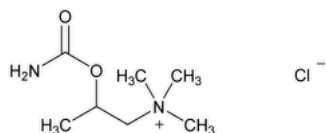


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-42859396-560F-4406-AC1B-33253633465E_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M9350_04_01
 DOI Ref: 38z57

© 2025 USPC
 Do not distribute

Bethanechol Chloride



$C_7H_{17}ClN_2O_2$ 196.68

1-Propanaminium, 2-[(aminocarbonyl)oxy]-*N,N,N*-trimethyl-, chloride, ($\pm$);

($\pm$)-(2-Hydroxypropyl)trimethylammonium chloride carbamate CAS RN®: 590-63-6; UNII: H4QBZ2LO84.

DEFINITION

Bethanechol Chloride contains NLT 98.0% and NMT 101.5% of bethanechol chloride ($C_7H_{17}ClN_2O_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#) ▲ (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.
- **C.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#): Meets the requirements

ASSAY

PROCEDURE

Buffer: 29 mg/L of edetic acid in a solution prepared as follows. Transfer a portion of edetic acid to a suitable volumetric flask. Dissolve in water, using 50% of the final flask volume. Add 0.3 mL of nitric acid per L, and dilute with water to volume.

Mobile phase: Acetonitrile and *Buffer* (5:95)

System suitability solution: 0.1 mg/mL of bethanechol chloride in a solution prepared as follows. Transfer a portion of bethanechol chloride to a suitable volumetric flask. Add 4% of the final flask volume of 0.1 N sodium hydroxide, and allow to stand for 15 min. Add 4% of the final flask volume of 0.1 N hydrochloric acid. Dissolve in and dilute with *Mobile phase* to volume.

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

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

Chromatographic system

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

Mode: LC

Detector: Conductivity

Column: 3.9-mm × 15.0-cm; packing L55

Temperatures

Detector: 35°

Column: 30°

Flow rate: 1 mL/min

Injection volume: 25 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

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

Suitability requirements

Resolution: NLT 0.8 between desacetyl methacholine and bethanechol chloride, *System suitability solution*

Tailing factor: NMT 3.5, *Standard solution*

Relative standard deviation: NMT 3.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of bethanechol chloride ($C_7H_{17}ClN_2O_2$) in the portion of Bethanechol 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 Bethanechol Chloride RS](#) in the *Standard solution* (mg/mL)
- C_U = concentration of Bethanechol Chloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–101.5% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%
- ORGANIC IMPURITIES**

Buffer: 0.48 g/L of methanesulfonic acid in water

Mobile phase: Acetonitrile and *Buffer* (5:95)

System suitability solution: 0.1 mg/mL of bethanechol chloride in a solution prepared as follows. Transfer a portion of bethanechol chloride to a suitable volumetric flask. Add 4% of the final flask volume of 0.1 N sodium hydroxide, and allow to stand for 15 min. Add 4% of the final flask volume of 0.1 N hydrochloric acid. Dissolve in and dilute with *Mobile phase* to volume.

Standard solution: 1 µg/mL of [USP Bethanechol Chloride RS](#) in *Mobile phase*

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

Chromatographic system

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

Mode: LC

Detector: Conductivity

Column: 3.9-mm × 15.0-cm; packing L55

Temperatures

Detector: 35°

Column: 30°

Flow rate: 1 mL/min

Injection volume: 50 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

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

Suitability requirements

Resolution: NLT 0.8 between desacetyl methacholine and bethanechol chloride, *System suitability solution*

Relative standard deviation: NMT 10.0% for bethanechol chloride, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

- r_U = peak response of any impurity from the *Sample solution*
- r_S = peak response of bethanechol chloride from the *Standard solution*
- C_S = concentration of [USP Bethanechol Chloride RS](#) in the *Standard solution* (mg/mL)
- C_U = concentration of Bethanechol Chloride in the *Sample solution* (mg/mL)
- F = relative response factor (see [Table 1](#))

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

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Desacetyl metha choline ^a	0.9	1.2	1.0
Bethanechol chloride	1.0	—	—

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Any individual unspecified impurity	—	1.0	0.1
Total impurities	—	—	1.5

^a 2-Hydroxypropyltrimethyl ammonium chloride.

SPECIFIC TESTS

- [pH \(791\)](#)
Sample solution: 10 mg/mL of Bethanechol Chloride in water
Acceptance criteria: 5.5–6.5
- [Loss on Drying \(731\)](#)
Analysis: Dry at 105° for 2 h.
Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Bethanechol Chloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
BETHANECHOL CHLORIDE	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 38(4)

Current DocID: **GUID-42859396-560F-4406-AC1B-33253633465E_4_en-US**
DOI: https://doi.org/10.31003/USPNF_M9350_04_01
DOI ref: [38z57](#)