Active Ingredient: Meloxicam

Dosage Form; Route: Disintegrating tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 15 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: The drug product should be placed on the tongue until it dissolves without water.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 15 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See comments above

Analyte to measure (in appropriate biological fluid): Meloxicam in plasma

Bioequivalence based on (90% CI): Meloxicam

Waiver request of in vivo testing: 7.5 mg based on (i) acceptable bioequivalence studies on the 15 mg strength, (ii) proportional similarity of the formulations across the two strengths, and (iii) acceptable in vitro dissolution testing of the two strengths

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 the two strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.