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Draft Guidance on Carbinoxamine Maleate

May 2025

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Active Ingredient:	Carbinoxamine maleate
Dosage Form:	Tablet, orally disintegrating[1]
Route:	Oral
Strengths:	2 mg, 4 mg, 6 mg, 8 mg
Recommended Studies:	Two options: (1) one in vivo bioequivalence study with pharmacokinetic endpoints using the designated reference standard (RS) for carbinoxamine maleate elixir, or (2) one in vivo bioequivalence study with pharmacokinetic endpoints using the designated RS for carbinoxamine maleate orally disintegrating tablet (ODT)

I. Option 1: One in vivo bioequivalence study with pharmacokinetic endpoints using the designated RS for carbinoxamine maleate elixir[2]

1. Type of study: Fasting
   Design: Single-dose, three-treatment, three-period crossover in vivo
   Strength: 8 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Conduct the study by testing one carbinoxamine maleate ODT (1 × 8 mg) of the test product, administered with water and without water, compared to 8 mg (10 mL) of the designated RS with water.

[1] New dosage form identified is the subject of an approved suitability petition (FDA-2023-P-4321).
[2] The currently designated RS is carbinoxamine maleate solution, 4 mg/5 mL.

II. Option 2: One in vivo bioequivalence study with pharmacokinetic endpoints using the designated RS for carbinoxamine maleate ODT[3]

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 8 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Conduct the study by testing one carbinoxamine maleate ODT (1 × 8 mg) of the test product, administered without water and one carbinoxamine maleate ODT (1 × 8 mg) of the designated RS without water.

Analyte to measure: Carbinoxamine in plasma

Bioequivalence based on (90% CI): Carbinoxamine

Waiver request of in vivo testing: 2 mg, 4 mg, and 6 mg strengths based on (i) an acceptable bioequivalence study on the 8 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

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 all strengths of the test product and the RS.[4] Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended May 2025

Unique Agency Identifier: PSG_008955-ODT

[3] This option can be used when a petitioned ANDA for carbinoxamine maleate ODT is approved and designated as the RS.
[4] If the RS is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.