

Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Aug-2016
Document Type: Dietary Supplement Monographs
DocId: GUID-9675273F-438B-442C-ADC5-ECE82C075415_1_en-US
DOI: https://doi.org/10.31003/USPNF_M35764_01_01
DOI Ref: c14ao

© 2025 USPC
Do not distribute

Powdered Goldenseal

DEFINITION

Powdered Goldenseal is Goldenseal reduced to a fine or very fine powder. It contains NLT 2.0% of hydrastine ($C_{21}H_{21}NO_6$) and NLT 2.5% of berberine ($C_{20}H_{18}NO_4$), calculated on the dried basis.

IDENTIFICATION

• A. [HPTLC FOR ARTICLES OF BOTANICAL ORIGIN \(203\)](#).

Standard solution: Prepare a composite solution containing 0.5 mg/mL of [USP Hydrastine RS](#) and 0.025 mg/mL of [USP Berberine Chloride RS](#) in methanol

Sample solution: Sonicate 0.25 g of Powdered Goldenseal root and rhizome in 4 mL of 80% methanol for 30 min. Withdraw the supernatant, and wash the residue twice with 2-mL aliquots of methanol. Combine the supernatant and rinsates in a 20-mL volumetric flask, and adjust with methanol to volume. Mix well and filter before use.

[NOTE—If prolonged storage is required, keep the *Sample solution* refrigerated.]

Chromatographic system

Mode: HPTLC

Adsorbent: Chromatographic silica gel with an average particle size of 5 µm (HPTLC plate)¹

Application volume: 5 µL each of *Standard solution* and *Sample solution* as 8-mm bands

Temperature: Ambient, not to exceed 30°

Developing solvent system: A mixture of ethyl acetate, methanol, formic acid, and water (50:10:6:3)

System suitability

Sample: *Standard solution*

Apply as a band and dry in air. Condition at a relative humidity of about 33%. Develop in a saturated chamber until the solvent front has migrated over a path of 6 cm. Dry in a stream of cold air, and examine under long-wave (365 nm) UV light.

Suitability requirements

Chromatographic pattern: Under long-wave UV (365 nm), the chromatogram exhibits a dark-blue band at about one-third of the migration distance due to hydrastine and a bright yellow band at roughly halfway due to berberine.

Analysis

Samples: *Standard solution* and *Sample solution*

Treat and examine the *Samples* as described in *System suitability*.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits a bright blue fluorescent band due to hydrastine close to the application line; additional deep blue zones may be observed immediately above and below this band. In the middle third of the chromatogram, a deep blue band coincident with hydrastine and a bright yellow fluorescent band coincident with berberine in the *Standard solution* are observed. Proximal to the solvent front, a deep blue band is seen. The presence of a second yellow band below that of berberine, commonly ascribed to palmatine, is a likely sign of adulteration. The deep blue hydrastine band helps distinguish Powdered Goldenseal from numerous berberine-containing species.

COMPOSITION

• CONTENT OF BERBERINE AND HYDRASTINE AND LIMIT OF PALMATINE

Mobile phase: Dissolve 9.93 g of monobasic potassium phosphate in 730 mL of water and add 270 mL of acetonitrile. Mix, filter, and degas.

Solvent: A mixture of 0.1 M monobasic potassium phosphate and acetonitrile (60:40)

Standard solution: 0.05 mg/mL each of [USP Berberine Chloride RS](#) and [USP Hydrastine RS](#) in a mixture of methanol and water (1:1)

System suitability solution: Prepare a solution of palmatine chloride in a mixture of water and methanol (1:1) with a known concentration of about 0.05 mg/mL. Mix equal volumes of this solution and the *Standard solution*.

Sample solution: Transfer about 0.12 g of Powdered Goldenseal, accurately weighed, to a 50-mL volumetric flask. Add 40 mL of *Solvent*, sonicate for 5 min, and shake for 10 min. Dilute with *Solvent* to volume, mix, and filter.

Chromatographic system

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

Mode: LC

Detector: UV 235 nm

Column: 4.6-mm × 150-mm; packing L1

Flow rate: 1.8 mL/min

Injection volume: 10 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

Suitability requirements

Resolution: NLT 1.5 between the berberine and palmatine peaks; NLT 1.5 between the hydrastine and palmatine peaks, *System suitability solution*

Capacity factor: NLT 3.0 for the hydrastine peak, *Standard solution*

Column efficiency: NLT 5000 theoretical plates, determined from the hydrastine and berberine peaks, *Standard solution*

Tailing factor: NMT 2.0, determined from the hydrastine and berberine peaks, *Standard solution*

Relative standard deviation: NMT 2.5%, determined from the hydrastine and berberine peaks in repeated injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentages of hydrastine (C₂₁H₂₁NO₆) and berberine (C₂₀H₁₈NO₄) in the portion of Powdered Goldenseal taken:

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

r_U = peak area of berberine or hydrastine from the *Sample solution*

r_S = peak area of berberine or hydrastine from the *Standard solution*

C_S = concentration of berberine or hydrastine in the *Standard solution* (mg/mL)

V = volume of the *Sample solution* (mL)

W = weight of Powdered Goldenseal used to prepare the *Sample solution* (mg)

Using the values from the chromatogram of the *Sample solution*, divide the peak area of berberine by the area of any peak at the locus for palmatine (if present).

Acceptance criteria: NLT 2.0% of hydrastine (C₂₁H₂₁NO₆) and NLT 2.5% of berberine (C₂₀H₁₈NO₄) on the dried basis. The ratio of the berberine peak area to any peak area at the locus for palmatine is more than 50:1.

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:** The powder is dark yellow to moderately greenish-yellow with an aromatic odor and bitter taste. Abundant starch granules are present and are either spherical or ovoid; the granules are simple or compounded, with an occasional slit-shaped hilum. Parenchyma cells range from polygonal to round and are filled with starch or brown resin. Tracheary elements with slit-shaped pits and a few large reticulated vessels are present, as are beaded, thick-walled elongated epidermal cells. Thin fragments of cork layer are also present.

• [ARTICLES OF BOTANICAL ORIGIN, Foreign Organic Matter\(561\)](#): NMT 2.0%

• [LOSS ON DRYING \(731\)](#)

Sample: 2 g of Powdered Goldenseal, finely powdered

Analysis: Dry the *Sample* at 100° for 5 h.

Acceptance criteria: NMT 12.0%

• [ARTICLES OF BOTANICAL ORIGIN, Total Ash\(561\)](#): NMT 9%

• [ARTICLES OF BOTANICAL ORIGIN, Acid-Insoluble Ash\(561\)](#): NMT 5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store protected from light and moisture.
- **LABELING:** The label states the Latin binomial and, following the official name, the parts of the plant contained in the article.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Berberine Chloride RS](#)
[USP Hydrastine RS](#)

¹ Suitable commercially available plates are HPTLC Silica Gel 60 F₂₅₄ from EMD Millipore (e.g., Part No. 1.05642.0001).

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

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