

COMMON SAGE FOR HOMOEOPATHIC PREPARATIONS

SALVIA OFFICINALIS FOR HOMOEOPATHIC PREPARATIONS

Salvia officinalis ad praeparationes homoeopathicas

DEFINITION

Fresh, flowering aerial part of Salvia officinalis L.

IDENTIFICATION

- A. Stem ligneous at the base, showing a surface covered with very short, glandular trichomes and a rectangular section. Opposite, simple leaves without evergreen stipules, greenish-grey, dull, coarse due to numerous trichomes on both sides. Lanceolate-shaped lamina, with frequently two lobes at the base; with thinly serrated margins and wafer-like surface between the net of thin veins giving a shagreened aspect to the underside. Lower leaves, 4-6 cm long and 2 cm large, petiolate and ovate at the apex; sessile upper leaves with a more acute apex. Inflorescences in loose spikes at the end of the twigs, composed of fake, 3-6 flowered verticils each. Zygomorphous flowers. Pubescent, evergreen and bilabiate calyx ending by 5 lanceolate teeth. Corolla measuring up to 4 cm long, usually purplish-blue, tube comprising a ring of trichomes inside; ending with an upper lip, bulging and slightly straightened up, and a three-lobed, pendent lower lip. Androecium reduced to 2 stamens; each one composed of a single, fertile loculus, fixed on a long pole articulated on the filament. Superior ovary topped by a long style and an irregularly bifid stigma, composed of 4 carpels with ovules.
- B. Examine a sample of abaxial epidermis, using *chloral hydrate solution R*: abaxial, stomatiferous and piliferous epidermis with sinuous cells; diacytic stomata (2.8.3) Trichomes of various types: multicellular covering trichomes, articulated, curved consisting of narrow and elongated cells and a very thick basal cell, glandular trichomes with multicellular foot (1-4 cells) and uni or bi cellular head, glandular trichomes with unicellular foot and octocellular head of labiatae type.

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 $^{\circ}$ C for 2 h.

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

STOCK

DEFINITION

Common sage mother tincture is prepared with ethanol (55 per cent *V/V*), using the fresh, flowering aerial part of *Salvia officinalis* L.

Content: minimum 0.035 per cent m/m of total flavonoids, expressed as luteolin-7-glucoside ($C_{21}H_{20}O_{11}$; M_r 448.4).

PRODUCTION

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

CHARACTERS

Appareance: dark brown liquid.

IDENTIFICATION

Thin-layer chromatography (2.2.27).

Test solution. Mother tincture.

Reference solution. Dissolve 5 mg of rutin R and 5 mg of luteolin-7-glucoside R in 20 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, anhydrous formic acid R, ethyl acetate R (10:10:80 V/V//V).

Application: 20 µL [or 5 µL] as bands.

Development: over a path of 10 cm [or 7 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			
	A green zone		
Luteolin-7-glucoside: an orange zone	An orange zone (luteolin-7-glucoside) An orange zone		
Rutin: an orange zone	An orange zone (rutin) An orange zone		
Reference solution	Test solution		

TESTS

Ethanol content (2.9.10): 50 per cent V/V to 60 per cent V/V.

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

Thujone: maximum 0.1 per cent m/m.

Gas chromatography (2.2.28).

Internal standard solution. Dissolve 30 mg of car-3-ene R in ethanol (96 per cent) R and dilute to 100.0 mL with the same solvent.

Test solution. Dissolve 1.000 g of mother tincture in 2.0 mL of internal standard solution and dilute to 10.0 mL with *ethanol* (96 per cent) R.

Reference solution. Dissolve 0.100 g of thujone R in ethanol (96 per cent) R and dilute to 100.0 mL with the same solvent. Dilute 5.0 mL of the solution to 25.0 mL with ethanol (96 per cent) R. To 5.0 mL of the solution, add 2.0 mL of internal standard solution and dilute to 10.0 mL with ethanol (96 per cent) R.

Column:

- material: fused silica,
- size: $I = 30 \text{ m}, \emptyset = 0.53 \text{ mm},$
- stationary phase: poly(dimethylsiloxane) R (film thickness: 1.5 μm).

Carrier gas: helium for chromatography R.

Flow rate: 24 mL/min.

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Temperature:

	Time (min)	Temperature (°C)	Speed (°C / min)
Column	0-10	60	
	10-20	$60 \rightarrow 70$	1
	20-25	70	
	25-32	70 → 240	25
	32-40	240	
Injection port		250	
Detector		250	

Detection: flame ionisation.

Injection: direct 2 µL.

Calculate the percentage content m/m of α -thujone and β -thujone from the expression:

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

 A_1 = sum of the areas of the peaks due to α -thujone and β -thujone in the test solution,

 A_2 = sum of the areas of the peaks due to α -thujone and β -thujone in the reference solution,

 $A_{1'}$ = area of the peak due to the internal standard in the test solution,

 A_2 = area of the peak due to the internal standard in the reference solution,

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

 m_2 = mass of *thujone R* sample in the reference solution, in grams.

ASSAY

Ultraviolet and visible absorption spectrophotometry (2.2.25).

Stock solution. Evaporate 0.800 g of mother tincture to dryness under reduced pressure. Dilute the residue with 25.0 mL of *glacial acetic acid R* (5 per cent V/V) in *methanol R*.

Test solution. To 10.0 mL of stock solution, add 1.0 mL of aluminium chloride reagent R and dilute to 25.0 mL with a solution of glacial acetic acid R (5 per cent V/V) R in methanol R.

Compensation liquid of the test solution. Dilute 10.0 mL of stock solution to 25.0 mL with a solution of glacial acetic acid R (5 per cent V/V) in methanol R.

Reference stock solution. Dissolve 10.0 mg of luteolin-7-glucoside R in a solution of glacial acetic acid R (5 per cent V/V) in methanol R and dilute to 100.0 mL with the same solvent. Dilute 10.0 mL of the solution to 20.0 mL with a solution of glacial acetic acid R (5 per cent V/V) in methanol R.

Reference solution. To 5.0 mL of reference stock solution, add 1.0 mL of aluminium chloride reagent R and dilute to 25.0 mL with a solution of glacial acetic acid R (5 per cent V/V) in methanol R.

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Compensation liquid of the reference solution. Dilute 5.0 mL of reference stock solution to 25.0 mL with glacial acetic acid R (5 per cent V/V) in methanol R.

Thirty min after the addition of the last reagent, measure the absorbance of the test solution at 395 nm, in comparison with the compensation liquid of the test solution, and the absorbance of the reference solution in comparison with the compensation liquid of the reference solution.

Calculate the percentage content m/m of total flavonoids, expressed as luteolin-7-glucoside, from the expression.

$$\frac{A_1 \times m_2 \times 6.25}{A_2 \times m_1}$$

 A_1 = absorbance of the test solution,

 A_2 = absorbance of the reference solution,

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

 m_2 = mass of *luteolin-7-glucoside R* sample, in grams.

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