

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
DOI Ref: c1pau

© 2025 USPC
Do not distribute

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	Rebecca C. Potts 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
DOI: https://doi.org/10.31003/USPNF_M30207_02_01
DOI ref: [c1pau](#)