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Draft Guidance on Metoclopramide Hydrochloride

October 2024

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Active Ingredient: Metoclopramide 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 comments: Exclude geriatric subjects. Subjects should be instructed not to use central nervous system depressants (e.g., alcohol), drive, or operate machinery until their cognitive function returns to baseline level.

Analyte to measure: Metoclopramide in plasma

Bioequivalence based on (90% CI): Metoclopramide

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 in the formulations across 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*.