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# Bethanechol Chloride Compounded Oral Solution

**DEFINITION**

Bethanechol Chloride Compounded Oral Solution 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 Solution 5 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

| | |
|---|---|
| Bethanechol Chloride | 500 mg |
| Vehicle for Oral Solution (regular or sugar-free), *NF*, a sufficient quantity to make | 100 mL |

Add *Bethanechol Chloride* powder and about 20 mL of *Vehicle for Oral Solution* to a mortar, and mix. Add the *Vehicle for Oral Solution* 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 enough *Vehicle for Oral Solution* to bring 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 Solution 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 Solution 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 of 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 portion of Oral Solution 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 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 SOLUTION | Brian Serumaga<br>Science Program Manager | CMP2020 Compounding 2020 |

**Chromatographic Database Information:** Chromatographic Database

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