COMMON BARBERRY FOR HOMOEOPATHIC PREPARATIONS

BERBERIS VULGARIS FOR HOMOEOPATHIC PREPARATIONS

Berberis vulgaris ad praeparationes homoeopathicas

Other Latin name used in homoeopathy: **Berberis**

DEFINITION

Dried root bark, entire or fragmented of *Berberis vulgaris* L.

Content: minimum 2.0 per cent of total alkaloids, expressed as berberine ($C_{20}H_{19}NO_5$; M_r 353.4) (dried drug).

CHARACTERS

Presence of yellow fluorescence under ultraviolet light at 365 nm.

IDENTIFICATION

A. Fragments of various size 1-2 cm up to 15 cm long and 1 mm to 1 cm thick. Greyish-brown outside surface, smooth, wrinkled or sometimes chapped with outside layers easily exfoliating. Dark yellow inside surface, longitudinally striated. Fibrous fracture, marked with concentric striations. Remains of wood, bright yellow, sometimes sticking to the bark.

B. Reduce the root bark to a powder (355). The powder is yellowish-brown. Examine under a microscope using *chloral hydrate solution R.* The powder presents the following characteristic elements: numerous fragments of brown suber; sclerous cells either free or in clusters; liberous fibres, narrow and elongated with thickened cell-walls; numerous prisms of calcium oxalate; scarce reticulate or pitted vessels. Examine under a microscope using a 500 g/L solution of *glycerol R*: rounded starch granules, about 2-7 µm in diameter.

C. Thin-layer chromatography (*2.2.27*).

Test solution. Add 30 mL of *ethanol* (60 per cent *V/V*) *R*, to 3.0 g of powdered drug (355). Heat on a water-bath at 60 °C, under a reflux condenser for 15 min. Allow to cool. Filter.

Reference solution. Dissolve 20 mg of *berberine chloride R* and 10 mg of *sanguinarine nitrate R* in 20 mL of *ethanol* (*96 per cent*) *R*.

Plate: *TLC silica gel plate R.*

Mobile phase: *anhydrous formic acid R, water R, ethyl acetate R* (10:10:80 *V/V/V*).

Application: 20 µL as bands.

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

Development: over a path of 10 cm.

Drying: in air.

Detection A: examine in ultraviolet light at 365 nm.

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

Top of the plate	
	A purplish-blue zone
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Berberine (chloride): an intense yellow zone Sanguinarine (nitrate): an orange zone	An intense yellow zone (berberine) A yellow zone
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	One to two blue zones
Reference solution	**Test solution**

Detection B: spray with *potassium iodobismuthate solution R*. Examine in daylight.

Results B: 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	
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Berberine (chloride): an orange zone Sanguinarine (nitrate): an orange zone	An orange zone (berberine) An orange zone
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Reference solution	**Test solution**

TESTS

Berberis aquifolium. Examined under a microscope, the cross-section of the drug shows neither a thick subero-phellodermic zone, nor multiseriate medullary rays. The presence of such elements shows adulteration by *Berberis aquifolium* Pursh.

Loss on drying (*2.2.32*): maximum 10.0 per cent, determined on 1.000 g of powdered drug (355) by drying in an oven at 105 °C for 2 h.

Total ash (*2.4.16*): maximum 8.0 per cent.

Ash insoluble in hydrochloric acid (*2.8.1*): maximum 2.0 per cent.

ASSAY

Ultraviolet and visible absorption spectrophotometry (*2.2.25*).

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

Test solution. Place 1.000 g of powdered drug (355) in a flask, add 20 mL of *ethanol* (60 per cent *V/V*) *R.* Shake for 30 min and filter into a 50.0 mL volumetric flask. Repeat the operation onto the residue. Dilute to 50.0 mL with *ethanol* (60 per cent *V/V*) *R.* Dilute 4.0 mL of this solution into a 50.0 mL volumetric flask and dilute with *0.05 M sulfuric acid in methanol R*.

Compensation liquid. 0.05 M sulfuric acid in methanol R.

Immediately after the addition of the last reagent, measure the absorbance of the solution at 425 nm, in comparison with the compensation liquid.

Calculate the percentage content of total alkaloids, expressed as berberine, from the expression:

$$\frac{A \times 625}{163 \times m}$$

i.e. taking the specific absorbance of berberine, to be 163.

A = absorbance of the test solution at 425 nm,
m = mass of the sample, in grams.

STOCK

DEFINITION

Barberry mother tincture is prepared with ethanol (55 per cent *V/V*), using the dried root bark, entire or fragmented of *Berberis vulgaris* L.

Adjusted content: minimum 0.10 per cent and maximum 0.30 per cent *m/m* of total alkaloids, expressed as berberine ($C_{20}H_{19}NO_5$; M_r 353.4).

CHARACTERS

Appearance: yellowish-brown to reddish-brown liquid.

PRODUCTION

Method 1.1.10 (2371). Drug fragmented into segments 1-2 cm long. Maceration time: 3-5 weeks.

IDENTIFICATION

Thin-layer chromatography (*2.2.27*).

Test solution. Mother tincture.

Reference solution. Dissolve 20 mg of *berberine chloride R* and 10 mg of *sanguinarine nitrate R* in

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

20 mL of *ethanol (96 per cent) R*.

Plate: *TLC silica gel plate R*.

Mobile phase: *anhydrous formic acid R, water R, ethyl acetate R* (10:10:80 *V/V/V*).

Application: 20 µL as bands.

Development: over a path of 10 cm.

Drying: in air.

Detection A: examine in ultraviolet light at 365 nm.

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

Top of the plate	
	A purplish-blue zone
-----	-----
Berberine (chloride): an intense yellow zone Sanguinarine (nitrate): an orange zone	An intense yellow zone (berberine) A yellow zone
-----	-----
	One to two blue zones
Reference solution	**Test solution**

Detection B: spray with *potassium iodobismuthate solution R*. Examine in daylight.

Results B: 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	
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Berberine (chloride): an orange zone Sanguinarine (nitrate): an orange zone	An orange zone (berberine) An orange zone
-----	-----
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 0.7 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 100.0 mL volumetric flask, place 2.000 g of mother tincture and dilute to 100.0 mL with *0.05 M sulfuric acid in methanol R*.

Compensation liquid. 0.05 M sulfuric acid in methanol R.

Immediately after the addition of the last reagent, measure the absorbance of the solution at 425 nm, in comparison with the compensation liquid.

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

$$\frac{A \times 100}{163 \times m}$$

i.e. taking the specific absorbance of berberine, to be 163.

A = absorbance of the test solution at 425 nm,
m = mass of the mother tincture sample, in grams.

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