than 1 of the 30 Pledges is less than 90.0% of the labeled amount.

**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, Method I (921):** not more than 0.0% 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 content, Method II (611):** between 92.5% and 107.5% of the labeled amount of C\(_{37}H_{67}NO_{13}\).

**Assay**—Proceed as directed under Antibiotics—Microbial Assays (81), using an accurately measured volume of Topical Solution diluted quantitatively with Buffer No. 3 to yield a Test Dilution having a concentration assumed to be equal to the median dose level of the Standard.

**Erythromycin Tablets**

* Erythromycin Tablets contain not less than 90.0 percent and not more than 120.0 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 quantity of finely powdered Tablets 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.”

**Dissolution** (711)—

- **Medium**: 0.05 M pH 6.8 phosphate buffer (see Buffer solutions in the section Reagents, Indicators, and Solutions); 900 mL.
- **Apparatus 2**: 50 rpm.
- **Time**: 60 minutes.

**Test solution**—If necessary, dilute a filtered portion of the solution under test with Medium to obtain a concentration of about 0.28 mg of erythromycin per mL, and mix.

**Standard solution**—Dissolve an accurately weighed quantity of USP Erythromycin RS in methanol (not more than 1 mL of methanol for each 14 mg of the Reference Standard), and dilute with water, quantitatively and with mixing, to obtain a stock solution containing about 0.56 mg per mL. Immediately prior to use, dilute the stock solution quantitatively with water to obtain a Standard solution having a known concentration of about 0.28 mg per mL.

**Procedure**—Transfer 5.0-mL portions of the Test solution and the Standard solution to separate 25-mL volumetric flasks, and treat each as follows: Add 2.0 mL of water, and allow to stand for 5 minutes with intermittent swirling. Add 15.0 mL of 0.25 N sodium hydroxide, dilute with Medium to volume, and mix. Heat to 60° for 5 minutes, and allow to cool. Concomitantly determine the absorbances of these solutions at the wavelength of maximum absorbance (about 236 nm, with a suitable spectrophotometer, using blank solutions similarly prepared, except that 2.0 mL of 0.5 N sulfuric acid is substituted for the 2.0 mL of water. Calculate the amount of C\(_{37}H_{67}NO_{13}\) dissolved.

**Tolerances**—Not less than 70% (Q) of the labeled amount of C\(_{37}H_{67}NO_{13}\) dissolved in 60 minutes.

**Uniformity of dosage units** (905): meet the requirements.

**Loss on drying (731):** Dry about 100 mg of powdered Tablets in a capillary-stoppered bottle in vacuum at 60° for 3 hours: it loses not more than 5.0% of its weight.

**Assay**—Place not less than 4 Tablets in a high-speed glass blender jar with 200 mL of methanol, and blend for 3 minutes. Add 300 mL of Buffer No. 3, and blend for 3 minutes. Proceed as directed under Antibiotics—Microbial Assays (81), using an accurately measured volume of this stock test solution diluted quantitatively with Buffer No. 3 to yield a Test Dilution having a concentration assumed to be equal to the median dose level of the Standard.

**Erythromycin Delayed-Release Tablets**

* Erythromycin Delayed-Release Tablets contain not less than 90.0 percent and not more than 120.0 percent of the labeled amount of erythromycin (C\(_{37}H_{67}NO_{13}\)).

**Packaging and storage**—Preserve in tight containers.

**Labeling**—The label indicates that the Tablets are enteric-coated. The labeling indicates the Dissolution Test with which the product complies.

**USP Reference standards** (11)—
USP Erythromycin RS

**Identification**—Prepare a test solution by mixing a quantity of finely powdered Tablets 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.”

**Dissolution** (711)—Proceed as directed for Procedure for Method B under Apparatus 1 and Apparatus 2, Delayed-Release Dosage Forms.

**TEST 1**—If the product complies with this test, the labeling indicates that it meets USP Dissolution Test 1.

- **Apparatus 1**: 100 rpm.
- **Times**: 60 minutes, Stage 1; 60 minutes, Stage 2.

**Acid stage**—Using 900 mL of simulated gastric fluid TS (prepared without pepsin) in place of 0.1 N hydrochloric acid, conduct this stage of the test for 1 hour, and do not perform an analysis of the medium.

**Buffer stage**—Using 900 mL of 0.05 M pH 6.8 phosphate buffer (see Buffer Solutions in the section Reagents, Indicators, and Solutions), conduct this stage of the test for 60 minutes.
Test solution—If necessary, dilute a filtered portion of the solution under test with Dissolution Medium to obtain a solution having a concentration of about 0.28 mg of erythromycin per mL, and mix.

Procedure—Transfer a 2.0-mL portion of the Test solution to a suitable separator. Add 6 mL of pH 1.2 buffer (see Solutions in the section Reagents, Indicators, and Solutions), and 8 mL of a solution of bromocresol purple, prepared by dissolving 1 g of bromocresol purple in 1 L of pH 4.5 phosphate buffer, and mix. Extract with 40.0 mL of chloroform. Determine the amount of C$_{37}$H$_{67}$NO$_{13}$ dissolved from USP Erythromycin RS, and treat similarly.

TEST 2—If the product complies with this test, the labeling indicates that it meets USP Dissolution Test 2. Proceed as directed under Test 1, except to use Apparatus 2 at 75 rpm.

Uniformity of dosage units (905): meet the requirements.

Water, Method I (921): not more than 6.0%, 20 mL of methanol containing 10% of imidazole being used in place of methanol in the titration vessel.

Assay—Place not fewer than 4 Tablets in a high-speed glass blender jar with 200 mL of methanol, and blend for 3 minutes. Add 300 mL of Buffer No. 3, and blend for 3 minutes. Proceed as directed under Antibiotics—Microbial Assays (81), using an accurately measured volume of this stock test solution diluted quantitatively with Buffer No. 3 to yield a Test Dilution having a concentration assumed to be equal to the median dose level of the Standard.

**Erythromycin and Benzoyl Peroxide Topical Gel**

Erythromycin and Benzoyl Peroxide Topical Gel is a mixture of Erythromycin in a suitable gel vehicle containing benzoyl peroxide and one or more suitable dispersants, stabilizers, and wetting agents. It contains not less than 90.0 percent and not more than 125.0 percent of the labeled amounts of erythromycin (C$_{37}$H$_{67}$NO$_{13}$) and benzoyl peroxide (C$_{14}$H$_{10}$O$_{4}$).

Packaging and storage—Before mixing, preserve the Erythromycin and the vehicle containing benzoyl peroxide in separate, tight containers. After mixing, preserve the mixture in tight containers.

USP Reference standards (11)—USP Erythromycin RS

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—


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:

$$125C(R_0 / R_i)$$

in which C is the concentration, in mg per mL, of benzoyl peroxide in the Standard preparation, and $R_0$ and $R_i$ 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**

$$C_{37}H_{67}NO_{13} \cdot C_{14}H_{10}O_4 \cdot 1056.39$$

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