

Powdered Asian Ginseng Extract

Powdered Asian Ginseng Extract is prepared from Asian Ginseng by maceration, percolation, or both processes performed at room temperature with suitable solvents such as alcohol, methanol, water, or mixtures of these solvents, and by concentrating the fluidextract at temperatures below 50°C. The ratio of the starting crude plant material to Powdered Extract is between 3:1 and 7:1. It contains not less than 3.0 percent of ginsenosides Rg₁, Re, Rb₁, Rc, Rb₂, and Rd combined, calculated on the anhydrous basis. It may contain other added substances.

Identification—

A: [Thin-Layer Chromatographic Identification Test 201](#) —

Adsorbent: 0.2-mm layer of chromatographic silica gel mixture on a high-performance thin-layer chromatographic plate.

Extraction column— Use a solid-phase extraction column that contains packing L1 with a sorbent mass to column volume ratio of 360 mg per 0.85 mL, or equivalent. Condition the column prior to use by washing with 3 mL of methanol and with 8 mL of water.

Test solution— Transfer about 1.0 g of Powdered Extract, accurately weighed, to a 25-mL volumetric flask, and dissolve in water, sonicating if necessary. Dilute with water to volume, and mix. Transfer 4.0 mL of this solution to the Extraction column, wash with 10 mL of water, and discard the eluate. Elute the column with 2 mL of methanol, and collect the eluate in a suitable vial.

Standard solution— Transfer about 0.1 g of [USP Powdered Asian Ginseng Extract RS](#), accurately weighed, to a 5-mL volumetric flask, and proceed as directed for Test solution, beginning with “dissolve in water”.

Developing solvent system: a mixture of chloroform, methanol, and water (65:35:10). Use the lower phase.

Spray reagent: a mixture of alcohol, acetic anhydride, and sulfuric acid (18:1:1).

Procedure— Proceed as directed in the chapter. Saturate the chamber with Developing solvent system for 2 hours. Spray with Spray reagent, and heat in an oven at 105°C for 10 minutes.

Immediately examine the plate in white light: the chromatogram of the Test solution exhibits, among other spots, eight brown-violet spots at the R_F values of about 0.70, 0.60, 0.50, 0.36, 0.30,

0.28, 0.20, and 0.18, corresponding in color and RF values to those obtained in the chromatogram of the Standard solution.

B: Add 2 mL of glacial acetic acid to 0.1 g of Powdered Extract, warm for 5 minutes in a hot water bath, and filter. Gently add 0.5 mL of sulfuric acid to 1.0 mL of the filtrate: a red-brown color develops at the zone of contact.

C: The retention times of the peaks for ginsenosides Rg₁, Re, Rf, Rb₁, Rb₂, Rc, and Rd in the chromatogram of the Test solution correspond to those in the chromatogram of the Standard solution, as obtained in the test for Content of ginsenosides. The ratio of the peak area of Rb₂ to the peak area of Rb₁ is not less than 0.4.

[Microbial enumeration](#) [2021](#) — The total aerobic microbial count does not exceed 300 cfu per g, and the total combined molds and yeasts count does not exceed 100 cfu per g. It meets the requirements of the tests for absence of Salmonella species, Escherichia coli, and Staphylococcus aureus.

[Water, Method I](#) [921](#) : not more than 7.0%, determined on a 0.15-g specimen.

[Pesticide residues](#) [561](#) : meets the requirements.

[Heavy metals](#) [231](#) : 30 µg per g.

Content of ginsenosides—

Diluent— Prepare a mixture of water and alcohol (6:4).

Solution A— Use filtered and degassed water.

Solution B— Prepare a filtered and degassed mixture of acetonitrile and water (8:2).

Mobile phase— Use variable mixtures of Solution A and Solution B as directed for Chromatographic system. Make adjustments if necessary.

Standard solution— Transfer an accurately weighed amount of USP Powdered Asian Ginseng Extract RS to a suitable volumetric flask, fill the flask with Diluent to about 60% of its nominal volume, dissolve by sonicating for 10 minutes, dilute with Diluent to volume to obtain a solution having a known concentration of about 24 mg per mL, mix, and filter.

Test solution— Proceed as directed for Standard solution, except to use Powdered Extract.

Chromatographic system— The liquid chromatograph is equipped with a 203-nm detector, a 4.6-mm × 2.0-cm guard column that contains packing L1, and a 4.6-mm × 15-cm analytical column that contains 3-µm packing L1. The flow rate is about 1.5 mL per minute. The column temperature is maintained at 25 . The chromatograph is programmed as follows.

Time (minutes)	Solution A (%)	Solution B (%)	Elution
0	76	24	equilibration
0–12	76	24	isocratic
12–28	76→65	24→35	linear gradient
28–51.5	65→56.5	35→43.5	linear gradient
51.5–52.5	56.5→0	43.5→100	linear gradient
52.5–64.5	0→76	100→24	linear gradient
64.5–77	76	24	isocratic

Chromatograph the Standard solution, and record the peak areas as directed for Procedure: the chromatogram is similar to the Reference Chromatogram provided with the lot of [USP Powdered Asian Ginseng Extract RS](#) being used; and the relative standard deviation, determined for the sum of the peak areas for the six major ginsenosides, for replicate injections is not more than 2.0%.

Procedure— Separately inject equal volumes (about 20 µL) of the Standard solution and the Test solution into the chromatograph, record the chromatograms, identify the peaks for the ginsenosides by comparison with the Reference Chromatogram provided with the lot of [USP Powdered Asian Ginseng Extract RS](#) being used, and measure the peak areas for the six major ginsenosides. Calculate the percentage of each relevant ginsenoside (R_{g1}, Re, R_{b1}, Rc, R_{b2}, and Rd) in the portion of Powdered Extract taken by the formula: $(W_S / W_T)(r_U / r_S)P$ in which W_S is the weight, in mg, of [USP Powdered Asian Ginseng Extract RS](#) taken to prepare the Standard solution; W_T is the weight, in mg, of Powdered Extract taken to prepare the Test solution; r_U and r_S are the peak areas for each relevant ginsenoside obtained from the Test solution and the Standard solution, respectively; and P is the labeled amount, in percentage, of each relevant ginsenoside in [USP Powdered Asian Ginseng Extract RS](#). Calculate the Content of ginsenosides, in percentage, by adding the percentages of each relevant ginsenoside.

[Alcohol content, Method II](#) 611 : not more than 0.25%.

Other requirements— It meets the requirements for Packaging and Storage and for Labeling under [Botanical Extracts](#) [565](#) .