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Native Guggul Extract

DEFINITION

Native Guggul Extract is prepared from Guggul, using ethyl acetate, alcohol, or methanol. The ratio of starting crude plant material to Native Extract is approximately 9:1. It contains NLT 5.0% of guggulsterones *E* and *Z*, calculated on the anhydrous basis as guggulsterone *Z*. It does not contain added substances.

IDENTIFICATION

• A. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST

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

Sample solution: Homogenize Native Guggul Extract by heating in a water bath at 60°–80°. Prepare a 5-mg/mL solution in acetonitrile with heating.

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

Application volume: 10 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the *Samples* as bands to a suitable plate. 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 UV light at 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 guggulsterone *E* and *Z*, respectively. Both bands correspond in R_f to bands in the chromatogram from the *Standard solution*.

• B. HPLC IDENTIFICATION TEST

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: Homogenize the Native Guggul Extract by heating in a water bath at 60°–80°. Dissolve a weighed quantity of homogenized Native Extract, with heating, in acetonitrile to obtain a solution having a known concentration of about 0.2 mg/mL of guggulsterones *E* and *Z*. 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 size: 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 from *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 the guggulsterone Z peak (replicate injections), *Standard solution B*

Analysis

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

Allow *Standard solution A* to elute for NLT two times the retention time of guggulsterone Z, as determined in *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 Native Guggul Extract 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 *Sample solution* (mL)

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

Acceptance criteria: NLT 5.0% of guggulsterones E and Z, calculated as guggulsterone Z, on the anhydrous basis

CONTAMINANTS

Change to read:

- [▲ BOTANICAL EXTRACTS \(565\), Preparations, General Pharmacopeial Requirements, Pesticide Residues ▲](#) (CN 1-MAY-2020): Meets the requirements
- [BOTANICAL EXTRACTS, Residual Solvents\(565\)](#): Meets the requirements
- [MICROBIAL ENUMERATION TESTS \(2021\)](#): The total aerobic microbial count does not exceed 10^4 cfu/g, and the total combined yeasts and molds count does not exceed 10^3 cfu/g.
- [ABSENCE OF SPECIFIED MICROORGANISMS \(2022\)](#): It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

SPECIFIC TESTS

- [WATER DETERMINATION, Method 1a\(921\)](#): NMT 5.0%

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 and, following the official name, the part of the plant from which the article was derived. It meets other labeling requirements under [Botanical Extracts \(565\)](#).
- [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
NATIVE GUGGUL EXTRACT	Anton Bzhelyansky Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 34(4)

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