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Powdered Gymnema

DEFINITION

Powdered Gymnema is Gymnema reduced to powder or very fine powder. It contains NLT 1.0% of gymnemic acids, calculated as gymnemagenin on the dried basis.

IDENTIFICATION

• **A.** Meets the requirements for *Specific Tests, Botanical Characteristics*

• **B.** [HPTLC FOR ARTICLES OF BOTANICAL ORIGIN \(203\)](#).

Standard solution A: 0.5 mg/mL of [USP Gymnemagenin RS](#) in methanol

Standard solution B: 20 mg/mL of [USP Native Gymnema Extract RS](#) in methanol. Sonicate for 10 min, centrifuge, and use the supernatant.

Sample solution: About 0.5 g of Powdered Gymnema in 5 mL of methanol. Sonicate for 10 min, centrifuge, and use the supernatant.

Chromatographic system

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

Application volume: 5 µL as 8-mm bands

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

Developing solvent system: A mixture of dichloromethane, methanol, and formic acid (75:25:10)

Developing distance: 6 cm

Derivatization reagent: A mixture of methanol and sulfuric acid (9:1)

Analysis

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

Apply the *Samples* as bands, and dry in air. Develop the chromatograms in a saturated chamber, remove the plate from the chamber, dry in air, derivatize the plate with *Derivatization reagent*, heat at 110° for 3 min, and examine under white light and under UV at 365 nm.

System suitability: The chromatogram of *Standard solution B* shows two bands clearly separated at an R_f of about 0.6–0.7 below the band due to gymnemagenin in *Standard solution A*. The most prominent band is located at about one-third of the chromatogram, visible as brown in color under white light and blue under UV.

Acceptance criteria: The chromatogram of the *Sample solution* shows the following bands corresponding in color and position to bands in the chromatogram of *Standard solution B*: two bands at an R_f of about 0.6–0.7, below the band due to gymnemagenin in *Standard solution A*. The most prominent band is at about one-third of the chromatogram, visible as brown in color under white light and blue under UV; in the lower third of the chromatogram, under UV, are one light blue-greenish band and a dark band underneath.

• **C. HPLC**

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

Acceptance criteria: The chromatogram of the *Sample solution* shows a major peak at a retention time corresponding to that of the gymnemagenin peak in the chromatogram of *Standard solution A* and an additional peak corresponding to deacylgymnemic acid.

COMPOSITION

• **CONTENT OF GYMNEMIC ACIDS**

Solution A: Dissolve 0.14 g of anhydrous potassium dihydrogen phosphate in 900 mL of water, and add 0.5 mL of phosphoric acid. Dilute with water to 1000 mL, mix, filter, and degas.

Solution B: Acetonitrile

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
20	45	55
25	40	

Time (min)	Solution A (%)	Solution B (%)
30	40	60
35	75	25
40	75	25

Solvent: 50% Ethanol in water

Potassium hydroxide solution: 12% Potassium hydroxide in water

Hydrochloric acid solution: 4 N hydrochloric acid

Standard solution A: 0.3 mg/mL of [USP Gymnemagenin RS](#) in methanol

Standard solution B: Transfer about 0.25 g of [USP Native Gymnema Extract RS](#) to a 100-mL round-bottom flask fitted with a reflux condenser.

Add 25 mL of *Solvent* and 2 mL of *Potassium hydroxide solution*, reflux on a water bath for 1 h, and cool to room temperature. Add 5.5 mL of *Hydrochloric acid solution*, reflux on a water bath for 2 h, and cool to room temperature. Adjust the solution with *Potassium hydroxide solution* to a pH of 7.5–8.5, transfer to a 50-mL volumetric flask, dilute with *Solvent* to volume, and mix. Before injection, pass through a membrane filter having a 0.45-µm or finer pore size, discarding the first few mL of the filtrate.

Sample solution: Transfer about 0.75 g of Powdered Gymnema, accurately weighed, to a 100-mL round-bottom flask fitted with a reflux condenser. Add 25 mL of *Solvent* and 2 mL of *Potassium hydroxide solution*, reflux on a water bath for 1 h, and cool to room temperature. Add 5.5 mL of *Hydrochloric acid solution*, reflux on a water bath for 2 h, and cool to room temperature. Adjust the solution with *Potassium hydroxide solution* to a pH of 7.5–8.5, filter into a 100-mL volumetric flask, dilute with *Solvent* to volume, and mix. Before injection, pass through a membrane filter having a 0.45-µm or finer pore size, discarding the first few mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm, 100 Å, packing L1

Column temperature: 25°

Flow rate: 1.6 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

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

Tailing factor: NMT 1.5 for the gymnemagenin peak, *Standard solution A*

Relative standard deviation: NMT 2.0% for the gymnemagenin peak, *Standard solution A*

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 Native Gymnema Extract RS](#) being used, identify the retention times of the peaks corresponding to deacylgymnemic acid and gymnemagenin from the *Sample solution*.

Calculate the percentage of gymnemic acids, calculated as gymnemagenin, in the portion of Powdered Gymnema taken:

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

r_U = peak area of gymnemagenin from the *Sample solution*

r_S = peak area of gymnemagenin from *Standard solution A*

C_S = concentration of gymnemagenin in *Standard solution A* (mg/mL)

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

W = weight of Powdered Gymnema used to prepare the *Sample solution* (mg)

Acceptance criteria: NLT 1.0% on the dried basis

CONTAMINANTS

• [ARTICLES OF BOTANICAL ORIGIN, Limits of Elemental Impurities\(561\)](#): Meets the requirements

• [ARTICLES OF BOTANICAL ORIGIN, Pesticide Residue Analysis\(561\)](#): Meets the requirements

• [MICROBIAL ENUMERATION TESTS \(2021\)](#): The total aerobic bacterial count does not exceed 10⁵ cfu/g, the total combined molds and yeasts count does not exceed 10³ cfu/g, and the bile-tolerant Gram-negative bacteria do not exceed 10³ cfu/g.