American Ginseng Tablets

American Ginseng Tablets contain Powdered American Ginseng Extract. Tablets contain not less than 90.0 percent and not more than 110.0 percent of Extract, calculated as the sum of ginsenosides Rg_1, Re, Rb_1, Rc, Rb_2, and Rd.

Packaging and storage— Preserve in tight containers, protected from light. Store at controlled room temperature.

Labeling— The label states the Latin binomial and, following the official name, the article from which the Tablets were prepared. The label also indicates the amount of Extract, in mg per Tablet. Label the Tablets to indicate the percentage of total ginsenosides in the Extract contained in the Tablets.

Identification—

A: Proceed as directed for Identification A under American Ginseng, using the following Test solution.

Test solution— Reduce the Tablets to a very fine powder. Transfer a quantity of the powder, equivalent to about 100 mg of Extract, to a conical flask. Extract at 55 with three 20-mL portions of a mixture of water and methanol (8:2). Evaporate the combined extracts to dryness under vacuum at 45℃to 50℃. Dissolve the residue in 5 mL of methanol.

B: The retention times of the peaks for ginsenosides Rg1, Re, Rb1, Rb2, Rc2, and Rd in the chromatogram of the Test solution correspond to those in the chromatogram of Standard solution 1, as obtained in the test for Content of ginsenosides under American Ginseng. The ratio of the peak response for Rb2 to the peak response for Rb1 is less than 0.4; and the ratio of the peak response for Rg1 to the peak response for Rb1 is less than 0.3. The chromatogram shows no significant peak at the retention time corresponding to that of the RF for ginsenoside in the chromatogram of Standard solution 2, as obtained in the test for Content of ginsenosides under American Ginseng.

Microbial enumeration 2021 — The total aerobic microbial count does not exceed 104 cfu per g. The total combined molds and yeasts count does not exceed 1000 cfu per g. It meets the requirements of the tests for absence of Salmonella species and Escherichia coli.

Disintegration 2040 : meet the requirements.

Weight variation 2091 : meet the requirements.

Content of ginsenosides—

Mobile phase and Chromatographic system— Proceed as directed for the Content of ginsenosides under American Ginseng.

Standard solution— Prepare a solution of USP Powdered American Ginseng Extract RS in a mixture of water and alcohol (6:4) having a known concentration of about 1 mg of Rb1 per mL.

Test solution— Accurately weigh not fewer than 20 Tablets, and reduce to a very fine powder. To a conical flask, transfer an accurately weighed portion of the powder expected to contain an amount of Extract equivalent to about 15 mg of total ginsenosides. Add 15 mL of methanol, and shake to mix. Sonicate the mixture at 25℃to 30℃for 30 minutes. Cool, pass through filter paper, and return the residue to the conical flask. Add another 15 mL of methanol, sonicate the mixture at 25℃to 30℃for 30 minutes, and filter. Wash the residue with three 15-mL portions of methanol. Evaporate the combined extracts and washings to dryness under vacuum at 45℃to 50℃. Quantitatively transfer the residue to a 10.0-mL volumetric flask, using small volumes of methanol, and dilute with methanol to volume.

Procedure— Proceed as directed for Procedure in the test for Content of ginsenosides under American Ginseng. Separately calculate the quantity, in mg, of each relevant ginsenoside (Rg1, Re, Rb_1, Rc, Rb_2, and Rd) in the portion of Tablets taken to prepare the Test solution by the formula:

$$0.1PC(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Powdered American Ginseng Extract RS in the Standard solution; P is the labeled content of the corresponding ginsenoside in the USP Powdered American Ginseng Extract RS; and rU and rS are the peak responses of the relevant ginsenosides obtained from the Test solution and the Standard solution, respectively. Calculate the content of ginsenosides as the sum of the individual quantities of Rg_1, Re, Rb_1, Rc, Rb_2, and Rd.