

Guidance on Hydroxyzine Pamoate

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Active ingredient: Hydroxyzine Pamoate

Form/Route: Suspension/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 25 mg/ 5mL
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 25 mg/ 5mL
Subjects: Healthy males and nonpregnant females, general population.
Additional comments:

Analytes to measure: Hydroxyzine and cetirizine in plasma

Bioequivalence based on (90% CI): Hydroxyzine

Waiver request of in-vivo testing: Not Applicable

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 note that a dosage unit is based on the labeled concentration of the suspension product. Please use the dosage unit (5 ml). A total of 12 units from 12 different bottles should be used. Specifications will be determined upon review of the application.