Identification—Prepare *Standard preparation* and an *Assay preparation* as directed in the *Assay,* except to omit the *Internal standard solution*, and chromatograph as directed in the *Assay:* the *Assay preparation* exhibits a major peak for benzoyl peroxide, the retention time of which corresponds to that exhibited by the *Standard preparation*.

Minimum fill ⟨755⟩: meets the requirements.

Limit of benzoyl peroxide related substances—

Mobile phase A, Mobile phase B, Standard preparation A, Standard preparation B, Standard preparation C, Standard preparation D, Resolution solution, and *Chromatographic system*—Proceed as directed in the test for *Related compounds* under *Benzoyl Peroxide Gel*.

Test preparation—Transfer an accurately weighed quantity of Topical Gel, equivalent to about 100 mg of benzoyl peroxide, to a 50-mL volumetric flask, add 25 mL of acetonitrile, shake vigorously to disperse the specimen, sonicate for 5 minutes, dilute with acetonitrile to volume, mix, and filter.

Procedure—Proceed as directed for *Procedure* in the test for *Related compounds* under *Benzoyl Peroxide Gel:* it meets the limits stated.

Assay for erythromycin—Proceed as directed for erythromycin under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately weighed portion of Topical Gel blended for 3 to 5 minutes in a high-speed glass blender jar containing 0.5 mL of polysorbate 80 and an accurately measured volume of *Buffer No. 3* sufficient to obtain a stock solution having a convenient concentration of erythromycin. Dilute an accurately measured volume of this stock solution quantitatively with *Buffer No. 3* to obtain a *Test Dilution* having a concentration of erythromycin assumed to be equal to the median dose level of the Standard.

Assay for benzoyl peroxide—

Mobile phase, Internal standard solution, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Benzoyl Peroxide Gel*.

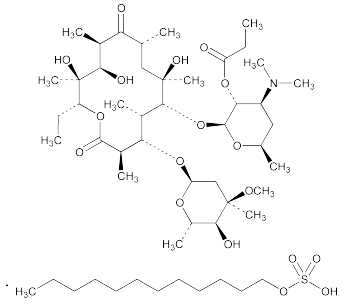
Assay preparation—Prepare as directed for *Assay preparation* in the *Assay* under *Benzoyl Peroxide Gel*, using Topical Gel.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Benzoyl Peroxide Gel*. Calculate the quantity, in mg, of benzoyl peroxide ($C_{14}H_{10}O_4$) in the portion of Topical Gel taken by the formula:

$$125C(R_U / R_S)$$

in which C is the concentration, in mg per mL, of benzoyl peroxide in the *Standard preparation*, and R_U and R_S are the ratios of benzoyl peroxide peak response to ethyl benzoate peak response obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Erythromycin Estolate



$C_{40}H_{71}NO_{14} \cdot C_{12}H_{26}O_4S$ 1056.39

Erythromycin, 2′-propanoate, dodecyl sulfate (salt).

Erythromycin 2′-propionate dodecyl sulfate (salt) [3521-62-8].

» Erythromycin Estolate has a potency equivalent to not less than 600 µg of erythromycin ($C_{37}H_{67}NO_{13}$) per mg, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Erythromycin RS
USP Erythromycin Estolate RS

Identification, *Infrared Absorption* ⟨197K⟩**.**

Crystallinity ⟨695⟩: meets the requirements.

Water, *Method I* ⟨921⟩: not more than 4.0%, 20 mL of methanol containing 10% of imidazole being used in place of methanol in the titration vessel.

Free erythromycin—Prepare a test solution of it in methanol containing 10.0 mg per mL. Prepare a Standard solution of USP Erythromycin RS in methanol containing 0.3 mg per mL. [NOTE—Prepare these solutions immediately before use.] Prepare a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Before using, place the plate in an unlined developing chamber containing about 100 mL of methanol, and allow the solvent front to move to the top of the plate, marking the direction of travel. Remove the plate, and allow to dry. Apply separate 1-µL volumes of the test solution and the Standard solution on the plate, allow the spots to dry, and develop the chromatograms in a freshly prepared solvent system consisting of a mixture of methanol and chloroform (85:15) until the solvent front has moved about one-half of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the plate to dry. Place the plate under a hood, and spray uniformly with a solution consisting of 150 mg of xanthydrol dissolved in a mixture of hydrochloric acid and glacial acetic acid (92.5:7.5). Heat the sprayed plate in an oven at 100° for 5 minutes. [*Caution—Avoid exposure to acid fumes when removing the plate from the oven.]* Examine the plate for reddish violet spots: free erythromycin has an R_F value of about 0.3, and erythromycin estolate has an R_F value of about 0.7. Any spot corresponding to free erythromycin obtained from the test solution does not exceed in size or intensity that of the principal spot obtained from the Standard solution (3.0%).

Assay—Proceed with Erythromycin Estolate as directed for erythromycin under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately weighed quantity of Erythromycin Estolate dissolved in methanol to obtain a solution containing the equivalent of 1.0 mg of erythromycin per mL. Immediately dilute quantitatively with 9 volumes of *Buffer No. 3*, and allow to stand at room temperature for 18 hours. Dilute a portion of this solution quantitatively with *Buffer No. 3* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

Erythromycin Estolate Capsules

» Erythromycin Estolate Capsules contain the equivalent of not less than 90.0 per cent and not more than 115.0 per cent of the labeled amount of erythromycin ($C_{37}H_{67}NO_{13}$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Erythromycin RS
USP Erythromycin Estolate RS

Identification—Prepare a test solution by mixing a quantity of Capsule contents with methanol to obtain a concentration equivalent to about 20 mg of erythromycin per mL. Prepare a