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Erythromycin Topical Solution

» Erythromycin Topical Solution is a solution of Erythromycin in a suitable vehicle. It contains not less than 90.0 percent and not more than 125.0 percent of the labeled amount of $C_{37}H_{67}NO_{13}$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
USP Erythromycin RS

Identification—Prepare a test solution by mixing a portion of the Topical Solution with methanol to obtain a concentration of about 2.5 mg of erythromycin per mL. Proceed as directed in the *Identification* test under *Erythromycin Delayed-Release Capsules*, beginning with "Prepare a Standard solution of USP Erythromycin RS."

Water Determination, *Method I* ⟨921⟩: not more than 8.0% if it contains 20 mg per mL, or not more than 5.0% if it contains 15 mg per mL, or not more than 2.0% if it contains acetone, 20 mL of a mixture of pyridine and methanol (1:1) being used in place of methanol in the titration vessel.

Alcohol Determination, *Method II* ⟨611⟩: between 92.5% and 107.5% of the labeled amount of C_2H_5OH.

Assay—Proceed as directed under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately measured volume of Topical Solution diluted quantitatively with *Buffer B.3* to yield a *Test Dilution* having a concentration 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.

Topic/Question	Contact	Expert Committee
ERYTHROMYCIN TOPICAL SOLUTION	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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