

Draft Guidance on Meloxicam

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

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.