

## Sceletium tortuosum Aerial Parts

### Proposed For Development Version 0.1

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#### 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 H<sub>2</sub>SO<sub>4</sub>, 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> [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)

