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Glycopyrrolate Injection

» Glycopyrrolate Injection is a sterile solution of Glycopyrrolate in Water for Injection. It contains not less than 93.0 percent and not more than 107.0 percent of the labeled amount of glycopyrrolate ($C_{19}H_{28}BrNO_3$).

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

USP Reference standards ⟨11⟩—

USP Glycopyrrolate RS

Identification—

Spray reagent—Dissolve 2 g of bismuth subnitrate in a solution consisting of 100 mL of water and 25 mL of glacial acetic acid (*Solution A*). Dissolve 40 g of potassium iodide in 100 mL of water (*Solution B*). Add 10 mL of *Solution A* and 10 mL of *Solution B* to a solution consisting of 100 mL of water and 20 mL of glacial acetic acid, and mix.

Procedure—Pipet an amount of Injection equivalent to about 1 mg of glycopyrrolate into a 10-mL volumetric flask, dilute with water to volume, and mix to obtain the test solution. Prepare a Standard solution of USP Glycopyrrolate RS in water containing about 0.1 mg of glycopyrrolate per mL. Apply 30 µL of the test solution and 30 µL of the Standard solution to a suitable thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of butyl alcohol, glacial acetic acid, and water (3:1:1) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, and allow to air-dry. Spray the plate with *Spray reagent*, and allow to air-dry: the R_F value and color of the principal spot obtained from the test solution correspond to those obtained from the Standard solution.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 555.5 USP Endotoxin Units per mg of glycopyrrolate.

pH ⟨791⟩: between 2.0 and 3.0.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

Mobile phase—Dissolve 1.0 g of anhydrous sodium sulfate and 200 mg of sodium 1-pentanesulfonate in 615 mL of water in a 1000-mL volumetric flask. Add 3.0 mL of 1 N sulfuric acid, 235 mL of acetonitrile, and 150 mL of methanol, and mix. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Glycopyrrolate RS in *Mobile phase*, and dilute quantitatively with *Mobile phase* to obtain a solution having a known concentration of about 0.2 mg per mL.

Resolution solution—Prepare a solution of benzaldehyde in *Mobile phase* containing about 0.5 mg per mL. Transfer 2.0 mL of this solution to a 25-mL volumetric flask, dilute with *Standard preparation* to volume, and mix.

Assay preparation—Dilute a volume of Injection, quantitatively if necessary, with *Mobile phase* to obtain a solution having a concentration of about 0.2 mg of glycopyrrolate per mL.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 222-nm detector and a 3.9-mm × 30-cm column containing packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed under *Procedure:* the resolution, *R,* between the benzaldehyde and glycopyrrolate peaks is not less than 3.0. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure:* the relative standard deviation for replicate injections is not more than 1.0%.

Procedure—Separately inject equal volumes (about 35 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of glycopyrrolate ($C_{19}H_{28}BrNO_3$) in each mL of the Injection taken by the formula:

$$C(L/D)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Glycopyrrolate RS in the *Standard preparation; L* is the labeled quantity, in mg per mL, of glycopyrrolate in the Injection; D is the concentration, in mg per mL, of glycopyrrolate in the *Assay preparation,* on the basis of the labeled

quantity and the extent of dilution; and r_U and r_S are the glycopyrrolate peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
GLYCOPYRROLATE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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