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# Cyclopentolate Hydrochloride Ophthalmic Solution

» Cyclopentolate Hydrochloride Ophthalmic Solution is a sterile, aqueous solution of Cyclopentolate Hydrochloride. It may contain suitable buffers and other additives. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of  $C_{17}H_{25}NO_3 \cdot HCl$ .

**Packaging and storage**—Preserve in tight containers, and store at controlled room temperature.

**USP REFERENCE STANDARDS (11)**—  
[USP Cyclopentolate Hydrochloride RS](#)

**Identification**—Place in a 125-mL separator a volume of Ophthalmic Solution, equivalent to about 50 mg of cyclopentolate hydrochloride, and place in a second separator about 50 mg of [USP Cyclopentolate Hydrochloride RS](#) dissolved in 5 mL of water. Treat each solution as follows. Add 1 g of potassium carbonate, and extract with two 10-mL portions of ether. Pass the ether extracts through ether-washed filter paper, collect the filtrate in a small beaker, and evaporate to dryness: the residue so obtained responds to [Identification](#) test [A](#) under [Cyclopentolate Hydrochloride](#).

**STERILITY TESTS (71)**: meets the requirements.

**pH (791)**: between 3.0 and 5.5.

**Assay**—

*Buffer solution, Mobile phase, Standard preparation, and Chromatographic system*—Proceed as directed in the [Assay](#) under [Cyclopentolate Hydrochloride](#).

*Assay preparation*—Transfer an accurately measured volume of Ophthalmic Solution, equivalent to about 10 mg of cyclopentolate hydrochloride, to a 100-mL volumetric flask, dilute with water to volume, and mix.

*Procedure*—Proceed as directed in the [Assay](#) under [Cyclopentolate Hydrochloride](#). Calculate the quantity, in mg, of cyclopentolate hydrochloride ( $C_{17}H_{25}NO_3 \cdot HCl$ ) in each mL of the Ophthalmic Solution taken by the formula:

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

in which V is the volume, in mL, of Ophthalmic Solution taken, and the other terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
CYCLOPENTOLATE HYDROCHLORIDE OPHTHALMIC SOLUTION	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**  
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