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Change to read:

Asian Ginseng Root and Rhizome Dry Extract

DEFINITION

Change to read:

Asian Ginseng Root and Rhizome Dry Extract is prepared from the dried roots and rhizomes of *Panax ginseng* C.A.Mey by extraction with water or hydroalcoholic mixtures. It contains NLT 3.0% 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) on the anhydrous basis; the content of total ginsenosides is NLT 90% and NMT 110% of the labeled amount. It may contain suitable added substances as carriers.

IDENTIFICATION

Change to read:

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

Standard solution A: 0.5 mg/mL each of USP Ginsenoside Rg₁ RS and USP Ginsenoside Rb₁ RS in methanol. (USP 1-Aug-2021)

Standard solution B: 10 mg/mL of USP Powdered Asian Ginseng Extract RS in methanol. Sonicate for 15 min, centrifuge, and use the supernatant. (USP 1-Aug-2021)

Sample solution: 10 mg/mL of Asian Ginseng Root and Rhizome Dry Extract in methanol. 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 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.

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 ginsenosides Rd, Re, Rf, and 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 ginsenosides Re, Rf, and 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 ginsenosides Rd, Re, Rf (distinction from *P. quinquefolius* root and rhizome), and 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 ginsenosides Re, Rf (distinction from *P. quinquefolius* root and rhizome), and 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), 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; 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 (malonyl ginsenosides are absent in water extract and steamed roots and rhizomes of *P. ginseng*); 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 or similar to that of ginsenoside Rb₂ (differentiation from aerial parts of *P. ginseng*).▲ (USP 1-Aug-2021)

Delete the following:

▲• **C.** The retention times of the peaks for ginsenosides Rg₁, Re, Rf, Rb₁, Rb₂, Rc, and Rd in the *Sample solution* chromatogram correspond to those in 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 NLT 0.4 (differentiation from American Ginseng).▲ (USP 1-Aug-2021)

COMPOSITION

Change to read:

• CONTENT OF GINSENOSES

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