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-noticesresources](http://hmc.usp.org/about/general-noticesresources).[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 \( 10^4 \) 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*)

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