

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Dec-2015
Document Type: Dietary Supplement Monographs
DocId: GUID-18B936A0-FF11-46D6-8F73-571373B3D4D6_1_en-US
DOI: https://doi.org/10.31003/USPNF_M2775_01_01
DOI Ref: v4v7j

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Boswellia serrata

DEFINITION

Boswellia serrata is the oleogum resin obtained by incision or produced by spontaneous exudation from the stem and branches of *Boswellia serrata* Roxb. (Fam. Burseraceae). It contains NLT 1.0% of the keto derivatives of β -boswellic acid, calculated on the dried basis as the sum of 11-keto- β -boswellic acid and 3-acetyl-11-keto- β -boswellic acid.

IDENTIFICATION

• **A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#).**

Standard solution: Treat a quantity of [USP Boswellia serrata Extract RS](#) with gentle heating in methanol to obtain a solution having a known concentration of 30 mg/mL, cool, centrifuge, and use the supernatant.

Sample solution: Use the *Sample solution*, prepared as directed in the test below for *Content of Keto-Derivatives of β -Boswellic Acids*, and concentrate to 10% of the volume.

Adsorbent: 0.25-mm layer of chromatographic silica gel

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

Derivatization reagent: Prepare a solution of 10% sulfuric acid in methanol. [NOTE—Prepare immediately before use.]

Application volume: 10 μ L

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the samples as bands to a suitable thin-layer chromatographic plate (see [Chromatography \(621\)](#)). Use a saturated chamber.

Develop until the solvent front has moved up about 90% of the plate. Remove, dry, and examine under UV light at 254 nm. Dip in the *Derivatization reagent*, heat for 5–10 min at 100°, and examine under white light.

Acceptance criteria: Under UV light at 254 nm, the *Sample solution* exhibits two main zones due to 11-keto- β -boswellic acid and 3-acetyl-11-keto- β -boswellic acid at R_f values of about 0.30 and 0.36, respectively, corresponding to zones from the *Standard solution*. Under white light, the *Sample solution* exhibits two additional zones due to β -boswellic acid and 3-acetyl- β -boswellic acid at R_f values of about 0.49 and 0.58, respectively, corresponding to zones from the *Standard solution*. Other, less intense zones are observed for the *Sample solution* and the *Standard solution*.

• **B.** The 210-nm chromatogram of the *Sample solution*, in the test for *Content of Keto-Derivatives of β -Boswellic Acids*, exhibits peaks for 11-keto- β -boswellic acid, 3-acetyl-11-keto- β -boswellic acid, β -boswellic acid, and 3-acetyl- β -boswellic acid at retention times that correspond to those in the 210-nm chromatogram of *Standard solution B* and the 210-nm reference chromatogram provided with the [USP Boswellia serrata Extract RS](#).

COMPOSITION

• **CONTENT OF KETO-DERIVATIVES OF β -BOSWELLIC ACIDS**

Standard solution A: Dissolve a quantity of USP 3-Acetyl-11-keto- β -Boswellic Acid RS in methanol to obtain a solution having a known concentration of 0.1 mg/mL.

Standard solution B: Treat a quantity of [USP Boswellia serrata Extract RS](#) with gentle heating in methanol to obtain a solution having a known concentration of 10 mg/mL. Before injection, pass through a filter of 0.45- μ m pore size.

Sample solution: Transfer about 2.0 g of crushed *Boswellia serrata* to a round-bottom flask, and reflux in 50 mL of methanol on a water bath for 15 min, stirring magnetically. Repeat until the extract is colorless. Evaporate the combined extracts to about 50 mL, transfer to a 100-mL volumetric flask, and dilute with methanol to volume. Before injection, pass through a filter of 0.45- μ m pore size, and discard the first few mL of the filtrate.

Mobile phase: Prepare a filtered and degassed mixture of acetonitrile, water, and glacial acetic acid (900:100:0.1). Make adjustments if necessary.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm $\times$ 25-cm; packing L1

Flow rate: See [Table 1](#).

Table 1

Time (min)	Flow Rate (mL/min)
0	1
5	1.5
10	2
30	2
32	1
45	1

Injection volume: 20 µL

System suitability

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

[NOTE—The relative retention times for 11-keto-β-boswellic acid and 3-acetyl-11-keto-β-boswellic acid are about 1.0 and 1.4, respectively.]

Suitability requirements: The chromatogram of *Standard solution B* is similar to the 254-nm reference chromatogram provided with the lot of [USP Boswellia serrata Extract RS](#) being used.

Relative standard deviation: NMT 2.0% for the 3-acetyl-11-keto-β-boswellic acid peak in replicate injections, *Standard solution A*

Tailing factor: NMT 1.5, 3-acetyl-11-keto-β-boswellic acid peak, *Standard solution A*

Analysis

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

Using the chromatogram of *Standard solution B* and the reference chromatogram provided with the lot of [USP Boswellia serrata Extract RS](#) being used, identify the retention times of the peaks of 11-keto-β-boswellic acid and 3-acetyl-11-keto-β-boswellic acid in the *Sample solution*.

Separately calculate the percentages of the two analytes in the portion of *Boswellia serrata* taken:

$$\text{Result} = (r_U/r_S) \times (C_S/W) \times 10F$$

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

r_S = peak area of 3-acetyl-11-keto-β-boswellic acid from *Standard solution A*

C_S = concentration of USP 3-Acetyl-11-keto-β-Boswellic Acid RS in *Standard solution A* (mg/mL)

W = weight of *Boswellia serrata* taken to prepare the *Sample solution* (g)

F = conversion factor for each analyte: 0.93 for 11-keto-β-boswellic acid and 1.0 for 3-acetyl-11-keto-β-boswellic acid

Acceptance criteria: Add the percentages calculated for 11-keto-β-boswellic acid and 3-acetyl-11-keto-β-boswellic acid; NLT 1.0% on the dried basis.

IMPURITIES

- [ARTICLES OF BOTANICAL ORIGIN, Limits of Elemental Impurities \(561\)](#): Meets the requirements
- [ARTICLES OF BOTANICAL ORIGIN, Foreign Organic Matter \(561\)](#): NMT 2.0%
- [ARTICLES OF BOTANICAL ORIGIN, Pesticide Residue Analysis \(561\)](#): Meets the requirements

SPECIFIC TESTS

• **BOTANICAL CHARACTERISTICS**

Macroscopic: It occurs as small ovoid tears, sometimes forming agglomerated masses up to 5 cm long and 2 cm thick; whitish to golden yellow; fracture is brittle, and fractured surface is waxy and translucent characteristic aromatic odor; aromatic, slightly mucilaginous taste.

• [LOSS ON DRYING \(731\)](#)

Sample: 1.0 g of *Boswellia serrata*, finely powdered

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

Acceptance criteria: NMT 12.0%

• [ARTICLES OF BOTANICAL ORIGIN, Total Ash \(561\)](#)

Sample: 2.0 g of *Boswellia serrata*, finely powdered

Acceptance criteria: NMT 2.0%

• [ARTICLES OF BOTANICAL ORIGIN, Acid-Insoluble Ash\(561\)](#): NMT 0.5%

• [ARTICLES OF BOTANICAL ORIGIN, Alcohol-Soluble Extractives, Method 2 \(561\)](#): NLT 56%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, protected from light and moisture, and store in a cool place.