

Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Aug-2022
Document Type: Dietary Supplement Monographs
DocId: GUID-1CA79DC4-8888-4180-9F58-BAC4D65D54CB_2_en-US
DOI: https://doi.org/10.31003/USPNF_M5293_02_01
DOI Ref: 7f6wq

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Powdered Forskohlii

DEFINITION

Powdered Forskohlii is Forskohlii reduced to a powder or very fine powder. It contains NLT 0.4% of forskolin, calculated on the dried basis.

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 stock solution:** Use the *Sample solution*, prepared as directed in the test for *Content of Forskolin*.
- Sample solution:** Dilute 10 mL of the *Sample stock solution* with acetonitrile to 25 mL.
- 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:** Toluene and ethyl acetate (85:15)
- Spray reagent:** 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. Use a 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 white light.

Acceptance criteria: The chromatogram of 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 in the chromatogram of *Standard solution A*; 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 in the *Sample solution* correspond in position and color to those in *Standard solution B*. Other minor zones may be observed in 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 in the chromatogram of *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* chromatogram shows an additional peak corresponding to isoforskolin.

COMPOSITION

Change to read:

• **CONTENT OF FORSKOLIN**

- Solution A:** Acetonitrile, filtered and degassed
- Solution B:** Water, filtered and degassed
- 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 about 3.0 g of accurately weighed Powdered Forskohlii to a 100-mL round-bottom flask fitted with a reflux condenser. Add 50 mL of acetonitrile, reflux for 20 min, cool to room temperature, and decant the supernatant. Repeat until the extract is colorless. Combine the extracts, filter, concentrate under vacuum, and adjust the volume with acetonitrile to 100 mL. Before injection, pass through a membrane filter having a 0.45-µm or finer pore size, discarding the first 5 mL of the filtrate.
- System suitability solution:** *Standard solution A* and 0.01% toluene in acetonitrile (1:1)
- Mobile phase:** See [Table 1](#).

Table 1

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

Time (min)	Solution A (%)	Solution B (%)
25	45	55
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°**Flow rate:** 1.8 mL/min**Injection volume:** 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 of *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 taken:

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

 r_U = peak area of forskolin from the *Sample solution* r_S = peak area 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 in the *Sample solution* (mg/mL)**Acceptance criteria:** NLT 0.4% on the dried basis**IMPURITIES**

- [ARTICLES OF BOTANICAL ORIGIN, Acid-Insoluble Ash\(561\)](#): NMT 2%
- [ARTICLES OF BOTANICAL ORIGIN, Limits of Elemental Impurities\(561\)](#): Meets the requirements
- [ARTICLES OF BOTANICAL ORIGIN, Pesticide Residue Analysis\(561\)](#): Meets the requirements

SPECIFIC TESTS

- **BOTANICAL CHARACTERISTICS:** Yellowish brown powder; characteristic and pleasant aromatic odor; and slightly bitter to pungent taste. Under a microscope, it shows the presence of parenchyma cells with oleoresin canals, starch grains and prisms of calcium oxalate; oil globules; simple starch grains, cork cells; sclereids; stone cells; pitted vessels; and thin-walled fibers.

- [LOSS ON DRYING \(731\)](#)

Sample: 1.0 g of Powdered Forskohlii**Analysis:** Dry the *Sample* at 105° for 3 h.**Acceptance criteria:** NMT 12.0%

- [ARTICLES OF BOTANICAL ORIGIN, Total Ash\(561\)](#)

Sample: 1.0 g of Powdered Forskohlii**Acceptance criteria:** NMT 6%

- [ARTICLES OF BOTANICAL ORIGIN, Alcohol-Soluble Extractives, Method 2\(561\)](#): NLT 25.0%