

Draft Guidance on Ibuprofen; Pseudoephedrine Hydrochloride

October 2024

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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*.