

Draft Guidance on Nabumetone

October 2024

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Active Ingredient: Nabumetone

Dosage Form: Tablet

Route: Oral

Strengths: 500 mg, 750 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: 750 mg

Subjects: Healthy males and non-pregnant, non-lactating females

Additional comments: None

Analyte to measure: 6-methoxy-2-naphthyl-acetic acid (6-MNA)

Bioequivalence based on (90% CI): 6-methoxy-2-naphthyl-acetic acid (6-MNA)

Waiver request of in vivo testing: 500 mg based on (i) acceptable bioequivalence study on the 750 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between 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*.