

Draft Guidance on Prasugrel Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Prasugrel hydrochloride

Dosage Form; Route: Tablets; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 10 mg
Subjects: Healthy males and nonpregnant females, general population

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 10 mg
Subjects: Healthy males and nonpregnant females, general population

Analytes to measure (in appropriate biological fluid): Metabolite R-138727 and metabolite R-95913 in plasma

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

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: 5 mg strength based on (i) acceptable bioequivalence studies on the 10 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulation across both strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).