

Sceletium tortuosum Aerial Parts

Proposed For Development Version 0.1

Sceletium tortuosum Aerial Parts

DEFINITION

The article consists of the dried aerial parts of *Sceletium tortuosum* (L.) N.E. Br. (Family Aizoaceae). It meets the *Acceptance criteria* under the *Assay*.

SYNONYMS

Mesembryanthemum tortuosum L.

Sceletium tortuosum (L.) N.E. Brown

POTENTIAL CONFOUNDING MATERIALS

Aptenia species

SELECTED COMMON NAMES

African: Kanna, channa, kougoed (fermented article)

English: Sceletium

French: Sceletium

German: Sceletium

Italian: Sceletium

CONSTITUENTS OF INTEREST

Alkaloids: Mesembrine, mesembranol, mesembrenol, mesembrenone, and tortuosamine

IDENTIFICATION

• A. BOTANICAL CHARACTERISTICS

Macroscopic: Prostrate to scrambling perennial succulent herb; fresh article is bright green, shiny and succulent; stem carries overlapping pairs of leaves that have shiny water cells (bladder cell idioblasts) on their surfaces; leaf is flat and triangular, with tips incurved, 30–40 mm long, 10–15 mm wide. The dried plant material appears fibrous with small greenish-brown leaves.

Microscopic: (To Come)

• B. THIN-LAYER CHROMATOGRAPHY

Standard solution A: 0.2 mg/mL of USP Mesembrine RS (To Come) in methanol

Standard solution B: 0.4 mg/mL of USP *Sceletium tortuosum* Alkaloids RS (To Come) in methanol. Sonicate if necessary.

Sample solution: Transfer about 2.0 g of *Sceletium tortuosum* Aerial Parts, powdered (500 µm mesh size), to a 30-mL centrifuge tube, add 24 mL of 0.5 M H₂SO₄, vortex for 15 s, and centrifuge at 5000 RPM for 15 min. Filter the supernatant into a separatory funnel, add 6.0 mL of 20% aqueous ammonia solution, mix, add 14 mL of dichloromethane, mix by gentle swirling for 10 min, and allow to separate. Filter the supernatant into a clean round-bottom flask. Repeat the extraction with dichloromethane, combine the filtrates, and evaporate under reduced pressure. Dissolve 0.4 mg/mL of the residue in methanol. Sonicate if necessary.

Chromatographic system

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

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

Application volume: 2 µL, as 8-mm bands

Relative humidity: Condition the plate to a relative humidity of about 47% using a suitable device.

Developing solvent system: Dichloromethane, methanol, and 10% ammonium hydroxide solution (90:10:0.1)

Developing distance: 7 cm

Derivatization reagent: Iodoplatinate reagent – 3 mg/mL hydrogen hexachloroplatinate (IV) hydrate in water. Before use, dilute 1:1 with a solution of 6% potassium iodide in water.

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 chromatogram in a saturated chamber, remove

the plate from the chamber, and dry in air. Derivatize with *Derivatization reagent* and dry. Examine under visible light.

System suitability: The chromatogram of *Standard solution B* exhibits a brownish-violet band at an R_f corresponding to the mesembrine band in the chromatogram of *Standard solution A*. Other bands shown in the chromatogram of *Standard solution B* include: the most intense band as a brownish-violet band at about the middle of the chromatogram; two brownish-violet bands in the lower-third section of the chromatogram, one close to the start due to mesembranol and the other at a higher R_f due to mesembrenol; and a brownish-violet band in the upper-third section of the chromatogram, at a higher R_f than that of mesembrine, due to mesembrenone. The bands due to mesembrine and mesembrenone are separated.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits a band due to mesembrine corresponding in color and R_f to the band in the chromatogram of *Standard solution A*, and the following bands corresponding to similar bands in the chromatogram of *Standard solution B*: the most intense band as a brownish-violet band at about the middle of the chromatogram, two brownish-violet bands in the lower-third section of the chromatogram due to mesembranol and mesembrenol, and a brownish-violet band in the upper-third section of the chromatogram due to mesembrenone.

ASSAY

• CONTENT OF ALKALOIDS

CALL FOR SUBMISSION OF VALIDATED INFORMATION

Additional information including validation data will be required to complete the development of the Assay. For requirements, please see under "*Composition*" and related sections in the guidelines document "*Monographs in the Herbal Medicines Compendium*" at <http://hmc.usp.org/about/general-notice-resources> [1].

Interested parties are encouraged to submit their proposals to complete the monograph.

CONTAMINANTS

• ELEMENTAL IMPURITIES—PROCEDURES <233>

Acceptance criteria

Arsenic: NMT 2 µg/g

Cadmium: NMT 0.3 µg/g

Lead: NMT 5 µg/g

Mercury: NMT 0.2 µg/g

- **ARTICLES OF BOTANICAL ORIGIN, *General Method for Pesticide Residues Analysis* <561>:** Meets the requirements
- **MICROBIAL ENUMERATION TESTS <61>:** 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 does not exceed 10^3 cfu/g.
- **TESTS FOR SPECIFIED MICROORGANISMS <62>:** Meets the requirements of the tests for the absence of *Salmonella* species and *Escherichia coli*

SPECIFIC TESTS

- **ARTICLES OF BOTANICAL ORIGIN, *Foreign Organic Matter* <561>:** NMT 1%
- **ARTICLES OF BOTANICAL ORIGIN, *Water-Soluble Extractives, Method 1* <561>:** NLT 15%
- **LOSS ON DRYING <731>**
 - Analysis:** Dry 1.0 g of *Sceletium tortuosum* Aerial Parts, finely powdered, at 105° for 2 h.
 - Acceptance criteria:** NMT 12%
- **ARTICLES OF BOTANICAL ORIGIN, *Total Ash* <561>**
 - Analysis:** 4.0 g of *Sceletium tortuosum* Aerial Parts, finely powdered
 - Acceptance criteria:** NMT 5%
- **ARTICLES OF BOTANICAL ORIGIN, *Acid-Insoluble Ash* <561>**
 - Analysis:** 6.0 g of *Sceletium tortuosum* Aerial Parts, finely powdered
 - Acceptance criteria:** NMT 1%

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 parts of the plant contained in the article.
- **USP REFERENCE STANDARDS <11>**
 - USP Mesembrine RS (To Come)
 - USP *Sceletium tortuosum* Alkaloids RS (To Come)