

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Naproxen

October 2024

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Active Ingredient: Naproxen

Dosage Form: Tablet

Route: Oral

Strengths: 250 mg, 375 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: Naproxen in plasma

Bioequivalence based on (90% CI): Naproxen

Waiver request of in-vivo testing: 250 mg and 375 mg strengths based on (i) 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

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).¹ Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended July 2008; Revised October 2024

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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*.