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Review Article on Erythromycin Lactobionate

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ABSTRACT

Erythromycin Lactobionate is a macrolide antibiotic formulated for parenteral use, especially in patients who cannot take oral medications. This article presents the formulation strategy, step-wise manufacturing process, and comprehensive evaluation techniques used to ensure the quality, safety, and efficacy of the erythromycin injection. Detailed discussion on formulation ingredients, sterile techniques, lyophilization, and sterility evaluation is included, meeting regulatory requirements and industry standards.

KEY WORDS: Antibiotics**.** Erythromycin lactobionate, Formulation, Evaluation.

INTRODUCTION

ANTIBIOTICS

Antibiotics are chemical substances used to inhibit the growth of or destroy bacteria, playing a pivotal role in modern medicine by treating bacterial infections effectively. They were first discovered in the early 20th century, with Alexander Fleming's identification of penicillin in 1928 marking a major breakthrough (Fleming, 1929). Since then, antibiotics have significantly reduced mortality and morbidity associated with infectious diseases and have become a cornerstone in healthcare for procedures such as surgeries, chemotherapy, and organ transplants.

ERYTHROMYCIN LACTOBIONATE

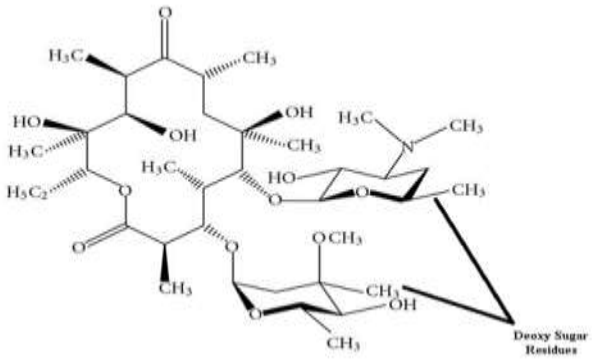
Erythromycin Lactobionate is a water-soluble salt form of erythromycin, a macrolide antibiotic derived from *Streptomyces erythraeus*. It is primarily used in parenteral formulations due to its improved solubility and stability compared to other erythromycin salts. As an antibiotic, it exerts its action by binding to the 50S ribosomal subunit of susceptible bacteria, thereby inhibiting protein synthesis and exerting a bacteriostatic effect.

Erythromycin lactobionate is especially valuable in clinical settings where oral administration is not feasible, such as in severely ill, unconscious, or post-operative patients. It is commonly employed to treat a wide range of infections caused by Gram-positive bacteria and some Gram-negative organisms, including respiratory tract infections, skin and soft tissue infections, pelvic inflammatory disease, Legionnaires' disease, and certain sexually transmitted infections.

The parenteral form is often reserved for moderate to severe infections and is an effective alternative in patients allergic to penicillins. Erythromycin's broad-spectrum activity, coupled with a favorable safety profile, makes erythromycin lactobionate a key therapeutic option in hospital and intensive care settings.

MACROLIDE ANTIBIOTICS

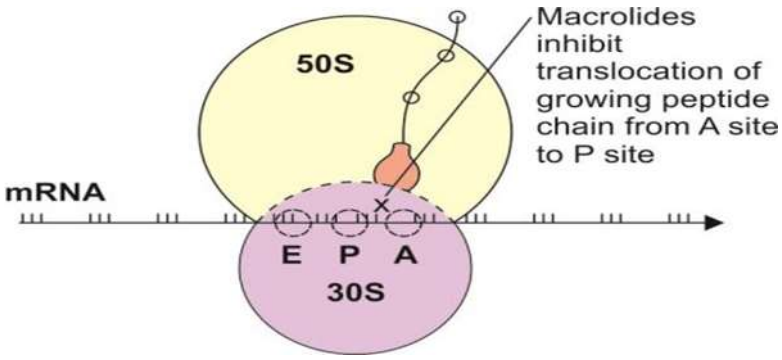
The macrolide antibiotics are those that consist of a large lactone ring to which sugars are attached. Antibiotics in this group include Erythromycin,clarithromycin,azithromycin. Certain macrolides have antibiotic or antifungal properties and are used in pharmaceutical antimicrobial therapy. The first macrolide used in this manner was erythromycin in 1952; it was often used for infections in patients who were allergic to penicillin or whose infections were penicillin-resistant.



Structure of Erythromycin

MECHANISM OF ACTION

Macrolides bind to the 50s ribosomal subunit of bacteria and prevent the translocation of aminoacyl tRNA from A site to P site transfering of genetic informations are blocked ,no peptide chain elongation which result in the inhibition of protein syntheis.



FORMULATION

Formulations in pharmaceuticals refer to the process of combining the active drug (API – Active Pharmaceutical Ingredient) with other substances (called excipients) to create a final medicinal product that is safe, effective, and acceptable for use.

INGREDIENTS

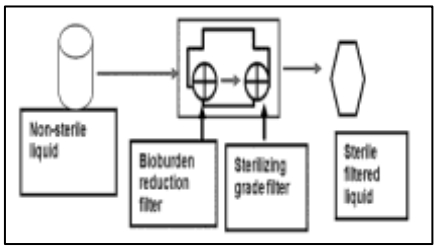
Ingredient	**Quantity**	**Function**
Erythromycin Lactobionate	500 mg per vial	Active pharmaceutical ingredient
Lactobionic Acid	~244 mg per vial	Stabilizer and solubilizer
Sterile Water for Injection (SWFI)	10 mL	Solvent
Sodium Chloride (Normal Saline)	0.9%	Maintains isotonicity
Sodium Bicarbonate	1 mL of 4% solution	Buffering agent

MANUFACTURING PROCESS OF ERYTHROMYCIN INJECTION

1. Cleaning and Washing

All containers and closures are washed thoroughly with detergent, rinsed with tap water, followed by distilled water, and finally with water for injection (WFI). Rubber closures are cleaned with 0.5% sodium pyrophosphate solution and rinsed thoroughly.

2. Preparation of Solution



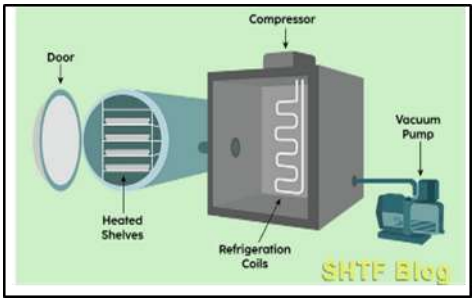
- All ingredients are weighed accurately in an aseptic environment.
- Erythromycin lactobionate is dissolved in WFI under aseptic conditions.
- pH is adjusted to 6.0–7.5 using 0.1 N NaOH or HCl.
- Solution is filtered through a 0.22 µm sterilizing grade membrane filter.

3. Filling

- Sterile solution is filled into 10 mL or 20 mL vials using an aseptic filling machine.
- Each vial is filled with a precise volume (e.g., 5 mL).
- Nitrogen overlay may be used to prevent oxidation.
- Vials are partially stoppered with sterile rubber closures.

4. Freeze Drying (Lyophilization)

Lyophilization involves:



- Freezing the solution to −40°C to −50°C.
- Primary drying: Vacuum applied; shelf temperature raised to −20°C to 0°C.
- Secondary drying: Temperature raised to 20–30°C to remove bound moisture.

5 .Sealing

- Vials are sealed with aluminum caps using a crimping tool.
- Ensures tamper-evident and sterile closure.

EVALUATION

Evaluation of parenterals refers to the systematic assessment of sterile injectable products to ensure their safety, efficacy, quality, and compliance with regulatory standards. This includes a series of physical, chemical, biological, and microbiological tests performed during and after manufacturing.They are as follows

❖ **Sterility Testing**

Methods:

- **Direct Transfer Method:** Inoculate portions into Thioglycollate and Soybean-Casein Digest Media.
- **Membrane Filtration:** Suitable for oily/alcohol-based preparations. Filters are incubated in FTM and SCM.

❖ **Clarity Test**

- Visual inspection against black/white backgrounds.
- Must be free from particulate matter, turbidity, or discoloration.
- Advanced tests: Coulter counter, light scattering, microscopy.

❖ **Pyrogen Testing**

- **Rabbit Test:** Monitors rise in body temperature post IV injection.
- **BET/LAL Test:** Detects endotoxins using amoebocyte lysate from horseshoe crab.
- Erythromycin max limit: 500 EU (1 EU/mg for 500 mg vial).

❖ **Leak Testing**

- Vacuum Decay Test
- Bubble Emission Test
- High Voltage Leak Detection (HVLD)

PACKAGING AND LABELLING

1. Primary Packaging

- **Vials:** Type I borosilicate glass, sizes 10–50 mL.
- **Rubber Stoppers:** Sterilizable butyl rubber.
- **Aluminum Seals:** Flip-off caps for tamper evidence.

2. Secondary and Tertiary Packaging

- **Cartons:** Printed inserts for storage/reconstitution.
- **Transport Boxes:** Corrugated fiberboard, may include insulation.

3. Labelling Requirements

- Name of the preparation
- Quantity and concentration
- Mfg. Lic. No., Batch No.
- Date of manufacture and expiry
- Storage conditions
- Retail price
- Manufacturer's address

Stability and Storage

- Stable for **up to 8 hours** at 25°C.
- Protect from light and excessive heat.
- Store in a dry place between 2°C and 8°C (refrigerated conditions) if possible.
- Once reconstituted, use immediately or as per validated holding time.

CONCLUSION

The formulation and development of erythromycin lactobionate injection requires stringent aseptic practices, validated sterilization, and robust packaging to maintain product integrity. Through stepwise evaluation and compliance with regulatory tests such as sterility, clarity, pyrogen, and leak integrity, the formulation ensures therapeutic effectiveness and patient safety. Advances in lyophilization and endotoxin detection technologies have greatly improved the shelf-life and reliability of erythromycin parenterals.

REFERENCES

1.Fleming A. On the antibacterial action of cultures of a *Penicillium*, with special reference to their use in the isolation of *B. influenzae*. *Br J Exp Pathol*. 1929;10(3):226–36.

2.Katzung BG, Trevor AJ. *Basic and Clinical Pharmacology*. 15th ed. New York: McGraw-HilEducation; 2021.

3.World Health Organization. Antimicrobial resistance [Internet]. Geneva: WHO; 2020 [cited2025 Jun 29].

4.Brunton LL, Hilal-Dandan R, Knollmann BC. *Goodman & Gilman's The Pharmacological Basis of Therapeutics*. 13th ed. New York: McGraw-Hill Education; 2018.

5.Golan DE, Tashjian AH, Armstrong EJ, Armstrong AW. *Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy*. 4th ed. Philadelphia: Wolters Kluwer; 2017.

6.Madigan MT, Bender KS, Buckley DH, Sattley WM, Stahl DA. *Brock Biology of Microorganisms*. 16th ed. New York: Pearson; 2018. p. 788–794.

7. Aulton ME, Taylor KM. *Aulton's pharmaceutics: The design and manufacture of medicines*. 5th ed. Edinburgh: Churchill Livingstone; 2018. p. 701–703.

8.Sweetman SC, editor. *Martindale: The complete drug reference*. 36th ed. London: Pharmaceutical Press; 2009. p. 259–261.

9. Tripathi KD. *Essentials of Medical Pharmacology*. 8th ed. New Delhi: Jaypee Brothers Medical Publishers; 2018.

10. Gilter, B., et al,Torsades de Pointes Induced by Erythromycin, Chest, Volume 105: 368-72, February 1994.