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Mangifera indica Bark Dry Extract

Proposed For Comment Version 0.2

***Mangifera indica* Bark Dry Extract**

DEFINITION

The article consists of the dried bark of *Mangifera indica* L. (Family Anacardiaceae) by extraction with methanol. The ratio of starting crude plant material to Dry Extract is between 12:1 and 10:1. It contains NLT 90.0% and NMT 110.0% of the labeled amount of mangiferin, calculated on the dried basis.

POTENTIAL CONFOUNDING MATERIALS

None known

CONSTITUENTS OF INTEREST

Xanthon: Mangiferin and isomangiferin

Triterpenes: Cycloart-24-en-3β,26-diol

Phenolic acid: Protocatechuic acid

IDENTIFICATION

- **A. Thin-Layer Chromatography**

  Standard solution A: 0.15 mg/mL of USP Mangiferin RS in methanol

  Standard solution B: 5 mg/mL of USP *Mangifera indica* Bark Dry Extract RS in methanol. Sonicate for 10 min, centrifuge, and use the supernatant.

  Sample solution: Sonicate about 50 mg of *Mangifera indica* Bark Dry Extract in 10 mL of *Solvent* for 10 min, centrifuge, and use the supernatant.

  Chromatographic system

  (See *Chromatography <621>, Thin-Layer Chromatography* [1].)

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

  Application volume: 4 µL each of *Standard solution A* and *Standard solution B,* and 2 µL of *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: Ethyl acetate, formic acid, and water (80:10:10)

  Developing distance: 7 cm

  Temperature: 25“

  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 a saturated chamber, remove the plate from the chamber, and dry. Examine under UV 254 and 366 nm.

  System suitability: Under UV 254 nm, the chromatogram of *Standard solution B* exhibits a black band similar in R_F to mangiferin in the chromatogram of *Standard solution A*. One weak band appears right above the origin and two weak bands appear above the mangiferin band. Under UV 366 nm, the chromatogram of *Standard solution B* exhibits a weak blue band similar in color and R_F to mangiferin in the chromatogram of *Standard solution A*. About six additional bands appear in the chromatogram with increasing R_F: a pale white/yellow band near the origin, a bright orange band slightly below the mangiferin band, a pale orange band above the mangiferin band, two blue bands near R_F of about 0.75, and a blue band near the solvent front.

  Acceptance criteria: Under UV 254 nm, the chromatogram of *Sample solution* exhibits a band corresponding in color and R_F to the mangiferin band in the chromatogram of *Standard solution A*. One weak band appears right above the origin. Under UV 366 nm, the chromatogram of *Sample solution* exhibits a weak blue band similar in color and R_F to mangiferin in the chromatogram of *Standard solution A*. About six additional bands appear in the chromatogram with increasing R_F: a pale white/yellow band near the origin, a bright orange band slightly below the mangiferin band, a pale orange band above the mangiferin band, two blue bands near R_F of about 0.75, and a pale blue band near the solvent front.

- **B. HPLC**

  Analysis: Proceed as directed in the *Assay* for *Content of Mangiferin*.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits a peak at a retention time corresponding to the peak due to mangiferin in *Standard solution B*.

ASSAY

- **Content of Mangiferin**

Solution A: Dissolve 0.136 g of monobasic potassium phosphate in 900 mL of water, add 0.5 mL of *o*-phosphoric acid, dilute with water to 1 L, and mix.

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.01	85	15
10	80	20
15	80	20
20	85	15
25	85	15

Solvent: 70% Methanol in water

Standard solution A: 0.1 mg/mL of USP Mangiferin RS in *Solvent*

Standard solution B: Accurately weigh USP *Mangifera indica* Bark Dry Extract RS, equivalent to 10 mg of mangiferin, into a 100-mL volumetric flask, add 50 mL of *Solvent,* and dissolve in a boiling water bath for 15 min with sonication. Cool the solution and dilute with *Solvent* to volume. Mix well and pass through a membrane filter of 0.45-µm pore size.

Sample solution: Accurately weigh *Mangifera indica* Bark Dry Extract, equivalent to 10 mg of mangiferin, into a 100-mL volumetric flask, add 50 mL of *Solvent,* and dissolve in a boiling water bath for 15 min with sonication. Cool the solution and dilute with *Solvent* to volume. Mix well and pass through a membrane filter of 0.45-µm pore size.

Chromatographic system

(See *Chromatography* <621>, *System Suitability*.)

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1 (similar to Merck kGaA Purospher Star LP HPLC Column, RP-18)

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

Chromatogram similarity: The chromatogram of *Standard solution B* is similar to the reference chromatogram provided with the lot of USP *Mangifera indica* Bark Dry Extract RS being used.

Tailing factor: NMT 1.5, *Standard solution A*

Relative standard deviation: NMT 2.0%, *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 *Mangifera indica* Bark Dry Extract RS being used, identify the retention time of the peak corresponding to mangiferin.

Calculate the percentage of mangiferin in the portion of *Mangifera indica* Bark Dry Extract taken:

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

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

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

C_S = concentration of USP Mangiferin RS in *Standard solution A* (mg/mL)

C_U = concentration of *Mangifera indica* Bark Dry Extract in the *Sample solution* (mg/mL)

Calculate the percentage of the labeled amount of mangiferin in the portion of Dry Extract taken:

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

P = content of mangiferin as determined above (%)

L = labeled amount of magiferin (%)

Acceptance criteria: 90.0%–110.0% on the dried basis

CONTAMINANTS

- **Elemental Impurities—Procedures <233>**

  Acceptance criteria

  Arsenic: NMT 2.0 µg/g

  Cadmium: NMT 1.0 µg/g

  Lead: NMT 5.0 µg/g

  Mercury: NMT 0.2 µg/g

- **Articles of Botanical Origin,** *General Method for Pesticide Residues Analysis* **<561>:** Meets the requirements
- **Articles of Botanical Origin,** *Test for A* [2]*flatoxins* **<561>:** Meets the requirements
- **Microbial Enumeration Tests <2021>:** The total aerobic bacterial count does not exceed 10^4 cfu/g, the total combined molds and yeasts count does not exceed 10^2 cfu/g, and the bile-tolerant Gram-negative bacteria does not exceed 10^2 cfu/g.
- **Absence of Specified Microorganisms <2022>:** Meets the requirements of the tests for the absence of *Salmonella* species, *Escherichia coli,* and *Staphylococcus aureus*

SPECIFIC TESTS

- **Loss on Drying <731>**

  Sample: 1 g of *Mangifera indica* Bark Dry Extract

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

  Acceptance criteria: NMT 10%

- **Articles of Botanical Origin,** *Total Ash* **<561>:** NMT 5%
- **Articles of Botanical Origin,** *Acid-Insoluble Ash* **<561>:** NMT 1.5%
- **Other Requirements:** It meets the requirements of the *Residual Solvents* test in *Botanical Extracts* <565>.

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 the part(s) of the plant contained in the article. It meets other labeling requirements in *Botanical Extracts* <565>.
- **USP Reference Standards <11>**

  USP *Mangifera indica* Bark Dry Extract RS

  USP Mangiferin RS

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