

Contains Nonbinding Recommendations

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Draft Guidance on Rufinamide

October 2024

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Active Ingredient: Rufinamide

Dosage Form: Tablet

Route: Oral

Strengths: 200 mg, 400 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 400 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

Analyte to measure: Rufinamide in plasma

Bioequivalence based on (90% CI): Rufinamide

Waiver request of in vivo testing: 200 mg based on (i) acceptable bioequivalence study on the 400 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations across both 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 both strengths 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*.