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Draft Guidance on Carbinoxamine Maleate

August 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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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 carbinoxamine maleate.

Active Ingredient: Carbinoxamine maleate

Dosage Form; Route: Tablet; oral

Recommended studies:

Carbinoxamine maleate tablets are a DESI[1] effective drug for which there are no known or suspected bioequivalence problems, and as such is rated "AA" in the FDA/CDER's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book").

Analyte to measure: Not applicable

Bioequivalence based on (90% CI): Not applicable

[1] Drug Efficacy Study Implementation

Waiver request of in vivo testing: 4 mg pursuant to 21 CFR 320.22(c) if the in vitro dissolution profiles of the proposed product are comparable to those of the reference product

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

Since the tablet has a functional score, additional dissolution profile testing should be conducted for each segment of the split tablet after manual and mechanical splitting as per Guidance for Industry on Tablet Scoring: *Nomenclature, Labeling, and Data for Evaluation*.

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