

**CHRISTMAS ROSE  
FOR HOMOEOPATHIC PREPARATIONS**

**HELLEBORUS NIGER  
FOR HOMOEOPATHIC PREPARATIONS**

*Helleborus niger* ad praeparationes homoeopathicas

DEFINITION

Fresh, underground organ of *Helleborus niger* L.

CHARACTERS

Macroscopic characters described under identification.

IDENTIFICATION

Blackish-brown, short, twisting, knotty rhizome, unevenly ramified, measuring up to 6 cm long and 10 mm in diameter, bearing numerous ring scars, scales, big buds and some remains of stalks and leaves, on its upper part. Whitish fracture with horny appearance. Underside edged by a beard of thin brown, crumbly, adventive roots, about 4 cm long and 2 mm in diameter.

TESTS

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

**Loss on drying** (2.2.32): minimum 60.0 per cent, determined on 10.0 g of finely-cut drug, by drying in an oven at 105 °C for 2 h.

**STOCK**

DEFINITION

Christmas rose 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 (65 per cent V/V), using fresh, underground organ of *Helleborus niger* L.

*Content*: minimum 0.10 per cent *m/m* of total saponosides, expressed as ruscogenines.

CHARACTERS

*Appearance*: light yellow liquid.

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*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 2 mg of *convallatoxine R* and 5 mg of *digitoxin R* in 10 mL of *methanol R*.

*Plate:* TLC silica gel plate *R*.

*Mobile phase:* *water R*, *methanol R*, *ethyl acetate R*, (8:11:81 V/V/V).

*Application:* 40 µL, as bands.

*Development:* over a path of 10 cm.

*Drying:* in air.

*Detection:* spray with a solution of 1 g of *dinitrobenzoic acid R* in 100.0 mL of a mixture composed of equal quantities of *methanol R* and *potassium hydroxide 2 M*. 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	
Digitoxin: a purple zone	An orange-pink zone
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Convallatoxine: a purple zone	-----
-----	One to two orange-pink zones
<b>Reference solution</b>	<b>Test solution</b>

## TESTS

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

**Dry residue** (2.8.16): minimum 0.9 per cent *m/m*.

## ASSAY

*Ultraviolet and visible absorption spectrophotometry* (2.2.25).

*Test solution.* In a 50.0 mL volumetric flask, place 20.00 g of mother tincture accurately weighed and dilute to 50.0 mL with *ethanol* (60 per cent V/V) *R*. In a 100 mL rounded flask, place 5.0 mL of this solution and evaporate to dryness, under reduced pressure. Dissolve in 5.0 mL of *water R*. Add 10 mL of *butanol R* saturated with *water R*. Seal tightly. Shake vigorously for 2 min. Centrifuge and

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collect the supernatant. Repeat the operation 3 times with 10 mL of *butanol R* saturated with *water R*. Combine the butanolic layers. Evaporate to dryness, under reduced pressure. Dissolve the residue in 15 mL of *methanol R*. Transfer the entire mixture in a 20.0 mL volumetric flask and dilute to 20.0 mL with *methanol R*. In a 100 mL volumetric flask, evaporate 1.0 mL of methanolic solution to dryness, under reduced pressure and add 10.0 mL of *sulfuric acid R*. Seal. Shake. Allow the coloration to develop for exactly 1 h.

*Compensation liquid. Sulfuric acid R*

Measure the absorbance of the test solution at 395 nm in comparison with the compensation liquid.

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

$$\frac{A \times 2000}{354 \times m}$$

i.e: taking the specific absorbance of ruscogenines to be 354 at 395 nm,

*A* = absorbance of the test solution at 395 nm,

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

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