

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Cabergoline

December 2025

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Active Ingredient:	Cabergoline
Dosage Form:	Tablet
Route:	Oral
Strengths:	0.25 mg, ¹ 0.5 mg
Recommended Study:	One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period, two sequence, crossover in vivo
Strength: 0.5 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comment: $AUC_{(0-72h)}$ may be used in place of $AUC_{(0-t)}$ when comparing the extent of absorption, due to cabergoline’s long half-life. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of cabergoline. Alternatively, a parallel study design may be considered.

Analyte to measure: Cabergoline in plasma

Bioequivalence based on (90% CI): Cabergoline

Waiver request of in vivo testing of additional strength: Justification based on (i) an acceptable bioequivalence study on the 0.5 mg strength, (ii) acceptable comparative in vitro dissolution studies between the additional strength and the 0.5 mg strength using 12 units per strength, and (iii) proportional similarity of the formulations between both strengths.

¹Strength identified is the subject of an approved suitability petition (FDA-2021-P-1082).

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)² Specifications will be determined upon review of the abbreviated new drug application.

If 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 *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation*.^a

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Unique Agency Identifier: PSG_020664

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

² If the RLD is not available, refer to the most recent version of the guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.