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Draft Guidance on Metronidazole

November 2025

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Active Ingredient: Metronidazole

Dosage Form: Tablet

Route: Oral

Strengths: 125 mg[1], 250 mg, 500 mg

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: 500 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Metronidazole in plasma

Bioequivalence based on (90% CI): Metronidazole

Waiver request of in vivo testing: 125 mg and 250 mg strengths based on (i) an acceptable bioequivalence study on the 500 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

[1] The strength identified is the subject of an approved suitability petition (FDA-2018-P-3861).

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 all strengths of the test product and reference listed drug (RLD).[2] Specifications will be determined upon evaluation of the abbreviated new drug application.

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