

Draft Guidance on Emtricitabine; Rilpivirine Hydrochloride; Tenofovir Disoproxil Fumarate

October 2024

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Active Ingredients:	Emtricitabine; Rilpivirine hydrochloride; Tenofovir disoproxil fumarate
Dosage Form:	Tablet
Route:	Oral
Strength:	200 mg; EQ 25 mg Base; 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: 200 mg; EQ 25 mg Base; 300 mg Subjects: Healthy males and non-pregnant, non-lactating females Additional comments: Females of reproductive potential should use effective contraception during the study.
Analytes to measure:	Emtricitabine, rilpivirine, and tenofovir in plasma
Bioequivalence based on (90% CI):	Emtricitabine, rilpivirine, and tenofovir
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 2015; Revised October 2024

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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*.