



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

## Beclometasone Aqueous Nasal Spray

### [General Notices](#)

Beclometasone Nasal Spray

### Action and use

Glucocorticoid.

### DEFINITION

Beclometasone Aqueous Nasal Spray is an aqueous suspension of either Beclometasone Dipropionate or Beclometasone Dipropionate Monohydrate in a suitable container fitted with an appropriate nasal delivery system.

*The liquid nasal spray complies with the requirements stated under Nasal Preparations and with the following requirements.*

### Content of beclometasone dipropionate, $C_{28}H_{37}ClO_7$

80.0 to 120.0% of the amount stated to be delivered by actuation of the valve.

### IDENTIFICATION

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

- (1) Evaporate a quantity of the nasal spray containing the equivalent of 0.5 mg of beclometasone dipropionate to dryness and dissolve the residue in 0.5 mL of [acetone](#).
- (2) 0.1% w/v of [beclometasone dipropionate BPCRS](#) in [acetone](#).

#### CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

#### 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 principal peak in the chromatogram obtained with solution (1) corresponds to the peak due to beclometasone dipropionate in the chromatogram obtained with solution (2).

### TESTS

#### Related substances

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

- (1) Evaporate a quantity of the nasal spray containing the equivalent of 0.5 mg of beclometasone dipropionate to dryness and dissolve the residue in 2 mL of [acetone](#). Evaporate the solution to a volume such that the whole solution can be applied to the plate.
- (2) 0.1% w/v of [beclometasone dipropionate BPCRS](#).
- (3) Dilute 1 volume of solution (2) to 2 volumes.
- (4) Dilute 1 volume of solution (2) to 4 volumes.

#### CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating [silica gel](#).
- (b) Use the mobile phase described below.
- (c) Apply separately to the plate the whole of solution (1) and 10 µL of each of solutions (2), (3) and (4).
- (d) Develop the plate to 15 cm.
- (e) After removal of the plate, allow it to dry in air, spray with [alkaline tetrazolium blue solution](#) and heat at 50° for 5 minutes. Cool and spray again with [alkaline tetrazolium blue solution](#).

#### MOBILE PHASE

3 volumes of [methanol](#) and 97 volumes of [1,2-dichloroethane](#).

#### LIMITS

In the chromatogram obtained with solution (1):

any [secondary spot](#) is not more intense than the spot in the chromatogram obtained with solution (2) (2%);

not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3) (1%);

not more than two such spots are more intense than the spot in the chromatogram obtained with solution (4) (0.5%).

Disregard any spot with an R<sub>f</sub> value of more than 0.85.

## ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions.

- (1) Discharge the container a sufficient number of times to obtain the equivalent of 0.5 mg of beclometasone dipropionate, add 30 mL of mobile phase, mix with the aid of ultrasound, dilute to 50 mL with mobile phase and filter. Dilute 3 volumes of this solution to 20 volumes with the mobile phase.
- (2) 0.00015% w/v of [beclometasone dipropionate BPCRS](#) in the mobile phase.
- (3) 0.00015% w/v each of [testosterone propionate BPCRS](#) and [beclometasone dipropionate BPCRS](#) in the mobile phase.

#### CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (10 cm × 4.6 mm) packed with [octadecylsilyl silica gel for chromatography](#) (5 µm) (Spherisorb ODS 1 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 2 mL per minute.
- (d) Use a column temperature of 50°.
- (e) Use a detection wavelength of 239 nm.
- (f) Inject 20 µL of each solution.

#### MOBILE PHASE

30 volumes of [water](#) and 70 volumes of [methanol](#).

#### SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the two principal peaks is at least 2.0.

#### DETERMINATION OF CONTENT

<https://nhathuocngocanh.com/bp/>

Calculate the average content of  $C_{28}H_{37}ClO_7$  delivered by a single actuation of the valve using the declared content of  $C_{28}H_{37}ClO_7$  in [\*beclometasone dipropionate BPCRS\*](#).

## **LABELLING**

The quantity of active ingredient is stated in terms of the equivalent amount of beclometasone dipropionate.