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Add the following:

▲*Picrorhiza* Species Root and Rhizome Dry Extract

DEFINITION

Picrorhiza Species Root and Rhizome Dry Extract consists of the dried root and rhizome of *Picrorhiza kurroa* Royle ex Benth. (Fam. Plantaginaceae) by extraction with hydroalcoholic mixtures.[1] *Picrorhiza* Species Root and Rhizome Dry Extract may contain suitable added substances as carriers. It contains NLT 90.0% and NMT 110.0% of the labeled amount of iridoid glycosides, calculated as the sum of picroside I and picroside II on the anhydrous basis.

IDENTIFICATION

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

Standard solution A: 0.5 mg/mL of USP Picroside I RS in methanol

Standard solution B: 80 mg/mL of USP *Picrorhiza kurroa* Root and Rhizome Dry Extract RS in methanol. Sonicate for 15 min, centrifuge, and use the supernatant.

Sample solution: Sonicate 150 mg of *Picrorhiza* Species Root and Rhizome Dry Extract in 5 mL of methanol for 15 min. Centrifuge and use the supernatant.

Chromatographic system

(See standard parameters as defined in *HPTLC for Articles of Botanical Origin ⟨203⟩*, *Table 1*.)

Application volume: 2 µL each of *Standard solution A*, *Standard solution B*, and the *Sample solution*, as 8-mm bands

Developing solvent system: 2-Butanone, isopropyl alcohol, and 98% formic acid (90:10:5)

Derivatization reagent: Prepare the anisaldehyde–sulfuric acid reagent as follows. Add 20 mL of acetic acid and 10 mL of sulfuric acid to 170 mL of cold methanol and mix well. After cooling to room temperature, add 1 mL of anisaldehyde.

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. Treat with the *Derivatization reagent*, heat for 3 min at 100°, and examine under long-wave UV light and under white light.

System suitability

Under long-wave UV light: *Standard solution B* exhibits about 5–6 blue or purple bands and/or yellow, brown, or green bands in the lower-half section, with the band near the middle section (near R_F 0.45) corresponding to picroside I in *Standard solution A*. The intense blue fluorescent band at about R_F 0.25 corresponds to picroside II. Additional blue or purple and/or pink or green fluorescent bands are observed in the upper-half section.

Under white light: *Standard solution B* exhibits about 4–5 brown bands in the lower-half section, with the most intense band close to the upper-most section (near R_F 0.45) and corresponding in R_F and color to picroside I in *Standard solution A*. Another intense band (near R_F 0.25) corresponds to picroside II.

Acceptance criteria

Under long-wave UV light: The *Sample solution* exhibits a blue or purple fluorescent band and/or a yellow, brown, or green fluorescent band in the lower-half section (near R_F 0.45) corresponding in R_F and color to picroside I in *Standard solution A*. The most intense blue fluorescent band (near R_F 0.25) corresponds to picroside II. Additional blue or purple and/or pink or green fluorescent bands are observed in the upper-half section.

Under white light: The *Sample solution* exhibits about 4–5 brown bands in the lower-half section, with the most intense band close to the upper-most section (near R_F 0.45) and corresponding in R_F and color to picroside I in *Standard solution A*. Another intense band (near R_F 0.25) corresponds to picroside II.

• **B. HPLC**

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

Acceptance criteria: The *Sample solution* exhibits the most intense peak at a retention time corresponding to picroside I in *Standard solution A* and *Standard solution B*. The second most intense peak is picroside II. Two additional peaks are observed between picroside I and picroside II with about a quarter of the intensity of picroside I. One minor peak is observed before picroside II.

COMPOSITION

• **Content of Iridoid Glycosides**

Solution A: Dissolve 0.136 g of anhydrous potassium phosphate, monobasic in 900 mL of water, and add 0.5 mL of phosphoric acid. Dilute with water to 1000 mL.

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	85	15
7	80	20
15	70	30
20	20	80
25	85	15
30	85	15

Standard solution A: 0.015 mg/mL of USP Picroside I RS in methanol

Standard solution B: 0.6 mg/mL of USP *Picrorhiza kurroa* Root and Rhizome Dry Extract RS in methanol. Sonicate if necessary. Before injection, pass the solution through a suitable membrane filter of 0.45-µm or finer pore size. Discard the first few milliliters of the filtrate.

Sample solution: *Picrorhiza* Species Root and Rhizome Dry Extract in methanol at a concentration equivalent to 0.015 mg/mL of picroside I according to the label claim. Sonicate if necessary. Before injection, pass the solution through a suitable membrane filter of 0.45-µm or finer pore size. Discard the first few milliliters of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 263 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between picroside I and picroside II, *Standard solution B*

Tailing factor: NMT 1.5 for picroside I, *Standard solution A*

Relative standard deviation: NMT 2.5% for picroside I in repeated injections, *Standard solution A*

Chromatogram similarity: The chromatogram of *Standard solution B* is similar to the reference chromatogram provided with the lot of USP *Picrorhiza kurroa* Root and Rhizome Dry Extract RS being used.

Analysis

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

Using the chromatograms of *Standard solution A* and *Standard solution B* and the reference chromatogram provided with the lot of USP *Picrorhiza kurroa* Root and Rhizome Dry Extract RS being used, identify the retention times of the peaks corresponding to picroside I and picroside II. The approximate relative retention times of the peaks for picroside I and picroside II are 1.00 and 0.77, respectively.

Calculate separately the percentages of picroside I and picroside II in the portion of *Picrorhiza* Species Root and Rhizome Dry Extract taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times F \times 100$$

r_U = peak area of picroside I or picroside II from the *Sample solution*

r_S = peak area of picroside I from *Standard solution A*

C_S = concentration of USP Picroside I RS in *Standard solution A* (mg/mL)

C_U = concentration of *Picrorhiza* Species Root and Rhizome Dry Extract in the *Sample solution* (mg/mL)

F = conversion factor for the analyte (1.0 for picroside I, 1.74 for picroside II)

Calculate the content of iridoid glycosides as the sum of the percentages of picroside I and picroside II.

Calculate the percentage of the labeled amount of iridoid glycosides in the portion of *Picrorhiza* Species Root and Rhizome Dry Extract taken:

$$\text{Result} = (P/L) \times 100$$

P = content of iridoid glycosides, as determined previously (%)

L = labeled amount of iridoid glycosides (%)

Acceptance criteria: 90.0%–110.0% on the anhydrous basis

CONTAMINANTS

• **Articles of Botanical Origin** ⟨561⟩, *Limits of Elemental Impurities*: Meets the requirements

• **Articles of Botanical Origin** ⟨561⟩, *Pesticide Residue Analysis*: Meets the requirements

• **Microbial Enumeration Tests** ⟨2021⟩: The total aerobic bacterial count does not exceed 10^5 cfu/g, the total combined molds and yeasts count does not exceed 10^3 cfu/g, and the bile-tolerant Gram-negative bacterial count does not exceed 10^3 cfu/g.

• **Absence of Specified Microorganisms** ⟨2022⟩, *Test Procedures, Test for Absence of Salmonella Species* and *Test for Absence of Escherichia coli*: Meets the requirements

SPECIFIC TESTS

• **Water Determination** ⟨921⟩, *Method III*

Sample: 2.0 g of *Picrorhiza* Species Root and Rhizome Dry Extract, finely powdered

Analysis: Dry the *Sample* at 105° for 2 h.

Acceptance criteria: NMT 5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, protected from light and moisture, and store at controlled room temperature.

• **Labeling:** The label states the Latin binomial of the plant from which the article was prepared. It meets the other labeling requirements in *Botanical Extracts* ⟨565⟩.

• **USP Reference Standards** ⟨11⟩

USP *Picrorhiza kurroa* Root and Rhizome Dry Extract RS

USP Picroside I RS▲ (USP 1-May-2024)

[1] The synonym status of the species names *Picrorhiza kurroa* Royle ex Benth. and *Picrorhiza kurrooa* Royle is unresolved at this time.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PICRORHIZA SPECIES ROOT AND RHIZOME DRY EXTRACT	Nam-Cheol Kim Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

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