SABADILLA
FOR HOMOEOPATHIC PREPARATIONS

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Schoenocaulon officinale ad praeparationes homoeopathicas

Other Latin name used in homoeopathy: **Sabadilla officinarum**

DEFINITION

Dried seed of *Schoenocaulon officinale* A. Gray (*Sabadilla officinarum* Brandt & Ratzeb).

*Conten*t: minimum 3.5 per cent of total alkaloids, expressed as cevadine ($C_{32}H_{49}NO_9$; M_r 591.8).

CHARACTERS

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

Practically odourless; the powdered drug is strongly sternutatory and irritant to the eyes.

IDENTIFICATION

A. The seed of sabadilla is blackish-brown, glossy; reaching 5-9 mm long and about 2 mm wide. It is elongated, angular, and more pointed at one end, sometimes being slightly curved. The surface is longitudinally striated with a groove at the base. The transverse section shows whitish, fleshy, oily albumen within a dark seminal integument and a small, basal embryo.

B. Reduce the seed to a powder (355). The powder is brown. Examine under a microscope using *chloral hydrate solution R.* The powder shows the following elements: fragments of epidermis consisting of brown, elongated, polyhedral cells with finely and regularly thickened walls; fragments of mesocarp with more or less ovoid and cellulosic cells; fragments of albumen with irregularly thickened, cellulose-walled cells, crammed with oil droplets.

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

Test solution. Add 30 mL of *ethanol* (65 per cent *V/V*) *R* to 3.0 g of powdered drug (355). Heat at 60 °C, under a reflux condenser for 15 min. Allow to cool. Filter.

Reference solution. Dissolve 5 mg of *berberine R* and 5 mg of *veratrine R* in 10 mL of *ethanol* (60 per cent *V/V*) *R*.

Plate: *TLC silica gel plate R.*

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

Mobile phase: *glacial acetic acid R, water R, butanol R* (10:10:40 *V/V/V*).

Application: 20 µL as bands.

Development: over a path of 10 cm.

Drying: in air.

Detection: spray with *potassium iodobismuthate solution R.* Examine in daylight.

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

Top of the plate	
------ Veratrine: an orange zone Berberine: an orange zone ------	------ An orange zone (veratrine) An orange zone ------
Reference solution	**Test solution**

TESTS

Foreign matter (*2.8.2*): complies with the test for foreign matter.

Loss on drying (*2.2.32*): maximum 10.0 per cent, determined on 1.0 g powdered drug (355), by drying in an oven at 105 °C for 2 h.

Total ash (*2.4 16*): maximum 10.0 per cent, determined on 1.0 g powdered drug (355).

ASSAY

To 2.00 g of powdered drug (355), add 2 mL of *dilute ammonia R1* and 50 mL of *ether R*. Place under magnetic agitation for 30 min. Allow to separate. Filter. Repeat the extraction process twice.
Dry the combined ether phases over *anhydrous sodium sulfate R*. Filter. Rinse the sodium sulfate and the filter with a few millilitres of *ether R*. Evaporate the combined ether layers under reduced pressure. Dissolve the residue in 5 mL of *ethanol R*. Add 20 mL of *light petroleum R1*, 10 mL of *carbon dioxide-free water R*, 0.3 mL of *methyl red mixed solution R* and 20.0 mL of 0.02 M *hydrochloric acid R*. Titrate with 0.02 M *sodium hydroxide R* until the indicator turns green, shaking after each addition of sodium hydroxide.
1 mL of 0.02 M *hydrochloric acid R* corresponds to 11.84 mg of total alkaloids, expressed as cevadine.

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

STOCK

DEFINITION

Sabadilla mother tincture complies with the requirements of the general technique for the preparation of mother tinctures (see *Homoeopathic Preparations (1038)* and French pharmacopoeia Supplement). The mother tincture is prepared with ethanol (65 per cent *V/V*), using the whole, dried seed of *Schoenocaulon officinale* A. Gray *(Sabadilla officinarum* Brandt and Ratzeb).

Adjusted content: minimum 0.20 per cent *m/m* and maximum 0.40 per cent *m/m* of total alkaloids, expressed as cevadine ($C_{32}H_{49}NO_9$; M_r 591.8).

CHARACTERS

Appearance: orange-yellow to orange-red liquid.

IDENTIFICATION

Thin-layer chromatography (*2.2.27*).

Test solution. Mother tincture.

Reference solution. Dissolve 5 mg of *berberine R* and 5 mg of *veratrine R* in 10 mL of *ethanol* (60 per cent *V/V*) *R*.

Plate: *TLC silica gel plate R.*

Mobile phase: *glacial acetic acid R, water R, butanol R* (10:10:40 *V/V/V*).

Application: 20 µL as bands.

Development: over a path of 10 cm.

Drying: in air.

Detection: spray with *potassium iodobismuthate solution R.* Examine in daylight.

Results: see below the sequence of zones present in the chromatograms obtained with the reference solution and test solution. Furthermore other faint 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	
------	------
Veratrine: an orange zone Berberine: an orange zone	An orange zone An orange zone (veratrine)
------	------
Reference solution	**Test solution**

TESTS

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

Dry residue (*2.8.16*): minimum 0.5 per cent *m/m*.

ASSAY

Evaporate the ethanol from 20.00 g of mother tincture under reduced pressure. Transfer the whole quantity of residue into a separating funnel, using a few millilitres of *water R*. Add 3 mL of *ammonia R1* then extract by successive fractions of *ether R* until the alkaloids have been totally extracted. Evaporate to dryness a few millilitres of the ether solution, take up with *0.25 M sulfuric acid* and check out the absence of alkaloids with *potassium tetraiodomercurate solution R*. Dry the combined ether phases over *anhydrous sodium sulfate R*. Filter. Rinse the sodium sulfate and the filter with a few millilitres of *ether R*. Evaporate the combined ether phases under reduced pressure. Dissolve the residue in 5 mL of *ethanol R.* Add 20 mL of *light petroleum R1*, 10 mL of *carbon dioxide-free water R,* 0.3 mL of *methyl red mixed solution R* and 20.0 mL of 0.02 M *hydrochloric acid R*. Titrate with *0.02 M sodium hydroxide R* until the indicator turns green, shaking after each addition of sodium hydroxide.

1 mL of 0.02 M *hydrochloric acid R* corresponds to 11.84 mg of total alkaloids, expressed as cevadine.

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