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Add the following:

^Chinese Skullcap Root Dry Extract

DEFINITION

Chinese Skullcap Root Dry Extract is prepared from Chinese Skullcap Root (*Scutellaria baicalensis* Georgi) by extraction with water or hydroalcoholic mixtures. It contains NLT 90% and NMT 110% of the labeled amount of total flavone glucuronides calculated as the sum of baicalein 7-O-glucuronide ($C_{21}H_{18}O_{11}$) and wogonin 7-O-glucuronide ($C_{22}H_{20}O_{11}$) on the dried basis, and NLT 90% and NMT 110% of the labeled amount of total flavone aglycones calculated as the sum of baicalein ($C_{15}H_{10}O_5$) and wogonin ($C_{16}H_{12}O_5$) on the dried basis. It may contain suitable added substances as carriers.

IDENTIFICATION

• A. HPTLC FOR ARTICLES OF BOTANICAL ORIGIN (203)

Standard solution A: 1.0 mg/mL of [USP Baicalein 7-O-Glucuronide RS](#) and 0.5 mg/mL of [USP Baicalein RS](#) in [methanol](#). Sonicate to dissolve.

Standard solution B: 50 mg/mL of [USP Scutellaria baicalensis Root Dry Extract RS](#) in [methanol](#). Sonicate for 15 min, centrifuge, and use the supernatant.

Sample solution: 50 mg/mL of Chinese Skullcap Root Dry Extract in [methanol](#). Sonicate for 15 min, centrifuge, and use the supernatant.

Chromatographic system

Adsorbent: Chromatographic silica gel F₂₅₄ mixture

Application volume: 3 µL, as 8-mm bands

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

Temperature: About 25°

Developing solvent system: [Toluene](#), [ethyl acetate](#), [methanol](#), and [formic acid](#) (6:4:1:2)

Developing distance: 6 cm

Derivatization reagent A: 10 mg/mL of [2-aminoethyl diphenylborinate](#) in [methanol](#)

Derivatization reagent B: 50 mg/mL of [polyethylene glycol 4000](#) in [alcohol](#)

Analysis

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

Apply the *Samples* as bands and dry in air. Develop in a saturated chamber, remove the plate from the chamber, and dry the plate at 100° for 3 min. Treat the plate with *Derivatization reagent A*, and dry for 5 min with a current of cool air. Immediately treat the plate with *Derivatization reagent B*, dry for 5 min with a current of cool air, and examine under UV light at 365 nm.

System suitability

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

Suitability requirements: *Standard solution A* exhibits two dark bands, one due to baicalein 7-O-glucuronide in the lower-third section and one due to baicalein in the middle-third section. *Standard solution B* exhibits four dark bands: two corresponding in R_f and color to the bands due to baicalein 7-O-glucuronide and baicalein in *Standard solution A*; one above baicalein 7-O-glucuronide due to wogonin 7-O-glucuronide; and one above baicalein due to wogonin. *Standard solution B* exhibits two blue bands below baicalein, a light-yellow band coeluted with wogonin 7-O-glucuronide, and a yellow band below baicalein 7-O-glucuronide.

Acceptance criteria: The *Sample solution* exhibits four dark bands: two corresponding in R_f and color to the bands due to baicalein 7-O-glucuronide and baicalein in *Standard solution A* and *Standard solution B*; and one above baicalein 7-O-glucuronide due to wogonin 7-O-glucuronide and one above baicalein due to wogonin, both corresponding in R_f and color to similar bands in *Standard solution B*. The *Sample solution* exhibits additional colorful bands including two blue bands below baicalein, a light-yellow band coeluted with wogonin 7-O-glucuronide, a yellow band below baicalein 7-O-glucuronide, and some other faint bands corresponding in R_f and color to similar bands in *Standard solution B*. There are no significant red bands observed in the upper half of the chromatogram (the leaves of *S. lateriflora*, *S. scordiifolia*, *S. barbata*, and *S. indica* display multiple red bands in the upper-half section above baicalein).

• B. HPLC

Analysis: Proceed as directed in the test for *Content of Flavone Glucuronides and Flavone Aglycones*.

Acceptance criteria: The *Sample solution* exhibits the most intense peak corresponding to baicalein 7-O-glucuronide and a smaller peak corresponding to baicalein in *Standard solution A*. The *Sample solution* also exhibits peaks due to wogonin 7-O-glucuronide, wogonin, and two unidentified peaks with similar intensities as wogonin, between baicalein 7-O-glucuronide and wogonin 7-O-glucuronide, at retention times corresponding to the same constituents in *Standard solution B*. No other peak in the chromatogram is between the relative retention

time of 0.5 for baicalein 7-O-glucuronide and 1.2 for wogonin is more intense than the peak corresponding to wogonin. The content ratio of wogonin 7-O-glucuronide relative to baicalein 7-O-glucuronide is NLT 0.1 and NMT 0.3, and the content ratio of total flavone glucuronides to total flavone aglycones is NLT 4.0.

COMPOSITION

• CONTENT OF FLAVONE GLUCURONIDES AND FLAVONE AGLYCONES

[NOTE—Protect solutions from light and proceed under low actinic light. The standard solutions and the *Sample solution* are stable for 24 h at room temperature.]

Solution A: 0.1% [phosphoric acid](#) in [water](#)

Solution B: [Acetonitrile](#)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	78	22
10	75	25
15	75	25
25	68	32
30	60	40
35	60	40
40	50	50
45	5	95
50	5	95
50.1	78	22
60	78	22

Solvent: [Methanol](#) and [water](#) (7:3)

Standard stock solution: 0.50 mg/mL of [USP Baicalein 7-O-Glucuronide RS](#) and 0.10 mg/mL of [USP Baicalein RS](#) in [methanol](#)

Standard solution A: 0.10 mg/mL of [USP Baicalein 7-O-Glucuronide RS](#) and 0.02 mg/mL of [USP Baicalein RS](#) from *Standard stock solution* diluted with *Solvent*

Standard solution B: 1 mg/mL of [USP Scutellaria baicalensis Root Dry Extract RS](#) in *Solvent*. Sonicate for 15 min, centrifuge, and pass through a suitable membrane filter of 0.45-µm or finer pore size.

Sample solution: Transfer about 50 mg of Chinese Skullcap Root Dry Extract accurately weighed into a suitable flask, add 50.0 mL of *Solvent*, and close tightly. Weigh the filled flask accurately, and sonicate for 30 min. Cool to room temperature and adjust to the initial weight by adding *Solvent*, if needed. Before injection, pass through a suitable membrane filter of 0.45-µm or finer pore size, and discard the first portion of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 276 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 3 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between the peak of baicalein 7-O-glucuronide and the small peak before it, *Standard solution B*

Tailing factor: NMT 2.0 for the baicalein 7-O-glucuronide and baicalein peaks, *Standard solution A*

Relative standard deviation: NMT 2.0% for the baicalein 7-O-glucuronide and baicalein peaks in repeated injections, *Standard solution A*