

Herbal Medicines Compendium

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Ammi majus Fruit

Proposed For Development Version 0.1

Ammi majus Fruit

DEFINITION

The article consists of the dried ripe fruits of *Ammi majus* L. (Family Apiaceae). It meets the *Acceptance criteria* under the *Assay*.

SYNONYMS

Ammi glaucifolium L.

Ammi majus var. *glaucifolium* (L.) Mérat

Ammi majus var. *glaucifolium* (L.) Noulet

Ammi majus var. *isophyllum* Lowe

Ammi majus subsp. *procerum* (Lowe) Menezes

Ammi majus var. *tenuifolium* Lowe

POTENTIAL CONFOUNDING MATERIALS

Ammi visnaga Fruit

SELECTED COMMON NAMES

Arabic: خلة (Khillah, Killah shaytani)

Berber: Athrilal, Thalilen, Lattilel, Akhella

Danish: Kongeskærm

English: Bishop's weed, greater Ammi

French: Ammi commun

German: Ammei, Grosser Ammei

CONSTITUENTS OF INTEREST

Coumarins and coumarin glycosides: Xanthotoxin, bergapten, and imperatorin

IDENTIFICATION

• A. BOTANIC CHARACTERISTICS

Macroscopic: Fruit, cremocarp, is nearly cylindrical, usually separated into its two mericarps, rarely entire, sometimes a part of the pedicel attached. Mericarp is small, slightly concave on the commissural side, slightly tapering towards the apex, and is 2–2.5 mm long and 0.75 mm wide; crowned with a nectary disc-like stylopod that is reddish-brown to greenish-brown; rough and marked with five broad, distinct, yellowish-brown primary ridges, alternating with four equally prominent dark brown secondary ridges. Internally the mericarp has a pericarp with six vittae, four in the dorsal and two in commissural

side, a large orthospermous endosperm in which is embedded a small apical embryo. Carpophore is forked and each branch enters the apex of the mericarp and is joined to the raphe.

Microscopic

Transverse cut: Mericarp almost a pentagon in outline with orthospermous seed, attached with raphae on its commissural surface. Mesocarp contains five vascular strands each lying under the primary ridge and six vittae, four on dorsal surface and two on commissural surface.

Transverse section: Shows a layer of epicarp, with each cell embedded with small cluster crystals of calcium oxalate; occasional stomata is seen with striated cuticle; the mesocarp is composed of six to ten layers of tangentially elongated parenchymatous cells, embedded with a small vascular strands under the primary ridge and a vitta under the secondary ridge, two being placed on ventral side. The upper sides of vittae are externally lined with radiating club-shaped cells and are internally encircled by dark brown polygonal-tabular cells of the epithelium; the isolated vittae are blunt at the base and tapered sharply at its apex. The endocarp consists of a layer of narrow, elongated, rectangular tangentially running cells; followed by a layer of testa and thick-walled cellulosic parenchymatous cells of the endosperm containing fixed oil, aleurone grains and microrosette crystals of calcium oxalate.

• B. THIN-LAYER CHROMATOGRAPHY

Standard solution A: Dissolve 2.5 mg of USP Xanthotoxin RS (to come) in 10 mL of methanol.

Standard solution B: Reflux 0.5 g of USP *Ammi majus* Fruit Powder RS (to come) with 10 ml of methanol for 6 h. Repeat three times, filter, and combine the filtrates. Dry the extract under reduced pressure and dissolve the residue in 10 mL of methanol.

Sample solution: Reflux about 0.5 g of *Ammi majus* Fruit, finely powdered, with 10 ml of methanol for 6 h. Repeat three times, filter, and combine the filtrates. Dry the extract under reduced pressure and dissolve the residue in 10 mL of methanol.

Chromatographic system

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

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

Application volume: 10 µL each of *Standard solution A*, *Standard solution B*, and *Sample solution*, as 8-mm bands

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

Developing solvent system: Toluene, ethyl acetate, methanol, and glacial acetic acid (8: 1.8: 0.1: 0.1)

Developing distance: 6 cm

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 chromatograms in a saturated chamber, remove the plate from the chamber, and dry. Examine under UV 366 nm.

System suitability: The chromatogram of *Standard solution B* exhibits six blue fluorescent bands, all below the R_f of the green band corresponding to xanthotoxin in *Standard solution A*. Slightly above the band representing xanthotoxin there is a broad double band that appears green on the upper side and bluish on the lower side. A faint blue band may also be seen near the solvent front.

Acceptance criteria: The *Sample solution* exhibits a green fluorescent band corresponding in color and R_f to the xanthotoxin band in *Standard solution A*, six blue fluorescent bands, all below the R_f of the xanthotoxin band, and a double green and blue band above the xanthotoxin band. These bands correspond in color and R_f to similar bands in the chromatogram of *Standard solution B*.

ASSAY

• Content of Constituents of Interest

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 of 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 10⁵ cfu/g, the total combined molds and yeasts count does not exceed 10³ cfu/g, and the bile-tolerant Gram-negative bacteria does not exceed 10³ cfu/g.

• **TESTS FOR SPECIFIED MICROORGANISMS <62>:** Meets the requirements of the tests for the absence of *Salmonella* species and *Escherichia coli*

SPECIFIC TESTS

• DIFFERENTIATING *AMMI MAJUS* FRUIT FROM *AMMI VISNAGA* FRUIT

Analysis: Boil about 50 mg of *Ammi majus* Fruit, finely powdered, with 5 ml of water for 1 min and filter. Add 1 or 2 drops of the filtrate to 1 ml of sodium hydroxide solution (1N in water).

Acceptance criteria: No rose-red color is obtained (distinction from *Ammi visnaga* Fruit, a rose-red color is seen).

• FLUORESCENCE TEST

Analysis: Prepare an alcohol extract of *Ammi majus* Fruit (1 in 10).

Acceptance criteria: A blue fluorescence when examined under ultraviolet light.

• ABSENCE OF STARCH

Analysis: Examine powdered *Ammi majus* Fruit under a microscope using water as a mounting medium. Add a few drops of iodine and potassium iodide TS 1.

Acceptance criteria: No blue color is observed.

• **ARTICLES OF BOTANICAL ORIGIN, Foreign Organic Matter <561>:** NMT 2%

• **ARTICLES OF BOTANICAL ORIGIN, Total Ash <561>**

Analysis: 2.0 g of *Ammi majus* Fruit, finely powdered

Acceptance criteria: NMT 7%

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 of the plant contained in the article.

- **USP REFERENCE STANDARDS <11>**

USP *Ammi majus* Fruit Powder RS (to come)

USP Xanthotoxin RS (to come)

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