

Powdered Echinacea pallida Extract

Powdered Echinacea pallida Extract is prepared from Echinacea pallida roots by extraction with hydroalcoholic mixtures or other suitable solvents. The ratio of the starting crude plant material to Powdered Extract is between 2:1 and 8:1. It contains not less than 4.0 percent and not more than 5.0 percent of total phenols, calculated as the sum of caftaric acid ($C_{13}H_{12}O_9$), chicoric acid ($C_{22}H_{18}O_{12}$), chlorogenic acid ($C_{16}H_{18}O_9$), and echinacoside ($C_{35}H_{46}O_{20}$) on the dried basis.

Packaging and storage— Preserve in tight, light-resistant containers, and store in a cool place.

Labeling— The label states the Latin binomial and, following the official name, the parts of the plant from which the article was prepared. The label bears a statement indicating that Echinacea pallida may cause rare allergic reactions, rashes, or aggravate asthma. It meets the requirements for Labeling under [Botanical Extracts](#) [565](#) .

Identification—

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

Standard solution 2, Developing solvent system, Spray reagent 1, Spray reagent 2, and

Procedure— Proceed as directed for Identification test A under Echinacea angustifolia.

Test solution— Dissolve 1.0 g of Powdered Extract in 10 mL of methanol. Allow to settle before use.

Standard solution 1— Dissolve an accurately weighed quantity of USP Powdered Echinacea pallida Extract RS in methanol to obtain a solution having a known concentration of about 100 mg per mL.

B: The retention time of the major peak in the chromatogram of the Test solution corresponds to that of the echinacoside peak in the chromatogram of Standard solution 1, as obtained in the test for Content of total phenols.

Content of total phenols—

Solvent, Solution A, Solution B, Mobile phase, and Standard solution 2— Proceed as directed for Content of total phenols under Echinacea angustifolia.

Standard solution 1— Proceed as directed for Content of total phenols under Echinacea angustifolia, except to use USP Powdered Echinacea pallida Extract RS instead of USP Powdered Echinacea angustifolia Extract RS.

Test solution— Transfer about 60 mg of Powdered Extract, accurately weighed, to an appropriate round-bottom flask equipped with a condenser. Add 25.0 mL of Solvent, and heat under reflux while shaking by mechanical means for 15 minutes. Centrifuge, or pass through a membrane filter having a 0.45- μm or finer porosity.

Chromatographic system— Prepare as directed for Content of total phenols under *Echinacea angustifolia*. 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 pallida* Extract RS. Chromatograph Standard solution 2, and record the peak responses as directed for Procedure: the capacity factor, k' is not less than 3.0; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.5%.

Procedure— Proceed as directed for Content of total phenols under *Echinacea angustifolia*. Separately calculate the percentage of each relevant component of total phenols in the portion of Powdered Extract taken by the formula:

$$2500F(C/W)(r_i / r_S)$$

in which F is the response factor and is equal to 0.695 for chicoric acid, 0.881 for caftaric acid, 1.000 for chlorogenic acid, and 2.220 for echinacoside; C is the concentration, in mg per mL, of [USP Chlorogenic Acid RS](#) in Standard solution 2; W is the weight, in mg, of the portion of Powdered Extract taken; and r_i and r_S 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 Powdered Extract taken by adding the individual percentages calculated.

Other requirements— It meets the requirements of the tests for Microbial enumeration, Loss on drying, Heavy metals, and Organic volatile impurities under [Powdered *Echinacea angustifolia* Extract](#), and it meets the requirements for Residual Solvents and Pesticide Residues under

[Botanical Extracts](#) 565 .