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# Polymyxin B Sulfate and Hydrocortisone Otic Solution

» Polymyxin B Sulfate and Hydrocortisone Otic Solution is a sterile solution containing not less than 90.0 percent and not more than 130.0 percent of the labeled amount of polymyxin B, and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of hydrocortisone ($C_{21}H_{30}O_5$). It may contain one or more suitable buffers and preservatives.

[NOTE—Where Polymyxin B Sulfate and Hydrocortisone Otic Solution is prescribed without reference to the quantity of polymyxin B or hydrocortisone contained therein, a product containing 10,000 Polymyxin B Units and 5 mg of hydrocortisone per mL shall be dispensed.]

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

**USP REFERENCE STANDARDS ⟨11⟩**—
USP Hydrocortisone RS
USP Polymyxin B Sulfate RS

**STERILITY TESTS ⟨71⟩**: meets the requirements.

**pH ⟨791⟩**: between 3.0 and 5.0.

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

**Assay for hydrocortisone**—

*Mobile phase*—Prepare a suitable solution of about 500 volumes of methanol, 500 volumes of water, and 1 volume of glacial acetic acid, such that the retention time of hydrocortisone is between 6 and 10 minutes.

*Standard preparation*—Dissolve a suitable quantity of USP Hydrocortisone RS, accurately weighed, in a mixture of methanol and water (1:1) to obtain a solution having a known concentration of about 0.15 mg per mL.

*Assay preparation*—Transfer an accurately measured volume of Otic Solution, equivalent to about 15 mg of hydrocortisone, to a 100-mL volumetric flask, dilute with a mixture of methanol and water (1:1) to volume, and mix.

*Chromatographic system* (see *Chromatography ⟨621⟩*)—The chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph five replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation 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 by means of a suitable microsyringe or sampling valve, adjusting the specimen size and other operating parameters such that the peak obtained from the *Standard preparation* is about 0.6 full-scale. Record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{21}H_{30}O_5$ in each mL of the Otic Solution taken by the formula:

$$(100C/V)(H_U/H_S)$$

in which $C$ is the concentration, in mg per mL, of USP Hydrocortisone RS in the *Standard preparation*, $V$ is the volume, in mL, of the portion of Otic Solution taken, and $H_U$ and $H_S$ are the peak responses 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 |
|---|---|---|
| POLYMYXIN B SULFATE AND HYDROCORTISONE OTIC SOLUTION | Ying Han<br>Associate Science & Standards Liaison | BIO42020 Biologics Monographs 4 - Antibiotics |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | BIO42020 Biologics Monographs 4 - Antibiotics |

**Chromatographic Database Information:** Chromatographic Database

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