Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Oxaprozin

November 2025

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

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Active Ingredient: Oxaprozin

Dosage Form: Capsule

Route: Oral

Strength: 300 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: 300 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Oxaprozin in plasma

Bioequivalence based on (90% CI): Oxaprozin

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times*:*

Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD)[1]. Provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[2], such as the ability to discriminate changes in critical quality attributes that could potentially impact drug product performance. For drug products containing high solubility drug substances that meet the rapidly dissolving criteria, demonstration of discriminating ability is not required.[3]

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[1] If the RLD is not available, refer to the most recent version of the guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.
[2] Applicant-developed, United States Pharmacopeia (USP) drug product monograph or Dissolution Database methods (http://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm).
[3] Refer to the most recent version of the guidance for industry *Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances.*