This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

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”).

**Analogue to measure:** Not applicable

**Bioequivalence based on (90% CI):** Not applicable

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\(^1\) Drug Efficacy Study Implementation

Recommended Aug 2021
**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/](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*.

**Unique Agency Identifier:** PSG_008915