

Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-Aug-2019
 Document Type: USP Monographs
 DocId: GUID-C478DE63-68CE-4365-88D9-0B881B5ABD37_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M35600_02_01
 DOI Ref: nk7ty

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Glycopyrrolate Tablets

DEFINITION

Glycopyrrolate Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of glycopyrrolate ($C_{19}H_{28}BrNO_3$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

▲ • **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (USP 1-Aug-2019)

ASSAY

Change to read:

• PROCEDURE

Buffer solution: Prepare a solution of 1.0 g of [sodium sulfate anhydrous](#) and 200 mg of [sodium 1-hexanesulfonate monohydrate](#) in 650 mL of [water](#). To this solution add 3.0 mL of [1 N sulfuric acid](#), and mix.

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer solution* (20:15:65)

Standard solution: 0.1 mg/mL of [USP Glycopyrrolate RS](#) in *Mobile phase*

Sample solution: ▲ Nominally ▲ (USP 1-Aug-2019) 0.1 mg/mL of glycopyrrolate in *Mobile phase*. Prepare by transferring 10 Tablets to a suitable volumetric flask. Add *Mobile phase* to 50% of the volume of the flask, and sonicate for 10 min or until the Tablets disintegrate completely. Add *Mobile phase* to 75% of the volume of the flask, shake mechanically for 30 min, and dilute with *Mobile phase* to volume. Centrifuge a portion of the solution, and pass the supernatant through a suitable filter, discarding the first few milliliters of the filtrate.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 222 nm. ▲ For *Identification B*, use a diode array detector in the range of 210–400 nm. ▲ (USP 1-Aug-2019)

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1.2 mL/min

Injection volume: 50 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of glycopyrrolate ($C_{19}H_{28}BrNO_3$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of glycopyrrolate from the *Sample solution*

r_S = peak response of glycopyrrolate from the *Standard solution*

C_S = concentration of [USP Glycopyrrolate RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of glycopyrrolate in the *Sample solution* (mg/mL)

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: Water; 500 mL

Apparatus 1: 100 rpm

Time: 45 min

Buffer solution: 1.0 g of [sodium sulfate anhydrous](#) and 200 mg of [sodium 1-pentanesulfonate](#) in 620 mL of [water](#)

Mobile phase: [Acetonitrile](#), [methanol](#), *Buffer solution*, and [1 N sulfuric acid](#) (200:180:620:3)

Standard stock solution: 0.2 mg/mL of [USP Glycopyrrolate RS](#) in *Medium*. A small volume of [methanol](#), not exceeding 20% of the final volume, can be used to solubilize glycopyrrolate.

Standard solution: ($L/500$) mg/mL of glycopyrrolate in *Medium* from the *Standard stock solution*, where L is the label claim in mg/Tablet.

Prepare this solution fresh, and refrigerate immediately at 5°.

Sample solution: Pass a portion of the solution under test through a suitable filter, discarding the first few milliliters of the filtrate. Refrigerate the samples at 5°.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Temperatures

Autosampler: 5°

Column: 40°

Flow rate: 1.2 mL/min

Injection volume: 80 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the ▲ (USP 1-Aug-2019) percentage of the labeled amount of glycopyrrolate dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S/L) \times V \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of ▲ [USP Glycopyrrolate RS](#) ▲ (USP 1-Aug-2019) in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 500 mL

Tolerances: NLT 75% (Q) of the labeled amount of glycopyrrolate ($C_{19}H_{28}BrNO_3$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Buffer solution: Prepare a solution of 1.0 g of [sodium sulfate anhydrous](#) and 200 mg of [sodium 1-hexanesulfonate monohydrate](#) in 650 mL of [water](#). To this solution add 3.0 mL of [1 N sulfuric acid](#), and mix.