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Carteolol Hydrochloride Ophthalmic Solution

» Carteolol Hydrochloride Ophthalmic Solution is a sterile, aqueous, isotonic solution of Carteolol Hydrochloride. It contains a suitable antimicrobial preservative. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{16}H_{24}N_2O_3 \cdot HCl$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
USP Carteolol Hydrochloride RS

Identification—

A: Prepare a test solution by diluting a suitable volume of Ophthalmic Solution with water, if necessary, to obtain a solution containing about 1 mg of carteolol hydrochloride per mL. Separately apply 10 µL of the test solution and 10 µL of a Standard solution of USP Carteolol Hydrochloride RS in water containing about 1 mg per mL to the starting line of a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry. Line a chromatographic chamber with filter paper, and saturate the paper with a solvent system consisting of a mixture of chloroform, methanol, and ammonium hydroxide (50:20:1). Place the plate in the chamber, and develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and allow to air-dry. Examine the plate under short-wavelength UV light: the R_F value of the principal spot in the chromatogram obtained from the test solution corresponds to that in the chromatogram obtained from the Standard solution.

B: The retention time of the carteolol peak in the chromatogram of the *Assay preparation* obtained as directed in the *Assay* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH ⟨791⟩: between 6.0 and 8.0.

Change to read:

Assay—

▲*Buffer, Mobile phase, Standard stock solution, Standard solution, System suitability stock solution, System suitability solution, Chromatographic system,* and *System suitability*▲ *(ERR 1-Sep-2020)* —Proceed as directed in the *Assay* under *Carteolol Hydrochloride*.

▲*Diluent*—Prepare a mixture of *Buffer* and methanol (1:1).▲ (ERR 1-Sep-2020)

Assay preparation—Transfer an accurately measured volume of Ophthalmic Solution, equivalent to about 10 mg of carteolol hydrochloride, to a 100-mL volumetric flask, dilute with *Diluent* to volume, and mix. Pass a portion of this solution through a filter having a porosity of 0.5 µm or finer, discarding the first 2 mL of the filtrate, and use the filtrate as the *Assay preparation*.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard* ▲*solution*▲ (ERR 1-Sep-2020) and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in mg, of $C_{16}H_{24}N_2O_3 \cdot HCl$ in each mL of the Ophthalmic Solution taken by the formula:

$$100(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Carteolol Hydrochloride RS in the *Standard* ▲*solution*;▲ (ERR 1-Sep-2020) V is the volume, in mL, of Ophthalmic Solution taken; and r_U and r_S are the carteolol peak responses obtained from the *Assay preparation* and the *Standard* ▲*solution*,▲ (ERR 1-Sep-2020) respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CARTEOLOL HYDROCHLORIDE OPHTHALMIC SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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