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Banaba Leaf Dry Extract

DEFINITION

Banaba Leaf Dry Extract consists of the dried leaves of *Lagerstroemia speciosa* (L.) Pers. (Fam. Lythraceae) by extraction with hydroalcoholic mixtures. It contains NLT 90.0% and NMT 110.0% of the labeled amount of corosolic acid ($C_{30}H_{48}O_4$), calculated on the dried basis.

IDENTIFICATION

• A. THIN-LAYER CHROMATOGRAPHY

Standard solution A: 0.2 mg/mL of [USP Corosolic Acid RS](#) in methanol

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

Sample solution: Banaba Leaf Dry Extract in methanol at a concentration equivalent to 0.2 mg/mL of corosolic acid according to the label claim. Sonicate if necessary.

Chromatographic system

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

Mode: HPTLC

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

Application volume: 6 μ L as 8-mm bands

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

Column temperature: 25°

Developing solvent system: A mixture of toluene, ethyl acetate, and acetic acid (55:45:0.5)

Developing distance: 6 cm

Derivatization reagent: 85 mL of ice-cooled methanol mixed with 10 mL of glacial acetic acid, 5 mL of sulfuric acid, and 0.5 mL of *p*-anisaldehyde

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 an unsaturated chamber, remove the plate from the chamber, and dry. Treat with *Derivatization reagent*, heat for 3 min at 100°, and examine under visible light.

System suitability: Under visible light, the chromatogram of *Standard solution B* exhibits the most intense band, a violet or blue band, with similar R_f and color as the corosolic acid band in the chromatogram of *Standard solution A*; a blue band close to the start (about R_f 0.1), consistent with asiatic acid; two minor blue bands in between the corosolic and asiatic bands; a minor blue band due to virgatic acid, above the band due to corosolic acid; and just below the asiatic band, a minor brown band. *Standard solution B* also exhibits two minor violet bands, separated, at about three-fourths of the chromatogram; the band with the lower R_f corresponds to oleanolic acid.

Acceptance criteria: Under visible light, the chromatogram of the *Sample solution* exhibits the most intense band as a violet band corresponding in color and R_f to the band due to corosolic acid in the chromatogram of *Standard solution A*, as well as the following bands corresponding to similar bands of *Standard solution B*: a minor blue band close to the start (about R_f 0.1), two minor purple bands below the corosolic acid, two minor blue bands above the corosolic acid, and two minor violet bands, which are separated, at about three-fourths of the chromatogram.

• B. HPLC

Analysis: Proceed as directed in *Content of Corosolic Acid*.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits a group of three peaks. The one in the center is the most intense of the group and occurs at a retention time corresponding to that of corosolic acid in the chromatogram of *Standard solution A*. The peak that elutes before corosolic acid has about one-half to one-third of the intensity of that of corosolic acid, and the peak that elutes after corosolic acid has the lesser intensity of the three and is consistent with virgatic acid. A minor peak due to oleanolic acid elutes later in the chromatogram.

COMPOSITION

• CONTENT OF COROSOLIC ACID

Solution A: Dilute 0.1% phosphoric acid in water.

Solution B: Acetonitrile

Mobile phase: A mixture of *Solution A* and *Solution B* (4:6)

Standard solution A: 0.1 mg/mL of [USP Corosolic Acid RS](#) in methanol

Standard solution B: 5.0 mg/mL of [USP Lagerstroemia speciosa Leaf Dry Extract RS](#) in methanol. Sonicate if necessary. Before injection, pass through a membrane filter of 0.45-µm or finer pore size. Discard the first few mL of the filtrate.

Sample solution: Banaba Leaf Dry Extract in methanol at a concentration equivalent to 0.1 mg/mL of corosolic acid according to the label claim. Sonicate if necessary. Before injection, pass through a membrane filter of 0.45-µm or finer pore size. Discard the first few mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 205 nm

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

Flow rate: 1.6 mL/min

Injection volume: 20 µL

System suitability

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

[NOTE—The approximate relative retention times of the individual peaks for corosolic acid, virgatic acid, and oleanolic acid are 1.00, 1.1, and 3.2, respectively.]

Suitability requirements

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

Resolution: NLT 1.5 between the corosolic acid peak and the preceding peak, *Standard solution B*

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

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

Analysis

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

Identify the relative retention times of the peaks for corosolic acid, virgatic acid, and oleanolic acid of the *Sample solution*.

Calculate the percentage of the labeled amount of corosolic acid in the portion of Banaba Leaf Dry Extract taken:

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

r_U = peak area of corosolic acid from the *Sample solution*

r_S = peak area of corosolic acid from *Standard solution A*

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

C_U = concentration of Banaba Leaf Dry Extract in the *Sample solution* (mg/mL)

Calculate the percentage of the labeled amount of corosolic acid in the portion of Extract taken:

$$\text{Result} = (P/L) \times 100$$

P = content of corosolic acid as determined above (%)

L = labeled amount of corosolic acid (%)

Acceptance criteria: 90.0%–110.0% of the labeled amount of corosolic acid on the dried basis

CONTAMINANTS

• [ELEMENTAL IMPURITIES—PROCEDURES \(233\)](#)

Acceptance criteria

Arsenic: NMT 2.0 µg/g

Cadmium: NMT 0.5 µg/g

Lead: NMT 5 µg/g

Mercury: NMT 0.2 µg/g

Change to read:

• [BOTANICAL EXTRACTS \(565\)](#), [Preparations](#), [General Pharmacopeial Requirements](#), [Pesticide Residues](#)  (CN 1-MAY-2020): Meets the requirements

• [MICROBIAL ENUMERATION TESTS \(2021\)](#): The total aerobic microbial count does not exceed 10⁴ cfu/g, and the total combined molds and yeasts count does not exceed 10³ cfu/g.

• [MICROBIAL PROCEDURES FOR ABSENCE OF SPECIFIED MICROORGANISMS \(2022\)](#): Meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*

SPECIFIC TESTS

• [LOSS ON DRYING \(731\)](#)

Sample: 2.0 g of Banaba Leaf Dry Extract

Analysis: Dry the *Sample* at 105° for 2 h.