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Tienchi Ginseng Root and Rhizome Powder Capsules

DEFINITION

Tienchi Ginseng Root and Rhizome Powder Capsules contain Tienchi Ginseng Root and Rhizome Powder. They contain NLT 5.0% of ginsenosides calculated as the sum of notoginsenoside R1 ($C_{47}H_{80}O_{18}$), ginsenoside Rg1 ($C_{42}H_{72}O_{14}$), ginsenoside Re ($C_{48}H_{82}O_{18}$), ginsenoside Rb1 ($C_{54}H_{92}O_{23}$), and ginsenoside Rd ($C_{48}H_{82}O_{18}$) from the labeled amount of Tienchi Ginseng Root and Rhizome Powder.

IDENTIFICATION

Change to read:

• **A. HPTLC for Articles of Botanical Origin ⟨203⟩**

Standard solution A: 0.5 mg/mL of USP Ginsenoside Rg1 RS in methanol

Standard solution B: 5 mg/mL of USP *Panax notoginseng* Root and Rhizome Dry Extract RS in methanol. Sonicate for about 10 min, centrifuge, and use the supernatant.

Sample solution: Transfer a finely powdered portion of the contents of the Capsules, equivalent to 0.4 g of Tienchi Ginseng Root and Rhizome Powder, to a suitable container, add 10.0 mL of methanol, and sonicate for 20 min. Centrifuge, and use the supernatant.

Chromatographic system

Adsorbent: Chromatographic silica gel F_{254} mixture

Application volume: 4 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, dehydrated alcohol, and water ▲(60:45:6.5)▲ (USP 1-May-2019)

Developing distance: 6 cm

Derivatization reagent: 10% sulfuric acid in alcohol. Prepare fresh. Keep alcohol cold over ice. Carefully and gradually add sulfuric acid.

Analysis

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

Apply the *Samples* as bands to a suitable HPTLC plate, 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 5 min, and examine immediately under white light and under UV light at 366 nm.

System suitability

Under white light: The chromatogram of *Standard solution B* exhibits five main reddish-violet bands. A band in the upper-half section corresponding in R_F to the band of ginsenoside Rg1 in *Standard solution A*; a band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated between the bands of ginsenoside Rg1 and ginsenoside Rb1—the lower band due to ginsenoside Rd, the middle due to ginsenoside Re, and the upper due to notoginsenoside R1. The two most intense bands are due to ginsenoside Rb1 and ginsenoside Rg1.

Under UV light at 366 nm: The chromatogram of *Standard solution B* exhibits a pinkish-violet band at an R_F corresponding to the ginsenoside Rg1 band in *Standard solution A*; a blue fluorescent band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated between the bands of ginsenoside Rg1 and ginsenoside Rb1—the lower due to ginsenoside Rd, the middle due to ginsenoside Re, and the upper due to notoginsenoside R1 (the band due to ginsenoside Rd is blue fluorescent, while the other two bands are pinkish violet). The two most intense bands in the chromatogram are due to ginsenoside Rb1 and ginsenoside Rg1.

Acceptance criteria

Under white light: The chromatogram of the *Sample solution* exhibits five main reddish-violet bands corresponding in R_F to similar bands in *Standard solution B*: a band in the upper-half section corresponding in R_F to ginsenoside Rg1 in *Standard solution A*; a band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated between the bands of ginsenoside Rg1 and ginsenoside Rb1—the lower band due to ginsenoside Rd, the middle due to ginsenoside Re, and the upper due to notoginsenoside R1. The two most intense bands are due to ginsenoside Rb1 and ginsenoside Rg1.

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Under UV light at 366 nm: The chromatogram of the *Sample solution* exhibits bands corresponding in R_F to similar bands in *Standard solution B*: a pinkish-violet band at an R_F corresponding to the ginsenoside Rg1 band in *Standard solution A*; a blue fluorescent band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated between the bands of ginsenoside Rg1 and ginsenoside Rb1—the lower due to ginsenoside Rd, the middle due to ginsenoside Re, and the upper due to notoginsenoside R1 (the band due to ginsenoside Rd is blue fluorescent, while the other two bands are pinkish violet). The two most intense bands are due to ginsenoside Rb1 and ginsenoside Rg1.

• **B. LC**

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

Acceptance criteria: The retention times of the notoginsenoside R1, ginsenoside Rg1, ginsenoside Re, ginsenoside Rb1, and ginsenoside Rd peaks of the *Sample solution* correspond to those of *Standard solution B*. The two most intense peaks are due to ginsenoside Rg1 and ginsenoside Rb1.

STRENGTH

Change to read:

• **Content of Ginsenosides**

Extraction solvent: Methanol and water (70:30)

Solution A: 0.03% phosphoric acid in water (v/v)

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	83	17
2.4	80	20
3.5	70	30
4.2	69	31
5.0	58	42
5.1	0	100
6.0	0	100
6.1	83	17
7.5	83	17

Standard solution A: 0.04 mg/mL of USP Ginsenoside Rg1 RS in ▲*Extraction solvent*.▲ (USP 1-May-2019) Sonicate to dissolve, if necessary.

Standard solution B: 3.0 mg/mL of USP *Panax notoginseng* Root and Rhizome Dry Extract RS in *Extraction solvent*. Sonicate for about 10 min, centrifuge, and use the supernatant. Before injection, pass through a polytetrafluoroethylene (PTFE) membrane filter of 0.2-µm pore size, and discard the first portion of the filtrate.

Sample solution: Determine the total weight of 20 Capsules. Open the Capsules and combine their contents in an appropriate container. Weigh the empty Capsule shells and calculate the average fill weight per Capsule. Thoroughly mix and finely powder the contents of the Capsules. Transfer a portion of the Capsule contents, equivalent to 0.3 g of Tienchi Ginseng Root and Rhizome Powder to a 50-mL centrifuge tube. Add 10 mL of *Extraction solvent*, and sonicate for 20 min. Centrifuge, and transfer the supernatant to a 25-mL volumetric flask. Repeat this extraction with 10 mL of *Extraction solvent*, and sonicate for 10 min. Combine the extracts in a volumetric flask, dilute with *Extraction solvent* to volume, and mix. Before injection, pass through a PTFE membrane filter of 0.2-µm pore size, and discard the first portion of the filtrate.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

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