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Bethanechol Chloride Compounded Oral Suspension

DEFINITION

Bethanechol Chloride Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of bethanechol chloride ($C_7H_{17}ClN_2O_2$).

Prepare Bethanechol Chloride Compounded Oral Suspension 5 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Bethanechol Chloride	500 mg
Vehicle: a 1:1 mixture of Vehicle for Oral Solution (regular or sugar-free), <i>NF</i> , and Vehicle for Oral Suspension, <i>NF</i> , a sufficient quantity to make	100 mL

If using *Bethanechol Chloride* tablets, add to a suitable mortar and comminute to a fine powder, or add the *Bethanechol Chloride* powder to the mortar. Add about 20 mL of the *Vehicle*, and mix to a uniform paste. Add the *Vehicle* in small portions almost to volume, and mix thoroughly after each addition. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add sufficient *Vehicle* to final volume, and mix well.

ASSAY

• PROCEDURE

Mobile phase: Acetonitrile and water (33:67)

Standard solution: 500 µg/mL of [USP Bethanechol Chloride RS](#) in *Mobile phase*

Sample solution: Agitate the container of Oral Suspension for 30 min on a rotating mixer, remove a 10-mL sample, and store in a clear glass vial at -70° until analyzed. At the time of analysis, remove the sample from the freezer, allow it to reach room temperature, and mix with a vortex mixer for 30 s. Dilute a suitable volume of Oral Suspension with *Mobile phase* to obtain a nominal concentration of 500 µg/mL of bethanechol chloride.

Chromatographic system

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

Mode: LC

Detector: UV 200 nm

Column: 4.6-mm × 25-cm; 5-µm packing L11

Flow rate: 0.7 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for bethanechol chloride is about 3 min.]

Suitability requirements

Relative standard deviation: NMT 3.1% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of bethanechol chloride ($C_7H_{17}ClN_2O_2$) in the volume of Oral Suspension 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* (µg/mL)

C_U = nominal concentration of bethanechol chloride in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH** (791): 3.9–4.9

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at room temperature, or in a refrigerator.
- **BEYOND-USE DATE:** NMT 60 days after the day on which it was compounded when stored at room temperature, or in a refrigerator
- **LABELING:** Label it to state that it is to be well shaken, and to state the *Beyond-Use Date*.
- **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 COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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