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Oxytetracycline Hydrochloride and Polymyxin B Sulfate Ophthalmic Ointment

DEFINITION

Oxytetracycline Hydrochloride and Polymyxin B Sulfate Ophthalmic Ointment is a sterile ointment containing Oxytetracycline Hydrochloride and Polymyxin B Sulfate. It contains the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of oxytetracycline and NLT 90.0% and NMT 125.0% of the labeled amount of polymyxin B.

ASSAY

• **Oxytetracycline**

(See *Antibiotics—Microbial Assays* ⟨81⟩.)

Sample solution: Transfer a suitable, weighed quantity of the Ophthalmic Ointment to a separator, add 50 mL of ether, and shake. Add 20 mL of 0.1 N hydrochloric acid, shake, and allow to separate. Collect the acid layer, and repeat the extraction with three additional 20-mL portions of 0.1 N hydrochloric acid. Combine the acid extracts in a 100-mL volumetric flask, and dilute with 0.1 N hydrochloric acid to volume. Dilute a portion of this solution with 0.1 N hydrochloric acid to obtain a solution containing NLT 150 µg/mL of oxytetracycline.

Analysis: Proceed as directed in the chapter, using a suitable aliquot of the *Sample solution* diluted with water, to yield a *Test Dilution* having an oxytetracycline concentration that is nominally equivalent to the median level of the standard.

Acceptance criteria: 90.0%–120.0%

• **Polymyxin B**

(See *Antibiotics—Microbial Assays* ⟨81⟩.)

Sample solution: Transfer nominally 10,000 USP Polymyxin B Units from the Ophthalmic Ointment to a 15-mL centrifuge tube. Add 10 mL of ether, stir, and centrifuge for 10 min. Decant, and discard the clear ether. Wash the residue with 10 mL of ether, and centrifuge for 10 min, decanting and discarding the clear ether. Wash the residue with several 10-mL portions of acetone, centrifuging, decanting, and discarding each washing until the yellow color is removed from the residue. Take care not to remove any of the residue with the washings. Add 0.2 mL of polysorbate 80 to the residue, and mix. Transfer the mixture to a 100-mL volumetric flask with the aid of *Buffer B.6*, and dilute with the same solvent to volume.

Analysis: Proceed as directed in the chapter, using a suitable aliquot of the *Sample solution* diluted with *Buffer B.6*, to yield a *Test Dilution* having a polymyxin B concentration that is nominally equivalent to the median level of the standard.

Acceptance criteria: 90.0%–125.0%

SPECIFIC TESTS

• **Sterility Tests** ⟨71⟩**:** Meets the requirements

• **Other Requirements:** It meets the requirements for *Particulate and Foreign Matter* and *Container Contents* in *Ophthalmic Products—Quality Tests* ⟨771⟩, *Drug Product Quality, Universal Tests, Particulate and Foreign Matter* and *Container Contents*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in collapsible ophthalmic ointment tubes. Store at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Oxytetracycline RS
USP Polymyxin B Sulfate RS

Topic/Question	Contact	Expert Committee
OXYTETRACYCLINE HYDROCHLORIDE AND POLYMYXIN B SULFATE OPHTHALMIC OINTMENT	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

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