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Polymyxin B Sulfate and Trimethoprim Ophthalmic Solution

» Polymyxin B Sulfate and Trimethoprim Ophthalmic Solution is a sterile, isotonic, aqueous solution of Polymyxin B Sulfate and Trimethoprim Sulfate or of Polymyxin B Sulfate and Trimethoprim that has been solubilized with Sulfuric Acid. It contains not less than 90.0 percent and not more than 130.0 percent of the labeled amount of polymyxin B and the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amount of trimethoprim ($C_{14}H_{18}N_4O_3$). It contains one or more preservatives.

Packaging and storage—Preserve in tight, light-resistant containers, and store at controlled room temperature.

Labeling—Label it to indicate that it is to be stored at 15° to 25°, protected from light.

USP Reference Standards ⟨11⟩—
USP Polymyxin B Sulfate RS
USP Trimethoprim RS

Identification—

A: It meets the requirements for polymyxin B under *Thin-Layer Chromatographic Identification Test* ⟨201BNP⟩.

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

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 4.0 and 6.2.

Assay for polymyxin B—Proceed as directed for polymyxin B under *Antibiotics—Microbial Assays ⟨81⟩*, using an accurately measured volume of Ophthalmic Solution, diluted quantitatively and stepwise with *Buffer B.6*, to obtain a *Test Dilution* having a concentration of polymyxin B assumed to be equal to the median dose level of the Standard.

Assay for trimethoprim—

Diluent—Prepare a mixture of 0.01 N hydrochloric acid and acetonitrile (870:130).

Mobile phase—Dissolve 1.65 g of ethanesulfonic acid in 1000 mL of a mixture of water and acetonitrile (870:130). Adjust with 10 N sodium hydroxide or 0.1 N hydrochloric acid to a pH of 3.5. Pass this solution through a filter having a 0.5-µm or finer porosity, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Trimethoprim RS in *Diluent* to obtain a solution having a known concentration of about 0.04 mg per mL.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Solution, equivalent to about 1 mg of trimethoprim, to a 25-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L11. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the tailing factor is not more than 1.5, when calculated at 10% height of the peak; 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 responses for the major peaks. Calculate the quantity, in mg, of trimethoprim ($C_{14}H_{18}N_4O_3$) in each mL of the Ophthalmic Solution taken by the formula:

$$25(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Trimethoprim RS in the *Standard preparation; V* is the volume, in mL, of Ophthalmic Solution taken to prepare the *Assay preparation;* and r_U and r_S are the trimethoprim peak area responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Topic/Question	Contact	Expert Committee
POLYMYXIN B SULFATE AND TRIMETHOPRIM OPHTHALMIC SOLUTION	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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