Active ingredient: Morphin Sulfate

Form/Route: Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 30 mg
   Subjects: Healthy males and non-pregnant females, general population.
   Additional Comments: Please use a narcotic antagonist such as naltrexone. Please consult a physician who is an expert in the administration of opioids for an appropriate dose of narcotic antagonist.

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 30 mg
   Subjects: Healthy males and non-pregnant females, general population.
   Additional Comments: Please see comments above.

Analytes to measure (in appropriate biological fluid): Morphine and Morphine-6-Glucuronide in plasma.

Bioequivalence based on (90% CI): Morphine

Waiver request of in-vivo testing: 15 mg strength based on (i) acceptable bioequivalence studies on the 30 mg strength, (ii) acceptable in vitro dissolution testing for all strengths, and (iii) proportional similarity in the formulations across all strengths.

Dissolution test method and sampling times:

Please note that Dissolution Method Database is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please 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 application.

Recommended Feb 2010