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Erythromycin Pledgets

» Erythromycin Pledgets are suitable absorbent pads impregnated with Erythromycin Topical Solution. Pledgets contain not less than 90.0 percent of the labeled volume of Erythromycin Topical Solution.

Packaging and storage—Preserve in tight containers.

Labeling—Label Pledgets to indicate that each Pledge is to be used once and then discarded. Label Pledgets also to indicate the volume, in mL, of Erythromycin Topical Solution contained in each Pledge, and the concentration, in mg of erythromycin per mL, of the Erythromycin Topical Solution.

USP REFERENCE STANDARDS (11)—

[USP Erythromycin RS](#)

Identification—Prepare a test solution by shaking one Pledge with methanol, and diluting appropriately 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 μ L 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.

Other requirements—The Erythromycin Topical Solution expressed from Pledgets meets the requirements for Water and [Alcohol content](#) under [Erythromycin Topical Solution](#).

Topical solution assay—Proceed as directed for erythromycin under [Antibiotics—Microbial Assays \(81\)](#), using the solution expressed from not less than 10 Pledgets. Dilute an accurately measured volume of this 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.

Assay and minimum volume—Proceed as directed for erythromycin under [Antibiotics—Microbial Assays \(81\)](#), assaying 10 Pledgets individually. Transfer 1 Pledge to a suitable container, add about 50 mL of *Buffer B.3*, and shake for 2 minutes. Transfer the solution so obtained to a 100-mL volumetric flask. Wash the Pledge with two 20-mL portions of *Buffer B.3*, add the washings to the 100-mL volumetric flask, dilute with *Buffer B.3* to volume, and mix. Dilute an accurately measured volume of this 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. Calculate the volume, in mL, of Erythromycin Topical Solution in each Pledge taken by dividing the number of mg of erythromycin in each individual Pledge by the number of mg of erythromycin in each mL of Erythromycin Topical Solution as obtained in the *Topical Solution assay*. The volume of Erythromycin Topical Solution in each Pledge is not less than 90.0% of the labeled amount. If this requirement is not met, determine the volume of Erythromycin Topical Solution in each of 20 additional Pledgets. The volume of Erythromycin Topical Solution in not more than 1 of the 30 Pledgets is less than 90.0% of the labeled amount.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ERYTHROMYCIN PLEDGETS	Rebecca C. Potts Associate Scientific Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

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