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Add the following:

^Japanese Sophora Flower Powder

DEFINITION

Japanese Sophora Flower Powder consists of the dried opened flowers of *Styphnolobium japonicum* (L.) Schott (Syn. *Sophora japonica* L.) reduced to a fine or very fine powder. It contains NLT 7.5% and NMT 14% of total flavonol glycosides calculated as the sum of rutin ($C_{27}H_{30}O_{16}$), kaempferol-3-O-rutinoside ($C_{27}H_{30}O_{15}$), and isorhamnetin-3-O-rutinoside ($C_{28}H_{32}O_{16}$) on the dried basis; NLT 6.5% and NMT 13% of rutin on the dried basis; and NLT 0.4% and NMT 1.0% of quercetin ($C_{15}H_{10}O_7$) on the dried basis.

IDENTIFICATION

• A. [HPTLC FOR ARTICLES OF BOTANICAL ORIGIN \(203\)](#)

Standard solution A: 0.5 mg/mL of [USP Rutin RS](#) and 0.1 mg/mL each of [USP Isorhamnetin-3-O-Rutinoside RS](#) and [USP Quercetin RS](#) in [methanol](#). Sonicate to dissolve.

Standard solution B: 10 mg/mL of [USP Sophora japonica Flower Dry Extract RS](#) in [methanol](#). Sonicate for 10 min, centrifuge, and use the supernatant.

Sample solution: 20 mg/mL of Japanese Sophora Flower Powder in [methanol](#). Sonicate for 10 min, centrifuge, and use the supernatant.

Chromatographic system

Adsorbent: Silica gel with fluorescence indicator F_{254} , precoated plates, for HPTLC

Application volume: 2 μ L, as 8-mm bands

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

Temperature: $20 \pm 5^\circ$

Developing solvent system: [n-Butyl acetate](#), [methanol](#), [water](#), and [formic acid](#) (7.5:2:1:1)

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

Derivatization reagent B: 50 mg/mL of [polyethylene glycol 400](#) 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 and remove the plate from the chamber. After drying in air, examine the plate under UV light at 254 nm. Then dry the plate at 100° for 3 min. Treat the hot plate with *Derivatization reagent A*, and dry for 5 min in a current of cool air. Immediately treat the plate with *Derivatization reagent B*, dry for 5 min in a current of cool air, and examine under long wavelength UV light (about 365 nm).

System suitability

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

Suitability requirements

Under UV light at 254 nm:

Standard solution A exhibits a quenching band due to rutin and a faint quenching band due to isorhamnetin-3-O-rutinoside right above rutin in the lower-third, and a faint quenching band due to quercetin in the upper-third section. *Standard solution B* exhibits a quenching band corresponding in R_f to rutin, two faint quenching bands right above rutin, one of them with a lower R_f corresponding to isorhamnetin-3-O-rutinoside in *Standard solution A*. In the upper-third, *Standard solution B* exhibits a faint quenching band corresponding in R_f to quercetin in *Standard solution A*.

Under long wavelength UV light: *Standard solution A* exhibits a yellow band due to rutin; a green band right above the rutin band due to isorhamnetin-3-O-rutinoside in the lower-third; and a yellow band due to quercetin in the upper-third of the chromatogram. *Standard solution B* exhibits a yellow band corresponding in R_f to the rutin in *Standard solution A*; several faint yellow bands below the rutin band; a pair of green bands above the rutin band, one of them corresponding in R_f to isorhamnetin-3-O-rutinoside in *Standard solution A*; and a weak yellow band above the green bands. In the upper-third section, *Standard solution B* exhibits a yellow band corresponding in R_f to quercetin in *Standard solution A*.

Acceptance criteria**Under UV light at 254 nm:**

The *Sample solution* exhibits a quenching band corresponding in R_F to rutin; two faint quenching bands right above rutin, one of them with a lower R_F corresponding to isorhamnetin-3-O-rutinoside; and a faint quenching band corresponding in R_F to quercetin. No additional significant quenching band is observed in the *Sample solution* (Japanese Sophora fruits exhibit three intense quenching bands, two above rutin and one below rutin).

Under long wavelength UV light: The *Sample solution* exhibits the following bands corresponding to similar bands in *Standard solution B*: a yellow band corresponding in R_F to the rutin band in *Standard solution A*; up to 3 faint yellow bands below the rutin band in the lower-third section; a pair of green bands right above the rutin band, one of them corresponding to isorhamnetin-3-O-rutinoside in *Standard solution A*; and a weak yellow band above the green bands. In the upper-third section, the *Sample solution* exhibits a yellow band corresponding in R_F to quercetin band in *Standard solution A*; a light green band above the quercetin band; a faint blue band below the quercetin band; and a weak yellow band below the faint blue band. Besides the above mentioned green bands, no additional significant green band is observed in the *Sample solution* (Japanese Sophora fruits exhibit additional green bands above and below rutin).

• B. HPLC

Analysis: Proceed as directed in the test for *Content of Flavonol Glycosides and Quercetin*. Analyze the chromatogram between 0.7 relative retention time of rutin and the retention time of isorhamnetin.

Acceptance criteria: The *Sample solution* exhibits the most intense peak corresponding to rutin in *Standard solution A* and peaks due to kaempferol-3-O-rutinoside, isorhamnetin-3-O-rutinoside, quercetin, kaempferol, and isorhamnetin corresponding to the same constituents in *Standard solution B*. The 2 minor peaks of kaempferol and isorhamnetin may or may not be observed. Besides the above mentioned peaks, no other peak in the analyzed chromatogram is more intense than the peak corresponding to kaempferol-3-O-rutinoside. The relative content of rutin to total flavonol glycosides is about 90%. The content ratios of kaempferol-3-O-rutinoside, isorhamnetin-3-O-rutinoside, and quercetin relative to rutin are within the ranges listed in [Table 2](#).

COMPOSITION**• CONTENT OF FLAVONOL GLYCOSIDES AND QUERCETIN**

Solution A: 0.2% [formic acid](#) in [water](#)

Solution B: [Acetonitrile](#)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	82	18
8	82	18
10	75	25
20	70	30
25	64	36
30	60	40
31	5	95
40	5	95

Solvent: [Methanol](#) and [water](#) (8:2)

Standard solution A: 0.30 mg/mL of [USP Rutin RS](#) in *Solvent*

Standard solution B: 2 mg/mL of [USP Sophora japonica Flower Dry Extract RS](#) in *Solvent*. Sonicate for 30 min, centrifuge, and pass through a suitable membrane filter of 0.45- μ m or finer pore size.

Sample solution: Transfer about 40 mg of Japanese Sophora Flower Powder, accurately weighed, to a suitable flask. Add 10.0 mL of *Solvent* and close tightly. Weigh the filled flask accurately and sonicate for 30 min (140 W and 100 KHz). Cool to room temperature and adjust with