Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Cysteamine Bitartrate

May 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Cysteamine bitartrate

Dosage Form: Capsule

Route: Oral

Strengths: EQ 50 mg Base | EQ 150 mg Base

Reference Listed Drug: NDA 020392

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Class of study: Bioequivalence
   Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 150 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females

Analyte to measure: Cysteamine in plasma

Bioequivalence based on (90% CI): Cysteamine

Waiver request of in vivo testing additional strength: Justification based on (i) an acceptable bioequivalence study on the EQ 150 mg Base strength, (ii) acceptable comparative in vitro dissolution studies between the additional strength and EQ 150 mg Base strength using 12 units per strength, and (iii) proportional similarity of the formulations between strengths

Dissolution: Dissolution test(s) should be included for quality control and to support waiver request of in vivo testing of the additional strength. For the quality control dissolution method, provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[1] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

For drug products containing high solubility drug substances that meet the rapidly dissolving criteria, demonstration of discriminating ability may not be needed. For additional information, refer to the guidance for industry *Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances.*[a]

Document History: Recommended May 2026

[a] We update guidances periodically. For the most recent version of a guidance, refer to the FDA guidance webpage at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[1] Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm