BITTERSWEET FOR HOMOEOPATHIC PREPARATIONS

DULCAMARA FOR HOMOEOPATHIC PREPARATIONS

Solanum dulcamara ad praeparationes homoeopathicas

DEFINITION

Fresh, young, blooming, leafy-stem of Solanum dulcamara L.

CHARACTERS

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

Unpleasant odour.

IDENTIFICATION

- A. Greenish-grey, spindly stem. Alternate leaves; petiolated, sometimes geminate at the top; leaves with entire base, slightly cordiform; 3-lobed upper leaves with smaller lateral lobes, Multiflorous cyme inflorescence, pedunculated, opposite to the leaves. Purple, pentamerous flowers, seldom pink or white. Calyx, much smaller than the corolla, composed of triangular parts. Regular corolla, 12 mm to 20 mm large. Yellow stamens with connivent anthers.
- B. Take a sample from underside epidermis of a leaf. Examine under a microscope using *chloral hydrate solution R*. Lamina epidermis composed of cells with very sinuous cell-walls, numerous stomata of anisocytic type with 3-4 subsidiary cells (2.8.3), multicellular covering trichomes, tapered and straight, with slightly thickened and pitted walls about 200 µm long, and secretory trichomes with unicellular foot and multicellular head comprising a cell at the base of the swollen part then 2-4 club-shaped cells. Veins epidermis composed of parallelipipedic cells lined along the veins.

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

Bittersweet 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 fresh, young, blooming, leafy-stem of *Solanum dulcamara* L.

Content: minimum 0.03 per cent m/m of total saponosides, expressed as diosgenin ($C_{27}H_{42}O_3$; M_r 414.6).

CHARACTERS

Brown liquid.

IDENTIFICATION

Thin layer chromatography (2.2.27).

Test solution. Mother tincture.

Reference solution. Dissolve 10 mg of solasodine R and 5 mg of berberine chloride R in 20 mL of methanol R.

Plate: TLC silica gel plate R.

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

Application: 40 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	
Solasodine: an orange zone	
Berberine: an orange zone	An orange zone
	An orange zone
	An orange-brown 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*.

ASSAY

Ultraviolet and visible absorption spectrophotometry (2.2.25).

Test solution. In a 250 mL round-bottomed flask, place 10.0 g of mother tincture accurately weighed then evaporate the ethanol. Add 10 mL of *hydrochloric acid 1 M*. Heat under a reflux condenser for 30 min. Place the residue in a separating funnel and extract with 4 quantities each of 20 mL of *chloroform R*. Combine the chloroformic phases, dry over *anhydrous sodium sulfate R*, then evaporate to dryness. Dissolve the residue in 20.0 mL of *methanol R*. In a 25.0 mL volumetric flask, place 5.0 mL of this solution and dilute to 25.0 mL with *methanol R*. Take 1.0 mL of this solution and evaporate to dryness. Dissolve the residue in 10.0 mL of *sulfuric acid R*. Leave in contact for 1 h.

Reference solution. Prepare a range of solutions from an accurately weighed test sample of diosgenin R, about 30.0 mg dissolved in 50.0 mL of methanol R. In 5 volumetric flasks of 20.0 mL, place respectively: 1.0 mL, 2.0 mL, 3.0 mL, 4.0 mL and 6.0 mL of the solution previously obtained and dilute to the volume with methanol R. Take 1.0 mL of each solution and evaporate to dryness. Dissolve the residue in 10.0 mL of sulfuric acid R. Leave in contact for 1 h.

Compensation liquid: sulfuric acid R.

Measure the absorbance of the test solution and of the reference solution, immediately at 413 nm in comparison with the compensation liquid.

Plot the calibration line (standardisation line) and deduce *x*.

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

Calculate the percentage content m/m of total saponosides, expressed as diosgenin from the expression:

$$\frac{x \times 10}{m}$$

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

x = mass of diosgenin (mg) in 1 mL of solution.

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