

Guidance on Meloxicam

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Active ingredient: Meloxicam

Form/Route: Suspension/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Dose and Suspension Strength: 5 mL of 7.5 mg/5 mL
Subjects: Normal healthy males and females, general population
Additional Comments: Females should not be pregnant, and if applicable, should practice abstinence or contraception during the study.

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Dose and Suspension Strength: 5 mL of 7.5 mg/5 mL
Subjects: Normal healthy males and females, general population
Additional comments: Please see comment above.

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

Bioequivalence based on (90% CI): Meloxicam

Waiver request of in-vivo testing: Not Applicable

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. 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.