

## Mangifera indica Bark Dry Extract

### Proposed For Comment Version 0.2

#### *Mangifera indica* Bark Dry Extract

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#### 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 $\beta$ ,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  $\mu$ m (HPTLC plates)

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

### Chromatographic system

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

**Detector:** UV 254 nm

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

**Flow rate:** 1.5 mL/min

**Injection volume:** 20  $\mu$ 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 Aflatoxins <561>:** Meets the requirements
- **MICROBIAL ENUMERATION TESTS <2021>:** The total aerobic bacterial count does not exceed 10<sup>4</sup> cfu/g, the total combined molds and yeasts count does not exceed 10<sup>2</sup> cfu/g, and the bile-tolerant Gram-negative bacteria does not exceed 10<sup>2</sup> 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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