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Oxytetracycline Hydrochloride and Polymyxin B Sulfate Ointment

» Oxytetracycline Hydrochloride and Polymyxin B Sulfate Ointment contains the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amount of oxytetracycline ($C_{22}H_{24}N_2O_9$), and not less than 90.0 percent and not more than 125.0 percent of the labeled amount of polymyxin B.

Packaging and storage—Preserve in collapsible tubes, or in well-closed, light-resistant containers.

USP REFERENCE STANDARDS (11).—

[USP Oxytetracycline RS](#)

[USP Polymyxin B Sulfate RS](#)

MINIMUM FILL (755): meets the requirements.

WATER DETERMINATION, Method I (921): not more than 1.0%, 10 mL of a mixture of toluene and methanol (7:3) being used in place of methanol in the titration vessel.

Assay for oxytetracycline—Proceed with Ointment as directed in the [Assay for oxytetracycline](#) under [Oxytetracycline Hydrochloride and Hydrocortisone Ointment](#).

Assay for polymyxin B—Transfer an accurately weighed quantity of Ointment, equivalent to about 10,000 USP Polymyxin B Units, to a 15-mL centrifuge tube, add 10 mL of ether, stir, and centrifuge for 10 minutes. Decant and discard the clear ether. Wash the residue with 10 mL of ether, centrifuge for 10 minutes, 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. [NOTE—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*, dilute with the same solvent to volume, and mix. Proceed as directed for polymyxin B under [Antibiotics—Microbial Assays](#) (81), using an accurately measured volume of this solution diluted quantitatively with *Buffer B.6* to yield a *Test Dilution* having a concentration of polymyxin B assumed to be equal to the median dose level of the Standard.

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

We apologize for the inconvenience. The exact auxiliary information for this Documentary Standard is currently unavailable. Please contact Documentary Standards Support (stdsmonographs@usp.org) for assistance during this time.

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