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Rhodiola rosea Tablets

DEFINITION

Rhodiola rosea Tablets contain Powdered *Rhodiola rosea* Extract. They contain NLT 95.0% of the labeled amount of phenylpropenoid glycosides, calculated as the sum of rosarin ($C_{20}H_{28}O_{10}$), rosavin ($C_{20}H_{28}O_{10}$), and rosin ($C_{15}H_{20}O_6$); and NLT 95.0% of the labeled amount of salidroside ($C_{14}H_{20}O_7$).

IDENTIFICATION

Add the following:

▲ A. [HPTLC FOR ARTICLES OF BOTANICAL ORIGIN \(203\)](#)

Standard solution A: 2.0 mg/mL of [USP Salidroside RS](#) and 1.0 mg/mL of [USP Rosavin RS](#) in [absolute alcohol](#)

Standard solution B: 50 mg/mL of [USP Rhodiola rosea Root and Rhizome Dry Extract RS](#) in [absolute alcohol](#). Sonicate for 10 min, centrifuge, and use the supernatant.

Sample solution: Grind 10 Tablets to a powder, transfer the powder to a suitable container, and homogenize. Transfer a portion of the homogenized powder to a centrifuge tube and dilute with [absolute alcohol](#) to obtain a solution nominally equivalent to 50 mg/mL of extract. Sonicate for 10 min, centrifuge, and use the supernatant.

Adsorbent: Chromatographic silica gel with an average particle size of 5 µm (HPTLC plates)

Application volume: 5 µL, as 8-mm bands

Relative humidity: Condition the plate to a relative humidity of 33%.

Temperature: Ambient, not to exceed 30°

Developing solvent system: [Ethyl acetate](#), [methanol](#), [water](#), and [formic acid](#) (77:13:10:2)

Developing distance: 6 cm

Derivatization reagent: Dissolve 1 g of [diphenylamine](#) in 40 mL of [acetone](#), add 1 mL of [aniline](#), and mix. Carefully add 7.5 mL of [phosphoric acid](#) and mix.

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 and dry in air. Treat the plate with *Derivatization reagent*, heat at 120° for 5 min, and examine under white light.

System suitability: *Standard solution A* shows two bands in the lower half of the chromatogram. The band with a higher R_f is due to salidroside, and the band with a lower R_f is due to rosavin. *Standard solution B* exhibits, in the lower half of the chromatogram, two to four gray bands and several brownish bands, one above and the other below the gray bands; the most intense band is the brownish band with an R_f below the gray bands; the most intense gray band is the band at an R_f corresponding to rosavin in *Standard solution A*.

Acceptance criteria: The *Sample solution* exhibits an intense band corresponding in R_f and color to rosavin in *Standard solution A* and additional bands corresponding in R_f and color to similar bands in the chromatogram of *Standard solution B*; the most intense band is the brownish band with an R_f below the gray bands; the most intense gray band is that due to rosavin. Additional bands of varying coloration and intensity may be observed. ▲ (USP 1-May-2019)

Change to read:

• ▲ B. ▲ (USP 1-May-2019) HPLC

Analysis: Proceed as directed in the test for *Content of Phenylpropenoid Glycosides and Salidroside, Method 1* or *Method 2*.

Acceptance criteria: The *Sample solution* exhibits peaks at retention times corresponding to the peaks due to salidroside, rosarin, rosavin, and rosin in *Standard solution B* in *Method 1* or *Standard solution C* in *Method 2*.

STRENGTH

[NOTE—The strength requirement may be met by following either one of the specified methods; the method used should be stated on the label only if *Method 1* is not used.]

• **CONTENT OF PHENYLPROPENOID GLYCOSIDES AND SALIDROSIDE, Method 1**

Extraction solvent: [Methanol](#) and [water](#) (2:8)

Solution A: 0.2% o-phosphoric acid in [water](#)

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	94	6
10	94	6
11	85	15
21	77	23
22	10	90
24	10	90
25	94	6
35	94	6

Standard solution A: 0.04 mg/mL of [USP Rosavin RS](#) and 0.02 mg/mL of [USP Salidroside RS](#) in *Extraction solvent*. Sonicate to dissolve, if necessary.

Standard solution B: 2.0 mg/mL of [USP Rhodiola rosea Root and Rhizome Dry Extract RS](#) in *Extraction solvent*. Sonicate to dissolve, if necessary. Before injection, pass through a PVDF membrane filter of 0.45-µm or finer pore size.

Sample solution: Weigh NLT 20 Tablets, determine the average Tablet weight, and finely powder. Transfer a portion of finely powdered Tablets, nominally equivalent to 3 mg of phenylpropenoid glycosides (sum of rosarin, rosavin, and rosin) into a 50-mL volumetric flask. Add 40 mL of *Extraction solvent* and sonicate for 30 min. Cool to room temperature, dilute with *Extraction solvent* to volume, mix well, and pass through a PVDF membrane filter of 0.45-µm pore size.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 221 nm for 0–15 min and 251 nm for 15–35 min

Column: 4.6-mm × 15-cm; 3-µm packing L1

Column temperature: 40°

Flow rate: 1.25 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

Chromatogram similarity: The chromatogram obtained with *Standard solution B* is similar to the reference chromatogram provided with the lot of [USP Rhodiola rosea Root and Rhizome Dry Extract RS](#) being used.

Resolution: NLT 1.5 between the rosarin and rosavin peaks, *Standard solution B*

Relative standard deviation: NMT 2.0% for the rosavin and salidroside peaks in replicate injections, *Standard solution A*

Analysis

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

Using the chromatograms of *Standard solution A*, *Standard solution B*, and the reference chromatogram provided with the lot of [USP Rhodiola rosea Root and Rhizome Dry Extract RS](#) being used, identify the peaks corresponding to salidroside, rosarin, rosavin, and rosin in the *Sample solution*.

Calculate the percentage of the labeled amount of phenylpropenoid glycosides calculated as the sum of rosarin, rosavin, and rosin in the portion of Tablets taken: