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## Eleuthero Root and Rhizome Dry Extract Capsules

### DEFINITION

Eleuthero Root and Rhizome Dry Extract Capsules contain Eleuthero Root and Rhizome Dry Extract. They contain NLT 95% of the labeled amount of phenylpropanoid glucosides as the sum of 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. They may contain suitable added substances.

### IDENTIFICATION

Add the following:

#### ▲ 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](#) and 1 mg/mL of [USP Eleutheroside B RS](#) in methanol

**Standard solution B:** 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:** Open 10 Capsules, combine their contents in an appropriate container, and mix well. Transfer a portion of the Capsule contents to a centrifuge tube, and add *Solvent* to obtain a solution equivalent to 20 mg/mL of Eleuthero Root and Rhizome Dry Extract. Sonicate for 10 min, centrifuge, and use the supernatant.

#### Chromatographic system

**Adsorbent:** Chromatographic silica gel with an average particle size of 5 µm

**Application volume:** 10 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:** [Methylene chloride](#), [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*, 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*, heat at 100° for 5 min, and examine under white light and under UV light at 365 nm.

**System suitability:** Under white light, *Standard solution A* shows two brown bands in the middle-third section of the chromatogram. The band with a higher  $R_f$  is due to eleutheroside B, and the band with a lower  $R_f$  is due to eleutheroside E. *Standard solution B* exhibits two bands corresponding in color and  $R_f$  to the bands due to eleutheroside E and eleutheroside B in *Standard solution A*. *Standard solution B* exhibits two intense brown bands in the lower-third section near the starting position.

**Acceptance criteria:** Under white light, the *Sample solution* exhibits two brown bands corresponding in  $R_f$  and color to eleutheroside E and eleutheroside B in *Standard solution A*. The *Sample solution* exhibits two intense bands in the lower-third section, corresponding in color and  $R_f$  to the same bands in *Standard solution B*. Multiple weak bands may be observed in the *Sample solution* corresponding in color and  $R_f$  to similar bands in *Standard solution B*. 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*. ▲ (USP 1-May-2019)

Change to read:

#### • ▲B. ▲ (USP 1-MAY-2019) HPLC

**Analysis:** Proceed as directed in the test for *Content of Eleutherosides B and E*.

**Acceptance criteria:** The chromatogram of the *Sample solution* exhibits peaks at the retention times corresponding to the peaks due to eleutheroside B and eleutheroside E in the chromatogram of *Standard solution B*.

### STRENGTH

#### • CONTENT OF ELEUTHEROSIDES B AND E

**Extraction solvent:** [Methanol](#) and [water](#) (6:4)

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

**Solution B:** Acetonitrile

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

**Table 1**

| Time<br>(min) | Solution A<br>(%) | Solution B<br>(%) |
|---------------|-------------------|-------------------|
| 0             | 90                | 10                |
| 2             | 90                | 10                |
| 20            | 70                | 30                |
| 25            | 70                | 30                |
| 27            | 90                | 10                |
| 37            | 90                | 10                |

**Standard stock solution A:** 0.025 mg/mL of [USP Eleutheroside B RS](#) in methanol. Sonicate for 5 min to dissolve.

**Standard stock solution B:** 0.1 mg/mL of [USP Eleutheroside E RS](#) in methanol. Sonicate for 5 min to dissolve.

**Standard solution A:** Transfer 2.0 mL of *Standard stock solution A* and 1.0 mL of *Standard stock solution B* to a 10-mL volumetric flask, dilute with water to volume, and mix well.

**Standard solution B:** 1 mg/mL of [USP Powdered Eleuthero Extract RS](#) in *Extraction solvent*. Sonicate for 30 min and cool to room temperature. Dilute with water to a final concentration of 0.5 mg/mL. Before injection, pass through a PVDF membrane filter of 0.45-μm or finer pore size.

**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. Transfer a portion of the Capsule contents, nominally equivalent to 0.5 mg of phenylpropanoid glucosides (sum of eleutheroside B and eleutheroside E), to a 50-mL volumetric flask. Add 25 mL of *Extraction solvent* and sonicate for 30 min with occasional shaking. Shake the flask manually for 1 min, cool to room temperature, dilute with water to volume, mix well, and pass through a PVDF membrane filter of 0.45-μm or finer pore size.

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 220 nm

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

**Column temperature:** 35°

**Flow rate:** 0.8 mL/min

**Injection volume:** 20 μL

#### System suitability

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

#### Suitability requirements

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

**Relative standard deviation:** NMT 2.0% for the eleutheroside B and eleutheroside E peaks in replicate injections, *Standard solution A*

#### Analysis

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

Using the chromatogram from *Standard solution A* and the reference chromatogram provided with the lot of [USP Powdered Eleuthero Extract RS](#) being used, identify the peaks corresponding to eleutheroside B and eleutheroside E in the *Sample solution*. Measure the areas of the analyte peaks.

Calculate the quantity, in mg, of eleutheroside B and eleutheroside E in each Capsule taken:

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

$r_U$  = peak area of the relevant eleutheroside from the *Sample solution*

$r_S$  = peak area of the corresponding eleutheroside from *Standard solution A*

$C_S$  = concentration of the relevant eleutheroside in *Standard solution A* (mg/mL)

$V$  = volume of the solvent taken for preparation of the *Sample solution* (mL)

$W_{AV}$  = average fill weight per Capsule (mg)

$W$  = weight of the sample taken for preparation of the *Sample solution* (mg)