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

Benzydamine Oromucosal Spray

General Notices

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Benzydamine Oromucosal Spray is a solution of Benzydamine Hydrochloride in a suitable flavoured vehicle in a suitable metered-dose container.

The oromucosal spray complies with the requirements stated under Oromucosal Preparations and with the following requirements.

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

92.5 to 107.5% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Dilute the oromucosal spray, if necessary, with *absolute ethanol* to contain 0.15% w/v of Benzydamine Hydrochloride.
(2) 0.15% w/v of *benzydamine hydrochloride BPCRS* in *absolute ethanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a *TLC silica gel F_{254} precoated plate* (Merck silica gel 60 F_{254} plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 50 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)*.

MOBILE PHASE

30 volumes of *triethylamine* and 80 volumes of *toluene*.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).

TESTS

Acidity or alkalinity

5.0 to 7.0, Appendix V L.

Uniformity of weight

Weigh one unit. Fire one shot and reweigh the unit. Repeat four times, then repeat the entire process with 3 more units (20 shots). Determine the average weight delivered per shot. Not more than two of the individual weights deviate from the average weight by more than 10% and none deviates by more than 20%.

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

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Extract a quantity of the oromucosal spray containing 15 mg of Benzydamine Hydrochloride with seven 90-mL quantities of *chloroform*. Filter each extract through phase separating paper, evaporate the combined extracts to dryness and dissolve the residue in 10 mL of *methanol*.
(2) 0.0015% w/v of *1-benzyl-1*H*-indazol-3-ol BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a *TLC silica gel F_{254} plate*.
(b) Use the mobile phase as described below.
(c) Apply 20 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 (365 nm)*.

MOBILE PHASE

10 volumes of *glacial acetic acid*, 20 volumes of *chloroform* and 70 volumes of *cyclohexane*.

LIMITS

Any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (1%).

ASSAY

Carry out the method for *gas chromatography*, Appendix III B using the following solutions. Prepare a 0.075% w/v solution of *1-benzyl-3-(3-diethylamino-propoxy)-1*H*-indazole BPCRS* (internal standard) in *water* (solution A).

(1) Add 10 mL of solution A, 5 mL of *water*, 5 mL of 1M *sodium hydroxide* and 20 mL of *chloroform* to a quantity of the oromucosal spray containing 7.5 mg of Benzydamine Hydrochloride, diluted, if necessary to 5 mL with *water*, shake for 5 minutes, centrifuge and use the chloroform layer.
(2) Prepare solution (2) in the same manner as solution (1) but using 5 mL of solution containing 0.15% w/v of *benzydamine hydrochloride BPCRS* in *water* in place of a quantity of the oromucosal spray containing 7.5 mg of Benzydamine Hydrochloride, diluted, if necessary, to 5 mL with *water*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a glass column (2 m × 2 mm) packed with *acid-washed, diatomaceous support* (80 to 100 mesh) coated with 3% w/w of phenyl methyl silicone fluid (50% phenyl) (OV-17 is suitable).
(b) Use *nitrogen for chromatography* as the carrier gas at 30 mL per minute.
(c) Use isothermal conditions maintained at 260°.
(d) Use an inlet temperature of 300°.
(e) Use a flame ionisation detector at 300°.
(f) Inject 1 µL of each solution.

DETERMINATION OF CONTENT

Calculate the content of $C_{19}H_{23}N_3O$,HCl from the chromatograms obtained using the declared content of $C_{19}H_{23}N_3O$,HCl in *benzydamine hydrochloride BPCRS*.