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# Podophyllum Resin

General Notices

Podophyllin

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

| EAG/Panel/Working Party | Herbal and Complementary Medicines |
|---|---|
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| **Deadline for Comment** | 31st March 2025 |
| **Target Publication Date (subject to change)** | BP 2026 |
| **Notes** | Revised monograph<br>If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required.<br>**T: Identification** amended to replace chloroform and include HPTLC |

**Action and use**

Treatment of warts.

**Preparation**

Compound Podophyllin Paint

## DEFINITION

Podophyllum Resin is the resin obtained from rhizomes and roots of *Podophyllum hexandrum* Royle (*P. emodi* Wall) or *Podophyllum peltatum* L.

**Content**

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.

## CHARACTERS

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 *ether* and in 5M *ammonia*.

## IDENTIFICATION

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions in *methanol*. Alternatively, the method can be carried out using High-Performance Thin-Layer Chromatography, Appendix XI W, using the following solutions in *methanol*.

(1) 1% w/v of the substance being examined.
(2) 0.5% w/v of *podophyllotoxin EPCRS*.
(3) 0.1% w/v of *phenazone*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a TLC silica gel plate (5-40 µm) [or TLC silica gel plate (2-10 µm)].
(b) Use the mobile phase as described below.
(c) Apply as bands 10 µL of each solution.
(d) Develop the plate to 10 cm [or for HPTLC 7 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 *dichloromethane*.

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 and heating, 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 and heating, 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):

| Top of the plate | | |
|---|---|---|
| ------- | ------- | ------- |
| | | A quenching zone |
| | | A quenching zone |
| Podophyllotoxin: a quenching zone | A quenching zone | |
| ------- | ------- | ------- |
| Phenazone: a quenching zone | A quenching zone | |
| **Reference solution** | **Test solution (solutions containing *P. hexandrum*)** | **Test solution (solutions containing *P. peltatum*)** |

Visualisation under white light after spraying and heating:

| Top of the plate | | |
|---|---|---|
| ------- | ------- | ------- |
| | | A greyish zone |
| | | A greyish zone |
| Podophyllotoxin: a purplish zone | A purplish zone | A purplish zone |
| ------- | ------- | ------- |
| Phenazone: a purplish zone | A purplish zone | |
| **Reference solution** | **Test solution (solutions containing *P. hexandrum*)** | **Test solution (solutions containing *P. peltatum*)** |



## 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 (2.5%).

**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 from the resin of *P. hexandrum* weighs not less than 0.18 g and not more than 0.30 g (36 to 60%); the residue from the resin of *P. peltatum* weighs not more than 50 mg (10%).

### 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.