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American Ginseng Capsules

Change to read:

DEFINITION

American Ginseng Capsules contain ▲American Ginseng Root and Rhizome Dry Extract.▲ (USP 1-May-2022) Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of American Ginseng Root and Rhizome Dry Extract, calculated as the sum of ginsenoside Rg₁▲(C₄₂H₇₂O₁₄)▲ (USP 1-May-2022) ginsenoside Re▲(C₄₈H₈₂O₁₈)▲ (USP 1-May-2022) ginsenoside Rb₁▲(C₅₄H₉₂O₂₃)▲ (USP 1-May-2022) ginsenoside Rc▲(C₅₃H₉₀O₂₂)▲ (USP 1-May-2022) ginsenoside Rb₂▲(C₅₃H₉₀O₂₂)▲ (USP 1-May-2022) and ginsenoside Rd▲(C₄₈H₈₂O₁₈)▲ (USP 1-May-2022)

IDENTIFICATION

Change to read:

- A. ▲[HPTLC FOR ARTICLES OF BOTANICAL ORIGIN \(203\)](#)▲ (USP 1-May-2022)

Standard solution A: ▲0.5 mg/mL each of [USP Ginsenoside Rg1 RS](#) and [USP Ginsenoside Rb1 RS](#)▲ (USP 1-May-2022) in [methanol](#)

Standard solution B: ▲10 mg/mL of [USP Powdered American Ginseng Extract RS](#)▲ (USP 1-May-2022) in [methanol](#). ▲Sonicate for 15 min, centrifuge, and use the supernatant.▲ (USP 1-May-2022)

Sample solution

For soft-shell gelatin Capsules: Transfer a portion of the contents of Capsules, equivalent to 100 mg of ▲American Ginseng Root and Rhizome Dry▲ (USP 1-May-2022) Extract, to a separatory funnel containing 30 mL of a mixture of [hexanes](#), [methanol](#), and [water](#) (20:15:10), dissolve, and collect the lower layer. Wash the upper layer with three 15-mL portions of [methanol](#) and [water](#) (15:10), and combine the washings with the lower layer. Evaporate to dryness under vacuum at 45°–50°. Dissolve the residue in ▲10▲ (USP 1-May-2022) mL of [methanol](#).

For hard-shell gelatin Capsules: Transfer a portion of the contents of the Capsules, equivalent to 100 mg of ▲American Ginseng Root and Rhizome Dry▲ (USP 1-May-2022) Extract, to a conical flask. Extract at 55° with three 20-mL portions of [methanol](#) and [water](#) (2:8). Evaporate the combined extracts to dryness under vacuum at 45°–50°. Dissolve the residue in ▲10▲ (USP 1-May-2022) mL of [methanol](#).

▲Chromatographic system

Adsorbent: Silica gel, precoated plates, with fluorescence indicator F₂₅₄▲ for HPTLC▲ (USP 1-May-2022)

Application volume: ▲2 µL, as 8-mm bands

Relative humidity: Condition the plate to a relative humidity of about 33% using a suitable device.

Temperature: About 25°▲ (USP 1-May-2022)

Developing solvent system: ▲[Methylene chloride](#), [anhydrous ethanol](#), and [water](#) (60:45:6.5)

Derivatization▲ (USP 1-May-2022) **reagent:** ▲10% [sulfuric acid](#) in [alcohol](#). [NOTE—Prepare fresh. Slowly add sulfuric acid to ice-cold alcohol.]▲ (USP 1-May-2022)

Analysis

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

▲Apply the *Samples* as bands and dry in air. Develop in a saturated chamber, remove the plate from the chamber, and dry in air. Treat the plate with *Derivatization reagent*, heat at 105° for 10 min, and examine immediately under white light and UV light at 365 nm.

Suitability requirements

Under white light: *Standard solution A* exhibits a reddish-violet band due to ginsenoside Rb₁ in the lower-third section and a brown band due to ginsenoside Rg₁ in the middle-third section. In the lower-third section, *Standard solution B* exhibits a band corresponding in R_F and color to ginsenoside Rb₁ in *Standard solution A*, a dark brown band immediately above ginsenoside Rb₁, a brown band above the dark brown band due to ginsenoside Rc, and one yellowish-brown band above ginsenoside Rc. In the middle-third section, *Standard solution B* exhibits four brown bands, separately due to ginsenoside Rd, ginsenoside Re, an unknown band immediately below

ginsenoside Rg₁, and ginsenoside Rg₁ with increasing R_F; the latter corresponds in R_F and color to ginsenoside Rg₁ in *Standard solution A*.

Under UV light at 365 nm: *Standard solution A* exhibits a reddish-blue band due to ginsenoside Rb₁ in the lower-third section and a pinkish-violet band due to ginsenoside Rg₁ in the middle-third section. In the lower-third section, *Standard solution B* exhibits a band corresponding in R_F and color to ginsenoside Rb₁ in *Standard solution A*, a black band immediately above ginsenoside Rb₁, a blue band above the black band due to ginsenoside Rc, and a gray blue band above ginsenoside Rc. In the middle-third section, *Standard solution B* exhibits a blue band due to ginsenoside Rd and three pinkish-violet bands above ginsenoside Rd, separately due to ginsenoside Re, an unknown band immediately below ginsenoside Rg₁, and ginsenoside Rg₁ with increasing R_F; the latter corresponds in R_F and color to ginsenoside Rg₁ in *Standard solution A*.▲ (USP 1-May-2022)

Acceptance criteria

▲**Under white light:** In the lower-third section, the *Sample solution* exhibits a band corresponding in R_F and color to ginsenoside Rb₁ in *Standard solution A* and *Standard solution B*, a dark brown band immediately above ginsenoside Rb₁, a brown band above the dark brown band due to ginsenoside Rc (distinction from *Panax notoginseng* root and rhizome), and one yellowish-brown band above ginsenoside Rc corresponding in R_F to the same constituents in *Standard solution B*. In the middle-third section, the *Sample solution* exhibits four brown bands corresponding in R_F to the same constituents in *Standard solution B*, separately due to ginsenoside Rd, ginsenoside Re, an unknown band immediately below ginsenoside Rg₁, and ginsenoside Rg₁ with increasing R_F; the latter corresponds in R_F and color to ginsenoside Rg₁ in *Standard solution A*. The *Sample solution* does not exhibit a brown band due to ginsenoside Rf (distinction from *Panax ginseng* root and rhizome) above ginsenoside Re.

Under UV light at 365 nm: In the lower-third section, the *Sample solution* exhibits a band corresponding in R_F and color to ginsenoside Rb₁ in *Standard solution A* and *Standard solution B*, a black band immediately above ginsenoside Rb₁, a blue band above the black band due to ginsenoside Rc (distinction from *P. notoginseng* root and rhizome), and a gray blue band above ginsenoside Rc corresponding in R_F and color to the same constituents in *Standard solution B*. In the middle-third section, the *Sample solution* exhibits four bands corresponding in R_F and color to the same constituents in *Standard solution B*, including a blue band due to ginsenoside Rd and three pinkish-violet bands above ginsenoside Rd, separately due to ginsenoside Re, an unknown band immediately below ginsenoside Rg₁, and ginsenoside Rg₁ with increasing R_F; the latter corresponds in R_F and color to ginsenoside Rg₁ in *Standard solution A*. The *Sample solution* does not exhibit a pinkish-violet band due to ginsenoside Rf (distinction from *P. ginseng* root and rhizome) above ginsenoside Re.▲ (USP 1-May-2022)

Change to read:

• B. ▲LC

Analysis: Proceed as directed in the test for *Content of Ginsenosides*.

Acceptance criteria: The retention times of the peaks for ginsenoside Rg₁, ginsenoside Re, ginsenoside Ro, ginsenoside Rb₁, malonyl ginsenoside Rb₁, ginsenoside Rc, and ginsenoside Rd of the *Sample solution* correspond to those from *Standard solution B*, as obtained in the test for *Content of Ginsenosides*. The two most intense peaks are due to ginsenoside Re and ginsenoside Rb₁.▲ (USP 1-May-2022)

STRENGTH

Change to read:

• CONTENT OF GINSENOSES

▲[NOTE—Protect samples from light. *Standard solution A*, *Standard solution B*, *Sample solution A*, and *Sample solution B* are stable for 24 h at room temperature.]▲ (USP 1-May-2022)

Diluent: ▲[Methanol](#) and [water](#) (7:3)▲ (USP 1-May-2022)

Solution A: ▲0.003% [phosphoric acid](#) in [water](#)▲ (USP 1-May-2022)

Solution B: [Acetonitrile](#)

▲**Solvent A:** Upper phase of a mixture consisting of [hexanes](#), [methanol](#), and [water](#) (4:3:2)

Solvent B: Lower phase of a mixture consisting of [hexanes](#), [methanol](#), and [water](#) (4:3:2)▲ (USP 1-May-2022)

Mobile phase: ▲See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	83	17
0.5	83	17
3.5	81	