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Eleuthero Root and Rhizome Dry Extract

DEFINITION

Eleuthero Root and Rhizome Dry Extract is prepared from Eleuthero Root and Rhizome using hydroalcoholic mixtures. The ratio of the starting crude plant material to Dry Extract is between 13:1 and 25:1. It contains NLT 0.8% of phenylpropanoid glucosides as eleutheroside B ($C_{17}H_{24}O_9$), also referred to as syringin, and eleutheroside E ($C_{34}H_{46}O_{18}$), also referred to as syringaresinol diglucoside, calculated on the anhydrous basis. It may contain added substances.

IDENTIFICATION

- A. HPTLC FOR ARTICLES OF BOTANICAL ORIGIN (203).**
Solvent: Alcohol and water (1:1)
Standard solution A: 1 mg/mL of [USP Eleutheroside E RS](#) in [methanol](#)
Standard solution B: 1 mg/mL of [USP Eleutheroside B RS](#) in [methanol](#)
Standard solution C: 0.1 g of [USP Powdered Eleuthero Extract RS](#) in 5 mL of *Solvent*. Sonicate for 10 min, centrifuge, and use the supernatant.
Sample solution: 0.1 g of Eleuthero Root and Rhizome Dry Extract in 5 mL of *Solvent*. 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: 10 µL, as bands
Relative humidity: Condition the plate to a relative humidity of 33%.
Temperature: Ambient, not to exceed 30°
Developing solvent system: [Chloroform](#), [methanol](#), and water (35:15:2)
Developing distance: 6 cm
Derivatization reagent: To 18 mL of ice-cold [methanol](#) slowly and carefully add 2 mL of [sulfuric acid](#), and mix well. Allow the mixture to adjust to room temperature.
Analysis
Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, 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 100° for 5 min, and examine under white light and under UV light (365 nm).
Acceptance criteria: Under white light, the *Sample solution* exhibits two brown bands due to eleutheroside E and eleutheroside B at R_F values of about 0.34 and 0.45, corresponding in color and R_F to the bands exhibited by *Standard solution A* and *Standard solution B*, respectively. The *Sample solution* also exhibits two additional brown bands near the application zone, corresponding in color and R_F to the bands exhibited by *Standard solution C*. Other bands may be observed in the *Sample solution* and *Standard solution C* chromatograms. Under UV light, the *Sample solution* shows a brown band due to eleutheroside E corresponding in color and R_F to the band exhibited by *Standard solution A*.
B. HPLC: The *Sample solution* in the test for *Content of Eleutherosides B and E* shows a peak at a retention time corresponding to that of eleutheroside B in *Standard solution B* and a peak at a retention time corresponding to that of eleutheroside E in *Standard solution A*.

COMPOSITION

- CONTENT OF ELEUTHEROSIDES B AND E**
Solvent: [Methanol](#) and water (1:1)
Solution A: [Acetonitrile](#) and water (5:95)
Solution B: [Acetonitrile](#) and water (60:40)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	97	3
5	97	3

Time (min)	Solution A (%)	Solution B (%)
30	60	40
31	5	95
45	5	95
45.1	97	3
60	97	3

Standard solution A: 0.1 mg/mL of [USP Eleutheroside E RS](#) in [methanol](#). Transfer 2.0 mL to a 5-mL volumetric flask, and dilute with *Solvent* to volume.

Standard solution B: 0.1 mg/mL of [USP Eleutheroside B RS](#) in [methanol](#). Transfer 2.0 mL to a 5-mL volumetric flask, and dilute with *Solvent* to volume.

Standard solution C: 5.0 mg/mL of [USP Powdered Eleuthero Extract RS](#) in *Solvent*. Sonicate for 30 min, cool to room temperature, and decant. Before injection, pass through a nylon filter of 0.45-µm or finer pore size, discarding the first few milliliters of the filtrate.

Sample solution: Transfer 500 mg of Eleuthero Root and Rhizome Dry Extract, accurately weighed, to a 100-mL volumetric flask, add 80 mL of *Solvent*, and sonicate for 30 min. Cool to room temperature, dilute with *Solvent* to volume, and mix. Before injection, pass through a nylon filter of 0.45-µm or finer pore size, discarding the first few milliliters of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.0-mm × 25-cm; 5-µm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Samples: *Standard solution B* and *Standard solution C*

Suitability requirements

Chromatogram similarity: The chromatogram of *Standard solution C* is similar to the reference chromatogram provided with the lot of [USP Powdered Eleuthero Extract RS](#) being used.

Relative standard deviation: NMT 2.0% determined from the eleutheroside B peak in replicate injections, *Standard solution B*

Analysis

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

Identify the eleutheroside B and eleutheroside E peaks in the *Sample solution* by comparison with the chromatograms of *Standard solution B* and *Standard solution A*, respectively, and measure the peak areas.

Separately calculate the percentage of eleutheroside B and eleutheroside E in the portion of Eleuthero Root and Rhizome Dry Extract taken:

$$\text{Result} = (r_U/r_S) \times C_S \times (V/W) \times 100$$

r_U = peak area of eleutheroside E or eleutheroside B from the *Sample solution*

r_S = peak area of eleutheroside E or eleutheroside B from *Standard solution A* or *Standard solution B*, respectively

C_S = concentration of eleutheroside E or eleutheroside B in *Standard solution A* or *Standard solution B*, respectively (mg/mL)

V = volume of the *Sample solution* (mL)

W = weight of Eleuthero Root and Rhizome Dry Extract used to prepare the *Sample solution* (mg)

Acceptance criteria: NLT 0.8% on the anhydrous basis

CONTAMINANTS

- [BOTANICAL EXTRACTS \(565\), Preparations, General Pharmacopeial Requirements, Pesticide Residues](#): Meets the requirements
- [BOTANICAL EXTRACTS \(565\), Preparations, General Pharmacopeial Requirements, Residual Solvents](#): Meets the requirements
- [MICROBIAL ENUMERATION TESTS \(2021\)](#): The total aerobic microbial count does not exceed 10^4 cfu/g. The total combined yeasts and molds 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