

Contains Nonbinding Recommendations
Draft – Not for Implementation
Draft Guidance on Rosiglitazone Maleate
October 2024

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Active Ingredient: Rosiglitazone maleate

Dosage Form: Tablet

Route: Oral

Strengths: EQ 2 mg Base, EQ 4 mg Base, EQ 8 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 8 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Monitor blood glucose concentrations and signs and symptoms of hypoglycemia during the study. Implement appropriate hypoglycemia management protocol.

Analyte to measure: Rosiglitazone in plasma

Bioequivalence based on (90% CI): Rosiglitazone

Waiver request of in vivo testing: EQ 2 mg Base and EQ 4 mg Base strengths based on (i) acceptable bioequivalence study on the EQ 8 mg Base 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.

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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*.