

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Carbidopa; Levodopa

November 2025

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Active Ingredients: Carbidopa; Levodopa

Dosage Form: Tablet

Route: Oral

Strength: 25 mg; 100 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: 25 mg; 100 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

Analytes to measure: Carbidopa and levodopa in plasma

Bioequivalence based on (90% CI): Carbidopa and levodopa

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 for each of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

If any strength of the tablet product has a functional score, additional dissolution profile testing should be conducted for each segment of the split tablet after manual and mechanical splitting as per the most recent version of the FDA guidance for industry on *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation*.^a

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Unique Agency Identifier: PSG_214869

^a For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>

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*.