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

Glycopyrronium Bromide Oral Solution

General Notices

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

Action and use

Anticholinergic.

DEFINITION

Glycopyrronium Bromide Oral Solution is a solution of Glycopyrronium Bromide in a suitable flavoured vehicle.

The oral solution complies with the requirements stated under Oral Liquids and with the following requirements. Where appropriate, the oral solution also complies with the requirements stated under Unlicensed Medicines.

Content of glycopyrronium bromide, $C_{19}H_{28}BrNO_3$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions in *water*.
(1) Dilute a volume of the oral solution, if necessary, to produce a solution containing 0.01% w/v of Glycopyrronium Bromide.
(2) 0.01% w/v of *glycopyrronium bromide BPCRS*.
(3) Equal volumes of solutions (1) and (2).

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel* (Merck silica gel 60 plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 30 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air, spray with a solution containing 10 volumes of *potassium iodide solution*, 10 volumes of *potassium iodobismuthate solution*, 12 volumes of *glacial acetic acid* and 67 volumes of *water*.

MOBILE PHASE

20 volumes of *glacial acetic acid*, 20 volumes of *water* and 60 volumes of *butan-1-ol*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (3) appears as a single, compact spot.

CONFIRMATION

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

B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the principal peak in the chromatogram obtained with solution (2).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in the mobile phase.

(1) Dilute a quantity of the oral solution, if necessary, to produce a solution containing 0.01% w/v of Glycopyrronium Bromide.
(2) 0.01% w/v of *glycopyrronium bromide BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (3 µm) (Inertsil ODS-3 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 215 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

Dissolve 0.25 g of *sodium heptanesulfonate* in 615 mL of a 0.163% w/v solution of *anhydrous sodium sulfate*; add 3 mL of a 0.515% w/v solution of *sulfuric acid*, 150 mL of *methanol R2* and 235 mL of *acetonitrile R1*.

SYSTEM SUITABILITY

The Assay is not valid unless the *symmetry factor* of the principal peak in the chromatogram obtained with solution (2) is between 0.8 and 2.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{19}H_{28}BrNO_3$ in the oral solution using the declared content of $C_{19}H_{28}BrNO_3$ in *glycopyrronium bromide BPCRS*.

STORAGE

Glycopyrronium Bromide Oral Solution should be protected from light.