

Echinacea purpurea Aerial Parts

Echinacea purpurea Aerial Parts consists of the aerial parts of Echinacea purpurea (L.) Moench (Fam. Asteraceae). It is harvested during the flowering stage. It contains not less than 1.0 percent of chicoric acid, and not less than 0.01 percent of dodecatetraenoic acid isobutylamides (C₁₆H₂₅NO) on the dried basis.

Packaging and storage— Store in tight, light-resistant containers at controlled room temperature.

Labeling— The label states the Latin binomial and, following the official name, the parts of the plant contained in the article.

Botanical characteristics—

macroscopic— The herb is an erect, coarse, rough-hairy perennial, usually up to 90 cm tall, rarely up to 180 cm. The leaves are alternate and simple; the lowermost leaves are slender, long, and petioled, ovate to broadly lanceolate, mostly penta-nerved, acute or acuminate at the apex, abruptly narrowed or rarely cordate at the base, usually sharply dentate, and 7 to 20 cm long and 2.5 to 7.5 cm wide; the petioles are mostly winged at the summit. The upper leaves are narrower, often almost entirely sessile, lanceolate or ovate lanceolate, and usually with 3 veins.

The flower heads are radiate, to 15 cm across, solitary or few, and long-peduncled, with 12 to 20 rays, purple, crimson, or rarely pale; the bristle disks are often orange, 3.5 to 7.5 cm long; the involucre is depressed-hemispheric; the bracts are lanceolate, spreading or appressed, imbricated in 2 to 4 series, and hairy on the outer surface with ciliate margins; the receptacle is conical, the scales of the receptacle stiff, spinescent, and conspicuously longer than the disc flowers; the chaff is carinate and cuspidate; the achenes are 3 to 4 mm in length, tetrasided, obpyramidal, and thick; the pappus has a short, dentate crown.

microscopic—

Leaf— The leaf has a thickness of 200 to 350 μm, with an epidermis 9 to 13 μm thick, largely without chloroplasts; the stomata are 28 to 35 μm, abundant on the dorsal surface and fewer on the ventral surface; the mesophyll is clearly divided into palisade parenchyma and sponge parenchyma. The palisade parenchyma is one layer thick, with elongated cells 50 to 65 μm in length, oriented at right angles to the leaf surface, containing numerous chloroplasts. The sponge parenchyma is 150 to 250 μm thick, with cells of irregular shape, and has multiple cell layers, few chloroplasts, and large intercellular spaces. The phloem bundles of the lateral veins within the

sponge parenchyma are bound by a one-layer sheath of small parenchymous cells, with vascular elements of the midrib surrounded by large-celled parenchyma. The uniseriate trichomes are few in the ventral surface, numerous on the dorsal surface, typically tricelled, occasionally tetra- or pentacelled, 250 to 500 μm in length, each arising from an epidermal cell; the epidermal cell walls appear with moderate thickening; the vessels are various, scalariform, with variable reticulated width.

Petiole— The parenchyma appear without chloroplasts, in several layers adjacent to a layer of collenchyma; 5 to 7 phloem bundles of small- to medium-sized vessels are weakly lignified and embedded in the parenchyma in the form of an arc; the wing ribs of the upper surface of the slightly hollowed petiole are marginal.

Inflorescence— The epidermal cells of the ray florets are square, 50 μm , with a transparent, beaded cell wall; various elements of the asteraceous exhibit inflorescence; numerous multicellular jointed trichomes of the involucre bracts are 500 to 800 μm in length; tangential sections of the paleae with numerous fiber bundles are 10 to 15 μm in diameter and 100 to 150 μm in length; cell walls are thin. The epidermis of ray florets is reddish to violet; the epidermal cells from the end of the corolla form rounded papillae; a stigma of papillary cells is present; asteraceous pollen grains are 20 to 30 μm and spherical with a warty exine. Calcium oxalate is negative; crystals of inulin and starch granules are rare.

Identification—

A: [Thin-Layer Chromatographic Identification Test](#) 201 —

presence of chicoric acid and absence of echinacoside—

Test solution— Add 5 mL of diluted alcohol (7:3) to 0.5 g of the powdered plant material, and shake for 1 minute. Centrifuge, and use the supernatant.

Standard solution— Dissolve an accurately weighed quantity of USP Powdered Echinacea purpurea Extract RS in methanol to obtain a solution having a concentration of about 10 mg per mL.

Developing solvent system, Spray reagent 1, and Spray reagent 2— Prepare as directed for Identification test A under [Echinacea angustifolia](#).

Procedure— Proceed as directed in the chapter. Develop the chromatograms in Developing solvent system until the solvent front has moved not less than 18 cm, and dry the plate in a stream of air. Spray the plate with Spray reagent 1 followed by Spray reagent 2, and examine the plate under UV light at 365 nm: the chromatogram obtained from the Test solution shows a yellowish-green zone at an RF value of 0.75 due to chicoric acid and another yellowish-green zone at an RF value of 0.45 due to caftaric acid, both zones corresponding in color and RF value to zones in the chromatogram obtained from the Standard solution. The chromatogram obtained from the Test solution does not show or shows only traces of a zone at an RF value of 0.1 due to echinacoside (present in [Echinacea angustifolia](#) and in [Echinacea pallida](#)). Other colored zones of varying intensities may be observed in the chromatogram obtained from the Test solution.

B: The retention times for the relevant peaks in the chromatogram of the Test solution, mainly due to caftaric acid and chicoric acid, correspond to those in the chromatogram of Standard solution 1, as obtained in the test for Content of chicoric acid and caftaric acid. A peak for echinacoside is not detected or is very weak.

C: The retention times for the relevant peaks in the chromatogram of the Test solution, mainly due to dodecatetraenoic isobutyl amides, correspond to those in the chromatogram of Standard solution 1, as obtained in the test for Content of dodecatetraenoic isobutylamides.

[Microbial enumeration](#) [2021](#) — It meets the requirements of the tests for absence of Salmonella species and Escherichia coli. The total aerobic microbial count does not exceed 105 cfu per g, the total combined molds and yeasts count does not exceed 1000 cfu per g, and the enterobacterial count does not exceed 1000 cfu.

[Loss on drying](#) [731](#) — Dry 1 g of the powdered plant material: it loses not more than 12% of its weight.

[Foreign organic matter](#) [561](#) : not more than 3.0%.

[Total ash](#) [561](#) : not more than 10.0%, determined on 3 g.

[Acid-insoluble ash](#) [561](#) : not more than 2.5%.

[Pesticides residues](#) [561](#) : meet the requirements.

[Heavy metals, Method III](#) [231](#) : not more than 10 µg per g.

Content of chicoric acid and caftaric acid—

Solvent, Solution A, Solution B, Mobile phase, and Standard solution 2— Proceed as directed in the test for Content of total phenols under [Echinacea angustifolia](#).

Standard solution 1— Dissolve an accurately weighed quantity of USP Powdered Echinacea purpurea Extract RS in Solvent, shaking for 1 minute, and dilute with Solvent to obtain a solution having a known concentration of about 5 mg per mL. Pass through a membrane filter having a 0.45-µm or finer porosity.

Test solution— Proceed as directed for Content of phenols under [Echinacea angustifolia](#), except to use finely powdered Echinacea purpurea Aerial Parts instead of [Echinacea angustifolia](#).

Chromatographic system— The liquid chromatograph is equipped with a 330-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1. The column temperature is maintained at 35 . The flow rate is about 1.5 mL per minute. The chromatograph is programmed as follows.

Time (minutes)	Solution A (%)	Solution B (%)	Elution
0–13	90→78	10→22	linear gradient
13–14	78→60	22→40	linear gradient
14–17.5	60	40	isocratic
17.5–18	60→90	40→10	linear gradient
18–30	90	10	equilibration

Chromatograph Standard solution 1, and record the peak responses as directed for Procedure: the chromatogram obtained is similar to the Reference Chromatogram for total phenols provided with USP Powdered Echinacea purpurea Extract RS. Chromatograph Standard solution 2, and record the responses as directed for Procedure: the relative standard deviation for replicate injections is not more than 2%.

Procedure— Proceed as directed in the test for Content of total phenols under [Echinacea angustifolia](#). Separately calculate the percentages of caftaric acid (C₁₃H₁₂O₉) and chicoric acid (C₂₂H₁₈O₁₂) in the portion of Echinacea purpurea Aerial Parts taken by the formula:

$$2500F(C/W)(rU / rS)$$

in which F is the response factor and is equal to 0.695 for chicoric acid, 0.881 for caftaric acid, and 1.000 for chlorogenic acid; C is the concentration, in mg per mL, of [USP Chlorogenic Acid RS](#) in Standard solution 2; W is the weight, in mg, of Echinacea purpurea Aerial Parts taken; and rU and rS are the peak responses for the relevant analyte obtained from the Test solution and Standard solution 2, respectively. Calculate the percentage of total phenols in the portion of Echinacea purpurea Aerial Parts taken by adding the individual percentages calculated.

Content of dodecatetraenoic acid isobutylamides—

Mobile phase and Standard solution 2— Proceed as directed in the test for Content of dodecatetraenoic acid isobutylamides under [Echinacea angustifolia](#).

Standard solution 1— Proceed as directed for Content of dodecatetraenoic acid isobutylamides under [Echinacea angustifolia](#), except to use USP Powdered Echinacea purpurea Extract RS instead of USP Powdered [Echinacea angustifolia](#) Extract RS.

Test solution— Proceed as directed for Content of dodecatetraenoic acid isobutylamides under [Echinacea angustifolia](#), except to use Echinacea purpurea Aerial Parts instead of [Echinacea angustifolia](#).

Chromatographic system— Proceed as directed for Content of dodecatetraenoic acid isobutylamides under [Echinacea angustifolia](#), except to use the Reference Chromatogram for alkamides provided with USP Powdered Echinacea purpurea Extract RS instead of the Reference Chromatogram provided with USP Powdered Echinacea angustifolia Extract RS.

Procedure— Proceed as directed in the test for Content of dodecatetraenoic acid isobutylamides under [Echinacea angustifolia](#). Identify the peaks of the two isomers of dodecatetraenoic acid isobutylamides in the chromatogram obtained from the Test solution by comparison with the chromatogram obtained from Standard solution 1. Calculate the percentage of dodecatetraenoic acid isobutylamides in the portion of Echinacea purpurea Aerial Parts taken by the formula:

$$10(1.353)(C/W)(rU / rS)$$

in which 1.353 is the response factor for 2E,4E-hexadienoic acid isobutylamide; C is the concentration, in mg per mL, of USP 2E,4E-Hexadienoic Acid Isobutylamide RS in Standard solution 2; W is the weight, in g, of Echinacea purpurea Aerial Parts taken; rU is the sum of the peak responses of the relevant analytes obtained from the Test solution; and rS is the peak response obtained from Standard solution 2.