

Compound Podophyllin Paint

Compound Podophyllin Cutaneous Solution

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

EAG/Panel/Working Party	Herbal and Complementary Medicines
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Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. Definition Amended Identification Amended Total solids Amended

DEFINITION

Compound Podophyllin Paint is a *cutaneous solution* of Podophyllum Resin in [Compound Benzoin Tincture](#).

In making the [Compound Benzoin Tincture](#) used to prepare Compound Podophyllin Paint, the Ethanol (90 per cent) may be replaced by Industrial Methylated Spirit¹ diluted so as to be of equivalent ethanolic strength.

The paint complies with the requirements stated under Liquids for Cutaneous Application and with the following requirements.

IDENTIFICATION

Carry out the method for [thin-layer chromatography, Appendix III A](#), using the following solutions in [methanol](#).

- (1) 7% v/v of the paint.
- (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 10 µL of each solution.
- (d) Develop the plate to 10 cm.

(e) After removal of the plate, dry in air and examine under [ultraviolet light \(254 nm\)](#) to locate the quenching zone due to phenazone in solution (3). 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

Solutions manufactured using resin from 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.

Solutions manufactured using resin from 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 (pelatins) 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		
----- Podophyllotoxin: a quenching zone ----- Phenazone: a quenching zone	----- A quenching zone ----- A quenching zone	----- A quenching zone ----- A quenching zone
Reference solution	Test solution (solutions containing <i>P. hexandrum</i>)	Test solution (solutions containing <i>P. peltatum</i>)

Visualisation under white light after spraying:

Top of the plate		
<p>-----</p> <p>Podophyllotoxin: a purplish zone</p> <p>-----</p> <p>Phenazone: a purplish zone</p>	<p>-----</p> <p>A purplish zone</p> <p>-----</p> <p>A purplish zone</p>	<p>-----</p> <p>A greyish zone</p> <p>A greyish zone</p> <p>A purplish zone</p> <p>-----</p>
Reference solution	Test solution (solutions containing <i>P. hexandrum</i>)	Test solution (solutions containing <i>P. peltatum</i>)

TESTS

Weight per mL

0.925 to 0.975 g, [Appendix V G](#).

Total solids

The total solids, when determined by evaporating 1 mL to dryness on a water bath and drying the residue at 105° for 4 hours, fall within the range (declared amount of podophyllum + 12.0) to (declared amount of podophyllum + 19.0) % w/v.

¹ The law and the statutory regulations governing the use of Industrial Methylated Spirit must be observed.