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Guggul

DEFINITION

Guggul is the oleo-gum-resin obtained by incision or produced by spontaneous exudation from the stem and branches of *Commiphora wightii* (Arn.) Bhandari, also known as *Commiphora mukul* (Hook. ex. Stocks) Engl. or *Balsamodendrum mukul* (Hook.) (Fam. Burseraceae). It contains NLT 1.0% of guggulsterones *E* and *Z*, calculated on the dried basis as guggulsterone *Z*.

IDENTIFICATION

• A. THIN-LAYER CHROMATOGRAPHY

Standard solution: 10 mg/mL of [USP Purified Guggul Extract RS](#) with heating, in acetonitrile

Sample solution: Transfer about 0.5 g of crushed Guggul to a centrifuge tube. Add 25 mL of acetonitrile, and shake for 1 min. Heat in a water bath for 10–15 min with occasional shaking, cool, centrifuge, and use the supernatant.

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Developing solvent system: A mixture of hexane and ethyl acetate (6:4)

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture, typically 20 cm in length (TLC plates)

Application volume: 10 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the *Samples* as bands. Use a saturated chamber. Develop until the solvent front has moved about three-fourths the length of the plate, dry the plate, and examine under short-wave UV light (254 nm).

Acceptance criteria: The chromatogram of the *Sample solution* exhibits bands at R_f values of about 0.38 and 0.47, due to guggulsterones *E* and *Z*, respectively. Both bands correspond in R_f values to bands from the *Standard solution*.

• B. HPLC

Analysis: Proceed as directed in the test for *Content of Guggulsterones E and Z*.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits peaks for guggulsterones *E* and *Z* at retention times that correspond to those of *Standard solution A*.

COMPOSITION

• CONTENT OF GUGGULSTERONES *E* AND *Z*

Mobile phase: A mixture of acetonitrile and water (45:55)

Standard solution A: 10 mg/mL of [USP Purified Guggul Extract RS](#) with heating, in acetonitrile. Pass the solution through a filter of 0.45-µm pore size before injection.

Standard solution B: 0.1 mg/mL of [USP Guggulsterone Z RS](#) in acetonitrile. Pass the solution through a filter of 0.45-µm pore size before injection.

Sample solution: Transfer about 2.0 g of crushed Guggul to a conical flask, and extract four times with 50-mL portions of acetonitrile. Shake for 1 min, and reflux in a water bath for 30 min, stirring magnetically. Evaporate the combined extracts to about 50 mL, and transfer to a 100-mL volumetric flask. Dilute with acetonitrile to volume, and pass through a filter of 0.45-µm pore size before injection.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 242 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 2.0 mL/min

Injection volume: 20 µL

Column temperature: 27 ± 1°

System suitability

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

[NOTE—The relative retention times for guggulsterones *E* and *Z* are about 0.69 and 1.0, respectively.]

Suitability requirements

Chromatogram similarity: The chromatogram of *Standard solution A* is similar to the reference chromatogram provided with the lot of [USP Purified Guggul Extract RS](#) being used.

Resolution: NLT 2.0 between the guggulsterone Z peak and the peak before, *Standard solution A*

Tailing factor: NMT 1.5 for the guggulsterone Z peak, *Standard solution B*

Relative standard deviation: NMT 2.0% for replicate injections for the guggulsterone Z peak, *Standard solution B*

Analysis

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

Allow *Standard solution A* to elute for NLT 2 times the retention time of guggulsterone Z, as determined from *Standard solution B*. Using the chromatogram of *Standard solution A* and the reference chromatogram provided with the lot of [USP Purified Guggul Extract RS](#) being used, identify the retention times of the peaks corresponding to guggulsterone E and guggulsterone Z.

Calculate the percentage of guggulsterones E and Z as guggulsterone Z in the portion of Guggul taken:

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

r_U = sum of the peak responses of guggulsterones E and Z from the *Sample solution*

r_S = peak response of guggulsterone Z from *Standard solution B*

C_S = concentration of [USP Guggulsterone Z RS](#) in *Standard solution B* (mg/mL)

V = final volume of the *Sample solution*, 100 mL

W = weight of Guggul taken to prepare the *Sample solution* (mg)

Acceptance criteria: NLT 1.0% on the dried basis

CONTAMINANTS

- [ARTICLES OF BOTANICAL ORIGIN, Limits of Elemental Impurities\(561\)](#): Meets the requirements
- [ARTICLES OF BOTANICAL ORIGIN, Pesticide Residue Analysis\(561\)](#): Meets the requirements

SPECIFIC TESTS

BOTANICAL CHARACTERISTICS

Macroscopic: Guggul occurs in rounded or irregular conglomerates of tears, of variable sizes, light to dark brown, slightly sticky to touch, with characteristic and aromatic odor and an aromatic, astringent taste.

- [ARTICLES OF BOTANICAL ORIGIN, Foreign Organic Matter\(561\)](#): NMT 1%
- [ARTICLES OF BOTANICAL ORIGIN, Alcohol-Soluble Extractives, Method 2\(561\)](#): NLT 33%

ETHYL ACETATE SOLUBLE EXTRACTIVES

Sample: About 5.0 g of coarsely powdered Guggul

Analysis: Transfer the *Sample* to a glass-stoppered, conical flask. Add 25 mL of solvent hexane, insert a stopper into the flask, shake for 1 h, filter, and discard the filtrate. Repeat twice, and dry the residue in a vacuum over phosphorus pentoxide at room temperature for 8 h. Crush the dried material, and extract with four 25-mL quantities of ethyl acetate, by shaking each time for 1 h at room temperature, followed by filtration through a sintered glass funnel (porosity No. 3). Evaporate the combined filtrates under reduced pressure in a tared flask, dry the residue in a vacuum over phosphorus pentoxide at room temperature for 12 h, and weigh. Determine the percentage of the ethyl acetate soluble extractives calculated from the weight of Guggul taken.

Acceptance criteria: 22%–30%

- [LOSS ON DRYING \(731\)](#)

Sample: 1.0 g of Guggul

Analysis: Dry the *Sample* at 105° for 2 h.

Acceptance criteria: NMT 8.0%

- [RESIDUE ON IGNITION \(281\)](#): NMT 10.0%, ignited at 800 ± 25°
- [ARTICLES OF BOTANICAL ORIGIN, Acid-Insoluble Ash\(561\)](#): NMT 2.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, protected from light and moisture, and store in a cool place.
- **LABELING:** The label states the Latin binomial of the species of *Commiphora* from which the oleo-gum-resin was obtained and the official name.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Guggulsterone Z RS](#)
[USP Purified Guggul Extract RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
GUGGUL	Anton Bzhelyansky Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines