Podophyllin

Podophyllin

Details for the public consultation of this monograph are as follows:

<table>
<thead>
<tr>
<th>EAG/Panel/Working Party</th>
<th>Herbal and Complementary Medicines</th>
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<tbody>
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<td>BP 2025</td>
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<td>Notes</td>
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<td>If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required.</td>
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<td>Definition Amended</td>
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Action and use

Used in treatment of warts.

Preparation

Compound Podophyllin Paint

DEFINITION

Podophyllin Resin is the resin obtained from rhizomes and roots of Podophyllum hexandrum Royle (P. emodi Wall) or Podophyllum peltatum L. The resin obtained from P. hexandrum contains not less than 50.0% and not more than 60.0% of total aryltetralin lignans, calculated as podophyllotoxin. The resin obtained from P. peltatum contains not less than 14.0% and not more than 18.0% of total aryltetralin lignans, calculated as podophyllotoxin.

CHARACTERISTICS

An amorphous powder varying in colour from light brown to greenish yellow, or brownish grey masses; odour, characteristic; caustic.

Partly soluble in hot water, from which it is precipitated on cooling, in chloroform, in ether and in 5M ammonia.

IDENTIFICATION

Carry out the method for thin-layer chromatography, Appendix III A, using the following solutions in methanol.
(1) 1% w/v of the substance being examined.
(2) 0.5% w/v of podophyllotoxin.
(3) 0.1% w/v of phenazone.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating silica gel GF₂₅₄.
(b) Use the mobile phase as described below.
(c) Apply as bands 10 µL of each solution.
(d) Develop the plate to 10 cm.
(e) After removal of the plate, allow it to dry in air and examine under ultraviolet light (254 nm). Spray the plate with methanolic sulfuric acid (50%) and heat at 130° for 10 minutes.

MOBILE PHASE

1 volume of methanol and 25 volumes of chloroform.

CONFIRMATION

P. hexandrum

When viewed under ultraviolet light (254 nm), the chromatogram obtained with solution (1) exhibits quenching zones corresponding in position to the principal quenching zones in the chromatograms obtained with solutions (2) and (3). Other quenching zones may be present.

When viewed after spraying, the chromatogram obtained with solution (1) exhibits a purplish zone (podophyllotoxin) corresponding in position and colour to the principal zone in solution (2) and a purplish zone (4′-demethylpodophyllotoxin) corresponding in position to the quenching zone found in solution (3). Other coloured zones may be present.

P. peltatum

When viewed under ultraviolet light (254 nm), the chromatogram obtained with solution (1) exhibits a quenching zone corresponding in position to the principal quenching zone in the chromatogram obtained with solution (2) and two quenching zones above this, at about Rf 0.3 to 0.5. Other quenching zones may be present.

When viewed after spraying, the chromatogram obtained with solution (1) exhibits a purplish zone (podophyllotoxin) corresponding in position and colour to the principal zone in solution (2) and two greyish zones (peltatins) above this, at about Rf 0.3 to 0.5. Other coloured zones may be present.

Visualisation under UV light (254 nm):

<table>
<thead>
<tr>
<th>Top of the plate</th>
</tr>
</thead>
<tbody>
<tr>
<td>A quenching zone</td>
</tr>
<tr>
<td>A quenching zone</td>
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</table>
Visualisation under white light after spraying:

<table>
<thead>
<tr>
<th>Top of the plate</th>
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</thead>
<tbody>
<tr>
<td>Reference solution</td>
</tr>
<tr>
<td>A greyish zone</td>
</tr>
<tr>
<td>A purplish zone</td>
</tr>
</tbody>
</table>

**TESTS**

**Matter insoluble in ethanol (96%)**

Shake 1 g, finely powdered, with 20 mL of ethanol (96%) for 5 minutes, filter through a sintered-glass crucible (ISO 4793, porosity grade 2, is suitable), wash the filter with ethanol (96%) and dry at 105°. The residue weighs not more than 25 mg.

**Matter insoluble in 5M ammonia**

Shake 0.5 g, finely powdered, with 30 mL of 5M ammonia for 30 minutes at about 20°; filter through a sintered-glass crucible (ISO 4793, porosity grade 2, is suitable) and wash the flask and filter with 30 mL of water; the time taken for filtering and washing being not more than 10 minutes. Dry the filter and residue to constant weight at 105°. The residue weighs not less than 0.18 g and not more than 0.30 g.

**Loss on drying**

When dried to constant weight at 105°, loses not more than 5.0% of its weight. Use 1 g.

**Sulfated ash**

Not more than 1.0%, Appendix IX A.
ASSAY

Dissolve 0.5 g in sufficient ethanol (96%) to produce 100 mL. To 10 mL of this solution in a separating funnel add 190 mL of water and extract with six 30-mL quantities of dichloromethane. Combine the dichloromethane layers, extract with 10 mL of 0.2M sodium hydroxide followed by five 10-mL quantities of water and wash each of the six aqueous layers separately with the same 20-mL quantity of dichloromethane. Combine the dichloromethane solutions, filter through absorbent cotton and evaporate the filtrate to dryness. Dissolve the residue in sufficient ethanol (96%) to produce 100 mL, dilute 10 mL of this solution to 50 mL with ethanol (96%) and measure the absorbance of the resulting solution at the maximum at 292 nm, Appendix II B. Calculate the content of total aryltetralin lignans expressed as podophyllotoxin, taking 105.4 as the value of A (1%, 1 cm) at the maximum at 292 nm.

STORAGE

Podophyllum Resin should be protected from light. On exposure to light, or to temperatures above 25°, it becomes darker in colour.

LABELLING

The label states the botanical source.