Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-6BE31011-CDD6-437B-B284-8A21437FB098_4_en-US
DOI: https://doi.org/10.31003/USPNF_M30450_04_01
DOI Ref: 3mas8

Erythromycin Lactobionate for Injection

$C_{37}H_{67}NO_{13}.C_{12}H_{22}O_{12}$ 1092.22

Erythromycin mono(4-*O*-β-D-galactopyranosyl-D-gluconate) (salt).

Erythromycin lactobionate (1:1) (salt) CAS RN®: 3847-29-8.

» Erythromycin Lactobionate for Injection is a sterile, dry mixture of erythromycin lactobionate and a suitable preservative. It contains the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amount of erythromycin ($C_{37}H_{67}NO_{13}$).

Packaging and storage—Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*.

USP Reference Standards ⟨11⟩—

USP Erythromycin RS
USP Erythromycin Lactobionate RS

Constituted solution—At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

Change to read:

Identification, ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (CN 1-May-2020): the specimen and the Reference Standard being previously dried in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 1.0 USP Endotoxin Unit per mg of erythromycin.

pH ⟨791⟩: between 6.5 and 7.5, in a solution containing the equivalent of 50 mg of erythromycin per mL.

Water Determination, *Method I* ⟨921⟩: not more than 5.0%.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections when the constituted solution is diluted with filtered water to a concentration of not more than 5 mg of erythromycin base per mL before the test is performed.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—Proceed as directed for erythromycin under *Antibiotics—Microbial Assays ⟨81⟩*, using Erythromycin Lactobionate for Injection constituted as directed in the labeling. Withdraw all of the withdrawable contents where the package is represented as being a single-dose container; or, where the labeling specifies the amount of erythromycin equivalent in a given volume of the resultant preparation, withdraw an accurately measured volume. Dilute quantitatively with water to obtain a stock solution containing the equivalent of about 10 mg of erythromycin per mL. Dilute 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 LACTOBIONATE FOR INJECTION	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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