SOAPWORT
FOR HOMOEOPATHIC PREPARATIONS

SAPONARIA OFFICINALIS
FOR HOMOEOPATHIC PREPARATIONS

Saponaria officinalis ad praeparationes homoeopathicas

DEFINITION

Whole, fresh, flowering plant, *Saponaria officinalis* L.

IDENTIFICATION

A. Herbaceous plant, usually glabrous, measuring up to 70 cm high. Reddish-brown creeping rhizome, highly ramified, about 1 cm in diameter with a yellow section and bearing numerous adventive roots. Erect stem, cylindrical, simple or slightly ramose, green tinged with red, with bulges at the insertion of the leaves. Opposite leaves, entire, oval, lanceolate 10 cm long, acute at the apex and at the base; stalked lower leaves; glaucous, green lamina with 3-5 longitudinal ribs. Pentanmerous flowers, pink or more rarely pinkish-purple or white, about 2 cm in diameter, gathered in terminal biparous cymes; green sepals fused on half their length, shaping a long cylindrical tube, longitudinally striated, ending with 5 acute teeth; free petals usually entire with at their base an unguis inserted within the calyx and 2 small strips at their throat; androecium composed of 10 stamens and gynoecium of 2 fused carpels without internal division.

B. Examine a fragment of abaxial epidermis of the leaf, under a microscope using *chloral hydrate solution R*: epidermis covered with a finely striated cuticle, composed of cells with sinuous walls and numerous stomata of anomocytic or more rarely diacytic type (*2.8.3*), with frequent presence of spongy parenchyma with some cells containing big calcium oxalate clusters; epidermis from the lamina margin with cells in rounded papillae, bending towards the distal end of the leaf.

TESTS

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

Loss on drying (*2.2.32*): minimum 60.0 per cent, determined on 5.0 g of finely-cut drug, by drying in an oven at 105 °C for 2 h.

STOCK

DEFINITION

Soapwort mother tincture is prepared with ethanol (65 per cent *V/V*), using the whole, fresh, flowering plant, *Saponaria officinalis* L.

Content: minimum 0.080 per cent *m/m* of total flavonoids, expressed as vitexin ($C_{21}H_{20}O_{11}$; M_r 448.4).

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

PRODUCTION

Method 1.1.10 (2371). Drug fragmented into 5-7 cm long segments. Maceration time: 3-5 weeks.

CHARACTERS

Appearance: greenish-brown liquid.

IDENTIFICATION

Thin-layer chromatography (*2.2.27*).

Test solution. Mother tincture.

Reference solution. Dissolve 5 mg of *harpagoside R* and 5 mg of *aucubin R* in 40 mL of *ethanol* (*96 per cent*) *R*.

Plate: *TLC silica gel plate R* (5-40 µm) [or *TLC silica gel plate R* (2-10 µm)].

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

Application: 40 µL [or 20 µL] as bands.

Development: over a path of 10 cm [or 7 cm].

Drying: in air.

Detection: spray with *anisaldehyde solution R* then 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	
Harpagoside: a pinkish-brown zone	A purple zone
------	------
Aucubin: a greyish- brown zone	A greyish-blue zone A brown zone An orange zone
------	------
	A greenish-grey zone A brown 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 1.8 per cent *m/m*.

ASSAY

Ultraviolet and visible absorption spectrophotometry (*2.2.25*).

Stock solution. Place 2.000 g of mother tincture into a 100.0 mL volumetric flask and dilute to 100.0 mL with *ethanol* (60 per cent *V/V*) *R.*

Test solution. Place 5.0 mL of stock solution into a round-bottomed flask. Evaporate to dryness under reduced pressure and take up the residue with 5.0 mL of a mixture of 10 volumes of *methanol R* and 100 volumes of *glacial acetic acid R* then transfer into a 25.0 mL volumetric flask. Rinse the round-bottomed flask with 5.0 mL of a mixture of 10 volumes of *methanol R* and 100 volumes of *glacial acetic acid R* and pour into the volumetric flask. Add 10.0 mL of a 25.0 g/L *boric acid R* and 20.0 g/L *oxalic acid R* solution in *anhydrous formic acid R* and dilute to 25.0 mL with *glacial acetic acid R.*

Compensation liquid. Place 5.0 mL of stock solution into a round-bottomed flask. Evaporate to dryness under reduced pressure and take up the residue with 5.0 mL of a mixture of 10 volumes of *methanol R* and 100 volumes of *glacial acetic acid R* then transfer into a 25.0 mL volumetric flask. Rinse the round-bottomed flask with 5.0 mL of a mixture of 10 volumes of *methanol R* and 100 volumes of *glacial acetic acid R* and pour into the volumetric flask. Add 10.0 mL of *anhydrous formic acid R* and dilute to 25.0 mL with *glacial acetic acid R.*

Thirty min after the addition of the last reagent, measure the absorbance of the test solution at 401 nm, in comparison with the compensation liquid.

Calculate the percentage content *m/m* of total flavonoids, expressed as vitexine, from the expression:

$$\frac{A \times 500}{m \times 628}$$

i.e. taking the specific absorbance of vitexine, to be 628.

A = absorbance of the test solution at 401 nm,
m = mass of the mother tincture sample, in grams.

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