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Powdered Malabar-Nut-Tree, Leaf

DEFINITION

Powdered Malabar-Nut-Tree, Leaf is Malabar-Nut-Tree, Leaf reduced to a powder or very fine powder. It contains NLT 0.6% of vasicine, calculated on the dried basis.

IDENTIFICATION

• **A.** Powdered Malabar-Nut-Tree, Leaf meets the requirements in *Specific Tests, Botanical Characteristics*.

• **B. 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: Transfer about 2.0 g of Powdered Malabar-Nut-Tree, Leaf, accurately weighed, to a 250-mL round-bottom flask fitted with a reflux condenser. Add 50 mL of methanol, reflux for 15 min, cool to room temperature, and decant the supernatant. Repeat until the extract is colorless. Combine the extracts, filter, and concentrate under vacuum. Transfer into a 25-mL volumetric flask, and adjust to volume with methanol. [NOTE—Save the filtrate for use in the test for *Content of Vasicine*.]

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: 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. Using a saturated chamber, develop the chromatograms until the solvent front has moved up about three-fourths of the length 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 R_f 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 R_f 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.

• **C. 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 orthophosphate 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: Dilute the *Sample solution*, prepared as directed in *Identification test B* (1:5), with methanol. Before injection, pass through a membrane filter of 0.45-µm or finer pore size, and discard the first few mL 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 volume: 20 µL

System suitability

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

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

Suitability requirements

Chromatogram similarity: The chromatogram of *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 Malabar-Nut-Tree, Leaf taken:

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

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

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

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

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

W = weight of Powdered Malabar-Nut-Tree, Leaf taken to prepare the *Sample solution* (mg)

Acceptance criteria: NLT 0.6% 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 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 do 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

• BOTANICAL CHARACTERISTICS

Macroscopic: Greenish-brown powder; characteristic odor; and bitter taste

Microscopic: It shows parenchyma cells with elongated cystoliths; oil globules; epidermal cells with numerous stomata diacytic or anomocytic, glandular and nonglandular, 1- to 3-celled, thin-walled, warty trichomes.

• [LOSS ON DRYING \(731\)](#)

Sample: 1.0 g of Powdered Malabar-Nut-Tree, Leaf

Analysis: Dry the *Sample* at 105° for 3 h.

Acceptance criteria: NMT 12.0%

• [ARTICLES OF BOTANICAL ORIGIN, Total Ash\(561\)](#)

Sample: 1.0 g of Powdered Malabar-Nut-Tree, Leaf

Acceptance criteria: NMT 21.0%

• [ARTICLES OF BOTANICAL ORIGIN, Acid-Insoluble Ash\(561\)](#): NMT 2.0%

ADDITIONAL REQUIREMENTS

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