식품의약품안전처 보도참고자료

보도시점 배포 즉시 배포 2025. 7. 18.(금)

<USP-Herbal Medicines Compendium>

국내 자생종 참당귀, 미국생약규격집 최초 등재

- '참당귀(*Angelica gigas*)' 등재로 함유제품의 해외시장 진출 등 기대

식품의약품안전처(처장 오유경) **식품의약품안전평가원**(원장 강석연)은 **미국약전위원회(USP)***와의 **공동연구****를 통해 국내 자생종인 **참당귀**가 **최초**로 USP에서 발간하는 **미국생약규격집(HMC)**에 **등재**됐다고 밝혔다.

* 미국약전위원회(USP, **U**nited **S**tates **P**harmacopeial Convention) : 미국약전을 제·개정하고, 약전과 표준품에 대한 교육훈련을 제공하는 비영리기관

** 2012년 평가원-USP 간 업무협약(MOU) 체결로 의약품 등 공통 규격 개발 및 공동 약전 수재, 전문인력 교류, 심포지엄 개최 등 교류 추진

미국생약규격집(HMC, Herbal Medicines Compendium)은 미국 내 생약의 품질 표준 참조를 위한 기준서로, 이번 등재로 우황청심원(뇌졸중) 등의 원료인 **참당귀(*Angelica gigas*)**와 은교산(기침, 두통) 등의 원료인 **연교(*Forsythia suspensa*)**가 포함된 제품을 **미국**에 **수출**하는 경우 **해당 원료**의 **품질**이 **확보**된 것으로 **인정**받게 된다.

김현정 광동제약(주) 천연물의약 R&D 센터장은 "**전통적으로 많이 사용**되는 **국내 자생종**인 **참당귀**는 **한약제제 등**의 원료로 널리 활용되고 있는 대표 품목인 만큼, 이번 등재가 **생약 산업 활성화**의 **마중물**이 될 것이며 **미국시장 진출**에 **큰 도움**이 될 것으로 기대한다"고 밝혔다.

강석연 원장은 "이번 등재를 계기로 **미국**에 **제품**을 **수출**하려는 **국내 업계**와의 **소통**과 **국내산 생약 원료**의 **지속적인 미국생약규격집 등재**를 통해 **국내 생약**의 **국제적인 품질**을 **보장**하는 한편, **미국시장 진출**을 **지원**하는데 최선을 다하겠다"고 밝혔다.

담당 부서	식품의약품안전평가원 생약연구과	책임자	과 장	황진희 (043-719-4801)
		담당자	연구관	김종환 (043-719-4804)

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Herbal Medicines Compendium

Published on *Herbal Medicines Compendium* (https://hmc.usp.org)

Angelica gigas Root Powder

Final Authorized Version 1.0

***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 4.0% of total coumarins calculated as the sum of demethylsuberosin, decursin, and decursinol angelate, on the dried basis.

POTENTIAL CONFOUNDING MATERIALS

Angelica acutiloba (Siebold & Zucc.) Kitag.
Angelica acutiloba var. *sugiyamae* Hikino
Angelica sinensis (Oliv.) Diels

CONSTITUENTS OF INTEREST

Coumarins: Decursin, decursinol, decursinol angelate, nodakenin

IDENTIFICATION

- **A. Botanical Characteristics**

Macroscopic: Pale yellow-brown powder

Microscopic: The article contains yellow, subpolygonal cork cells varying in size. Fragments of oil cavities that contain yellow oil droplets or oil mass secretions are sometimes visible. Reticulate vessels are prevalent. Annular and scalariform vessels may also be present. Phloem parenchymatous cells are fusiform and have relatively thick walls. The surface has very fine oblique crisscross striations. Thin transverse septa are visible at times. Starch grains are mostly composed of subspheroidal granules.

- **B. HPTLC for Articles of Botanical Origin <203>** [1]

Standard solution A: 1.0 mg/mL of USP Decursin RS [2] in methanol

Standard solution B: 200 mg/mL of USP *Angelica gigas* Root Powder RS [2] in methanol. Sonicate for 10 min, and centrifuge or filter. Use the supernatant or filtrate.

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

Chromatographic system

(See *HPTLC for Articles of Botanical Origin* <203>, *Table 1* [1].)

Application volume: 4 µL each of the *Standard solutions* and *Sample solution*, as 8-mm bands

Developing solvent system: Toluene, ethyl acetate, and glacial acetic acid (90:10:1)

Analysis

Samples: *Standard solutions* 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 long-wave UV light.

System suitability: Under long-wave UV light, *Standard solution B* exhibits in the lower half of the chromatogram the most intense, bright fluorescence band corresponding in R_f and color to decursin in *Standard solution A*.

Acceptance criteria: Under long-wave UV light, the *Sample solution* exhibits in the lower half of the chromatogram the most intense fluorescence band corresponding in R_f and color to decursin in *Standard solution A*. The *Sample solution* exhibits about six to eight fluorescence bands in the lower half of the chromatogram; two faint fluorescence bands above decursin band, one fluorescence band below decursin corresponding to 7-demethylsuberosine, and two to three fluorescence bands near the solvent origin. No bright blue band should be observed in the upper half of the chromatogram.

- **C. HPLC**

Analysis: Proceed as directed in the *Assay* for *Content of Coumarins*.

Acceptance criteria: The *Sample solution* exhibits peaks at retention times corresponding to the peaks due to chlorogenic acid, demethylsuberosin, decursin, and decursinol angelate in *Standard solution B*, with the most intense peak at a retention time corresponding to decursin in *Standard solution A*. The peak height of decursinol angelate is about half that of decursin.

ASSAY

- **Content of Coumarins**

Solution A: 0.1% formic acid (98%, v/v) in water

Solution B: 0.1% formic acid (98%, v/v) 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
60.1	88	12
65	88	12

Solvent: Ethyl alcohol and water (7:3)

Standard solution A: 1.0 mg/mL of USP Chlorogenic Acid RS [3] and USP Decursin RS [2] in methanol

Standard solution B: Mix 100 mg of USP *Angelica gigas* Root Powder RS [2] with 20 mL of *Solvent*. Sonicate for 45 min, and centrifuge or filter. Use the supernatant or filtrate.

Sample solution: Transfer 200 mg of *Angelica gigas* Root Powder, accurately weighed, to a test tube and add 2 mL of *Solvent*. Sonicate for 45 min and cool down. Transfer 1 mL of this solution to a 20-mL volumetric flask, add 15 mL of *Solvent*, and mix well. Add *Solvent* to volume. Before injection, pass through a membrane filter of 0.45-µm pore size.

Chromatographic system

(See *Chromatography* <621>, *System Suitability* [1].)

Mode: LC

Detector: UV 325 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1 (YMC-Pack ODS-A or similar)

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Samples: *Standard solution A* and *Standard solution B*

Suitability requirements

Resolution: NLT 1.5 between decursin and decursinol angelate, *Standard solution B*

Tailing factor: NMT 2.0 for decursin, *Standard solution A*

Relative standard deviation: NMT 2.0 for the decursin peak in repeated injections, *Standard solution A*

Chromatogram similarity: The chromatogram of *Standard solution B* is similar to the reference chromatogram provided with the lot of USP *Angelica gigas* Root Powder RS [2] being used.

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Using the chromatograms of *Standard solution A*, *Standard solution B*, and the reference chromatogram provided with the lot of USP *Angelica gigas* Root Powder RS [2] being used, identify the retention time of the peaks corresponding to chlorogenic acid, demethylsuberosin, decursin, and decursinol angelate in the *Sample solution* chromatogram. See *Table 2* for the approximate relative retention times of demethylsuberosin, decursin, and decursinol angelate compared to chlorogenic acid.

Table 2

Analyte	Relative Retention Time	Conversion Factor
Chlorogenic acid	1.0	–
Demethylsuberosin	5.6	0.83
Decursin	7.5	1.00
Decursinol angelate	7.6	0.96

Calculate the percentage of coumarins as the sum of demethylsuberosin, decursin, and decursinol angelate in the portion of *Angelica gigas* Root Powder taken:

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

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

r_S = peak area of decursin from *Standard solution A*

C_S = concentration of USP Decursin RS [2] in *Standard solution A* (mg/mL)

V = volume of the *Sample solution* (mL)

W = weight of *Angelica gigas* Root Powder used to prepare the *Sample solution* (mg)

F = conversion factor for the relevant analyte (see *Table 2*)

Acceptance criteria: NLT 4.0% of total coumarins on the dried basis

CONTAMINANTS

- **Elemental Impurities—Procedures <233>** [1]

  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>,** [1]*Pesticide Residue Analysis* [1]**:** Meets the requirements
- **Microbial Enumeration Tests <61>** [1]**:** 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>** [1]**:** Meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*
- **Articles of Botanical Origin <561>,** [1]*Test for Aflatoxins* [1]**:** Meets the requirements

SPECIFIC TESTS

- **Articles of Botanical Origin <561>,** [1]*Methods of Analysis, Foreign Organic Matter* [1]**:** NMT 5.0%
- **Articles of Botanical Origin <561>,** [1]*Methods of Analysis, Alcohol-Soluble Extractives, Method 1* [1]**:** NLT 55%
- **Loss on Drying <731>** [1]

  Sample: 2.0 g of *Angelica gigas* Root Powder

  Analysis: Dry the *Sample* at 105º for 5 h.

  Acceptance criteria: NMT 10.0%

- **Articles of Botanical Origin <561>,** [1]*Methods of Analysis, Total Ash* [1]**:** NMT 6.0%
- **Articles of Botanical Origin <561>,** [1]*Methods of Analysis, Acid-Insoluble Ash* [1]**:** NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight 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>** [1]

  USP *Angelica gigas* Root Powder RS [2]

  USP Chlorogenic Acid RS [3]

  USP Decursin RS [2]

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Forsythia suspensa Fruit

Final Authorized Version 1.0

Forsythia suspensa Fruit

DEFINITION

The article consists of ripe or unripe dried fruit of *Forsythia suspensa* (Thunb.) Vahl (Fam. Oleaceae). It contains NLT 2.0% of forsythiaside, on the dried basis.

SYNONYMS

Forsythia fortunei Lindl.
Forsythia suspensa fo. *pubescens* Rehder
Forsythia suspensa var. *fortunei* (Lindl.) Rehder
Forsythia suspensa var. *latifolia* Rehder
Forsythia suspensa var. *sieboldii* Zabel
Ligustrum suspensum Thunb.
Rangium suspensum (Thunb.) Ohwi
Syringa suspensa Thunb.

POTENTIAL CONFOUNDING MATERIALS

Forsythia viridissima Lindl.

SELECTED COMMON NAMES

Chinese: 连翘
English: Forsythia, golden-bell, goldenbells, weeping forsythia, weeping goldenbells
Korean: 연교
Swedish: Hängforsythia

CONSTITUENTS OF INTEREST

Phenylpropanoid: Forsythiaside
Lignans: Phillygenin, pinoresinol, lariciresinol
Lignan glycoside: Phillyrin

IDENTIFICATION

- **A. Botanical Characteristics**

  Macroscopic: The fruit is an ovoid to elongated ellipsoid, 2-valved capsule, slightly compressed, 15-25 mm long and 5-13 mm in diameter. The apex is elongated to a point. At maturity, the valves separate

and spread like a beak at the apex, or the entire fruit splits in half. The base is slightly rounded to blunter-pointed and the fruit stalk sometimes persists. The outer surface is brown to greenish in young fruit, yellowish to reddish brown in old fruit, with uneven wrinkles or longitudinal striations; scattered raised lenticels throughout; and a longitudinal groove on each surface between the valve sutures. The inner surface of the fruit is pale and smooth, with a brittle longitudinal septum. Seeds are small, brown, somewhat irregularly shaped, usually lost in mature fruit. The fruit has a slight peculiar aroma and tastes bitter.

Microscopic: The exocarp consists of a single row of flat elongated cells, the outer surface of which is covered with a cuticle. The outer and middle portions of the mesocarp consist of parenchyma with scattered vascular bundles, which may contain stone cells; the inner mesocarp is a dense layer of stone cells and thick-walled fibers. The endocarp is a single layer of small flat thin-walled cells.

· **B. HPTLC for Articles of Botanical Origin <203>** [1]

Standard solution A: 5 mg/mL of USP Forsythiaside RS [2] in methanol

Standard solution B: Prepare 100 mg/mL of USP *Forsythia suspensa* Fruit Powder RS [2] in methanol by sonicating for 10 min, and filter. Use the filtrate.

Sample solution: 500 mg of *Forsythia suspensa* Fruit, finely powdered, in 5 mL of methanol. Sonicate for 10 min, filter or centrifuge, and use the filtrate or supernatant.

Chromatographic system

(See *HPTLC for Articles of Botanical Origin* <203>, *Table 1* [1])

Application volume: 2 µL each of the *Standard solutions* and *Sample solution*, as 8-mm bands

Developing solvent system: Toluene, acetone, ethyl acetate, formic acid (98%) and water (20:25:30:3:3)

Derivatization reagent: Anisaldehyde reagent prepared as follows. Slowly and carefully mix 85 mL of ice-cooled methanol with 10 mL of glacial acetic acid and 5 mL of sulfuric acid. Allow the mixture to cool to room temperature, then add 0.5 mL of anisaldehyde.

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Apply the *Samples* as bands and dry in air. Develop in a saturated chamber (20 min with filter paper), remove the plate from the chamber, and dry in air. Examine under long-wave UV light. Treat the plate with *Derivatization reagent*, heat at 100° for 3 min, and examine under white light.

System suitability: Under long-wave UV light, *Standard solution B* exhibits a fluorescent band in the lower half of the chromatogram corresponding in R_f and color to the forsythiaside band from *Standard solution A*. Under white light after derivatization, a brown band in the lower half of the chromatogram corresponding in R_f and color to the forsythiaside band from *Standard solution A*.

Acceptance criteria: Under long-wave UV light, in the lower half of the chromatogram, the *Sample solution* exhibits a fluorescent band corresponding in R_f and color to the forsythiaside band from *Standard solution A*. In the unripe fruit, two red bands, intense in upper R_f and pale in lower R_f, appear upper third of the chromatogram. In the ripe fruit, a red band with the same R_f as the upper red band in unripe fruit appears. One fluorescent band appears below that red band. Under white light after derivatization, the Sample solution exhibits a brown band in the lower half of the chromatogram corresponding in R_f and color to forsythiaside. One brown band appears above forsythiaside, and one or two additional brown bands appear below forsythiaside. One brown band appears in the upper half of the chromatogram, near R_f 0.65. One blue–purple band appears with one or two purple bands above it. In unripe fruit, an intense purple band appears above the blue–purple band.

· **C. HPLC**

Analysis: Proceed as directed in the *Assay* for *Content of Forsythiaside*.

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

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

ASSAY

- **Content of Forsythiaside**

Solution A: 0.3% glacial acetic acid in water

Solution B: Methanol

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
8	60	40
28	55	45
32	2	98
36	2	98
36.01	70	30
40	70	30

Solvent: Methanol and water (50:50)

Standard solution A: 1 mg/mL of USP Forsythiaside RS [2] in methanol

Standard solution B: 4 mg/mL of USP *Forsythia suspensa* Fruit Powder RS [2] in *Solvent* by sonicating for 60 min and pass through a membrane filter of 0.45-µm pore size.

Sample solution: Accurately transfer about 200 mg of *Forsythia suspensa* Fruit, finely powdered and accurately weighed, to a 100-mL test tube, and add 50.0 mL of *Solvent*. Cap tightly and sonicate for 60 min and cool down. Before injection, pass through a membrane filter of 0.45-µm pore size.

Chromatographic system

(See *Chromatography* <621>, *System Suitability* [2].)

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1 (YMC-Pack, ODS-A or similar)

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Samples: *Standard solution A* and *Standard solution B*

Suitability requirements

Resolution: NLT 2.0 between forsythiaside and the subsequent peak, *Standard solution B*

Tailing factor: NMT 2.0 for forsythiaside, *Standard solution A*

Relative standard deviation: NMT 2.0% for forsythiaside in replicate injections, *Standard solution A*

Chromatogram similarity: The chromatogram of *Standard solution B* is similar to the reference

chromatogram provided with the lot of USP *Forsythia suspensa* Fruit Powder RS [2] being used.

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Using the chromatograms of *Standard solution A*, *Standard solution B*, and the reference chromatogram provided with the lot of USP *Forsythia suspensa* Fruit Powder RS [2] being used, identify the retention times of the peaks corresponding to forsythiaside and phillyrin. The relative retention times of forsythiaside and phillyrin are 1.00 and 1.87, respectively.

Calculate the percentage of forsythiaside in the portion of *Forsythia suspensa* Fruit taken:

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

r_U = peak area of the forsythiaside from the *Sample solution*

r_S = peak area of the forsythiaside from *Standard solution A*

C_S = concentration of the USP Forsythiaside RS [2] in *Standard solution A* (mg/mL)

V = volume of the *Sample solution* (mL)

W = weight of *Forsythia suspensa* Fruit taken to prepare the *Sample solution* (mg)

Acceptance criteria: NLT 2.0%, on the dried basis

CONTAMINANTS

- **Elemental Impurities—Procedures <233>** [1]

Acceptance criteria

Arsenic: NMT 3 µg/g

Cadmium: NMT 0.3 µg/g

Lead: NMT 5 µg/g

Mercury: NMT 0.2 µg/g

- **Articles of Botanical Origin <561>,** [1]*Pesticide Residue Analysis*: [1] Meets the requirements
- **Microbial Enumeration Tests <61>** [1]**:** The total aerobic bacterial count does not exceed 10^3 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 10^2 cfu/g.
- **Tests for Specified Microorganisms <62>** [1]**:** Meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*

SPECIFIC TESTS

- **Articles of Botanical Origin <561>,** [1]*Methods of Analysis, Foreign Organic Matter* [1]: NMT 2.0%
- **Articles of Botanical Origin <561>,** [1]*Methods of Analysis, Alcohol-Soluble Extractives, Method 1* [1]: NLT 25%
- **Loss on Drying <731>** [1]

Sample: 2 g of *Forsythia suspensa* Fruit, finely powdered

Analysis: Dry the *Sample* at 105° for 5 h.

Acceptance criteria: NMT 9%

- **Articles of Botanical Origin <561>,** [1]*Methods of Analysis, Total Ash* [1]: NMT 4.0%
- **Articles of Botanical Origin <561>,** [1]*Methods of Analysis, Acid-Insoluble Ash* [1]: NMT 1.0%

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>** [1]

  USP *Forsythia suspensa* Fruit Powder RS [2]

  USP Forsythiaside RS [2]

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