

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-3 β ,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 μ m (HPTLC plates)

Application volume: 4 μ L each of *Standard solution A* and *Standard solution B*, and 2 μ L 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- μ m 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- μ m pore size.

Chromatographic system

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

Detector: UV 254 nm

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

Flow rate: 1.5 mL/min

Injection volume: 20 μ L

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 mangiferin (%)

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 10⁴ cfu/g, the total combined molds and yeasts count does not exceed 10² cfu/g, and the bile-tolerant Gram-negative bacteria does not exceed 10² 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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