

Draft Guidance on Ibuprofen; Pseudoephedrine Hydrochloride

October 2024

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Active Ingredients: Ibuprofen; Pseudoephedrine hydrochloride

Dosage Form: Suspension

Route: Oral

Strength: 100 mg/5 mL; 15 mg/5 mL

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: 100 mg/5 mL; 15 mg/5 mL

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

Additional comments: None

Analytes to measure: Ibuprofen and pseudoephedrine in plasma

Bioequivalence based on (90% CI): Ibuprofen and pseudoephedrine

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 each 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 August 2007; Revised October 2024

Unique Agency Identifier: PSG_021128

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*.