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Add the following:

▲Indian Barberry Stem Dry Extract

DEFINITION

Indian Barberry Stem Dry Extract is prepared from the dried stems of *Berberis aristata* DC. (Family Berberidaceae) by extraction with hydroalcoholic mixture. It contains NLT 90.0% and NMT 110.0% of the labeled amount of berberine, calculated on the dried basis.

IDENTIFICATION

• **A. HPTLC for Articles of Botanical Origin ⟨203⟩**

Standard solution A: 1 mg of USP Berberine Chloride RS in 8 mL of methanol and 1 mg of USP Palmatine Chloride RS in 16 mL of methanol

Standard solution B: Sonicate 50 mg of USP *Berberis aristata* Stem Dry Extract RS in 4 mL of 80% methanol for 10 min. Centrifuge or filter, and use the supernatant or the filtrate.

Sample solution: Transfer 0.1 g of Indian Barberry Stem Dry Extract into a 100-mL volumetric flask. Add 50 mL of methanol and sonicate for 10 min. Heat in a water bath for 10 min, cool, and dilute with methanol to volume. Centrifuge or filter, and use the supernatant or the filtrate.

Chromatographic system

Adsorbent: Chromatographic silica gel F_{254} mixture with an average particle size of 5 µm

Application volume: 10 µL each of *Standard solution A, Standard solution B,* and *Sample solution* as 8-mm bands

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

Temperature: About 25°

Developing solvent system: Ethyl acetate, formic acid, and water (80:10:10)

Developing distance: 7 cm

Derivatization reagent: Add 20 mL of acetic acid and 10 mL of sulfuric acid to 170 mL of cold methanol and mix well. After cooling to room temperature, add 1 mL of anisaldehyde to the mixture.

Analysis

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

Apply the *Samples* as bands and dry in air. Develop in a saturated chamber, remove the plate from the chamber, and dry in air. Examine under UV light at 254 and 365 nm before derivatization. Then treat with *Derivatization reagent*, and examine under white light.

System suitability

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

Suitability requirements: Under UV 254 nm light, *Standard solution B* exhibits one gray band near the middle of the chromatogram, slightly overlapping with a pale red band, at an R_F corresponding to the berberine band from *Standard solution A*. Two additional pale gray bands appear below the berberine band; the lower band corresponds in R_F to the palmatine band from *Standard solution A*. Under UV 365 nm light, *Standard solution B* exhibits one intense yellow band near the middle of the chromatogram at an R_F corresponding to berberine. A pale yellow band appears below the berberine band, and another yellow band, less intense than the band due to berberine, appears beneath it at an R_F corresponding to palmatine. Under white light after derivatization, *Standard solution B* exhibits one yellow band near the middle of the chromatogram at an R_F corresponding to berberine in *Standard solution A*.

Acceptance criteria: Under UV 254 nm light, the *Sample solution* exhibits a gray band near the middle of the chromatogram, slightly overlapping with a pale red band, at an R_F corresponding to berberine. Two pale gray bands appear below the berberine band with the lower R_F corresponding to palmatine in *Standard solution A*. Under UV 365 nm light, the *Sample solution* exhibits two intense yellow bands near the middle of the chromatogram; the higher R_F corresponds to berberine and the lower R_F corresponds to palmatine in *Standard solution A*. A pale yellow band appears between the berberine and palmatine bands. Under white light after derivatization, the *Sample solution* exhibits a yellow band near the middle of the chromatogram at an R_F corresponding to berberine in *Standard solution A*.

• **B. HPLC**

Analysis: Proceed as directed in the test for *Content of Berberine*.

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Acceptance criteria: The chromatogram of the *Sample solution* exhibits peaks at retention times corresponding to the peaks due to berberine in *Standard solution B*.

COMPOSITION

• **Content of Berberine**

Solution A: Transfer 0.6 g of sodium 1-hexanesulfonate into a 1-L volumetric flask, and add 900 mL of water to dissolve. Adjust with glacial acetic acid to a pH of 2.7, and dilute with water to volume.

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
10	70	30
18	70	30
22	20	80
26	20	80
30	90	10
35	90	10

Standard solution A: 0.1 mg/mL of USP Berberine Chloride RS in methanol

Standard solution B: Transfer USP *Berberis aristata* Stem Dry Extract RS, equivalent to 5 mg of berberine, into a 50-mL volumetric flask, and add 25 mL of methanol. Heat at 80° with sonication for 20 min. Cool the solution and dilute with methanol to volume. Pass through a membrane filter of 0.45-µm or finer pore size, and use the filtrate.

Sample solution: Transfer 0.1 g of Indian Barberry Stem Dry Extract, accurately weighed, into a 100-mL volumetric flask, and add 50 mL of methanol. Sonicate for 10 min with heating. Cool the solution and dilute with methanol to volume. Pass the solution through a membrane filter of 0.45-µm or finer pore size, and use the filtrate.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 348 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 25°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.7 between the berberine peak and the previous peak, *Standard solution B*

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

Relative standard deviation: NMT 2.0% for the berberine peak in repeated injections, *Standard solution A*

Chromatogram similarity: The chromatogram of *Standard solution B* is similar to the reference chromatogram provided with the lot of USP *Berberis aristata* Stem Dry Extract RS being used.

Analysis

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

Using the chromatograms of *Standard solution A*, *Standard solution B*, and the reference chromatogram provided with the lot of USP *Berberis aristata* Stem Dry Extract RS being used, identify the retention times of the peaks corresponding to berberine in the *Sample solution*.

Calculate the percentage of berberine in the portion of Indian Barberry Stem Dry Extract taken:

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