate from the chamber, dry, spray with the *Spray reagent*, heat for 5–10 min at 105°, and examine under visible light.

Acceptance criteria: The *Sample solution* exhibits a violet zone due to forskolin at an R_f value of approximately 0.3, corresponding in color and R_f to that from *Standard solution A*; and a minor violet zone, a pink zone, and a brick red zone at R_f values of approximately 0.1, 0.62, and 0.69, due to isoforskolin, 1,9-dideoxyforskolin, and crocetindialdehyde, respectively. Zones detected from the *Sample solution* correspond in position and color to zones from *Standard solution B*. Other minor zones may be observed from the *Sample solution* and *Standard solution B*.

• **B.** The *Sample solution* from the test for *Content of Forskolin* shows a main peak at a retention time corresponding to that of forskolin from *Standard solution A*. Identify other diterpene peaks in the *Sample solution* by comparison with *Standard solution B* and the reference chromatogram provided with the lot of [USP Powdered Forskohlii Extract RS](#) being used. The *Sample solution* shows an additional peak corresponding to isoforskolin.

COMPOSITION

Change to read:

• **CONTENT OF FORSKOLIN**

Solution A: Use filtered and degassed acetonitrile.

Solution B: Use filtered and degassed water.

Standard solution A: Sonicate a quantity of [USP Forskolin RS](#) in acetonitrile to obtain a solution having a known concentration of about 1.0 mg/mL.

Standard solution B: 5 mg/mL of [USP Powdered Forskohlii Extract RS](#) in acetonitrile. Sonicate for about 15 min, centrifuge, and use the supernatant. Before injection, pass through a membrane filter having a 0.45-µm or finer pore size.

Sample solution: Transfer an amount of Powdered Forskohlii Extract equivalent to about 25 mg of forskolin to a 25-mL volumetric flask, and add 15 mL of acetonitrile. Sonicate and heat in a water bath for about 10 min, cool, dilute with acetonitrile to volume, and mix. Before injection, filter through a membrane filter having a 0.45-µm or finer pore size, discarding the first 5 mL of the filtrate.

System suitability solution: A mixture of *Standard solution A* and 0.01% toluene in acetonitrile (1:1)

Mobile phase: See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)
0	45	55
25	45	55

Time (min)	Solution A (%)	Solution B (%)
28	95	5
35	95	5
36	45	55
45	45	55

Chromatographic system(See [Chromatography \(621\), System Suitability](#).)**Mode:** LC**Detector:** UV 220 nm**Column:** 4.6-mm × 25-cm; 5-μm, 100 Å▲; packing [L1](#)▲ (ERR 1-Aug-2022)**Column temperature:** 30 ± 2°**Flow rate:** 1.8 mL/min**Injection size:** 20 μL**System suitability****Samples:** *Standard solution A*, *Standard solution B*, and *System suitability solution*

[NOTE—The relative retention times for isoforskolin and forskolin are 0.51 and 1.00, respectively.]

Suitability requirements: The chromatogram from *Standard solution B* is similar to the reference chromatogram provided with the lot of [USP Powdered Forskohlii Extract RS](#) being used.**Relative standard deviation:** NMT 2% determined from the forskolin peak in repeated injections, *Standard solution A***Resolution:** NLT 1.5 between the forskolin and toluene peaks, *System suitability solution***Analysis****Samples:** *Standard solution A*, *Standard solution B*, and *Sample solution*Using the chromatogram of *Standard solution A*, *Standard solution B*, and the reference chromatogram provided with the lot of [USP Powdered Forskohlii Extract RS](#) being used, identify the retention times of the peaks corresponding to isoforskolin and forskolin.

Calculate the percentage of forskolin in the portion of Powdered Forskohlii Extract taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

 r_U = peak response of forskolin from the *Sample solution* r_S = peak response of forskolin from *Standard solution A* C_S = concentration of [USP Forskolin RS](#) in *Standard solution A* (mg/mL) C_U = concentration of Powdered Forskohlii Extract in the *Sample solution* (mg/mL)**Acceptance criteria:** NLT 90.0% and NMT 110.0% of the labeled amount of forskolin on the dried basis**IMPURITIES****ORGANIC IMPURITIES**

- **PROCEDURE:** [BOTANICAL EXTRACTS \(565\), Preparations, General Pharmacopeial Requirements, Pesticide Residues](#): Meets the requirements

SPECIFIC TESTS

- **LOSS ON DRYING (731):** Dry 1.0 g of Powdered Forskohlii Extract at 105° for 3 h: it loses NMT 5.0% of its weight.
- **MICROBIAL ENUMERATION TESTS (2021):** The total aerobic microbial count does not exceed 10⁴ cfu/g. The total combined yeasts and molds count does not exceed 10³ cfu/g.
- **MICROBIOLOGICAL PROCEDURES FOR ABSENCE OF SPECIFIED MICROORGANISMS (2022):** It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.
- **ARTICLES OF BOTANICAL ORIGIN, Test for Aflatoxins (561):** Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, protected from light and moisture, and store at controlled room temperature.
- **LABELING:** The label states the Latin binomial and, following the official name, the part of the plant from which the article was derived. It meets other labeling requirements under [Botanical Extracts \(565\)](#).
- **OTHER REQUIREMENTS:** It meets the requirements of the test for *Residual Solvents* under [Botanical Extracts \(565\)](#).
- **USP REFERENCE STANDARDS (11):**
[USP Forskolin RS](#)
[USP Powdered Forskohlii Extract RS](#)