

Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2016
Document Type: Dietary Supplement Monographs
DocId: GUID-2F59C7F4-052A-4FB5-A8FD-EE7127E84CA6_1_en-US
DOI: https://doi.org/10.31003/USPNF_M7588_01_01
DOI Ref: 26p1f

© 2025 USPC
Do not distribute

Astragalus Root Powder

DEFINITION

Astragalus Root Powder consists of the dried root of *Astragalus membranaceus* var. *mongholicus* (Bunge) P.K.Hsiao or *Astragalus membranaceus* (Fisch.) Bunge (Fam. Fabaceae) reduced to powder or very fine powder. Astragalus root is typically harvested from a 2- to 3-year-old plant in early fall. It contains NLT 0.04% of cycloartane saponins and NLT 0.03% of isoflavonoids calculated on the dried basis.

IDENTIFICATION

• A. HPTLC FOR ARTICLES OF BOTANICAL ORIGIN (203).

Standard solution A: 1 mg/mL of [USP Astragaloside IV RS](#) in methanol

Standard solution B: 2 mg/mL of [USP Daidzin RS](#) and 1 mg/mL of [USP Daidzein RS](#) in methanol

Standard solution C: 50 mg/mL of [USP Astragalus Root Dry Extract RS](#) in methanol. Sonicate for about 10 min, centrifuge, and use the supernatant.

Sample solution: Heat 3 g of Astragalus Root Powder in 50 mL of methanol for 50 min under reflux. Centrifuge, withdraw the supernatant, and evaporate to dryness under reduced pressure. Dissolve the residue in 1.0 mL of water. Transfer the resulting solution onto a 6-mL solid-phase extraction column containing 500 mg of sorbent previously conditioned with 3 mL of methanol and 3 mL of water.¹ Wash with 15 mL of water followed by 15 mL of 30% methanol, and discard the rinsate. Elute with 20 mL of methanol, collect the eluate, evaporate to dryness under reduced pressure, and dissolve the residue in 2 mL of methanol.

Chromatographic system

Adsorbent: Chromatographic silica gel with an average particle size of 5 µm (HPTLC plate)²

Application volume: 3 µL each of *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Sample solution* as 8-mm bands

Relative humidity: Condition the plate to a relative humidity of 33%.

Temperature: Ambient, not to exceed 30°

Developing solvent system: Ethyl acetate, methanol, and water (100:13.5:10)

Developing distance: 6 cm

Derivatization reagent: 10% Sulfuric acid in methanol. [NOTE—Prepare fresh. Slowly and gradually add sulfuric acid to ice-cold methanol, and mix well.]

System suitability

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

Suitability requirements

Chromatographic pattern: Under long-wave UV light (365 nm), following derivatization, *Standard solution A* exhibits an orange band in the middle of the lower third of the plate due to astragaloside IV, with a retardation factor (R_F) of approximately 0.15. In *Standard solution B*, daidzin and daidzein form bluish-grey bands with R_F of approximately 0.34 and 0.76, respectively; the proximal band is sharper, while the distal is somewhat diffuse. In *Standard solution C*, four orange bands are seen in the lower third of the plate, corresponding to astragalosides IV, III, II, and I with R_F of approximately 0.15, 0.18, 0.24, and 0.34, respectively. The R_F of the astragaloside I band approximates that of daidzin in *Standard solution B*. The upper two-thirds of the plate typically display a number of bluish, greenish, and pinkish diffuse bands, one of which corresponds to that of daidzein in *Standard solution B*.

Analysis

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

Apply the *Samples* as bands and dry in air. Develop in a saturated chamber. Air-dry, treat with *Derivatization reagent*, heat for 5 min at 100°, and examine under long-wave UV light (365 nm).

Acceptance criteria: Under long-wave UV light (365 nm), the *Sample solution* exhibits bands corresponding in color and R_F to similar bands from *Standard solution C*. In the lower third of the chromatogram, a number of orange bands are present; the most prominent ones corresponding to astragalosides I and II, with R_F of approximately 0.34 and 0.24, respectively. In the upper part of the chromatogram, a number of diffuse bands are present, and additional weak bands may appear with respect to those seen in *Standard solution C*. [NOTE—The root of *Hedysarum polybotros*, a common adulterant, does not show orange bands corresponding to astragalosides I and II.]

• B. HPLC

Analysis: Proceed as directed in the test for *Content of Isoflavonoids and Saponins*.

Acceptance criteria: The *Sample solution* exhibits peaks at the retention times corresponding to those of calycosin 7-O-β-D-glucopyranoside, ononin, calycosin, formononetin, astragaloside IV, astragaloside I, and astragaloside II from *Standard solution F*.

COMPOSITION**• CONTENT OF ISOFLAVONOIDS AND SAPONINS****Solution A:** 0.3% Formic acid**Solution B:** Acetonitrile**Mobile phase:** See [Table 1](#).**Table 1**

Time (min)	Solution A (%)	Solution B (%)
0	80	20
15	80	20
25	68	32
35	66	34
45	55	45
55	50	50
75	25	75
80	80	20
100	80	20

Standard solution A: Prepare a composite solution containing 0.4 mg/mL of [USP Astragaloside IV RS](#), 0.1 mg/mL of [USP Calycosin RS](#), 0.2 mg/mL of [USP Calycosin 7-O-β-D-Glucopyranoside RS](#), 0.05 mg/mL of [USP Formononetin RS](#), and 0.1 mg/mL of [USP Ononin RS](#) in methanol.

Standard solutions B, C, D, E: Prepare four consecutive two-fold serial dilutions of *Standard solution A* in methanol.

Standard solution F: Sonicate 150 mg of [USP Astragalus Root Dry Extract RS](#) in 5 mL of methanol. Pass through a nylon filter of 0.45-μm pore size, and discard the initial 1 mL of the filtrate.

Sample solution: Accurately weigh 1.5 g of Astragalus Root Powder, and transfer into a 100-mL round-bottomed flask. Attach the condenser and reflux in 60 mL of methanol for 3 h. Filter and evaporate methanol to dryness under reduced pressure, dissolve the residue in a small amount of methanol, and transfer quantitatively into a 5-mL volumetric flask. Adjust with methanol to volume and mix well. Pass through a nylon filter of 0.45-μm pore size, and discard the initial 1 mL of the filtrate.

Chromatographic system(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** HPLC**Detectors:** UV 280 nm and ELSD, connected in series**ELSD drift tube temperature:** Optimize according to the manufacturer's recommendations to achieve optimal signal-to-noise ratio, typically 105°.**ELSD carrier gas flow:** Optimize according to the manufacturer's recommendations to achieve optimal signal-to-noise ratio, typically 2.70 L/min.**Column:** 4.6-mm × 25-cm; 5-μm packing L1**Column temperature:** 25°**Flow rate:** 0.8 mL/min**Injection volume:** 15 μL**System suitability****Samples:** *Standard solutions A–E* and *Standard solution F***Suitability requirements****Chromatographic similarity:** The chromatogram of *Standard solution F* is similar to the reference chromatogram provided with the lot of [USP Astragalus Root Dry Extract RS](#) being used.**Theoretical plates:** NLT 3,000 for calycosin 7-O-β-D-glucopyranoside (UV) and astragaloside IV (ELSD) peaks, *Standard solution A***Correlation coefficient:** NLT 0.995 for each regression line as determined in *Analysis***Analysis****Samples:** *Standard solutions A–F* and *Sample solution*

Using the UV absorbance chromatograms of *Standard solutions A–E*, *Standard solution F*, and the reference chromatogram, provided with the lot of [USP Astragalus Root Dry Extract RS](#) being used, identify the specified isoflavonoids in the *Sample solution* chromatogram.