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Echinacea Species Dry Extract Tablets

DEFINITION

Echinacea Species Dry Extract Tablets contain one or more *Echinacea* Species (Fam. Asteraceae) Dry Extracts prepared from dried rhizome and roots of *Echinacea angustifolia* DC., dried rhizome and roots of *Echinacea pallida* (Nutt.) Nutt., dried rhizome and roots of *Echinacea purpurea* (L.) Moench, and dried aerial parts of *Echinacea purpurea* (L.) Moench. They contain NLT 90% and NMT 110% of the labeled amount of total phenols, calculated as the sum of caftaric acid ($C_{13}H_{12}O_9$),[1] chicoric acid ($C_{22}H_{18}O_{12}$),[2] echinacoside ($C_{35}H_{46}O_{20}$), and cynarin (1,3-di-*O*-caffeoylquinic acid) ($C_{25}H_{24}O_{12}$).[3]

IDENTIFICATION

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

For Tablets containing *Echinacea angustifolia* Dry Extract

Standard solution A: 0.2 mg/mL of USP Echinacoside RS and 0.2 mg/mL of cynarin in methanol

Standard solution B: 0.05 mg/mL of USP Caftaric Acid RS, 0.1 mg/mL of USP Chlorogenic Acid RS, and 0.05 mg/mL of USP Chicoric Acid RS in methanol

Standard solution C: 20 mg/mL of USP Powdered *Echinacea angustifolia* Extract RS in methanol. Shake to disperse, sonicate for 5 min, and centrifuge. Use the supernatant.

Sample solution: Transfer a portion of the powdered Tablets, equivalent to 100 mg of *Echinacea angustifolia* Dry Extract, to a centrifuge tube, add 5 mL of methanol, shake to disperse, sonicate for 5 min, and centrifuge. Use the supernatant.

Chromatographic system

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

Application volume: 5 µL each of *Standard solution C* and *Sample solution*, and 2 µL each of *Standard solution A* and *Standard solution B* as 8-mm bands

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

Temperature: Ambient, not to exceed 30°

Developing solvent system: Ethyl acetate, methyl ethyl ketone, water, and formic acid (5:3:1:1)

Developing distance: 6 cm

Derivatization reagent: 5 mg/mL of 2-aminoethyl diphenylborinate in ethyl acetate

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. Remove the plate from the chamber, heat at 100° for 5 min, treat while still warm with *Derivatization reagent*, dry in air, and examine under UV light at 366 nm.

System suitability: *Standard solution A* shows two major blue bands, one in the lower third section due to echinacoside, and the other band in the middle section due to dicaffeoylquinic acid (cynarin). *Standard solution B* shows two major blue bands at about the middle section due to caftaric acid (higher R_F) and chlorogenic acid (lower R_F) that are clearly separated, and a blue chicoric acid band in the upper third of the chromatogram.

Acceptance criteria: The *Sample solution* exhibits the following: the most prominent blue band in the lower third section at R_F corresponding to that of echinacoside in *Standard solution A* and *Standard solution C*; a prominent greenish-blue band in the middle section at R_F corresponding to cynarin in *Standard solution A* and *Standard solution C*; minor bands between the positions of echinacoside and cynarin. One of these is due to chlorogenic acid at R_F corresponding to that of chlorogenic acid in *Standard solution B*; very faint (or may be absent) blue bands at R_F corresponding to the caftaric acid and chicoric acid bands in *Standard solution B*.

For Tablets containing *Echinacea pallida* Dry Extract: Proceed as directed in *For Tablets containing Echinacea angustifolia Dry Extract*. For *Standard solution C* and the *Sample solution*, substitute USP Powdered *Echinacea angustifolia* Extract RS with USP Powdered *Echinacea pallida* Extract RS and *Echinacea angustifolia* Dry Extract with *Echinacea pallida* Dry Extract, respectively.

Acceptance criteria: The *Sample solution* exhibits the most prominent blue band in the lower third section at R_F corresponding to that of echinacoside in *Standard solution A* and *Standard solution C*; may exhibit bands of lesser intensity at the R_F corresponding to caftaric acid and chicoric acid in *Standard solution B* and *Standard solution C*; exhibits minor bands between the positions of echinacoside and caftaric acid. One of these is due to chlorogenic acid at an R_F corresponding to that of chlorogenic acid in *Standard solution B*. The *Sample solution* does not exhibit a blue band in the middle section at R_F corresponding to cynarin in *Standard solution A*.

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For Tablets containing *Echinacea purpurea* Root Dry Extract and *Echinacea purpurea* Aerial Parts Dry Extract: Proceed as directed in *For Tablets containing Echinacea angustifolia Dry Extract*. For *Standard solution C* substitute USP Powdered *Echinacea angustifolia* Extract RS with USP Powdered *Echinacea purpurea* Extract RS. For the *Sample solution*, substitute *Echinacea angustifolia* Dry Extract with *Echinacea purpurea* Root Dry Extract and *Echinacea purpurea* Aerial Parts Dry Extract.

Acceptance criteria: The *Sample solution* exhibits the most prominent blue band in the upper third section at R_F corresponding to chicoric acid in *Standard solution B* and *Standard solution C*; exhibits the second most prominent blue band at about the middle section at R_F corresponding to that of caftaric acid in *Standard solution B* and *Standard solution C*; may exhibit minor blue bands corresponding to similar bands in *Standard solution C*. One of these is due to chlorogenic acid at an R_F corresponding to chlorogenic acid in *Standard solution B*. The *Sample solution* does not exhibit a band at the same R_F of echinacoside in *Standard solution A*.

- **B. HPLC for Total Phenols**

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

Acceptance criteria: The chromatogram of the *Sample solution* prepared from Tablets labeled to contain extracts of *E. purpurea* roots or aerial parts exhibits peaks at the retention times of those due to caftaric acid, chlorogenic acid, and chicoric acid in the chromatogram of the *Standard solution*. The chromatogram of the *Sample solution* prepared from Tablets labeled to contain extract of *E. angustifolia* exhibits peaks at the retention times of those due to chlorogenic acid, cynarin, and echinacoside in the chromatogram of the *Standard solution*. The chromatogram of the *Sample solution* prepared from Tablets labeled to contain extract of *E. pallida* exhibits peaks at the retention times of those due to caftaric acid, chlorogenic acid, echinacoside, and chicoric acid in the chromatogram of the *Standard solution.*

- **C. HPLC for Presence of Alkylamides**

Analysis: Proceed as directed in the test for *Content of Dodecatetraenoic Acid Isobutylamides*.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits peaks at the retention times of those due to dodecatetraenoic acid isobutylamides in *Standard solution B* or *Standard solution C*, and the reference chromatogram provided with the lot of USP Powdered *Echinacea angustifolia* Extract RS or USP Powdered *Echinacea purpurea* Extract RS being used.

STRENGTH

- **Content of Total Phenols**

Solution A: Phosphoric acid in water (0.1 in 100)

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
3	90	10
16	78	22
17	60	40
20	60	40
20.5	90	10
25	90	10

Solvent: Alcohol and water (7:3)

Standard solution: 20 µg/mL of USP Caftaric Acid RS, 20 µg/mL of USP Chlorogenic Acid RS, 20 µg/mL of cynarin (1,3-di-*O*-caffeoylquinic acid), 60 µg/mL of USP Echinacoside RS, and 40 µg/mL of USP Chicoric Acid RS in *Solvent*

Sample solution: Weigh NLT 20 Tablets, determine the average Tablet weight, and finely powder. Transfer a portion of finely powdered Tablets, nominally equivalent to 60 mg of the labeled *Echinacea* Species Dry Extract, to a 100-mL round-bottom flask equipped with a condenser. Add 25.0 mL of *Solvent*, and heat under reflux for 15 min. Cool to room temperature, and pass through a filter of 0.45-µm or finer pore size.

Chromatographic system

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

Mode: LC

Detector: UV 330 nm

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

Column temperature: 35°

Flow rate: 1.5 mL/min

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