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Erythromycin Stearate Tablets

» Erythromycin Stearate Tablets contain the equivalent of 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.

USP Reference standards ⟨11⟩—

USP Erythromycin RS
USP Erythromycin Stearate RS

Identification—To a quantity of powdered Tablets add a volume of methanol sufficient to yield a solution containing the equivalent of about 5 mg of erythromycin per mL. Shake this mixture by mechanical means for about 30 minutes. Centrifuge a portion of this mixture, and use the clear supernatant as the test solution. Prepare a Standard solution of USP Erythromycin Stearate RS in methanol containing about 8 mg per mL. Apply separately 20 µL each of the test solution and the Standard solution to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture, and allow to dry. Place the plate in an unlined chromatographic chamber, and develop the chromatograms in a solvent system consisting of a mixture of methanol and chloroform (85:15) until the solvent front has moved about 9 cm. Remove the plate from the chamber, mark the solvent front, and allow the solvent to evaporate. Spray the plate with a methanolic solution of 2',7'-dichlorofluorescein (1 in 500), and examine the plate under long-wavelength UV light: the R_F values of the principal fluorescent spots obtained from the test solution correspond to those obtained from the Standard solution. Then spray the plate with a mixture of dehydrated alcohol, *p*-methoxybenzaldehyde, and sulfuric acid (90:5:5). Heat the plate at 100° for 10 minutes, and examine the chromatograms, in which the erythromycin appears as a black-to-purple spot: the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

Dissolution ⟨711⟩—

Medium: 0.05 M pH 6.8 phosphate buffer (see under *Solutions* in the section *Reagents, Indicators, and Solutions*); 900 mL.

Apparatus 2: 100 rpm.

Time: 120 minutes.

Stock standard solution—Dissolve an accurately weighed quantity of USP Erythromycin RS in methanol to obtain a solution containing about 14 mg per mL. Dilute quantitatively with water, and mix to obtain a solution having a known concentration of about 0.56 mg of USP Erythromycin RS per mL.

Working standard solution—On the day of use, dilute 25.0 mL of *Stock standard solution* with water to 50.0 mL, and mix.

Test solution—After 120 minutes, withdraw a portion of the solution under test, filter, and dilute with *Medium*, if necessary, to obtain a solution having an estimated concentration of about 0.28 mg of erythromycin per mL.

Procedure—Transfer 5.0-mL portions of the *Working standard solution* to two 25-mL volumetric flasks, one of which serves as a working standard blank. Similarly, transfer 5.0-mL portions of the *Test solution* to two 25-mL volumetric flasks, one of which serves as a blank for that *Test solution*. To each of the flasks designated as a blank add 2.0 mL of 0.5 N sulfuric acid and to the remaining flasks add 2.0 mL of water. Allow to stand for 5 minutes with intermittent swirling. To all flasks add 15.0 mL of 0.25 N sodium hydroxide, dilute with *Medium* to volume, and mix. Heat the flasks in a water bath at 60 ± 0.5° for 5 minutes, and allow to cool. Using a suitable spectrophotometer, determine the absorbance of each solution, corrected for its blank solution, at the wavelength of maximum absorbance at about 236 nm. Determine the amount of $C_{37}H_{67}NO_{13}$ dissolved from the *Test solution* in comparison with the solution obtained from the *Working standard solution*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{37}H_{67}NO_{13}$ is dissolved in 120 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—Proceed with Tablets as directed in the *Assay* under *Erythromycin Tablets*.

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

Chromatographic Database Information: Chromatographic Database

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