

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

### **Draft Guidance on Lefamulin Acetate**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Lefamulin acetate

**Dosage Form; Route:** Tablet; oral

**Recommended Study:** One study

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: EQ 600 mg Base  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: Exclude subjects with risk factors for prolonged QTc interval and Torsades de Pointes. Monitor subjects during the study for electrocardiogram changes. Females of reproductive potential should use effective contraception during the study and two days after the study.

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**Analyte to measure:** Lefamulin in plasma

**Bioequivalence based on (90% CI):** Lefamulin

**Waiver request of in vivo testing:** Not applicable

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.