DEVIL'S CLAW ROOT FOR HOMOEOPATHIC PREPARATIONS

HARPAGOPHYTUM FOR HOMOEOPATHIC PREPARATIONS

Harpagophytum ad praeparationes homoeopathicas

The herbal drug complies with the requirements of monograph Devil's claw root (1095).

STOCK

DEFINITION

Devil's claw root 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 dried secondary roots of *Harpagophytum procumbens* DC. and/or de *H.zeyheri* L. Decne.

Content: minimum 0.12 per cent m/m of harpagoside ($C_{24}H_{30}O_{11}$; M_f 494.5).

CHARACTERS

Appearance: red-brown liquid.

IDENTIFICATION

Thin-layer chromatography (2.2.27).

Test solution. Mother tincture.

Reference solution. Dissolve 10 mg of harpagoside R and 10 mg of aucubine R in methanol R and dilute to 10 mL with the same solvent.

Plate: TLC silica gel GF₂₅₄ plate R.

Mobile phase: ethanol (96 per cent V/V) R, methylene chloride R (10:20 V/V).

Application: 20 µL, as bands.

Development: over a path of 10 cm.

Drying: in air.

The Constant Charters and Constal Managraphs of the European Pharmacon

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

Detection A: examine in ultraviolet light at 254 nm.

Results A: see below the sequence of quenching zones present in the chromatograms of 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	
	Three dark zones
Harpagoside: a dark zone	A dark zone (harpagoside)
	Two dade sone
	Two dark zones
Reference solution	Test solution

Detection B: spray with anisaldehyde solution R. Heat the plate for 10 min at 100-105 °C. Examine in daylight.

Results B: see below the sequence of zones present in the chromatograms of 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	
Harpagoside: an intense purple zone	An intense purple zone (harpagoside)
	A brown zone
Aucubine: a brown zone	A purple-brown zone
Reference solution	Test solution

TESTS

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

Dry residue: minimum 2.5 per cent m/m.

ASSAY

Liquid chromatography (2.2.29).

Internal standard solution. In a 100.0 mL volumetric flask, dissolve 0.130 g of methyl cinnamate R in 50 mL of methanol R and dilute to 100.0 mL with the same solvent.

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

Test solution. In a 25.0 mL volumetric flask, place an accurately-weighed sample of 5.00 g of mother tincture and dilute to 25.0 mL with *methanol R*. To 10.0 mL of this solution add 1.0 mL of the internal standard solution and dilute to 25.0 mL with *methanol R*.

Reference solution. In a 10.0 mL volumetric flask, dissolve 4 mg of harpagoside R in methanol R and dilute to 10.0 mL with the same solvent.

Column:

- size: $I = 0.25 \text{ m}, \varnothing = 4.6 \text{ mm},$

- stationary phase: octadecylsilyl silica gel for chromatography R (5 μm),

- temperature: ambient.

Mobile phase: methanol R, water R (50:50 V/V).

Flow rate: 1.5 mL/min.

Detection: spectrophotometer at 278 nm.

Injection: 20 µL.

Inject the test solution. Adjust the sensitivity of the detector so that the height of the peak due to methyl cinnamate is about 50 per cent of the full scale of the recorder.

Determine the retention time of harpagoside using 20 μL of the reference solution examined in the same conditions as the test solution.

Calculate the percentage content m/m of harpagoside, from the expression:

$$\frac{m_2 \times A_1 \times 7.622}{m_1 \times A_2}$$

 A_1 = peak area for harpagoside in the test solution chromatogram,

 A_2 = peak area for methyl cinnamate in the reference solution chromatogram,

 m_1 = mass of the sample in grams,

 m_2 = mass of methyl cinnamate in 100.0 mL of internal standard solution in grams.

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