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Draft Guidance on Alectinib Hydrochloride

October 2025

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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: Alectinib hydrochloride

Dosage Form: Capsule

Route: Oral

Strength: EQ 150 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 150 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments:

- Female subjects of reproductive potential should practice abstention or contraception during the study and for one week after the last dose. Male subjects with female partners of reproductive potential should use effective contraception during the study and for three months after the last dose.
- $AUC_{(0\text{-}72h)}$ may be used in place of $AUC_{(0\text{-}t)}$ when comparing the extent of absorption, due to alectinib's long half-life. Ensure adequate washout periods between treatments in the crossover study. Alternatively, a parallel study design may be considered.

Analyte to measure: Alectinib in plasma

Bioequivalence based on (90% CI): Alectinib

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 evaluation 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 FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*