Active Ingredient: Tasimelteon

Dosage Form; Route: Capsule; oral

Recommended Studies: One in vivo study

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 20 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: Females subjects should not be pregnant or lactating, and, if applicable, should practice abstinence or contraception during the study

Analytes to measure (in appropriate biological fluid): Tasimelteon in plasma

Bioequivalence based on (90% CI): Tasimelteon

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site, available to the public at the following location: 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).