

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Darolutamide

October 2024

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Active Ingredient: Darolutamide

Dosage Form: Tablet

Route: Oral

Strength: 300 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 300 mg
Subjects: Healthy males
Additional comments: Males with female partners of reproductive potential should use effective contraception during the study and for one week after the last dose.

Analyte to measure: Darolutamide in plasma

Bioequivalence based on (90% CI): Darolutamide

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.

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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*.