



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

Benzydamine Cream

[General Notices](#)

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Benzydamine Cream contains Benzydamine Hydrochloride in a suitable basis.

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

Content of benzydamine hydrochloride, $C_{19}H_{23}N_3O \cdot HCl$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

A. Heat a quantity of the cream containing 25 mg of Benzydamine Hydrochloride with 50 mL of [absolute ethanol](#) until the cream is completely dissolved and place in an ice-bath until a white precipitate forms. Allow to warm to 20°, dilute to 100 mL with [absolute ethanol](#) and filter. Dilute 10 mL of the filtrate to 100 mL with [absolute ethanol](#). The [light absorption](#) of the resulting solution, [Appendix II B](#), in the range 230 to 350 nm exhibits a maximum at 308 nm.

B. In the test for 1-Benzyl-1H-indazol-3-ol, the principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

TESTS

1-Benzyl-1H-indazol-3-ol

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

(1) Extract a quantity of the cream containing 60 mg of Benzydamine Hydrochloride with 25 mL of hot [methanol](#), cool the solution in ice and filter; repeat the extraction twice, filtering each extract and evaporate the combined extracts to dryness using a rotary evaporator; dissolve the residue in 5 mL of [methanol](#).

(2) 1.2% w/v of [benzydamine hydrochloride BPCRS](#).

(3) 0.0024% w/v of [1-benzyl-1H-indazol-3-ol BPCRS](#).

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating [silica gel GF₂₅₄](#).

(b) Use the mobile phase as described below.

(c) Apply 40 µL of each solution.

(d) Develop the plate to 15 cm.

(e) After removal of the plate, dry in air and examine under [ultraviolet light \(254 nm and 365 nm\)](#).

MOBILE PHASE

30 volumes of [triethylamine](#) and 80 volumes of [toluene](#).

LIMITS

By each method of visualisation, any [secondary spot](#) in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (3) (0.2%).

ASSAY

To a quantity of the cream containing 25 mg of Benzydamine Hydrochloride add 50 mL of [ethanol \(96%\)](#), heat until the cream is completely dissolved and cool in an ice-bath until a white precipitate forms. Allow to warm to 20°, dilute to 100 mL with [ethanol \(96%\)](#) and filter. Dilute 10 mL of the filtrate to 100 mL with [ethanol \(96%\)](#) and measure the [absorbance](#) of the resulting solution at the maximum at about 308 nm, [Appendix II B](#), using [ethanol \(96%\)](#) in the reference cell. Calculate the content of $C_{19}H_{23}N_3O, HCl$ from the [absorbance](#) obtained with a solution containing 0.0025% w/v of [benzydamine hydrochloride BPCRS](#) in [ethanol \(96%\)](#) and using the declared content of $C_{19}H_{23}N_3O, HCl$ in [benzydamine hydrochloride BPCRS](#).