SWEET WOODRUFF FOR HOMOEOPATHIC PREPARATIONS

ASPERULA ODORATA FOR HOMOEOPATHIC PREPARATIONS

Galium odoratum ad praeparationes homoeopathicas

DEFINITION

Fresh, blooming, aerial part of Galium odoratum (L.) Scop. (Asperula odorata L.).

IDENTIFICATION

- A. Simple, erect stem, 10-30 cm high, smooth, quadrangular and knotty, sometimes bearing spindly, adventive roots. Two leaves and 2-6 stipules similar to the leaves are inserted on each node showing a ring of hairs. Green leaves slightly glossy, paler on the underside surface, oblong, lanceolate, acuminate at the apex, 2-4 cm long and 5-10 mm large. Edge of the leaves entire and rough to the touch. Main rib, clearly conspicuous on both sides. Flowers measuring about 3 mm, gathered in a distal corymbe. Calyx hardly dentate or not at all, yellowish-white, funnel-shaped corolla with a short tube of 4 petals, 4 stamens. Bilocular inferior ovary topped by a simple style.
- B. Take a sample of epidermis from the underside of the leaf. Examine under a microscope, using *chloral hydrate solution R*: abaxial epidermis of the rib, covered with a striated cuticle, composed of elongated cells with stiff cell-walls; epidermis of the lamina, glabrous, covered with a smooth cuticle composed of lobe-shaped cells, stomata of paracytic type (2.8.3).

TESTS

Foreign matter (2.8.2): maximum 5 per cent.

Loss on drying (2.2.32): minimum 75.0 per cent, determined on 5.0 g of finely-cut drug, by drying in an oven at 105 °C for 2 h.

STOCK

DEFINITION

Sweet woodruff mother tincture is prepared with ethanol (65 per cent V/V) using the fresh, blooming, aerial part of *Galium odoratum* (L.) Scop.

Content: minimum 0.030 per cent m/m of coumarin ($C_9H_6O_2$; M_f 146.1).

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

PRODUCTION

Method 1.1.10 (2371). Whole drug. Maceration time: 3-5 weeks.

CHARACTERS

Appearance: brownish-green liquid.

Harvested hay odour.

IDENTIFICATION

Thin layer chromatography (2.2.27).

Test solution. Mother tincture.

Reference solution. Dissolve 10 mg of coumarin R and 5 mg of o-coumaric acid R in 10 mL of ethanol (96 per cent) R.

Plate: TLC silica gel plate R.

Mobile phase: upper layer of the mixture dilute acetic acid R, ether R, toluene R (10:50:50 V/V/V).

Application: 20 µL, as bands.

Development: over a path of 10 cm.

Drying: in air.

Detection: spray with a 100 g/L solution of potassium hydroxide R in methanol R. 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.

Top of the plate		
Coumarin: an intense greenish-blue zone	An intense greenish-blue zone (Coumarin)	
o-coumaric acid: a greenish-blue zone	A greenish-blue zone (<i>o</i> -coumaric acid)	
	A blue zone	
Reference solution	Test solution	

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

TESTS

Ethanol (2.9.10): 60 per cent V/V to 70 per cent V/V.

Dry residue (2.8.16): minimum 1.0 per cent m/m.

ASSAY

Liquid chromatography (2.2.29).

Test solution. In a 20.0 mL volumetric flask, place 2.000 g of mother tincture and dilute to 20.0 mL with methanol R.

Reference solution. In a 100.0 mL volumetric flask, dissolve 15.0 mg of coumarin CRS in $methanol\ R$ and dilute to 100.0 mL with the same solvent. In a 20.0 mL volumetric flask, place 10.0 mL of this solution and dilute to 20.0 mL with $methanol\ R$.

Column:

- size: I = 0.25 m, $\emptyset = 4 \text{ mm}$,
- stationary phase: octylsilyl silica gel for chromatography R (5 μm),
- temperature: 30 °C.

Mobile phase:

- mobile phase A: water R, acidified to pH 2.0 with phosphoric acid R,
- mobile phase B: acetonitrile R.

Time (min)	Mobile phase A (per cent <i>V/V</i>)	Mobile phase B (per cent <i>V/V</i>)
0 – 1	85	15
1 – 10	$85 \rightarrow 60$	15 → 40
10 – 20	60	40

Flow rate: 0.8 mL/min.

Detection: spectrophotometer at 310 nm.

Injection: 10 µL.

Calculate the percentage content *m/m* of coumarin in the mother tincture from the expression:

$$\frac{m_2 \times A_1 \times 0.1 \times p}{m_1 \times A_2}$$

 A_1 = area of the peak due to coumarin in the chromatogram obtained with the test solution,

 A_2 = area of the peak due to coumarin in the chromatogram obtained with the reference solution,

 m_1 = mass of the mother tincture sample in the test solution, in grams,

 m_2 = mass of coumarin sample in the reference solution, in grams,

p = percentage content of coumarin in *coumarin CRS*.

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