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Change to read:

▲ (USP 1-May-2022) **American Ginseng ▲Root and Rhizome Dry▲ (USP 1-May-2022) Extract**

Change to read:

DEFINITION

▲ (USP 1-May-2022) American Ginseng ▲Root and Rhizome Dry▲ (USP 1-May-2022) Extract is prepared from the ▲ (USP 1-May-2022) dried roots and rhizomes▲ (USP 1-May-2022) of *Panax quinquefolius* L. ▲by extraction with water or hydroalcoholic mixtures.▲ (USP 1-May-2022) It contains NLT 10.0% of total ginsenosides, calculated ▲as the sum of ginsenoside Rg₁ (C₄₂H₇₂O₁₄), ginsenoside Re (C₄₈H₈₂O₁₈), ginsenoside Rb₁ (C₅₄H₉₂O₂₃), ginsenoside Rc (C₅₃H₉₀O₂₂), ginsenoside Rb₂ (C₅₃H₉₀O₂₂), and ginsenoside Rd (C₄₈H₈₂O₁₈),▲ (USP 1-May-2022) 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.▲ (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](#) in [methanol](#). Sonicate for 15 min, centrifuge, and use the supernatant.▲ (USP 1-May-2022)

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

Chromatographic system

Adsorbent: ▲[Silica gel with fluorescence indicator F₂₅₄](#)▲, [precoated plate](#), 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—Slowly add sulfuric acid to ice-cold alcohol. 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.]▲ (USP 1-May-2022)

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-May-2022)

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 *P. 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 and color 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 *P. 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.▲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, 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 constituents in *Standard solution B*. No significant peak corresponding to ginsenoside Rf (distinction from *P. ginseng* root and rhizome) is observed at the relative retention time of about 2.2 relative to ginsenoside Rg₁. The content ratios of ginsenoside Rb₂ to ginsenoside Rb₁ and ginsenoside Rg₁ to ginsenoside Rb₁ are NMT 0.2. The malonyl ginsenoside Rb₁ peak is between ginsenoside Rb₁ and ginsenoside Rc (malonyl ginsenoside Rb₁ is absent in water extract and the steamed roots and rhizomes of *P. ginseng* and *P. quinquefolium*s). The peak intensity of ginsenoside Rd is similar to that of ginsenoside Rc (differentiation from the leaves of *P. ginseng*).▲ (USP 1-May-2022)

COMPOSITION

Change to read:

• CONTENT OF GINSENOSES

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

Solution B: [Acetonitrile](#)▲▲ (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	19
5.0	77	23
15.0	70	30