



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

Diethylamine Salicylate Cream

[General Notices](#)

DEFINITION

Diethylamine Salicylate Cream is a dispersion of Diethylamine Salicylate in a suitable basis.

The cream complies with the requirements stated under Topical Semi-solid Preparations and with the following requirements.

Content of diethylamine salicylate, $C_{11}H_{17}NO_3$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

- A. To 5 g add 50 mL of 2M [sodium hydroxide](#), shake well and filter. Acidify 30 mL of the filtrate with [2M hydrochloric acid](#), cool and allow to stand. The [infrared absorption spectrum](#) of the resulting precipitate, after recrystallisation from [water](#) and drying at 105°, [Appendix II A](#), is concordant with the *reference spectrum* of salicylic acid ([RS 316](#)).
- B. To 5 mL of the filtrate obtained in test A, add 10 mL of [water](#) and 0.05 mL of [iron\(III\) chloride solution R1](#). A deep violet colour is produced.
- C. Mix 3 g with 25 mL of [chloroform](#) and shake with 20 mL of 0.1M [hydrochloric acid](#). To the acidic layer add 10 mL of 2M [sodium hydroxide](#) and boil. Diethylamine vapour is evolved, which turns moist [red litmus paper](#) blue.

ASSAY

To a quantity containing 50 mg of diethylamine salicylate add 30 mL of 0.5M [sodium hydroxide](#) and 15 mL of [ethanol \(96%\)](#), mix, heat under a reflux condenser for 30 minutes and cool. To the resulting mixture add 20 mL of 1M [hydrochloric acid](#), mix, dilute to 250 mL with [water](#) and filter. Shake 15 mL of the filtrate with 25 mL of [chloroform](#) for 2 minutes. To 5 mL of the chloroform layer add 10 mL of [iron\(III\) nitrate solution](#) and shake for 5 minutes. Centrifuge the aqueous layer and measure the [absorbance](#) at the maximum at 530 nm, [Appendix II B](#), using [iron\(III\) nitrate solution](#) in the reference cell. Calculate the content of salicylate as salicylic acid, $C_7H_6O_3$, from the [absorbance](#) obtained by repeating the operation using 15 mL of a 0.013% w/v solution of [salicylic acid](#) in 0.02M [hydrochloric acid](#), beginning at the words 'Shake 15 mL...'. Each g of salicylic acid is equivalent to 1.530 g of $C_{11}H_{17}NO_3$.