Pelargonium sidoides Root

Proposed For Development Version 0.1

Pelargonium sidoides Underground Organs

DEFINITION
The article consists of the dried underground organs of *Pelargonium sidoides* DC (Family Geraniaceae). It meets the *Acceptance criteria* under the Assay.

SYNONYMS
*Cortusina sidifolia* Eckl. & Zeyh.
*Geraniospermum sidifolium* Kuntze.
*Geranium sidifolium* Thunb.

POTENTIAL CONFOUNDING MATERIALS
*Pelargonium reniforme* Curtis.

SELECTED COMMON NAMES
African: Kalwerbossie, rabas, rabassam, umckaloabo
English: *Pelargonium sidoides*
French: *Pelargonium sidoides*
Italian: *Pelargonium sidoides*
Swedish: Mörk pelargon

CONSTITUENTS OF INTEREST
**Coumarins:** Scopoletin, umckalin, umckalin-7-O-methylether, fraxetin, artelin, and umckalin-7-β-glucoside

IDENTIFICATION
- **A. BOTANICAL CHARACTERISTICS**
  - **Macroscopic:** The root is covered with dark, partly reddish-brown, longitudinally fissured bark. Tuberous rhizomes.
  - **Microscopic:** *(To Come)*

- **B. THIN-LAYER CHROMATOGRAPHY**
  - **Standard solution A:** 0.1 mg/mL of USP Scopoletin RS in methanol
  - **Standard solution B:** Sonicate about 0.5 g of USP *Pelargonium sidoides* Root Powder RS *(To Come)* in 10 mL of methanol for 15 min. Centrifuge and use the supernatant.
  - **Sample solution:** Sonicate about 0.5 g of *Pelargonium sidoides* Root, finely powdered, in 10 mL of methanol for 15 min. Centrifuge and use the supernatant.

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

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

**Application volume:** 5 µL, as 8-mm bands

**Relative humidity:** Condition the plate to a relative humidity of about 30% using a suitable device.

**Developing solvent system:** Ethyl acetate, methanol, and water (76:14:10)

**Developing distance:** 6 cm

**Derivatization reagent:** 3% potassium hydroxide solution in 95% alcohol

### 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 UV light at 365 nm.

**System suitability:** The chromatogram of Standard solution B exhibits a blue fluorescent band at an $R_F$ corresponding to the scopoletin band in the chromatogram of Standard solution A. Other bands shown in the chromatogram of Standard solution B include two blue fluorescent bands in the lower-third section of the chromatogram, one or two bright blue fluorescent bands at about the middle of the chromatogram, and a blue fluorescent band at an $R_F$ above the band due to scopoletin.

**Acceptance criteria:** The chromatogram of the Sample solution exhibits a band due to scopoletin corresponding in color and in $R_F$ to the band in the chromatogram of Standard solution A. Other bands shown in the chromatogram of the Sample solution correspond to similar bands in the chromatogram of Standard solution B: two blue fluorescent bands in the lower-third section of the chromatogram, one or two bright blue fluorescent bands at about the middle of the chromatogram, and a blue fluorescent band at an $R_F$ above the band due to scopoletin.

### ASSAY

**CONTENT OF COUMARINS**

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.

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*
- **Articles of Botanical Origin, Test for Aflatoxins <561>:** Meets the requirements

**Specific Tests**
- **Articles of Botanical Origin, Foreign Organic Matter <561>:** NMT 2%
- **Loss on Drying <731>**
  
  Analysis: Dry 2.0 g of *Pelargonium sidoides* Root, finely powdered, at 105° for 2 h.
  
  Acceptance criteria: NMT 12%
- **Articles of Botanical Origin, Total Ash <561>**
  
  Analysis: 2.0 g of *Pelargonium sidoides* Root, finely powdered
  
  Acceptance criteria: NMT 12%
- **Articles of Botanical Origin, Acid-Insoluble Ash <561>**
  
  Analysis: 4.0 g of *Pelargonium sidoides* Root, finely powdered
  
  Acceptance criteria: NMT 3%

**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 Aflatoxins RS [2]
  - USP *Pelargonium sidoides* Powder Root RS (To Come)
  - USP Scopoletin RS [3]

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