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Echinacea Species Dry Extract Capsules

DEFINITION

Echinacea Species Dry Extract Capsules 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 Capsules 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 Capsule contents, 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 Capsules containing *Echinacea pallida* Dry Extract: Proceed as directed in *For Capsules 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*.

For Capsules containing *Echinacea purpurea* Root Dry Extract and *Echinacea purpurea* Aerial Parts Dry Extract: Proceed as directed in *For Capsules 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* chromatogram does not exhibit a band at the same R_F as 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 Capsules 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 Capsules 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 Capsules 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 the chromatogram of *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: Determine the total weight of 20 Capsules. Empty the Capsules, combine, and mix their contents to obtain a homogenous composite. Weigh the empty Capsule shells and calculate the average fill weight per Capsule. Transfer a portion of the Capsule contents, 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°