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Change to read:

Asian Ginseng Root and Rhizome Powder

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DEFINITION

Asian Ginseng Root and Rhizome Powder is the dried roots and rhizomes of *Panax ginseng* C.A.Mey. reduced to a fine or very fine powder. It contains NLT 0.8% of total ginsenosides calculated as the sum of ginsenoside Rg₁ (C₄₂H₇₂O₁₄), ginsenoside Re (C₄₈H₈₂O₁₈), ginsenoside Rf (C₄₂H₇₂O₁₄), ginsenoside Rb₁ (C₅₄H₉₂O₂₃), ginsenoside Rc (C₅₃H₉₀O₂₂), ginsenoside Rb₂ (C₅₃H₉₀O₂₂), and ginsenoside Rd (C₄₈H₈₂O₁₈); NLT 0.3% of the sum of ginsenosides Rg₁ and Re; and NLT 0.2% of ginsenoside Rb₁ on the dried basis.

IDENTIFICATION

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A. [HPTLC FOR ARTICLES OF BOTANICAL ORIGIN \(203\)](#) (USP 1-Aug-2021)

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

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

Sample solution: Transfer 1.0 g of Asian Ginseng Root and Rhizome Powder in 5.0 mL of [alcohol](#), sonicate for 15 min, centrifuge, and use the supernatant.

Chromatographic system (USP 1-Aug-2021)

Adsorbent: [Silica gel with fluorescence indicator F₂₅₄](#), [precoated plate](#), for HPTLC (USP 1-Aug-2021)

Application volume: 3 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-Aug-2021)

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

Derivatization (USP 1-Aug-2021) **reagent:** 10% [sulfuric acid](#) in [alcohol](#).

[NOTE—Prepare on the day of the test; it can be used for up to 1 week if stored in a tightly closed container in a cool place. Slowly add sulfuric acid to ice-cold alcohol.] (USP 1-Aug-2021)

Analysis

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

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. (USP 1-Aug-2021)

System suitability

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

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*, two to three reddish-violet bands below ginsenoside Rb₁, a dark brown band immediately above ginsenoside Rb₁, and a brown band above the dark brown band due to ginsenoside Rc. In the middle-third section, *Standard solution B* exhibits four brown bands, separately due to ginsenoside Rd, ginsenoside Re, ginsenoside Rf, 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*, two to three reddish-blue bands below ginsenoside Rb₁, a black band immediately above ginsenoside Rb₁, and a blue band above the black band due to 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, ginsenoside Rf, and ginsenoside Rg₁ with increasing R_F ; the latter corresponds in R_F and color to ginsenoside Rg₁ in *Standard solution A*. ▲ (USP 1-Aug-2021)

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*, two to three reddish-violet bands below ginsenoside Rb₁, a dark brown band immediately above ginsenoside Rb₁, and a brown band above the dark brown band due to ginsenoside Rc (distinction from *P. notoginseng* root and rhizome), corresponding in R_F and color to the same constituents in *Standard solution B*. In the middle-third section, the *Sample solution* exhibits four brown bands corresponding in R_F and color to the same constituents in *Standard solution B*, separately due to ginsenoside Rd, ginsenoside Re, ginsenoside Rf (distinction from *P. quinquefolius* root and rhizome), 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: 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*, two to three reddish-blue bands below ginsenoside Rb₁, a black band immediately above ginsenoside Rb₁, and a blue band above the black band due to ginsenoside Rc (distinction from *P. notoginseng* root and rhizome), 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, ginsenoside Rf (distinction from *P. quinquefolius* root and rhizome), and ginsenoside Rg₁ with increasing R_F ; the latter corresponds in R_F and color to ginsenoside Rg₁ in *Standard solution A*. ▲ (USP 1-Aug-2021)

Change to read:

• B. ▲HPLC

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

Acceptance criteria: The *Sample solution* exhibits peaks corresponding to the retention times of ginsenoside Rg₁ and ginsenoside Rb₁ in *Standard solution A* and *Standard solution B*. The *Sample solution* exhibits peaks due to ginsenoside Re, ginsenoside Rf (absent in the roots and rhizomes of *P. quinquefolius* and *P. notoginseng*), chikusetsusaponin V (ginsenoside Ro), malonyl ginsenoside Rb₁, ginsenoside Rc, ginsenoside Rb₂ (distinction from *P. notoginseng* root and rhizome; it does not contain chikusetsusaponin V and ginsenosides Rc and Rb₂), and ginsenoside Rd corresponding to the retention times of the same ginsenosides in *Standard solution B*. The content ratio of ginsenoside Rb₂ to ginsenoside Rb₁ is NLT 0.3 (differentiation from *P. quinquefolius* root and rhizome). Malonyl ginsenoside Rb₁ peak is between ginsenoside Rb₁ and ginsenoside Rc with peak intensity similar to that of ginsenoside Rc; one peak between ginsenoside Rc and ginsenoside Rb₂ is due to malonyl ginsenoside Rc; one peak between ginsenoside Rb₂ and ginsenoside Rd is due to malonyl ginsenoside Rb₂ (distinction from *P. ginseng* steamed root and rhizome that does not contain significant peaks due to malonyl ginsenosides); and these peaks correspond to the retention times for the same peaks in *Standard solution B*. The peak intensity of ginsenoside Rd is less than that of ginsenoside Rb₂ (differentiation from aerial parts of *P. ginseng*). ▲ (USP 1-Aug-2021)

COMPOSITION

Change to read:

• CONTENT OF GINSENOSES ▲ (USP 1-Aug-2021)

Solution A: ▲0.003% [phosphoric acid](#) in ▲ (USP 1-Aug-2021) [water](#)

Solution B: [Acetonitrile](#) ▲ (USP 1-Aug-2021)

Mobile phase: See [Table 1](#).

Table 1

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