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Carbachol Intraocular Solution

DEFINITION

Carbachol Intraocular Solution is a sterile solution of Carbachol in an aqueous medium. It contains NLT 90.0% and NMT 115.0% of the labeled amount of carbachol ($C_6H_{15}ClN_2O_2$). It contains no preservatives or antimicrobial agents.

IDENTIFICATION

• A.

Solution A: A saturated (filtered) ammonium reineckate solution

Analysis: To 5 mL of Intraocular Solution add 4–5 drops of *Solution A*.

Acceptance criteria: A pink precipitate is formed that is soluble in acetone; the acetone solution is red.

ASSAY

• PROCEDURE

Solution A: Dilute 1 volume of sodium hypochlorite TS with water to 15 volumes, and allow to stand for 30 min.

Solution B: *Solution A* and 1 N sodium hydroxide (50:50). Prepare fresh daily.

Solution C: Phenol in water (1 in 200)

Solution D: Potassium iodide in water (3 in 1000)

Standard solution: 100 µg/mL of [USP Carbachol RS](#) in water

Sample solution: Nominally 100 µg/mL of carbachol from a volume of Intraocular Solution in water

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: Maximum absorbance at about 590 nm

Cell: 1 cm

Blank: Water

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Transfer 2.0-mL portions each of the *Standard solution*, *Sample solution*, and *Blank* to separate 50-mL conical flasks. To each flask add 1.0 mL of 0.1 N hydrochloric acid. Treat each as follows. Add 4.0 mL of *Solution B*, rinsing the inner walls of the flask with small portions of water, mix, and allow to stand for 15 min, accurately timed. Add 2.0 mL of *Solution C*, rinsing the walls of the flask with *Solution C* and with additional small portions of water. Mix, and allow to stand for 5 min. Add 2.0 mL of 3.5 N hydrochloric acid, washing the sides of the flask upon addition. Rinse the flask sparingly with 0.1 N hydrochloric acid to ensure complete acidification of all content, then mix. Add 1.0 mL of *Solution D*, and allow to stand for 5 min. Add 3.0 mL of starch TS, mix, and transfer the solutions to 50-mL volumetric flasks with the aid of several small portions of water, and dilute each solution with water to volume.

Concomitantly determine the absorbances of the solutions from the *Sample solution* and the *Standard solution* against the *Blank*.

Calculate the percentage of the labeled amount of carbachol ($C_6H_{15}ClN_2O_2$) in the portion of Intraocular Solution taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

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

Acceptance criteria: 90.0%–115.0%

SPECIFIC TESTS

- [STERILITY TESTS \(71\)](#): Meets the requirements
- [pH \(791\)](#): 5.0–7.5

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, at controlled room temperature, and protect from freezing.

- **LABELING:** Label it to indicate that it is for single-dose intraocular use only, and that the unused portion is to be discarded.
- **USP REFERENCE STANDARDS (11).**
[USP Carbachol RS](#)

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

Topic/Question	Contact	Expert Committee
CARBACHOL INTRAOCULAR SOLUTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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