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Powdered Chinese Salvia

DEFINITION

Powdered Chinese Salvia is Chinese Salvia reduced to a powder or very fine powder. It contains NLT 0.1% tanshinone II_A; NLT 0.2% of total tanshinones, calculated as the sum of cryptotanshinone, tanshinone I, and tanshinone II_A; and NLT 3.0% of salvianolic acid B; all calculated on the dried basis.

IDENTIFICATION

• **A.** Powdered Chinese Salvia meets the requirements for *Specific Tests, Botanic Characteristics*.

• **B. THIN-LAYER CHROMATOGRAPHY**

Standard solution A: A mixture of about 0.5 mg/mL of [USP Tanshinone II_A RS](#) and about 1.5 mg/mL of [USP Salvianolic Acid B RS](#) in alcohol

Standard solution B: About 0.25 g of [USP Powdered Chinese Salvia Extract RS](#) in 5.0 mL of alcohol. Sonicate for 15 min, centrifuge, and use the supernatant.

Sample solution: About 1.0 g of Powdered Chinese Salvia in 5.0 mL of alcohol. Sonicate for 15 min, centrifuge, and use the supernatant.

Chromatographic system

(See [Chromatography \(621\), Thin-Layer Chromatography](#).)

Adsorbent: Chromatographic silica gel mixture with an average particle size of 2–10 µm (HPTLC plates)

Application volume: 5 µL, as 8-mm bands

Developing solvent system A: A mixture of ethyl acetate, chloroform, toluene, formic acid, and methanol (8:6:4:4:1)

Developing solvent system B: A mixture of solvent hexane and ethyl acetate (4:1)

Analysis

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

Apply the samples as bands to a suitable high performance thin-layer chromatographic plate. Use a saturated chamber, and condition the plate to a relative humidity of about 33% using a suitable device. Develop the chromatograms in *Developing solvent system A* until the solvent front has moved up about 40% of the plate. Remove the plate, and allow to dry. Develop the chromatograms in a saturated chamber containing *Developing solvent system B* until the solvent front has moved up about three-fourths of the plate. Remove the plate, dry, and examine under visible light and UV light at 254 nm and 365 nm.

Acceptance criteria

Under visible light, the chromatogram of the *Sample solution* exhibits three bands similar in positions and colors to bands in the chromatogram of *Standard solution B*. These include a pink band in the upper third of the chromatogram, similar in R_f and color to the tanshinone II_A band in the chromatogram of *Standard solution A*, a yellowish-orange band in the upper third of the chromatogram, and an orange band at about the middle of the chromatogram due to tanshinone I and cryptotanshinone, respectively.

Under UV light at 365 nm, the chromatogram of the *Sample solution* exhibits three blue bands similar in positions and colors to bands in the chromatogram of *Standard solution B*. These include an intense blue band in the lower third of the chromatogram corresponding in R_f and color to the salvianolic acid B band in the chromatogram of *Standard solution A*, and two minor blue bands in the lower third of the chromatogram and above the salvianolic acid B band, due to lithospermic acid and rosmarinic acid.

Under UV light at 254 nm, the chromatogram of the *Sample solution* exhibits intense quenching bands at R_f corresponding to those for tanshinone II_A and salvianolic acid B in the chromatogram of *Standard solution A*. The chromatogram of the *Sample solution* also exhibits other quenching bands corresponding in R_f to the bands in the chromatogram of the *Standard solution B*.

• **C. HPLC**

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

Acceptance criteria: The chromatogram of the *Sample solution* exhibits the most intense peak at a retention time corresponding to that of tanshinone II_A in the chromatogram of *Standard solution A*. The *Sample solution* chromatogram exhibits two additional peaks corresponding to tanshinone I and cryptotanshinone, of less intensity and accounting for about half of the total tanshinones content.

• **D. HPLC**

Analysis: Proceed as directed in the test for *Content of Salvianolic Acid B*.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits a peak at a retention time corresponding to that of salvianolic acid B in the chromatogram of *Standard solution A*.

COMPOSITION

• **CONTENT OF TANSHINONES**

Solution A: 0.02% phosphoric acid in water (v/v)

Solution B: Acetonitrile

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	39	61
6	39	61
20	10	90
20.5	39	61
25	39	61

[NOTE—Proceed under subdued light or use low-actinic glassware. The *Standard solution* and *Sample solution* are stable for 24 h at room temperature.]

Standard solution A: 0.02 mg/mL of [USP Tanshinone II_A RS](#) in methanol

Standard solution B: 2 mg/mL of [USP Powdered Chinese Salvia Extract RS](#) in methanol. Sonicate for 15 min, and pass through a membrane filter having a 0.45-μm pore size. Discard the first few mL of the filtrate.

Sample solution: About 300 mg of Powdered Chinese Salvia, accurately weighed, in 40 mL of methanol. Sonicate for 30 min, and filter into a 50-mL volumetric flask. Wash the residue and the filter paper with a few mL of methanol, adjust to volume with methanol, mix, and pass through a membrane filter having a 0.45-μm pore size. Discard the first few mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 270 nm

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

Column temperature: 20°

Flow rate: 1.0 mL/min

Injection volume: 10 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 Chinese Salvia Extract RS](#) being used.

Tailing factor: NMT 2.0 for the tanshinone II_A peak, *Standard solution A*

Relative standard deviation: NMT 2.0%, determined from the tanshinone II_A peak in repeated injections, *Standard solution A*

Resolution: NLT 1.5 between the cryptotanshinone and tanshinone I peaks, *Standard solution B*

Analysis

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

Using the chromatograms of *Standard solution A*, *Standard solution B*, and the reference chromatogram provided with the lot of [USP Powdered Chinese Salvia Extract RS](#) being used, identify the retention times of the peaks corresponding to different tanshinones in the *Sample solution* chromatogram. The approximate relative retention times of the different peaks for cryptotanshinone, tanshinone I, and tanshinone II_A are 0.75, 0.79, and 1.00, respectively.

Calculate the percentages of cryptotanshinone, tanshinone I, and tanshinone II_A in the portion of Powdered Chinese Salvia taken:

$$\text{Result} = (r_U/r_S) \times C_S \times (V/W) \times F \times 100$$

r_U = peak area of the relevant analyte from the *Sample solution*

r_S = peak area of tanshinone II_A from the *Standard solution A*

C_S = concentration of [USP Tanshinone II_A RS](#) in the *Standard solution A* (mg/mL)

V = volume of the *Sample solution* (mL)

W = weight of Powdered Chinese Salvia taken to prepare the *Sample solution* (mg)