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Erythromycin Tablets

» Erythromycin Tablets contain not less than 90.0 percent and not more than 120.0 percent of the labeled amount of $C_{37}H_{67}NO_{13}$.

[Note—Tablets that are enteric-coated meet the requirements for *Erythromycin Delayed-Release Tablets*.]

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 solution having 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 at 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 $C_{37}H_{67}NO_{13}$ is 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 B.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 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 TABLETS	Kishan Chandra Senior Scientist I, Documentary Standards	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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