EUROPEAN SANICLE FOR HOMOEOPATHIC PREPARATIONS

SANICULA EUROPAEA FOR HOMOEOPATHIC PREPARATIONS

Sanicula europaea ad praeparationes homoeopathicas

DEFINITION

Whole, fresh, flowering plant, *Sanicula europaea* L.

CHARACTERS

Macroscopic and microscopic characters described under identification tests A and B.

IDENTIFICATION

A. Glabrous plant. Simple stem, erect, spindly, 15-50 cm high. Glossy, basal leaves, dark green, measuring up to 6-10 cm, with long petioles and kidney-shaped palmatipartite, with 3-5 oblong segments, wedge-shaped, bifid or trifid and dentate-incised. Caulinary leaves (1-2 per stem) small and subsessile. White or slightly pink, sessile flowers displayed in globular heads, themselves gathered in irregular umbels, with 3-5 much unequal rays. Involucre comprising 2-4 incised leaflets. Calyx with 5 foliaceous teeth, erect, lanceolate-bearded, accrescent. Connivent petals, obovate-emarginate, with a long, inwardly bent tip.

B. Examine a sample of abaxial epidermis under a microscope, using *chloral hydrate solution R*. Midrib abaxial epidermis, covered with a thinly striated cuticle, composed of elongated cells. Lamina epidermis, glabrous, covered with a smooth cuticle, composed of cells with lobed outlines and stomata of anisocytic type *(2.8.3).*

TESTS

Foreign matter (*2.8.2*): maximum 5 per cent.

Loss on drying (*2.2.32*): minimum 70.0 per cent, determined on 5.0 g of finely-cut drug, by drying in an oven at 105 °C for 2 h.

The General Chapters and General Monographs of the European Pharmacopoeia and Preamble of the French Pharmacopoeia apply.

STOCK

DEFINITION

European sanicle mother tincture complies with the requirements of the general technique for the preparation of mother tinctures (see *Homoeopathic Preparations* (*1038*) and French Pharmacopoeia Authority Supplement). The mother tincture is prepared with ethanol (45 per cent *V/V*), using the whole, fresh, flowering plant, *Sanicula europaea* L.

CHARACTERS

Appearance: orange-brown liquid.

IDENTIFICATION

A. Thin-layer chromatography (*2.2.27*).

Test solution. Mother tincture.

Reference solution. Dissolve 2 mg of *chlorogenic acid R* and 2 mg of *caffeic acid R* in 10 mL of *ethanol* (*96 per cent*) *R.*

Plate: *TLC silica gel plate R.*

Mobile phase: *water R, methanol R, glacial acetic acid R, methylene chloride R* (2:3:8:15 *V/V/V/V*).

Application: 20 µL as bands.

Development: over a path of 10 cm.

Drying: in air.

Detection: first spray with a 10 g/L solution of *diphenylboric acid aminoethyl ester R* in *methanol R* then with a 50 g/L solution of *macrogol 400 R* in *methanol R.* Allow the plate to dry for about 30 min. Examine in ultraviolet light at 365 nm.

Results: see below the sequence of fluorescent zones present in the chromatograms obtained with the reference solution and the test solution. Furthermore other faint, fluorescent zones may be present in the chromatogram obtained with the test solution.

The General Chapters and General Monographs of the European Pharmacopoeia and Preamble of the French Pharmacopoeia apply.

Top of the plate	
Caffeic acid: a greenish-blue zone --- Chlorogenic acid: a greenish-blue zone ---	A greenish-blue zone A greenish-blue zone more or less intense (caffeic acid) A greenish-blue zone A greenish-yellow zone --- A greenish-blue zone (chlorogenic acid) ---
Reference solution	**Test solution**

B. Thin-layer chromatography (*2.2.27*).

Test solution. Mother tincture.

Reference solution. Dissolve 15 mg of *aescin R* and 10 mg of *rosmarinic acid R* in 10 mL of *ethanol* (*96 per cent*) *R.*

Plate: *TLC silica gel plate R.*

Mobile phase: *ethyl acetate R, water R, propanol R* (30:30:40 *V/V/V*).

Application: 20 µl (as bands).

Development: over a path of 10 cm.

Drying: in air.

Detection: spray with *anisaldehyde solution R* and heat at 100-105 °C for 10 min. Examine in daylight.

Results: see below the sequence of zones present in the chromatograms obtained with the reference solution and the test solution. Furthermore other faint zones may be present in the chromatogram obtained with the test solution.

Top of the plate	
Rosmarinic acid: a pinkish-brown zone Aescin: a purple zone	A pinkish-brown zone A purple zone A purple zone

The General Chapters and General Monographs of the European Pharmacopoeia and Preamble of the French Pharmacopoeia apply.

-----	A purple zone -----
-----	A large brownish-green zone -----
	A brownish-yellow zone
Reference solution	**Test solution**

TESTS

Ethanol (*2.9.10*): 40 per cent *V/V* to 50 per cent *V/V.*

Dry residue (*2.8.16*): minimum 1.5 per cent *m/m*.

The General Chapters and General Monographs of the European Pharmacopoeia and Preamble of the French Pharmacopoeia apply.