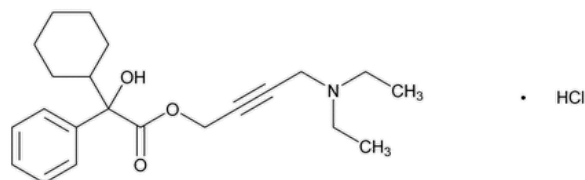


Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-AE6E49D2-D731-4F98-81A6-317CA8B5ECF7_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M59460_04_01
 DOI Ref: k8hpc

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Oxybutynin Chloride



$C_{22}H_{31}NO_3 \cdot HCl$ 393.95

Benzeneacetic acid, α -cyclohexyl- α -hydroxy-, 4-(diethyl amino)-2-butynyl ester hydrochloride, ($\pm$);

4-(Diethylamino)-2-butynyl ($\pm$)- α -phenylcyclohexaneglycolate hydrochloride CAS RN®: 1508-65-2; UNII: L9F3D9RENQ.

DEFINITION

Oxybutynin Chloride contains NLT 97.0% and NMT 102.0% of oxybutynin chloride ($C_{22}H_{31}NO_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: A solution containing 6.67 g/L of monobasic potassium phosphate and 8.55 g/L of dibasic potassium phosphate

Mobile phase: Acetonitrile and *Buffer* (49:51)

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

Sample solution: 0.1 mg/mL of Oxybutynin Chloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm $\times$ 7.5-cm; 3- μ m or 3.5- μ m packing L7

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 10 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of oxybutynin chloride ($C_{22}H_{31}NO_3 \cdot HCl$) in the portion of Oxybutynin Chloride taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_s = concentration of [USP Oxybutynin Chloride RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Oxybutynin Chloride in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0% on the dried basis

OTHER COMPONENTS

• **CHLORIDE CONTENT**

Sample: 600 mg of Oxybutynin Chloride, previously dried

Analysis: Dissolve the *Sample* in 100 mL of water, and add 5 mL of nitric acid. Titrate (see [Titrimetry \(541\)](#)) with 0.1 N silver nitrate VS, using a platinum–silver chloride electrode system. Each mL of 0.1 N silver nitrate is equivalent to 3.545 mg of chloride (Cl).

Acceptance criteria: 8%–10%

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%

• **ORGANIC IMPURITIES**

Buffer, Mobile phase, and Chromatographic system: Proceed as directed in the Assay.

System suitability stock solution: 100 µg/mL each of [USP Oxybutynin Related Compound B RS](#) and [USP Oxybutynin Related Compound C RS](#) in *Mobile phase*

Standard stock solution: 1.0 mg/mL of [USP Oxybutynin Chloride RS](#) in *Mobile phase*

System suitability solution: Transfer 10.0 mL of the *System suitability stock solution* to a 100-mL volumetric flask, add 10.0 mL of *Standard stock solution*, and dilute with *Mobile phase* to volume.

Standard solution: 7.5 µg/mL of [USP Oxybutynin Chloride RS](#) from *Standard stock solution* in *Mobile phase*

Sample solution: 5.0 mg/mL of Oxybutynin Chloride in *Mobile phase*

System suitability

Sample: *System suitability solution*

[NOTE—See [Table 1](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.1 between oxybutynin related compound B and oxybutynin related compound C

Relative standard deviation: NMT 2.0% for the oxybutynin peak

Analysis

Samples: *Standard solution* and *Sample solution*

Record the chromatograms for a total time of NLT twice the retention time of the oxybutynin peak.

Calculate the percentage of each impurity in the portion of Oxybutynin Chloride taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times (1/F) \times 100$$

r_u = peak response of each impurity from the *Sample solution*

r_s = peak response of oxybutynin from the *Standard solution*

C_s = concentration of [USP Oxybutynin Chloride RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Oxybutynin Chloride in the *Sample solution* (mg/mL)

F = relative response factor for each impurity (see [Table 1](#))

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Oxybutynin related compound A ^a	0.08	1.4	0.5