

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Dicyclomine Hydrochloride

October 2024

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Active Ingredient: Dicyclomine hydrochloride

Dosage Form: Tablet

Route: Oral

Strength: 20 mg

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: 20 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Exclude geriatric subjects due to the greater susceptibility of anticholinergic and central nerve system effects. Exclude subjects who have a condition of glaucoma, urinary retention, obstructive gastrointestinal disease, and reflux esophagitis. Subjects should be instructed not to engage in potentially hazardous activities requiring complete mental alertness, such as driving a motor vehicle or operating machinery until they have completely returned to their level of baseline cognitive functioning after taking dicyclomine.

Analyte to measure: Dicyclomine in plasma

Bioequivalence based on (90% CI): Dicyclomine

Waiver request of in vivo testing: Not applicable

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 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*.