Glycopyrronium Bromide Solution – BP 2023

These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for the Identification test for Glycopyrronium Bromide Solution by Thin Layer Chromatography as published in BP 2023.

1	Blank
2 & 3	0.01 % w/v Glycopyrronium bromide sample solutions
4	0.01 % w/v Glycopyrronium bromide standard solutions

TLC plate	Merck TLC silica gel 60 F254 (20 cm × 20 cm)
Plate preconditioning	Pre-heat at 110 °C for 10 minutes
Diluent	Water
Mobile Phase	Glacial acetic acid : water : butan-1-ol (20:20:60, v/v/v)
Mobile Phase volume	100 mL
Band application	3 mm band size with a spotting volume of 30 µL
Chamber saturation	Minimum 60 minutes at room temperature
Development	150 mm
Development time	240 minutes
Drying time	10 minutes in air
Derivatisation	Sprayed with a mixture of potassium iodide solution: potassium iodobismuthate solution : glacial acetic acid : water (10: 10: 12 : 67, v/v/v/v)
Visualisation	Derivatised plates were visualised under white light

Typical chromatogram for solution (4) in the Related substances test for Glycopyrronium Bromide Solution monograph as published in BP 2023.

Peak ID: 1: Benzaldehyde. 2: Glycopyrronium.

Column	Inertsil ODS-3 C18 (150 mm x 4.6 mm, 3 µm)
Method Ref.	Related substances for the Glycopyrronium Bromide Solution monograph from BP 2023
Mobile Phase A	Methanol : acetonitrile : buffer (15:23.5:61.5 v/v/v)
Mobile Phase B	Acetonitrile
Buffer	0.25 g of sodium heptanesulfonate was dissolved in 615 mL of a 0.163% w/v solution of anhydrous sodium sulfate and then 3 mL of 0.515% w/v solution of sulfuric acid was added.
Diluent	Mobile phase A
Flow rate	1.0 mL/min
Column Temp	25 °C
Injection Volume	20 µL
Detection	215 nm

Typical chromatogram for solution (2) in the Assay test for Glycopyrronium Bromide Solution monograph as published in BP 2023.

Peak ID: 1: Benzaldehyde. 2: Glycopyrronium.

Column	Inertsil ODS-3 C18 (150 mm x 4.6 mm, 3 µm)
Method Ref.	Related substances for the Glycopyrronium Bromide Solution monograph from BP 2023
Mobile Phase	Methanol : acetonitrile : buffer (15:23.5:61.5 v/v/v)
Buffer	0.25 g of sodium heptanesulfonate was dissolved in 615 mL of a 0.163% w/v solution of anhydrous sodium sulfate and then 3 mL of 0.515% w/v solution of sulfuric acid was added.
Diluent	Mobile phase
Flow rate	1.0 mL/min
Column Temp	25 °C
Injection Volume	20 µL
Detection	215 nm