

Status: Currently Official on 14-Feb-2025  
 Official Date: Official Prior to 2013  
 Document Type: USP Monographs  
 DocId: GUID-1BD31D84-8D46-45BB-873E-47E09DC28F24\_2\_en-US  
 DOI: [https://doi.org/10.31003/USPNF\\_M30207\\_02\\_01](https://doi.org/10.31003/USPNF_M30207_02_01)  
 DOI Ref: c1pau

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## Erythromycin Injection

» Erythromycin Injection is a sterile solution of Erythromycin in a polyethylene glycol vehicle. 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 multiple-dose containers.

**Labeling**—Label it to indicate that it is for veterinary use only. Label it to state that it is for intramuscular administration only.

**USP REFERENCE STANDARDS (11)**—

[USP Erythromycin RS](#)

**Identification**—Transfer a quantity of Injection, 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](#)."

**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.

**STERILITY TESTS (71)**—It meets the requirements when tested as directed for *Direct Inoculation of the Culture Medium* under *Test for Sterility of the Product to be Examined*.

**Other requirements**—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

**Assay**—Transfer an accurately measured volume of Injection, equivalent to about 50 mg of erythromycin, 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 Standard.

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

Topic/Question	Contact	Expert Committee
ERYTHROMYCIN INJECTION	<a href="#">Rebecca C. Potts</a> Associate Scientific Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. Information currently unavailable

**Current DocID: GUID-1BD31D84-8D46-45BB-873E-47E09DC28F24\_2\_en-US**

**Previous DocID: GUID-1BD31D84-8D46-45BB-873E-47E09DC28F24\_1\_en-US**

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