

## Guidance on Metoclopramide Hydrochloride

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**Active ingredient:** Metoclopramide Hydrochloride

**Form/Route:** Tablets/Oral

**Recommended studies:** 2 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.  
Additional Comments:

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

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**Analytes to measure:** Metoclopramide in plasma

**Bioequivalence based on (90% CI):** Metoclopramide

**Waiver request of in-vivo testing:** 5 mg based on (i) acceptable bioequivalence studies on the 10 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all strengths.

**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.