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Northern Schisandra Fruit Powder

DEFINITION

Northern Schisandra Fruit Powder consists of dried ripe fruits of *Schisandra chinensis* (Turcz.) Baill. (Fam. Schisandraceae) reduced to a powder or very fine powder. It contains NLT 0.40% of schisandrin (schisandrol A) on the dried basis; NLT 0.95% of lignans, calculated as the sum of schisandrin, schisandrol B, deoxyschisandrin (schisandrin A), and γ -schisandrin (schisandrin B) on the dried basis.

IDENTIFICATION

• A. THIN-LAYER CHROMATOGRAPHY

Standard solution A: 1.0 mg/mL of [USP Schisandrin RS](#) in ethanol

Standard solution B: Sonicate 50 mg/mL of [USP Schisandra chinensis Fruit Dry Extract RS](#) in alcohol for 10 min. Centrifuge, and use the supernatant.

Sample solution: Sonicate 2.5 g of Northern Schisandra Fruit Powder in 10 mL of alcohol for 10 min. Centrifuge, and use the supernatant.

Chromatographic system

(See [Chromatography \(621\), Thin-Layer Chromatography](#).)

Adsorbent: Chromatographic silica gel mixture with an average particle size of 5 μ m (HPTLC plates)

Application volume: 3 μ L, as 8-mm bands

Relative humidity: Condition the plate to a relative humidity of about 33% using a suitable device.

Developing solvent system: Toluene, ethyl acetate, and glacial acetic acid (23:6:1)

Developing distance: 6 cm

Derivatization reagent: 10% Sulfuric acid in ethanol. [NOTE—Slowly add sulfuric acid to ice-cold ethanol.]

Analysis

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

Apply the *Samples* as bands to a suitable HPTLC plate, and dry in air. Develop the chromatograms in a saturated chamber, remove the plate from the chamber, dry, and examine under UV light at 254 nm. Then treat the plate with *Derivatization reagent*, heat at 120° for 7 min, and examine under UV light at 366 nm.

System suitability: Under UV light at 254 nm, the chromatogram of *Standard solution B* exhibits an intense band corresponding in R_f to the band due to schisandrin in the chromatogram of *Standard solution A*. *Standard solution B* also exhibits a band due to deoxyschisandrin in the middle of the chromatogram and four or five bands between the positions of the bands of schisandrin and deoxyschisandrin. In the upper-half section *Standard solution B* exhibits an intense band corresponding to γ -schisandrin.

Acceptance criteria: Under UV light at 254 nm, the *Sample solution* chromatogram exhibits an intense band at an R_f corresponding to the band due to schisandrin in the chromatogram of *Standard solution A*. The *Sample solution* exhibits additional bands corresponding to similar bands in the chromatogram of *Standard solution B*. These include one or two bands below the position of schisandrin; a band due to deoxyschisandrin in the middle of the chromatogram; four or five bands between the positions of the bands of schisandrin and deoxyschisandrin; two or three bands in the upper-half section, the most intense band at an R_f corresponding to the band of γ -schisandrin.

Under UV light at 366 nm after derivatization, the chromatogram of the *Sample solution* does not exhibit an intense blue fluorescent band in the upper-third of the chromatogram.

• B. HPLC

Analysis: Proceed as directed in *Content of Lignans*.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits the most intense peak with a retention time corresponding to schisandrin in *Standard solution A*, and the peaks due to schisandrol B, deoxyschisandrin, and γ -schisandrin corresponding to the retention times for the same lignans in *Standard solution B*. There is no principal peak due to schisandrin A at a relative retention time of about 2.1 relative to schisandrin (distinction from [Northern Schisandra Fruit](#)).

COMPOSITION

• CONTENT OF LIGNANS

Solution A: Water

Solution B: Acetonitrile and methanol (1:1) (v/v)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	47	53
30	20	80

Standard solution A: 0.06 mg/mL of [USP Schisandrin RS](#) in methanol

Standard solution B: 10 mg/mL of [USP Schisandra chinensis Fruit Dry Extract RS](#) in methanol. Before injection, pass through a polytetrafluoroethylene filter of 0.2-µm pore size, and discard the first portion of the filtrate.

Sample solution: Transfer about 250 mg of Northern Schisandra Fruit Powder, accurately weighed, to a 50-mL centrifuge tube. Add 10.0 mL of methanol, and sonicate for 10 min (140 W, 42 kHz). Centrifuge, and transfer this solution to a 25-mL volumetric flask. Repeat this extraction one more time. Combine the extracts in the 25-mL volumetric flask. Adjust with methanol to volume, and mix. Before injection, pass through a polytetrafluoroethylene filter of 0.2-µm pore size, and discard the first portion of the filtrate.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: UPLC

Detector: UV 251 nm

Column: 2.1-mm × 15-cm; 1.8-µm packing L1

Column temperature: 35°

Flow rate: 0.3 mL/min

Injection volume: 3 µL

System suitability

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

[NOTE—The relative retention times of the peaks for schisandrin, schisandrol B, deoxyschisandrin, and γ-schisandrin are about 1.00, 1.29, 2.90, 3.31, respectively.]

Suitability requirements

Chromatogram similarity: The chromatogram of *Standard solution B* is similar to the reference chromatogram provided with the lot of [USP Schisandra chinensis Fruit Dry Extract RS](#) being used.

Tailing factor: NMT 2.0 for the schisandrin peak, *Standard solution A*

Relative standard deviation: NMT 2.0%, determined from the schisandrin peak in repeated injections, *Standard solution A*

Resolution: NLT 1.5 between the schisandrol B peak and its following peak, *Standard solution B*

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 Schisandra chinensis Fruit Dry Extract RS](#) being used, identify the retention times of the peaks corresponding to different lignans in the *Sample solution* chromatogram.

Calculate the percentages of schisandrin, schisandrol B, deoxyschisandrin, and γ-schisandrin in the portion of Powder taken:

$$\text{Result} = (r_u/r_s) \times C_s \times (V/W) \times F \times 100$$

r_u = peak area of the relevant analyte from the *Sample solution*

r_s = peak area of schisandrin from *Standard solution A*

C_s = concentration of [USP Schisandrin RS](#) in *Standard solution A* (mg/mL)

V = volume of the *Sample solution* (mL)

W = weight of Powder taken to prepare the *Sample solution* (mg)

F = conversion factor for analytes (1.00 for schisandrin, 1.21 for schisandrol B, 1.00 for deoxyschisandrin, and 1.23 for γ-schisandrin)