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Draft Guidance on Dicyclomine Hydrochloride

November 2021

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

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This is a new draft product-specific guidance for industry on generic dicyclomine hydrochloride.

Active Ingredient: Dicyclomine hydrochloride

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 20 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   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.

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 20 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: See comments above.

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 each strength of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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