Rhatany root

EUROPEAN PHARMACOPOEIA 5.0

Rhatany root

Ratanhiae radix

DEFINITION
Rhatany root, known as Peruvian rhatany, consists of the dried, usually fragmented, underground organs of Krameria triandra Ruiz and Pavon. It contains not less than 5.0 per cent of tannins, expressed as pyrogallol (C₆H₆O₃; M₁, 126.1), calculated with reference to the dried drug.

CHARACTERS
It has the macroscopic and microscopic characters described under identification tests A and B.

IDENTIFICATION
A. The taproot is dark red-brown and has a thick, knotty crown. The secondary roots are the same colour and nearly straight or somewhat tortuous. The bark is rugged to scaly in the older pieces and smooth with sharp, transverse fissures in the younger pieces; it separates readily from the wood. The fracture is fibrous in the bark and splintery in the wood. The smooth, transversely cut surface shows a dark brown-red bark about one third of the radius in thickness; a dense, pale red-brown and finely porous wood is present with numerous fine medullary rays; the central heartwood is often darker.

B. Reduce to a powder (355). The powder is brown-red. Examine under a microscope using chloral hydrate solution R. The powder shows cork cells containing dark brown phlobaphenes; fragments of un lignified phloem fibres, usually 12 µm to 30 µm in diameter with moderately thick walls; phloem parenchyma cells in files containing prisms and microcrystals of calcium oxalate; fragments of vessels usually 20 µm to 60 µm in diameter with bordered pits; fragments of tracheids up to 20 µm wide with slit-shaped pits. Examine under a microscope using a 50 per cent V/V solution of glycerol R. The powder shows rounded starch granules, simple or two-to-four compound, an individual granule measuring up to 30 µm in diameter and some granules being found in the cells of the medullary rays and in the parenchyma.

C. Examine by thin-layer chromatography (2.2.27), using a TLC silica gel plate R.

Test solution. To 1.0 g of the powdered drug (355) add 10 ml of a mixture of 3 volumes of water R and 7 volumes of alcohol R, shake for 10 min and filter. To the filtrate add 10 ml of light petroleum R and shake. Separate the light petroleum layer, add 2 g of anhydrous sodium sulphate R, shake and filter. Evaporate the filtrate to dryness. Dissolve the residue in 0.5 ml of methanol R.

Reference solution. Dissolve 5.0 mg of Sudan red G R in 10 ml of methanol R. Apply to the plate as bands 10 µl of each solution. Develop over a path of 15 cm using a mixture of 2 volumes of ethyl acetate R and 98 volumes of toluene R. Allow the plate to dry in air and spray the plate with a 5 g/l solution of fast blue B salt R. Allow the plate to dry in air and spray the plate with 0.1 M ethanolic sodium hydroxide. Examine in daylight. The chromatogram obtained with the reference solution shows in the lower third a red zone due to Sudan red G. The chromatogram obtained with the test solution shows a violet zone due to rhatany phenol I similar in position to the zone of Sudan red G in the chromatogram obtained with the reference solution, below it the brownish zone due to rhatany phenol II and below it the bluish-grey zone due to rhatany phenol III. Further zones may be present.

TESTS

Extractable matter: minimum 15.0 per cent.

To 2.00 g of the powdered drug (250) add a mixture of 8 g of water R and 12 g of alcohol R and allow to macerate for 2 h, shaking frequently. Filter, evaporate 5 g of the filtrate to dryness on a water-bath and dry at 100-105 °C for 2 h. The residue weighs a minimum of 75 mg.

Foreign matter (2.8.2). It complies with the test for foreign matter.

Loss on drying (2.2.32): maximum 10.0 per cent, determined on 1.000 g of the powdered drug (355) by drying in an oven at 100-105 °C for 2 h.

Total ash (2.4.16): maximum 8.0 per cent.

01/2005:0289

RHATANY TINCTURE

Ratanhiae tinctura

DEFINITION
Tincture produced from Rhatany root (0289).

Content: minimum 1.0 per cent m/m of tannins, expressed as pyrogallol (C₆H₆O₃; M₁, 126.1).

PRODUCTION
The tincture is produced from 1 part of the drug and 5 parts of ethanol (70 per cent V/V) by a suitable procedure.

CHARACTERS

Appearance: reddish-brown liquid.

IDENTIFICATION
Thin-layer chromatography (2.2.27).

01/2005:1888
**Test solution.** To 5 ml of the tincture to be examined, add 10 ml of light petroleum R and shake. Separate the light petroleum layer, add 2 g of anhydrous sodium sulphate R, shake and filter. Evaporate the filtrate to dryness. Dissolve the residue in 0.5 ml of methylene chloride R.

**Reference solution.** Dissolve 5 mg of thymol R and 10 mg of dichlorophenolindophenol, sodium salt R in 10 ml of alcohol (60 per cent V/V) R.

**Plate:** TLC silica gel plate R.

**Mobile phase:** methylene chloride R.

**Application:** 10 µl, as bands.

**Development:** over a path of 10 cm.

**Drying:** in air.

**Detection:** spray with a 5 g/l solution of fast blue B salt R; allow the plate to dry in air and spray with 0.1 M ethanolic sodium hydroxide; examine in daylight.

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

<table>
<thead>
<tr>
<th>Top of the plate</th>
<th>Reference solution</th>
<th>Test solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thymol: an orange brownish-yellow zone</td>
<td>A violet zone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>A greenish-grey zone</td>
<td>A bluish-grey zone</td>
</tr>
<tr>
<td></td>
<td>A yellowish-brown zone</td>
<td>A violet zone</td>
</tr>
<tr>
<td>Dichlorophenolindophenol: a greyish-blue zone</td>
<td>Reference solution</td>
<td>Test solution</td>
</tr>
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**TESTS**

**Ethanol (2.9.10):** 63 per cent V/V to 67 per cent V/V.

**Methanol and 2-propanol (2.9.11):** maximum 0.05 per cent V/V of methanol and maximum 0.05 per cent V/V of 2-propanol.

**ASSAY**

Carry out the determination of tannins in herbal drugs (2.8.14) using 2.500 g of the tincture to be examined.

**Rhubarb**

**DEFINITION**

Rhubarb consists of the whole or cut, dried underground parts of *Rheum palmatum* L. or of *Rheum officinale* Baillon or of hybrids of these two species or of a mixture. The underground parts are often divided; the stem and most of the bark with the rootlets are removed. It contains not less than 2.2 per cent of hydroxyanthracene derivatives, expressed as rhein (C_{15}H_{8}O_{6}, M, 284.2), calculated with reference to the dried drug.

**CHARACTERS**

Rhubarb has a characteristic, aromatic odour. It has the macroscopic and microscopic characters described under identification tests A and B.

**IDENTIFICATION**

A. The appearance is variable: disc-shaped pieces up to 10 cm in diameter and 1 cm to 5 cm in thickness; cylindrical pieces; oval or planoconvex pieces. The surface has a pinkish tinge and is usually covered with a layer of brownish-yellow powder. It shows, especially after moistening, a reticulum of darker lines. This structure causes the marbled appearance of the drug. The fracture is granular. The transverse section of the rhizome shows a narrow outer zone of radiating brownish-red lines. These medullary rays are crossed perpendicularly by a dark cambial ring. Inside this zone is a ring of small star-spot formations of anomalous vascular bundles. The root shows a more radiate structure.

B. Reduce to a powder (355). The powder is orange to brownish-yellow. Examine under a microscope using chloral hydrate solution R. The powder shows the following diagnostic characters: large calcium oxalate cluster crystals, which may measure more than 100 µm, and their fragments; reticulately thickened non-lignified vessels measuring up to 175 µm. Numerous groups of rounded or polygonal, thin-walled parenchyma cells. Sclereids and fibres are absent. Examine under a microscope using a 50 per cent V/V solution of glycerol R. The powder shows simple, rounded or compound (2 to 4) starch granules with a star-shaped hilum.

C. Examine by thin-layer chromatography (2.2.27), using a suitable silica gel as the coating substance.

**Test solution.** Heat 50 mg of the powdered drug (180) in a water-bath for 15 min with a mixture of 1 ml of hydrochloric acid R and 30 ml of water R. Allow to cool and shake the liquid with 25 ml of ether R. Dry the ether layer over anhydrous sodium sulphate R and filter. Evaporate the ether layer to dryness and dissolve the residue in 0.5 ml of ether R.

**Reference solution.** Dissolve 5 mg of emodin R in 5 ml of ether R.

Apply separately to the plate as bands 20 µl of each solution. Develop over a path of 10 cm using a mixture of 1 volume of anhydrous formic acid R, 25 volumes of ethyl acetate R and 75 volumes of light petroleum R. Allow the plate to dry in air and examine in ultraviolet light at 365 nm. The chromatogram obtained with the reference solution shows in its central part a zone of orange fluorescence (emodin). The chromatogram obtained with the test solution shows: a zone due to emodin; above the emodin zone, two zones of similar fluorescence (physcione and chrysophanol, in order of decreasing Rf value); below the emodin zone, also two zones of similar fluorescence (rhein and aloemodin, in order of decreasing Rf value). Spray with a 100 g/l solution of potassium hydroxide R in methanol R. All the zones become red to violet.

D. To about 50 mg of the powdered drug (180) add 25 ml of dilute hydrochloric acid R and heat the mixture on a water-bath for 15 min. Allow to cool, shake with 20 ml of ether R and discard the aqueous layer. Shake the ether layer with 10 ml of dilute ammonia R1. The aqueous layer becomes red to violet.

**TESTS**

**Rheum rhapsanicum.** Examine by thin-layer chromatography (2.2.27), using silica gel G R as the coating substance.

**Test solution.** To 0.2 g of the powdered drug (180) add 2 ml of methanol R and boil for 5 min under a reflux condenser. Allow to cool and filter. Use the filtrate as the test solution.