Active Ingredient: Oseltamivir phosphate

Dosage Form; Route: Suspension; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 6 mg base/mL at a dose of 75 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: N/A

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 6 mg base/mL at a dose of 75 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: N/A

Analytes to measure (in appropriate biological fluid): Oseltamivir and its active metabolite, oseltamivir carboxylate in plasma.

Please submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, 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): Oseltamivir

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at
the following location: [http://www.accessdata.fda.gov/scripts/cder/dissolution/](http://www.accessdata.fda.gov/scripts/cder/dissolution/). Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).