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## Erythromycin Topical Gel

» Erythromycin Topical Gel is Erythromycin in a suitable gel 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 as follows. To 1 g of Topical Gel in a 50-mL screw-capped tube, add 20 mL of 0.01 N hydrochloric acid, and heat in a water bath to reflux. Remove the tube from the water bath and shake it. Place the tube in the water bath again, and heat to reflux. Remove the tube from the water bath, and immediately decant a portion of the hot clear supernatant into a test tube. Allow to cool, add an equal volume of a mixture of methanol, water, and triethylamine (90:9:1), and mix. Concomitantly prepare a Standard solution as directed above, except to use 5 mg of [USP Erythromycin RS](#) and 5 mL of 0.01 N hydrochloric acid instead of 1 g of Topical Gel and 20 mL of 0.01 N hydrochloric acid. Separately apply 5  $\mu$ L of the test solution and the Standard solution to a thin-layer chromatographic plate (see [Chromatography \(621\)](#)), coated with a 0.25-mm layer of chromatographic silica gel. Place the plate in an unlined chromatographic chamber, and develop the chromatograms in a solvent system consisting of a mixture of methanol, water, and triethylamine (90:9:1) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chromatographic chamber, mark the solvent front, and allow the solvent to evaporate. Spray the plate with a mixture of alcohol, *p*-methoxybenzaldehyde, and sulfuric acid (90:5:5). Heat the plate at 100° for 10 minutes, and examine the chromatograms. The spots due to erythromycin are black to purple in color: the  $R_F$  value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

**MINIMUM FILL (755)**: meets the requirements.

**Assay**—Proceed as directed under [Antibiotics—Microbial Assays \(81\)](#), using an accurately weighed quantity of Topical Gel, equivalent to about 20 mg of erythromycin, blended for about 3 minutes in a high-speed glass blender jar containing 200.0 mL of *Buffer B.3* to which has been added 0.5% of polysorbate 80. Dilute an accurately measured volume of the blended solution quantitatively with *Buffer B.3* to obtain 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 GEL	<a href="#">Rebecca C. Potts</a> Associate Scientific Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. Information currently unavailable

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