



Edition: BP 2025 (Ph. Eur. 11.6 update)

Levomenthol Cream

[General Notices](#)

Menthol in [Aqueous Cream](#)

NOTE: This monograph has been developed to cover unlicensed formulations.

DEFINITION

Levomenthol Cream contains Levomenthol in [Aqueous Cream](#).

The cream complies with the requirements stated under [Topical Semi-solid Preparations](#) and with the following requirements. Where appropriate, the cream also complies with the requirements stated under [Unlicensed Medicines](#).

Content of levomenthol, $C_{10}H_{20}O$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

In the Assay, the chromatogram obtained with solution (2) shows a peak with the same retention time as the peak due to levomenthol in the chromatogram obtained with solution (3).

ASSAY

Carry out the method for [gas chromatography](#), [Appendix III B](#), using the following freshly prepared solutions.

- (1) 0.1% w/v of [camphor](#) (internal standard) in [industrial methylated spirit \(95%\)](#).
- (2) Disperse a quantity of the well-mixed cream containing 50 mg of Levomenthol in 20 mL of [industrial methylated spirit \(95%\)](#) and mix with the aid of ultrasound for 15 minutes. Transfer the liquid contents to a 50 mL graduated flask, rinse the original flask with two 10-mL quantities of [industrial methylated spirit \(95%\)](#), transfer the washings to the graduated flask and add sufficient [industrial methylated spirit \(95%\)](#) to produce 50 mL; mix well and filter (Whatman No. 1 paper is suitable) discarding the first 5 mL of filtrate. Add 10 mL of solution (1) to 10 mL of the filtrate and add sufficient [industrial methylated spirit \(95%\)](#) to produce 25 mL; mix well.
- (3) Mix 5 mL of a 0.2% w/v solution of [levomenthol BPCRS](#) in [industrial methylated spirit \(95%\)](#) with 10 mL of solution (1) and dilute to 25 mL with [industrial methylated spirit \(95%\)](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a fused silica column (10 m × 0.53 mm) bonded with a 0.25-µm layer of dimethylpolysiloxane.
- (b) Use [helium](#) as the carrier gas.
- (c) Use the gradient conditions described below.
- (d) Use an inlet temperature of 250°.
- (e) Use a flame ionisation detector at a temperature of 250°.
- (f) Inject 1 µL of each solution.

Time (Minutes)	Temperature	Comment
0 → 1	90°	isothermal
1 → 5	90° → 230°	linear gradient
5 → 9	230°	isothermal

When the chromatograms are recorded under the prescribed conditions the retention times are: levomenthol, about 2.1 minutes; camphor, about 2 minutes.

DETERMINATION OF CONTENT

Calculate the content of $C_{10}H_{20}O$ in the cream using the declared content of $C_{10}H_{20}O$ in [*levomenthol BPCRS*](#).