BIRCH TREE
FOR HOMOEOPATHIC PREPARATIONS

BETULA
FOR HOMOEOPATHIC PREPARATIONS

Betula ad praeparationes homoeopathicas

DEFINITION

Fresh bark of the stem of young twigs of *Betula alba* L. (*Betula pendula* Roth; *Betula verrucosa* Ehrh.) and/or of *Betula pubescens* Ehrh.

IDENTIFICATION

Stem bark of young twigs showing a smooth outside surface; white or brown; marked by long, horizontal lenticels, glabrous (*B .alba* L.) or pubescent (*B.pubescens* Ehrh.). This part easily comes off in very thin stripes. Inside bark, brown, a few mm thick, showing a granular fracture.

TESTS

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

Loss on drying (*2.2.32*): minimum 30.0 per cent, determined on 5.0 g of finely-cut drug, by drying in an oven at 105 °C for 2 h.

STOCK

DEFINITION

Birch tree mother tincture is prepared with ethanol (65 per cent *V/V*) using the fresh bark of the stem of young twigs of *Betula alba* L. (*Betula pendula* Roth; *Betula verrucosa* Ehrh.) and/or of *Betula pubescens* Ehrh.

Content: minimum 0.05 per cent *m/m* of betulin ($C_{30}H_{50}O_2$; M_r 442.7).

PRODUCTION

Method 1.1.10 (2371). Drug fragmented into 2-5 cm long segments. Maceration time: 3-5 weeks.

CHARACTERS

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

Appearance: orange-yellow to reddish-brown liquid.
IDENTIFICATION

Thin layer chromatography (*2.2.27*).

Test solution. Mother tincture.

Reference solution. Dissolve 10 mg of *betulin R* and 5 mg of *β-sitosterol R* in 10 mL of *ethanol* (*96 per cent*) *R*.

Plate: *TLC silica gel plate R*.

Mobile phase: *methanol R*, *ether R, toluene R* (5:10:85 *V/V/V).*

Application: 20 µL as bands.

Development: over a path of 10 cm.

Drying: in air.

Detection: first spray with *vanillin reagent R* and heat at 100-105 °C for about 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	
	Two to three purple zones
-----	-----
β-Sitosterol: a purple zone	
	A bluish-grey zone
Betulin: a dark purple zone	A dark purple zone (betulin)
-----	-----
	A purple zone
	A brownish-purple zone
	A purplish-grey zone
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 1.0 per cent *m/m*.

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ASSAY

Liquid chromatography (*2.2.29*).

Test solution. In a 20.0 mL volumetric flask, place 10.000 g of mother tincture and dilute to 20.0 mL with a mixture of 1 volume of *water R* and 9 volumes of *methanol R.*

Reference solution. In a 100.0 mL volumetric flask, dissolve 50.0 mg of *betulin R* in a mixture of 1 volume of *water R* and 9 volumes of *methanol R* and dilute to 100.0 mL with the same mixture.

Column:
– *size*: *l* = 0.25 m, Ø = 4 mm,
– *stationary phase*: *octadecylsilyl silica gel for chromatography R* (5 µm).
– *temperature*: 30 °C.

Mobile phase: *water R*, *methanol R2* (1:9 *V/V*).

Flow rate: 1.0 mL/min.

Detection: spectrophotometer at 201 nm.

Injection: 10 µL.

Retention time: betulin: about 11 min.

Calculate the percentage content *m/m* of betulin in the mother tincture, from the expression:

$$\frac{A_1 \times m_2 \times 0.2 \times p}{A_2 \times m_1}$$

A_1 = area of the peak due to betulin in the chromatogram obtained with the test solution,
A_2 = area of the peak due to betulin in the chromatogram obtained with the reference solution,
m_1 = mass of the mother tincture sample, in the test solution, in grams,
m_2 = mass of the sample of betulin in the reference solution, in grams,
p = percentage content of betulin in *betulin R*.

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