

Draft Guidance on Metformin Hydrochloride; Repaglinide

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Active ingredient: Metformin Hydrochloride; Repaglinide

Form/Route: Tablet/Oral

Recommended studies: 1 study

Type of study: Fed

Design: Single-dose, two-way, crossover *in-vivo*

Strength: 500 mg/2 mg

Subjects: Healthy males and nonpregnant females, general population

Additional Comments: The drug products should be administered with 240 mL of a 20% glucose solution in water, followed by 60 mL of the glucose solution administered every 15 minutes for up to 4 hours after dosing. Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

Analytes to measure: Metformin and repaglinide in plasma.

Bioequivalence based on (90% CI): Metformin and repaglinide

Waiver request of in-vivo testing: 500 mg/1 mg based on (i) acceptable bioequivalence studies on the 500 mg/2 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all strengths. Please refer to the Mirtazapine Tablet Draft Guidance for additional information regarding waivers of in-vivo testing.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please 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 application.