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Timolol Maleate Ophthalmic Solution

» Timolol Maleate Ophthalmic Solution is a sterile, aqueous solution of Timolol Maleate. It contains an amount of $C_{13}H_{24}N_4O_3S \cdot C_4H_4O_4$ equivalent to not less than 90.0 percent and not more than 110.0 percent of the labeled amount of timolol ($C_{13}H_{24}N_4O_3S$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference Standards ⟨11⟩—
USP Timolol Maleate RS

Identification—Dilute a suitable quantity of Ophthalmic Solution with water to obtain a solution having a concentration of about 20 µg of timolol per mL: the UV absorption spectrum of the solution so obtained exhibits maxima and minima at the same wavelengths as that of a similar preparation of USP Timolol Maleate RS, concomitantly measured.

Sterility Tests ⟨71⟩ : meets the requirements.

pH ⟨791⟩ : between 6.5 and 7.5.

Assay—

pH 2.8 phosphate buffer—Dissolve 11.1 g of monobasic sodium phosphate in 1000 mL of water, adjust with phosphoric acid to a pH of 2.8 ± 0.05, filter, and degas.

Diluent—Prepare a mixture of acetonitrile and *pH 2.8 phosphate buffer* (2:1).

Mobile phase—Prepare a mixture of *pH 2.8 phosphate buffer* and methanol (65:35). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*). [Note—Minimize the time the Reference Standard, the Ophthalmic Solution, the standard stock solution, the *Standard preparation,* and the *Assay preparation* are exposed to direct light.]

Standard preparation—Transfer about 34 mg of USP Timolol Maleate RS, accurately weighed, to a 25-mL volumetric flask, dissolve in and dilute with water to volume, and mix. Transfer 5.0 mL of this stock solution to a 50-mL volumetric flask, add 15 mL of *Diluent*, dilute with water to volume, and mix.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Solution, equivalent to about 5 mg of timolol, to a 50-mL volumetric flask, add 15 mL of *Diluent*, dilute with water to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 295-nm detector and a 4.6-mm × 15-cm column that contains 5-µm packing L1. The column temperature is maintained at 40°, and the flow rate is about 1.2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor is not more than 2.0, the column efficiency is not less than 3600 theoretical plates, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the peak area responses for the major peaks. Calculate the quantity, in mg, of timolol ($C_{13}H_{24}N_4O_3S$) in each mL of Ophthalmic Solution taken by the formula:

$$(316.43/432.49)(50C/V)(r_U/r_S)$$

in which 316.43 and 432.49 are the molecular weights of timolol and timolol maleate, respectively, C is the concentration, in mg per mL, of USP Timolol Maleate RS in the *Standard preparation*, V is the volume, in mL, of Ophthalmic Solution taken, and r_U and r_S are the peak area responses of the timolol peaks obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
TIMOLOL MALEATE OPHTHALMIC SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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