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Draft Guidance on Arimoclomol Citrate

December 2025

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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Active Ingredient: Arimoclomol citrate

Dosage Form: Capsule

Route: Oral

Strengths: EQ 47 mg Base, EQ 62 mg Base, EQ 93 mg Base, EQ 124 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 124 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Arimoclomol in plasma or serum

Bioequivalence based on (90% CI): Arimoclomol

Waiver request of in vivo testing: EQ 47 mg Base, EQ 62 mg Base, and EQ 93 mg Base strengths based on (i) an acceptable bioequivalence study on the EQ 124 mg Base 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 each of all strengths of the test and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

Product-specific testing conditions for in vitro feeding tube studies: The approved labeling for the RLD states that arimoclomol citrate capsule can be administered via feeding tubes with water. The labeling instruction on preparing suspension is to carefully open the capsule and sprinkle the entire contents into 20 mL of water. In vitro nasogastric (NG) tube and gastric (G) tube are recommended which include comparative recovery, sedimentation volume and redispersibility, in-use stability in designated dispersion media, and particle size distribution study. For general procedures of in vitro feeding tube studies, refer to the most recent version of the FDA guidance for industry *Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations*.[a]

Testing tube: NG tube (6 French) and G tube (12 French), each including

- Three different tube materials (e.g., polyvinylchloride, silicone, polyurethane) and/or designs (e.g., various numbers of ports and/or eyes, open or closed distal end, retention balloons), with at least one G tube should be tested with an inflated balloon design
- Reporting of the pH value of the water
- Holding times of 0 and 15 minutes
- Repeated administration

Sedimentation volume and redispersibility testing

In-use stability in designated dispersion media (i.e., water)

Particle size distribution study

Document History: Recommended December 2025

Unique Agency Identifier: PSG_214927

[a] For the most recent version of a guidance, check the FDA guidance website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[1] If the RLD is not available, refer to the most recent version of the guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.