Lycium barbarum Fruit

Proposed For Development Version 0.1

Lycium barbarum Fruit

DEFINITION
The article consists of the dried ripe fruit of Lycium barbarum L. (Family Solanaceae) collected in summer and autumn when the fruit turns red. It meets the Acceptance criteria under the Assay.

SYNONYMS
Boberella halimifolia (Mill.) E. H. L. Krause
Jasminoides flaccidum Moench
Lycium barbarum var. auranticarpum K. F. Ching
Lycium barbarum var. chinense (Mill.) Aiton
Lycium halimifolium Mill.
Lycium lanceolatum Veill.
Lycium turbinatum Veill.
Lycium vulgare Dunal.
Teremis elliptica Raf.

POTENTIAL CONFOUNDING MATERIALS
Lycium chinense Mill.
Lycium dasystemum Pojark
Lycium ruthenicum Murr.
Lycium truncatum Y. C. Wang
Lycium yunanense Kuang et A. M. Lu
Lycium barbarum L. var. auranticarpum K. F. Ching
Lycium chinense Mill. var. potaninii A. M. Lu
Lycium dasystemum Pojark var. rubricaullium A. M. Lu

SELECTED COMMON NAMES
Chinese: 枸杞
English: Chinese wolfberry, Goji berry, Himalayan goji, Tibetan goji, wolfberry
French: Lyciet à feuilles d'obione, Lyciet commun, Lyciet de barbarie
Japanese: クコシ (kukoshi)
Korean: 구기자 (gu gi ja)
Pinyin: Gouqizi
Spanish: Bayas de goji, Bayas tibetanas, Bayas tibetanas de goji, Cereza de goji, Cereza del tibet, Baya
CONSTITUENTS OF INTEREST
Coumarin: Scopoletin, \( p \)-coumaric acid
Carotenoids: \( \beta \)-Carotene, cryptoxanthin, physalin, zeaxanthin, zeaxanthin monopalmitate, zeaxanthin monomyristate

IDENTIFICATION

A. Botanical Characteristics

Macroscopic: Subfusiform or ellipsoid, 6–20 mm long, 3–10 mm in diameter. Externally red or dark red, with a protrudent style scar at the apex, and a white fruit stalk scar at the base. Pericarp pliable and shrunken; sarcocarp fleshy, soft, and viscous. Seeds 20–50, sub-reniform, flat and bent upward, 1.5–1.9 mm long, 1–1.7 mm wide, pale yellow or brownish-yellow

Microscopic

Transverse section of fruits: Pericarp cells have thick walls, covered with cuticle; mesocarp consists of multiple layers of parenchymatous cells, small in the outer layers and large inner layers, subpolygonal, thin wall, containing orange-red or reddish-brown granules.

Transverse section of seeds: Testa is made of rows of stone cells with U-shape thickening; endosperm, radicle and cotyledon cells contain oil globules.

B. Thin-Layer Chromatography

Standard solution A: 0.01 mg/mL of USP Scopoletin RS in methanol
Standard solution B: 0.2 mg/mL of USP Rutin RS in methanol
Standard solution C: To 0.1 g of USP Lycium barbarum Fruit Powder RS, add 7 mL of water, sonicate for 10 min, and centrifuge. Transfer 4 mL of the supernatant onto a 6 mL SPE C18 cartridge that has been conditioned as described later (see NOTE). The loaded cartridge is washed twice each with 1 mL of water–methanol (9:1) then eluted with 1 mL of methanol. [Note—Pre-condition the cartridge with 3 mL of methanol, dry, and then with 3 mL of water and don’t leave to dry before use. During loading, clean up, and elution, the flow rate of the solvent should not exceed 120 drops/min.]

Sample solution: To 0.1 g of Lycium barbarum Fruit, finely powdered, add 7 mL of water, sonicate for 10 min, and centrifuge. Treat as described under Standard solution C starting with "Transfer 4 mL of the supernatant onto a 6 mL SPE C18 cartridge"

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: 2 µL each of Standard solution A and Standard solution B, and 10 µL each of Standard solution C 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: Ethyl acetate, water, acetic acid, and formic acid (100:27:11:11)
Developing distance: 6 cm
Derivatization reagent A: 2-Aminoethyl diphenylborniate in ethyl acetate (5 mg/mL)
Derivatization reagent B: Polyethylene glycol 400 in methylene chloride (50 mg/mL)

Analysis

Samples: Standard solution A, Standard solution B, Standard solution C, 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, heat the plate at 100° for 3 min. Derivatize
the warm plate first with Derivatization reagent A, dry, and then with Derivatization reagent B, and dry. After 5 min, evaluate under UV light at 366 nm.

**System suitability:** Standard solution C chromatogram exhibits a blue fluorescent band in the upper-third section at an $R_f$ corresponding to that of the scopoletin band in the chromatogram of Standard solution A, and a yellowish-orange band in the lower-third section at an $R_f$ corresponding to that of the rutin band in the chromatogram of Standard solution B.

**Acceptance criteria:** The Sample solution exhibits seven bands in the lower half of the chromatogram, in the following order of increasing $R_f$: a yellowish-orange band, three blue fluorescent bands, a yellowish-orange band at an $R_f$ corresponding to that of the rutin band in the chromatogram of Standard solution B, and two blue fluorescent bands. The Sample solution chromatogram exhibits a blue fluorescent band in the upper-third section at an $R_f$ corresponding to that of the scopoletin band in the chromatogram of Standard solution A.

**ASSAY**

- **Content of Constituent 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 check the guidelines document “HMC Monographs for Herbal Medicines Compendium” under “Assay” at [http://hmc.usp.org/about/general-noticesresources](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*

**SPECIFIC TESTS**

- **Articles of Botanical Origin, Foreign Organic Matter <561>:** NMT 2.0%

- **Loss on Drying <731>:**

  **Analysis:** Dry 1.0 g of *Lycium barbarum* Fruit, finely powdered at 80°.

  **Acceptance criteria:** NMT 13%

- **Articles of Botanical Origin, Total Ash <561>:**

  **Analysis:** 3.0 g of *Lycium barbarum* Fruit, finely powdered

  **Acceptance criteria:** NMT 5%
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 *Lycium barbarum* Fruit Powder RS *(To Come)*
  USP Rutin RS [2]
  USP Scopoletin RS [3]

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