

**SIMAROUBA CEDRON
FOR HOMOEOPATHIC PREPARATIONS**

**CEDRON
FOR HOMOEOPATHIC PREPARATIONS**

Simaba cedron ad praeparationes homoeopathicas

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

DEFINITION

Dried cotyledons of the seed of *Simaba cedron* Planch. (*Quassia cedron* Baillon).

Content: minimum 0.15 per cent of quassinoids, expressed as santonin ($C_{15}H_{18}O_3$; M_r 246.3) (dried drug).

CHARACTERS

Macroscopic and microscopic characters described under identification tests A and B.

IDENTIFICATION

- A. Roughly elliptic organs, 3 cm to 5 cm long and 15 mm to 20 mm large. One side is convex the other one is flatter. Yellowish or greyish surface in some places, showing bumps and irregular shapes due to dessiccation. The inside is of a paler yellow.
- B. Reduce simarouba cedron to a powder (355). The powder is light brown. Examine under a microscope using *chloral hydrate solution R*. Numerous fragments of cotyledons composed of round to ovoid cells, with cellulose walls; rare wood vessels with spiral patterns. Examine under a microscope using *glycerol (50 per cent V/V) R*. Numerous starch granules rounded or truncated mostly simple, a few being two to three compounds.
- C. Thin layer chromatography (2.2.27).

Test solution. Add 30 mL of *ethanol (65 per cent V/V) R* to 3 g of the drug properly divided. Heat under a reflux condenser for 15 min. Allow to cool. Filter.

Reference solution. Dissolve 10 mg of *rutin R* and 10 mg of *isoquercitroside R* in 30 mL of *ethanol (96 per cent) R*.

Plate: TLC silica gel plate *R*.

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

Application: 30 μ L, as bands.

Development: over a path of 10 cm.

Drying: in air.

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

Detection: first spray with a 10 g/L solution of *diphenylboric acid aminoethyl ester R* in *methanol R* then with a 50 g/L solution of *macrogol 400 R* in *methanol R*. Allow the plate to dry in air for about 30 min. Examine in ultraviolet light at 365 nm.

Results: 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	
-----	Series of blue zones
Isoquercitroside : an orange zone	An intense blue zone
-----	-----
Rutin : an orange zone	
Reference solution	Test solution

TESTS

Loss on drying (2.2.32): maximum 11.0 per cent, determined on 1.0 g of powdered drug (355), by drying in an oven at 105 °C for 2 h.

Total ash (2.4.15): maximum 3.5 per cent.

ASSAY

Liquid chromatography (2.2.29).

Carry out the test protected from light. Prepare the solutions immediately before use.

Test solution. In a 100 mL round-bottomed flask with a ground glass neck, place 0.500 g of powdered drug (355) and 40 mL of *ethanol* (65 per cent V/V) *R*. Heat under a reflux condenser on a water-bath for 1 h. Allow to separate. Filter the supernatant on a plug of absorbent cotton. Dilute the residue in 40 mL of *ethanol* (65 per cent V/V) *R*, heat again under a reflux condenser on a water-bath for 1 h. Filter, wash the flask and the filter with *ethanol* (65 per cent V/V) *R*, then dilute to 100.0 mL with the same solvent.

Reference solution. In a 100.0 mL volumetric flask, dissolve 14.0 mg of *santonin R* in *ethanol* (65 per cent V/V) *R* and dilute to 100.0 mL with the same solvent. In a 50.0 mL volumetric flask, place 5.0 mL of this solution and dilute to 50.0 mL with *ethanol* (65 per cent V/V) *R*.

Column:

- size: $l = 25$ cm, $\varnothing = 4.6$ mm.
- stationary phase: *octadecylsilyl silica gel for chromatography R* (5 μ m).
- temperature: 30 °C.

Mobile phase:

- mobile phase A: *trifluoroacetic acid* (0.05 per cent V/V) *R*.

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

– mobile phase B: acetonitrile R.

Time (min)	Mobile phase A (per cent V/V)	Mobile phase B (per cent V/V)
0 - 15	90 → 70	10 → 30
15 - 30	70 → 15	30 → 85
30 - 32	15 → 0	85 → 100
32 - 42	0	100
42 - 45	0 → 90	100 → 10
45 - 55	90	10

Flow rate: 1.0 mL/min.

Detection: spectrophotometer at 240 nm.

Injection: 20 µL.

Elution order: retention time of main quassinoids: about 9 min and 11 min. Retention time of santonin about 24 min.

Calculate the percentage content of quassinoids, expressed as santonin, from the expression:

$$\frac{A_1 \times m_2 \times 10}{A_2 \times m_1}$$

A_1 = total areas of the main two peaks corresponding to quassinoids in the chromatogram obtained with the test solution,

A_2 = area of the peak of santonin in the chromatogram obtained with the reference solution,

m_1 = mass of the dried drug sample, in grams,

m_2 = mass of the sample of santonin in the reference solution, in grams.

STOCK

DEFINITION

Simarouba cedron 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 dried cotyledons of the seed of *Simaba cedron* Planch.

Content: minimum 0.010 per cent *m/m* of quassinoids, expressed as santonin ($C_{15}H_{18}O_3$; M_r 246.3).

CHARACTERS

Appearance: yellow liquid.

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 10 mg of *rutin R* and 10 mg of *isoquercitroside R* in 30 mL of *ethanol (96 per cent) R*.

Plate: TLC silica gel plate *R*.

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

Application: 30 µL, as bands.

Development: over a path of 10 cm.

Drying: in air.

Detection: first spray with a 10 g/L solution of *diphenylboric acid aminoethyl ester R* in *methanol R* then with a 50 g/L solution of *macrogol 400 R* in *methanol R*. Allow the plate to dry for about 30 min. Examine in ultraviolet light at 365 nm.

Results: 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	
-----	Series of blue zones
Isoquercitroside : an orange zone	An intense blue zone
-----	-----
Rutin : an orange 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 0.7 per cent *m/m*.

ASSAY

Liquid chromatography (2.2.29).

Test solution. In a 25.0 mL volumetric flask, place 2.000 g of mother tincture and dilute to 25.0 mL with *water R*. Filter.

Reference solution. In a 100.0 mL volumetric flask, dissolve 14.0 mg of *santonin R* in *ethanol (65 per cent V/V) R* and dilute to 100.0 mL with the same solvent. In a 50.0 mL volumetric flask, place

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

5.0 mL of this solution and dilute to 50.0 mL with *ethanol* (65 per cent V/V) R (carry out the test protected from light and inject the solution immediately).

Column:

- size: $l = 25$ cm, $\varnothing = 4.6$ mm.
- stationary phase: *octadecylsilyl silica gel for chromatography R* (5 μ m).
- temperature: 30 °C.

Mobile phase:

- mobile phase A: *trifluoroacetic acid* (0.05 per cent V/V) R.
- mobile phase B: *acetonitrile R*.

Time (min)	Mobile phase A (per cent V/V)	Mobile phase B (per cent V/V)
0 - 15	90 → 70	10 → 30
15 - 30	70 → 15	30 → 85
30 - 32	15 → 0	85 → 100
32 - 42	0	100
42 - 45	0 → 90	100 → 10
45 - 55	90	10

Flow rate: 1.0 mL/min.

Detection: spectrophotometer at 240 nm.

Injection: 20 μ L.

Elution order: retention time of main quassinoids: about 9 min and 11 min. Retention time of *santonin* about 24 min.

Calculate the percentage content m/m of quassinoids, expressed in *santonin*, from the expression:

$$\frac{A_1 \times m_2 \times 2.5}{A_2 \times m_1}$$

A_1 = total areas of the main two peaks corresponding to quassinoids in the chromatogram obtained with the test solution,

A_2 = area of the peak of *santonin* in the chromatogram obtained with the reference solution,

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

m_2 = mass of the sample of *santonin* in the reference solution, in grams.

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