CYCLAMEN
FOR HOMOEOPATHIC PREPARATIONS

CYCLAMEN EUROPAEUM
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Cyclamen europaeum ad praeparationes homoeopathicas

DEFINITION

Fresh, tubercle of *Cyclamen purpurascens* Mill.

CHARACTERS

Macroscopic characters described under identification.

IDENTIFICATION

Spherical tubercle, more or less flattened, about 2 cm thick and 3-10 cm in diameter. Thick, dark brown suber. The surface presents long, brown, thread-like roots, mainly at its base. White, fleshy inside.

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

Cyclamen 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 tubercle of *Cyclamen purpurascens* Mill.

Content: minimum 0.50 per cent *m/m* of triterpenic heterosides expressed as aescin ($C_{55}H_{86}O_{24}$; M_r 1,131.3).

CHARACTERS

Appearance: yellow liquid.

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

IDENTIFICATION

Thin layer chromatography (*2.2.27*).

Test solution. Mother tincture.

Reference solution. Dissolve 10 mg of *aescin R* and 5 mg of α-*hederin R* in 10 mL of *ethanol* (70 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 *antimony trichloride solution R*. 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	
α-hederin: a purple zone	
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	A purple zone
Aescin: a pale purple zone	A purple zone
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	A purple zone
Reference solution	**Test solution**

TEST

Ethanol (*2.9.10*): 40 per cent *V/V* to 50 per cent *V/V*.

Methanol and 2-propanol (*2.9.11*): maximum 0.05 per cent *V/V*; maximum 0.05 per cent *V/V*.

Dry residue (*2.8.16*): minimum 3.5 per cent *m/m*.

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

ASSAY

Ultraviolet and visible absorption spectrophotometry (*2.2.25*).

Test solution. In a 250 mL round-bottomed flask, evaporate 5.000 g of mother tincture to dryness under low pressure. Add 20 mL of *hydrochloric acid 0.1 M* to the residue and transfer into a separating funnel. Wash the flask with two quantities each of 5 mL of *hydrochloric acid 0.1 M.* Combine the acid solutions. Shake once with 60 mL and then with two quantities each of 50 mL of the upper layer of a mixture composed of 180 mL of *butanol R,* 30 mL of *methylene chloride R* and 90 mL of *hydrochloric acid 0.1 M,* rinsing the flask with the extractive solution. Separate the upper organic phase. Wash the combined organic phases with two quantities each of 30 mL of the lower phase of the previously described mixture. Combine the organic phases and evaporate to dryness under low pressure. Dissolve the residue in *glacial acetic acid R.* Transfer into a 50.0 mL volumetric flask. Wash the round-bottomed flask with small quantities of *glacial acetic acid R*, collecting the washings into the volumetric flask. Dilute to the volume with the same solvent. Take 1.0 mL of this solution, add 4.0 mL of *sulphuric acetic acid R*. Heat on a water-bath at 60 °C for 20 min, shaking from time to time. Cool quickly under tap water for 5 min.

Reference solution. In a 50.0 mL volumetric flask, dissolve 25.0 mL of *aescin R* in *glacial acetic acid R.* Dilute to 50.0 mL with the same solvent. Add 4.0 mL of *sulphuric acetic acid R* to 1.0 mL of this solution. Heat on a water-bath at 60 °C for 20 min, shaking from time to time. Cool quickly under tap water for 5 min.

Compensation liquid. Add 4.0 mL of *sulphuric acetic acid R* to 1.0 mL of *glacial acetic acid R*. Heat on a water-bath at 60 °C for 20 min, shaking from time to time. Quickly cool under tap water for 5 min.

Measure the absorbance of the test solution and of the reference solution, immediately at 520 nm, in comparison with the compensation liquid.

Calculate the percentage content *m/m* of triterpenic heterosides, expressed as aescin, from the expression:

$$\frac{A_1 \times m_2 \times 100}{A_2 \times m_1}$$

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 aescin sample in the reference solution, in grams.

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