

Contains Nonbinding Recommendations
Draft – Not for Implementation
Draft Guidance on Vardenafil Hydrochloride
October 2024

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Active Ingredient:	Vardenafil hydrochloride
Dosage Form:	Tablet, orally disintegrating
Route:	Oral
Strength:	10 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: 10 mg Subjects: Healthy males Additional comments: The orally disintegrating tablet should be placed on the tongue, allowed to disintegrate, and swallowed without water.
Analyte to measure:	Vardenafil in plasma
Bioequivalence based on (90% CI):	Vardenafil
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.

Document History: Recommended March 2012; Revised October 2024

Unique Agency Identifier: PSG_200179

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*.