

Draft Guidance on Montelukast Sodium

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Montelukast Sodium

Form/Route: Chewable Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover *in-vivo*
Strength: 5 mg
Subjects: Normal healthy males and females, general population
Additional Comments: The tablet should be swallowed whole.

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

Analytes to measure (in appropriate biological fluid): Montelukast in plasma.

Bioequivalence based on (90% CI): Montelukast

Waiver request of in-vivo testing: 4 mg based on (i) acceptable bioequivalence studies on the 5 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

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.