

Contains Nonbinding Recommendations

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Draft Guidance on Acoramidis Hydrochloride

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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:	Acoramidis hydrochloride
Dosage Form:	Tablet
Route:	Oral
Strength:	EQ 356 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 356 mg Base Subjects: Healthy males and non-pregnant, non-lactating females Additional comments: None
Analyte to measure:	Acoramidis in plasma
Bioequivalence based on (90% CI):	Acoramidis
Waiver request of in vivo testing:	Not applicable

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 the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

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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*.