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Banaba Leaf

DEFINITION

Banaba Leaf consists of the dried leaves of *Lagerstroemia speciosa* (L.) Pers. (Fam. Lythraceae). It contains NLT 0.2% of corosolic acid ($C_{30}H_{48}O_4$), calculated on the dried basis.

IDENTIFICATION

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

• **B. 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: About 0.2 g of Banaba Leaf, finely powdered, in 10 mL of methanol. Sonicate for 15 min, centrifuge, and use supernatant.

Chromatographic system

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

Mode: HPTLC

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

Application volume: 6 µL each of *Standard solution A* and *Standard solution B* and 8 µL of the *Sample solution* 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 toluene, ethyl acetate, and acetic acid (55:45:0.5)

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), a minor brownish band above the corosolic acid, and a minor violet band at about three-fourths of the chromatogram.

• **C. 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: Transfer about 5.0 g of Banaba Leaf, finely powdered and accurately weighed, to a round-bottom flask. Add 75 mL of methanol, reflux for 15 min, set aside to settle, and decant the supernatant. Repeat the extraction three more times, then combine the extracts. Filter, and concentrate under reduced pressure. Transfer to a 100-mL volumetric flask, adjust with methanol to volume, and mix. 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

Column temperature: 25°

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 1.0, 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 in the *Sample solution*.

Calculate the percentage of corosolic acid in the portion of Banaba Leaf taken:

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

r_U = peak area of corosolic acid from *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)

V = volume of *Sample solution* (mL)

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

Acceptance criteria: NLT 0.2% 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:

- [ARTICLES OF BOTANICAL ORIGIN, Pesticide Residue Analysis \(561\)](#) (CN 1-MAY-2019): Meets the requirements
- [MICROBIAL ENUMERATION TESTS \(2021\)](#): The total aerobic bacterial count does not exceed 10^5 cfu/g, the total combined molds and yeasts count does not exceed 10^3 cfu/g, and the bile-tolerant Gram-negative bacteria count does not exceed 10^3 cfu/g.
- [ABSENCE OF SPECIFIED MICROORGANISMS \(2022\)](#): Meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*

SPECIFIC TESTS

• **BOTANIC CHARACTERISTICS**

Macroscopic: Banaba leaves vary in shape, including lanceolate, oblong-lanceolate, oblong, and elliptic ovate. They are up to 34 cm long and 11 cm wide; olive green to yellowish brown; entirely or slightly wavy at the margins; base acute; apex acute to acuminate; leathery in texture; and petiolate with petioles up to 1 cm long.

Microscopic

Transverse section of the midrib: A layer of upper epidermis composed of rectangular to round cells covered with thin cuticle; a few layers of collenchyma cells; numerous layers of parenchyma cells, some containing cluster crystals of calcium oxalate with large intercellular spaces; groups of lignified fiber bundles; and secretory canals scattered in the parenchyma zone. Bicolateral vascular bundle encircled