

ER Formulation Characteristics & Differences

ZooPharm has developed a patented* formulation platform providing controlled release drug delivery of important pharmaceuticals from within several responsive bio-polymers. This novel technology provides timed release of the active compound as it diffuses from the polymer matrix while the novel polymer biodegrades. The ER polymer formulation has overcome the administration problems associated with previous solid implants, by dissolving the biodegradable polymers in a biocompatible solvent. When injecting the solution into the body using standard syringes and needles, the polymer in the solution precipitates or coagulates upon contact with aqueous body fluid to form an implant matrix.

ER Formulation Characteristics

- Controlled release system maintains desired drug concentrations for extended periods of time (from 72 hours to 90 days)
- Formulated from safe, reliable biodegradable polymers
 - Similar to material used in absorbable sutures
 - Elimination via tricarboxylic acid cycle as CO₂ and water
- Drug concentration delivered at consistent therapeutic levels without exceeding the maximum tolerable dose
- Active can be integrated within the matrix as a solution or suspension
- High drug stability
 - Polymer formulation protects the active drug from the physiological environment and improves its stability in vivo
- Excellent tissue compatibility reported
 - Liquid conforms to tissue and is non-irritating
- Reduces systemic exposure to high-toxicity actives (such as chemotherapeutics), eliminating adverse reactions and side effects
- No loss of drug during manufacturing
- Formulations can be sterile filtered or terminally sterilized

Buprenorphine ER-LAB Polymer System Description

The polymer system used for the buprenorphine (base) sustained release system consisted of a poly (DL-lactide-co-caprolactone) dissolved in N-methyl-2-pyrrolidone to provide an injectable formulation viscosity. Molecular weight was determined by gel permeation chromatography with a multi-angle light scattering detector (GPC-MALS). The active buprenorphine base was then dissolved in the liquid polymer system to produce the 0.5mg/ml concentration Buprenorphine ER-LAB test formulation.

***US Patent 8,187,640**

ER Formulation Differences

Buprenorphine ER-LAB

- Available in 0.5mg/ml and 1mg/ml concentrations.
- Developed specifically for use in some laboratory species, these formulations may eliminate many of the skin reactions that can occur in select strains of mice (and select rat strains).

Buprenorphine HCl ER

- Available in 1mg/ml, 3mg/ml and 10mg/ml concentrations.
- Used among a variety of research species including, but not limited to: ferrets, guinea pigs, rats, rabbits, primates, swine, and sheep. Not recommended for administration in mice

Dose Determination Guidelines*

- Dose determination for administration of our 3-Day sustained release **Buprenorphine ER** formulations are based on a **rate of 3x the normal daily dose**.
- It is suggested that when using **any of our ER formulations** for the first time, that your initial dosing should be calculated with regard to the lowest published veterinary formulary recommendations for each species.
- We also recommend that when using **any of our ER formulations**, that clinicians start with a single injection dose of Buprenorphine ER that is exactly 3X greater than the current standard buprenorphine you are using (i.e. Buprenex). Then, based on observed levels of analgesia provided, adjust the ER dose up or down as needed.

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