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Erythromycin Intramammary Infusion

» Erythromycin Intramammary Infusion is a solution of Erythromycin in a suitable vegetable oil vehicle. It contains one or more suitable preservatives. It contains 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 single-dose disposable syringes that are well-closed containers.

Labeling—Label it to indicate that it is for veterinary use only.

USP REFERENCE STANDARDS (11).—
[USP Erythromycin RS](#)

Identification—Transfer a quantity of Intramammary Infusion, equivalent to about 5 mg of erythromycin, to a separator containing 50 mL of solvent hexane. Shake until dissolved. Extract with three separate 20-mL portions of methanol. Combine the methanol extracts in a beaker, and evaporate to dryness. Dissolve the residue in 2 mL of methanol (test solution). Proceed as directed in the [Identification](#) test under [Erythromycin Delayed-Release Capsules](#), beginning with “Prepare a Standard solution of [USP Erythromycin RS](#).”

MINIMUM FILL (755): meets the requirements.

WATER DETERMINATION, Method I (921): not more than 1.0%, 20 mL of a mixture of toluene and methanol (7:3) being used in place of methanol in the titration vessel.

Assay—Transfer the contents of a syringe of Intramammary Infusion to a separator containing 50 mL of solvent hexane. Shake until dissolved. Wash with four separate 20-mL portions of a mixture of methanol and water (4:1). Combine the washings in a 100-mL volumetric flask, dilute with the methanol and water solution to volume, and mix. Proceed as directed for erythromycin under [Antibiotics—Microbial Assays \(81\)](#), using an accurately measured volume of this stock solution diluted quantitatively with *Buffer B.3* to yield a *Test Dilution* having a concentration of erythromycin assumed to be equal to the median dose level of the Reference Standard.

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

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

Chromatographic Database Information: [Chromatographic Database](#)

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