

Contains Nonbinding Recommendations
Draft – Not for Implementation
Draft Guidance on Montelukast Sodium
October 2024

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Active Ingredient:	Montelukast sodium
Dosage Form:	Granule
Route:	Oral
Strength:	EQ 4 mg Base/packet
Recommended Study:	One in vivo bioequivalence study with pharmacokinetic endpoints
1.	Type of study: Fasting Design: Single-dose, two-treatment, two-period crossover in vivo Strength: EQ 4 mg Base/packet Subjects: Healthy males and non-pregnant, non-lactating females Additional comments: None
Analyte to measure:	Montelukast in plasma
Bioequivalence based on (90% CI):	Montelukast
Waiver request of in vivo testing:	Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

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¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.