BOLDO FOR HOMOEOPATHIC PREPARATIONS

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Boldo ad praeparationes homoeopathicas

Other Latine name used in homoeopathy: Peumus boldus

The herbal drug complies with the monograph Boldo leaf (1396).

STOCK

DEFINITION

Boldo mother tincture is prepared with ethanol (55 per cent V/V) using the dried leaf of *Peumus boldus* Molina.

Adjusted content: minimum 0.008 per cent and maximum 0.020 per cent m/m of total alkaloids, expressed as boldine (C₁₉H₂₁NO₄; M_r 327.4).

PRODUCTION

Method 1.1.10 (2371). Drug fragmented into segments over 1 cm long. Maceration time: 3 to 5 weeks.

CHARACTERS

Appearance: dark brown liquid.

Characteristic odour.

IDENTIFICATION

Thin layer chromatography (2.2.27).

Test solution. To 5 mL of mother tincture add 1 mL of dilute hydrochloric acid R and 20 mL of water R, then heat under a reflux condenser for 10 min. Cool and filter. Add 2 mL of dilute ammonia R1 to the filtrate and extract twice with 20 mL of methylene chloride R each time. Combine the organic layers and evaporate to dryness, under reduced pressure. Dissolve the residue in 1 mL of methanol R.

Reference solution. Dissolve 2 mg of boldine R and 10 mg of hyoscine hydrobromide R in 5 mL of methanol R.

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

Plate: TLC silica gel plate R.

Mobile phase: diethylamine R, methanol R, toluene R (10:10:80 V/V/V).

Application: 20 µL, as bands.

Development: over a path of 12 cm.

Drying: in air, for 30 min at least.

Detection: first spray with *potassium iodobismuthate solution R2*. Allow the plate to dry in air for 5 min then spray with *sodium nitrite solution R*. Examine in day light.

Results: see below the sequence of zones present in the chromatograms obtained with the reference solution and the test solution. Furthermore other faint, brown zones may be present in the chromatogram obtained with the test solution.

Top of the plate	
Hyoscine (hydrobromide): a brown zone	A yellowish-brown zone
(ilyanoshomiae), a shomi zene	A yellowish-brown zone
	A brown zone
	A brown zone
Boldine: a brown zone	A brown zone (boldine)
Reference solution	Test solution

TESTS

Ethanol (2.9.10): 50 per cent V/V to 60 per cent V/V.

Dry residue (2.8.16): minimum 2.0 per cent m/m.

ASSAY

Liquid chromatography (2.2.29).

Test solution. Evaporate 20.00 g of mother tincture until you obtain about 10 mL residue. Alkalinize with *dilute ammonia R1* then shake with successive fractions of 20 mL of *methylene chloride R* until complete extraction of the alkaloids. Combine the organic layers then evaporate to dryness under reduced pressure. Dissolve the residue in the mobile phase and dilute to 20.0 mL with the same solvent.

Reference solution. In a 100.0 mL volumetric flask, dissolve 12 mg of boldine CRS in 100.0 mL of mobile phase. Take 2.0 mL of solution and dilute to 20.0 mL with the mobile phase.

Column:

- size: I = 0.25 m, $\emptyset = 4 \text{ mm}$,
- stationary phase: octadecylsilyl silica gel for chromatography R (5 μm).

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

French Pharmacopoeia 2009

Mobile phase: mix 16 volumes of solution A and 84 volumes of solution B.

- solution A: mix 99.8 mL of acetonitrile R and 0.2 mL of diethylamine R,
- solution B: mix 99.8 mL of water R and 0.2 mL of diethylamine R and adjust to pH 3 with anhydrous formic acid R.

Flow rate: 1.0 mL/min.

Detection: spectrophotometer at 304 nm.

Injection: 20 µL.

Relative retention with reference to boldine: isoboldine = about 0.9; isocorydine N-oxide = about 1.8, laurotetanine = about 2.2, isocorydine = about 2.8, and N-methyllaurotetanine = about 3.2. Additional peaks may be present.

Calculate the percentage content *m/m* of total alkaloids expressed as boldine, from the expression:

$$\frac{\sum A_1 \times m_2 \times 0.02 \times p}{A_2 \times m_1}$$

 $\sum A_1$ = sum of the areas of the peaks due to the 6 alkaloids identified in the chromatogram obtained with the test solution,

 A_2 = area of the peak due to boldine in the chromatogram obtained with the reference solution,

 m_1 = mass of mother tincture sample in the test solution, in grams,

 m_2 = mass of boldine sample in the reference solution, in grams,

p = percentage content of boldine in boldine CRS.