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Draft Guidance on Prasugrel Hydrochloride

October 2024

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Active Ingredient: Prasugrel hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 5 mg Base, EQ 10 mg Base

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: EQ 10 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comment: None

Analytes to measure: Metabolite R-138727 and metabolite R-95913 in plasma

Bioequivalence based on (90% CI): Metabolite R-138727 and metabolite R-95913

Active metabolite (R-138727) is not stable in aqueous solution and plasma. Provide detailed information for sample collection, processing, stabilization, and validation of analysis.

Waiver request of in vivo testing: EQ 5 mg Base strength based on (i) acceptable bioequivalence study on the EQ 10 mg Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulation between both 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 both 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*.