Contains Nonbinding Recommendations

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Draft Guidance on Vadadustat

November 2025

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Active Ingredient: Vadadustat

Dosage Form: Tablet

Route: Oral

Strengths: 150 mg, 300 mg, 450 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: 450 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with abnormal liver function tests or a history of gastrointestinal bleeding or peptic ulcer disease.

Analyte to measure: Vadadustat in plasma

Bioequivalence based on (90% CI): Vadadustat

Waiver request of in vivo testing: 150 mg and 300 mg strengths based on (i) an acceptable bioequivalence study on the 450 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.

Document History: Recommended November 2025

Unique Agency Identifier: PSG_215192

[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*.