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Angelica gigas Root Powder

Proposed For Development Version 0.1

***Angelica gigas* Root Powder**

DEFINITION

The article consists of the dried roots of *Angelica gigas* Nakai (Family Apiaceae), reduced to powder or very fine powder. It contains NLT 4.2% of caffeoylquinic acid and total coumarins calculated as the sum of chlorogenic acid, demethylsuberosin, decursin, and decursinol angelate on the dried basis.

POTENTIAL CONFOUNDING MATERIALS

Angelica acutiloba (Siebold & Zucc.) Kitag.
Angelica sinensis (Oliv.) Diels

CONSTITUENTS OF INTEREST

Coumarins: Decursin, decursinol, decursinol angelate, nodakenin

IDENTIFICATION

- **A. Botanical Characteristics:** To Come

· **B. HPTLC for Articles of Botanical Origin <203>**

Standard solution: 1.0 mg/mL each of USP Imperatorin RS, USP Osthole RS, and USP Isoimperatorin RS in methanol

Sample solution: 1 g of *Angelica gigas* Root Powder in 5 mL of methanol. Sonicate for 10 min and centrifuge or filter. Use supernatant or filtrate.

Chromatographic system

Adsorbent: Chromatographic silica gel F_{254} mixture

Application volume: 10 µL each of *Standard solution* and *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: Toluene, ethyl acetate, and acetic acid (90:10:1)

Developing distance: 6 cm

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the *Samples* as bands to a suitable HPTLC plate and dry in air. Develop the chromatograms in a saturated chamber (20 min with filter paper), remove the plate from the chamber, and examine under UV 365 nm light.

System suitability: To Come

Acceptance criteria: Under UV 365 nm light, the chromatogram of the *Sample solution* exhibits about 8 fluorescence bands in the lower half of the chromatogram. Three pale fluorescence bands appear above the broad fluorescence band near R_F 0.25 corresponding in color and R_F to the bands due to imperatorin, osthole, and isoimperatorin, with increasing R_F in the *Standard solution*.

· **C. HPLC**

Analysis: Proceed as directed in the *Assay* for *Content of Caffeoylquinic Acid and Total Coumarins.*

Acceptance criteria: The *Sample solution* exhibits the most intense peak at a retention time corresponding to each *Standard solution.*

ASSAY

- **Content of Caffeoylquinic Acid and Total Coumarins**

Solution A: 0.1% formic acid in water

Solution B: 0.1% formic acid in acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	88	12
10	82	18
25	80	20
30	50	50
60	50	50

Solvent: Ethyl alcohol and water (7:3)

Standard solution A: 0.2 mg/mL of USP Chlorogenic Acid RS in methanol

Standard solution B: 0.8 mg/mL of USP Demethylsuberosin RS in methanol

Standard solution C: 2 mg/mL of USP Decursin RS in methanol

Standard solution D: 2 mg/mL of USP Decursinol Angelate RS in methanol

Sample solution: Accurately transfer about 1.0 g of *Angelica gigas* Root Powder to a centrifugal tube, add 10 mL of *Solvent,* and weigh. Sonicate for 45 min, cool, and compensate the weight loss with *Solvent*. Before injection, pass through a membrane filter of 0.45-µm pore size.

Chromatographic system

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

Detector: UV 325 nm

Column: 4.6-mm × 25-cm; packing L1

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability: **To Come**

Analysis

Samples: *Standard solutions A–D* and *Sample solution*

Calculate the percentage of chlorogenic acid, demethylsuberosin, decursin, and decursinol angelate in the portion of *Angelica gigas* Root Powder taken:

$$\text{Result} = (r_U/r_S) \times C_S \times (V/W) \times 100$$

r_U = peak area of the corresponding analyte from the *Sample solution*

r_S = peak area of the corresponding analyte from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

V = volume of the *Sample solution*, mL

W = weight of *Angelica gigas* Root Powder taken to prepare the *Sample solution*, mg

Acceptance criteria: NLT 4.2% of caffeoylquinic acid and coumarins on the dried basis

CONTAMINANTS

• **Elemental Impurities—Procedures <233>**

Acceptance criteria

Arsenic: NMT 3.0 µg/g

Cadmium: NMT 0.3 µg/g

Lead: NMT 5.0 µg/g

Mercury: NMT 0.2 µg/g

• **Articles of Botanical Origin <561>,** *Pesticide Residue Analysis***:** 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 absence of *Salmonella* species and *Escherichia coli*
- **Articles of Botanical Origin <561>,** *Test for Aflatoxins***:** Meets the requirements

SPECIFIC TESTS

- **Articles of Botanical Origin <561>,** *Methods of Analysis, Foreign Organic Matter***:** NMT 5.0%
- **Articles of Botanical Origin <561>,** *Methods of Analysis, Alcohol-Soluble Extractives, Method 1***:** To Come
- **Articles of Botanical Origin <561>,** *Methods of Analysis, Water-Soluble Extractives, Method 2***:** To Come
- **Loss on Drying <731>: To Come**
- **Articles of Botanical Origin <561>,** *Methods of Analysis, Total Ash***:** NMT 6.0%
- **Articles of Botanical Origin** <561>**,** *Methods of Analysis, Acid-Insoluble Ash***:** To Come

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.
- **USP Reference Standards <11>**

  USP Chlorogenic Acid RS
  USP Decursin RS
  USP Decursinol Angelate RS
  USP Demethylsuberosin RS
  USP Imperatorin RS
  USP Isoimperatorin RS
  USP Osthole RS
