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Add the following:

^Red Asian Ginseng Root and Rhizome

DEFINITION

Red Asian Ginseng Root and Rhizome consists of the dried roots and rhizomes of cultivated *Panax ginseng* C.A.Mey. (Family *Araliaceae*) collected in the autumn, steamed until the material is reddish brown and translucent. 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 0.2% of the sum of ginsenosides Rg₁ and Re; and NLT 0.25% of ginsenoside Rb₁, all on the dried basis.

IDENTIFICATION

• **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](#)

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 finely powdered Red Asian Ginseng Root and Rhizome in 5.0 mL of [alcohol](#), sonicate for 15 min, centrifuge, and use the supernatant.

Chromatographic system

Adsorbent: [Silica gel with fluorescence indicator F₂₅₄](#), precoated plates, for HPTLC

Application volume: 3 µL, as 8-mm bands

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

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

Derivatization reagent: 10% of [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 and in a cool place. Keep alcohol cold over ice, and add sulfuric acid slowly.]

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*, and heat at 105° for 10 min. Immediately examine under white light and long wavelength UV light.

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 reddish violet band corresponding in R_F 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, due to ginsenosides Rd, Re, Rf, and Rg₁, respectively, with increasing R_F; the latter corresponds in R_F and color to ginsenoside Rg₁ in *Standard solution A*.

Under long wavelength UV light: *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 reddish blue band corresponding in R_F 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, due to ginsenosides Re, Rf, and Rg₁, respectively, with increasing R_F; the latter corresponds in R_F and color to ginsenoside Rg₁ in *Standard solution A*.

Acceptance criteria

Under white light: In the lower-third section, the *Sample solution* exhibits a reddish violet band corresponding in R_F to ginsenoside Rb₁ in *Standard solution A* and *Standard solution B*, a dark brown band immediately above ginsenoside Rb₁, and a brown band above the dark brown band due to ginsenoside Rc (distinction from *Panax notoginseng* root and rhizome) corresponding in R_F to those in *Standard*

solution B. No reddish violet bands appear below ginsenoside Rb₁ in the *Sample solution* (distinction from *P. ginseng* root and rhizome). In the middle-third section, the *Sample solution* exhibits four brown bands corresponding in R_F to those in *Standard solution B*, due to ginsenosides Rd, Re, Rf (absent in *Panax quinquefolius* root and rhizome), and Rg₁, respectively; the latter corresponds in R_F and color to ginsenoside Rg₁ in *Standard solution A*.

Under long wavelength UV light: In the lower-third section, the *Sample solution* exhibits a reddish blue band corresponding in R_F to ginsenoside Rb₁ in *Standard solution A* and *Standard solution B*, 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 to those in *Standard solution B*. No reddish blue bands appear below ginsenoside Rb₁ in the *Sample solution* (distinction from *P. ginseng* root and rhizome). In the middle-third section, the *Sample solution* exhibits four bands corresponding in R_F to those in *Standard solution B*, including a blue band due to ginsenoside Rd and three pinkish violet bands above ginsenoside Rd, due to ginsenosides Re, Rf (absent in *P. quinquefolius* root and rhizome), and Rg₁, respectively; the latter corresponds in R_F and color to ginsenoside Rg₁ in *Standard solution A*.

• B. HPLC

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

Acceptance criteria: The *Sample solution* exhibits peaks at the retention times corresponding to ginsenoside Rg₁ and ginsenoside Rb₁ in *Standard solution A* and *Standard solution B*, and 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 at the retention times corresponding to those in *Standard solution B*. The content ratio of ginsenoside Rb₂ to ginsenoside Rb₁ is NLT 0.2 and NMT 0.8 (distinction from *P. quinquefolius* root and rhizome). No peaks corresponding to malonyl ginsenosides Rb₁, Rc, and Rb₂ in *Standard solution B* appear in the *Sample solution* (distinction from *P. ginseng* root and rhizome). The peak intensity of ginsenoside Rd is less than that of ginsenoside Rb₂ (distinction from aerial parts of *P. ginseng*).

COMPOSITION

• CONTENT OF GINSENOSES

Solution A: 0.003% of [phosphoric acid](#) in [water](#)

Solution B: [Acetonitrile](#)

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
16.0	70	30
16.1	5	95
20.0	5	95
20.1	83	17
25.0	83	17

Solvent: [Methanol](#) and [water](#) (7:3)

Standard solution A: 0.15 mg/mL each of [USP Ginsenoside Rg1 RS](#) and [USP Ginsenoside Rb1 RS](#) in *Solvent*

Standard solution B: 10 mg/mL of [USP Powdered Asian Ginseng Extract RS](#) in *Solvent*. Sonicate for 10 min. Before injection, pass through a nylon filter of 0.22-μm pore size.

Sample solution: Transfer about 500 mg of finely powdered Red Asian Ginseng Root and Rhizome, accurately weighed to a suitable flask, add 25.0 mL of *Solvent*, and close tightly. Weigh the filled flask accurately and sonicate for 30 min. Cool to room temperature. Adjust to the