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Draft Guidance on Vardenafil Hydrochloride

October 2024

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Active Ingredient: Vardenafil hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: 2.5 mg, 5 mg, 10 mg, 20 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: 20 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: 2.5 mg, 5 mg, and 10 mg strengths based on (i) acceptable bioequivalence study on the 20 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

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

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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*.