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Powdered Malabar-Nut-Tree, Leaf Extract

DEFINITION

Powdered Malabar-Nut-Tree, Leaf Extract is prepared from Malabar-Nut-Tree, Leaf using suitable solvents such as water, methanol, or a mixture of these solvents. The ratio of plant material to extract is between 8:1 and 5:1. It contains NLT 90.0% and NMT 110.0% of the labeled amount of vasicine. It may contain suitable added substances as carriers.

IDENTIFICATION

• A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST](#)

Standard solution A: 0.5 mg/mL of [USP Vasicine RS](#) in methanol. Sonicate to dissolve if necessary.

Standard solution B: 50 mg/mL of [USP Powdered Malabar-Nut-Tree, Leaf Extract RS](#) in methanol. Sonicate for about 15 min, centrifuge, and use the supernatant.

Sample solution: 50 mg/mL of Powdered Malabar-Nut-Tree, Leaf Extract in methanol. Sonicate for about 15 min, centrifuge, and use the supernatant.

Adsorbent: Chromatographic silica gel with an average particle size of 10–15 µm (TLC plates)

Application volume: 10 µL, as 4-mm bands

Developing solvent system: A mixture of ethyl acetate, methanol, and ammonia (8:2:0.2)

Analysis

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

Apply the *Samples* as bands to a suitable thin-layer chromatographic plate (see [Chromatography \(621\)](#), [Thin-Layer Chromatography](#)). Use a saturated chamber. Develop the chromatograms until the solvent front has moved up about three-fourths of the plate. Remove the plate from the chamber, dry, and examine under UV at 254 nm.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits a quenching zone at an RF value of approximately 0.35 for vasicine, corresponding to a zone in the chromatogram of *Standard solution A*. The chromatogram of the *Sample solution* also exhibits an additional quenching zone at an RF value of approximately 0.53 for vasicinone, corresponding to a similar zone in the chromatogram of *Standard solution B*. Other minor zones may be observed in the *Sample solution* and *Standard solution B* chromatograms.

• **B. HPLC:** The chromatogram of the *Sample solution* from the test for *Content of Vasicine* shows a main peak at a retention time corresponding to that of vasicine in the chromatogram of *Standard solution A*. Identify other peaks in the *Sample solution* by comparison with the chromatogram of *Standard solution B* and the reference chromatogram provided with the lot of [USP Powdered Malabar-Nut-Tree, Leaf Extract RS](#) being used. The *Sample solution* shows an additional peak corresponding to vasicinone.

COMPOSITION

• CONTENT OF VASICINE

Buffer solution: Dissolve 1.36 g of anhydrous potassium dihydrogen phosphate in 900 mL of HPLC grade water. Add 2.0 mL of phosphoric acid. Dilute with water to 1000 mL, and filter.

Mobile phase: *Buffer solution*, acetonitrile, and tetrahydrofuran (92:5:3)

Standard solution A: 0.1 mg/mL of [USP Vasicine RS](#) in methanol. Sonicate to dissolve if necessary.

Standard solution B: 5.0 mg/mL of [USP Powdered Malabar-Nut-Tree, Leaf Extract RS](#) in methanol. Sonicate for about 15 min. Before injection, pass through a membrane filter of 0.45-µm or finer pore size.

Sample solution: 5.0 mg/mL of Powdered Extract in methanol. Sonicate for about 15 min. Before injection, pass through a membrane filter of 0.45-µm or finer pore size, and discard the first part of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-µm packing L10

Flow rate: 1.0 mL/min

Injection size: 20 µL

System suitability

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

[NOTE—The approximate relative retention times for vasicine and vasicinone peaks are 1.00 and 1.23, respectively.]

Suitability requirements

Chromatogram similarity: The chromatogram from *Standard solution B* is similar to the reference chromatogram provided with the lot of [USP Powdered Malabar-Nut-Tree, Leaf Extract RS](#) being used.

Resolution: NLT 2.0 between the vasicine and vasicinone peaks, *Standard solution B*

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

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 Powdered Malabar-Nut-Tree, Leaf Extract RS](#) being used, identify the retention times of the peaks corresponding to vasicine and vasicinone.

Calculate the percentage of vasicine in the portion of Powdered Extract taken:

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

r_U = peak response of vasicine from the *Sample solution*

r_S = peak response of vasicine from *Standard solution A*

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

C_U = concentration of Powdered Malabar-Nut-Tree, Leaf Extract in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0% of the labeled amount of vasicine

CONTAMINANTS

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 bacterial count does not exceed 10^4 cfu/g, and the total combined molds and yeasts 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

- **LOSS ON DRYING (731):** Dry 1.0 g of Powdered Extract at 105° for 3 h: it loses NMT 5.0% of its weight.
- **OTHER REQUIREMENTS:** It meets the requirements of the test for *Residual Solvents* in [Botanical Extracts \(565\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, protected from light and moisture, and store at controlled room temperature.
- **LABELING:** The label states the Latin binomial and, following the official name, the part of the plant from which the article was derived. It meets other labeling requirements in [Botanical Extracts \(565\)](#).
- **USP REFERENCE STANDARDS (11):**
[USP Powdered Malabar-Nut-Tree, Leaf Extract RS](#)
[USP Vasicine RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
POWDERED MALABAR-NUT-TREE, LEAF EXTRACT	Anton Bzhelyansky Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 36(6)

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