Active Ingredients: Erythromycin ethylsuccinate; Sulfisoxazole acetyl

Dosage Form: Route: Granule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 200 mg Base/5 mL; EQ 600 mg Base/5 mL
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: Applicants may consider using a reference-scaled average bioequivalence approach for erythromycin ethylsuccinate. If using this approach, provide evidence of high variability in the pharmacokinetic parameters (i.e., within-subject variability ≥ 30%) for the reference product. For detailed information on this approach, refer to the guidance for progesterone oral capsules.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 200 mg Base/5 mL; EQ 600 mg Base/5 mL
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See comments above.

Analytes to measure: Erythromycin ethylsuccinate and its active metabolite, erythromycin, and sulfisoxazole in plasma

Submit the erythromycin data as supportive evidence of comparable therapeutic outcome. For erythromycin, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and Cmax.

Bioequivalence based on (90% CI): Erythromycin ethylsuccinate and sulfisoxazole

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/](http://www.accessdata.fda.gov/scripts/cder/dissolution/). Conduct comparative dissolution testing on 12 dosage units for each of the test and reference products. Note that a dosage unit for a suspension is the labeled strength (5 mL). Specifications will be determined upon review of the abbreviated new drug application.