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, 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 dessication. 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.  


Application: 30 µL, 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.  

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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.

<table>
<thead>
<tr>
<th>Top of the plate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>-----</td>
</tr>
<tr>
<td>Isoquercitrose : an orange zone</td>
</tr>
<tr>
<td>-----</td>
</tr>
<tr>
<td>Rutin : an orange zone</td>
</tr>
</tbody>
</table>

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, Ø = 4.6 mm.
– stationary phase: octadecylsilyl silica gel for chromatography R (5 µm).
– 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.

French Pharmacopoeia 2007
-- mobile phase B: acetonitrile R.

<table>
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<tr>
<th>Time (min)</th>
<th>Mobile phase A (per cent V/V)</th>
<th>Mobile phase B (per cent V/V)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 15</td>
<td>90 → 70</td>
<td>10 → 30</td>
</tr>
<tr>
<td>15 - 30</td>
<td>70 → 15</td>
<td>30 → 85</td>
</tr>
<tr>
<td>30 - 32</td>
<td>15 → 0</td>
<td>85 → 100</td>
</tr>
<tr>
<td>32 - 42</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>42 - 45</td>
<td>0 → 90</td>
<td>100 → 10</td>
</tr>
<tr>
<td>45 - 55</td>
<td>90</td>
<td>10</td>
</tr>
</tbody>
</table>

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.
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.


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.

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<td>Isoscutellaria : an orange zone</td>
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<td>Rutin : an orange zone</td>
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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

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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: \( l = 25 \text{ cm}, \; \varnothing = 4.6 \text{ mm} \).
- stationary phase: octadecylsilyl silica gel for chromatography R (5 µm).
- temperature: 30 °C.

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\( m_1 \) = mass of the mother tincture sample, in grams,
\( m_2 \) = mass of the sample of santonin in the reference solution, in grams.