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Erythromycin Delayed-Release Capsules

» Erythromycin Delayed-Release Capsules contain not less than 90.0 percent and not more than 115.0 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

Identification—Prepare a test solution by mixing a quantity of finely ground Capsule contents with methanol to obtain a concentration of about 2.5 mg of erythromycin per mL. Prepare a Standard solution of USP Erythromycin RS in methanol containing 2.5 mg per mL. Apply separately 10 µL of each 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 chromatogram in a solvent system consisting of a mixture of methanol and chloroform (85:15) until the solvent front has moved about 7 cm. Remove the plate from the 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 chromatogram, in which 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⟩—Proceed as directed for *Procedure* for *Method B* under *Apparatus 1 and Apparatus 2, Delayed-Release Dosage Forms.*

Apparatus 1: 50 rpm.

Times: 60 minutes for *Acid Stage;* 60 minutes for *Buffer Stage*.

Procedure—Transfer the contents of 1 Capsule to the apparatus. Proceed as directed for *Acid Stage*, 900 mL of 0.06 N hydrochloric acid being placed in the vessel instead of 1000 mL of 0.1 N hydrochloric acid, and the apparatus operated for 60 minutes instead of 2 hours. Do not perform an analysis at the end of the *Acid stage*. Continue as directed for *Buffer Stage*, 900 mL of the pH 6.8 phosphate buffer being used instead of 1000 mL. Determine the amount of $C_{37}H_{67}NO_{13}$ dissolved after 120 minutes by assaying a filtered portion of the solution under test as directed under *Antibiotics—Microbial Assays* ⟨81⟩.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{37}H_{67}NO_{13}$ is dissolved in 120 minutes.

Water Determination, *Method I* ⟨921⟩**:** not more than 7.5%, 20 mL of methanol containing 10% of imidazole being used in place of methanol in the titration vessel.

Assay—Proceed as directed under *Antibiotics—Microbial Assays* ⟨81⟩, using not less than 5 Capsules blended for about 3 minutes in a high-speed glass blender jar containing 200 mL of methanol. Add 300 mL of *Buffer B.3,* and blend again for about 3 minutes. Dilute an accurately measured volume of this stock 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 DELAYED-RELEASE CAPSULES	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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