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Draft Guidance on Nilotinib Tartrate

November 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: Nilotinib tartrate

Dosage Form: Tablet

Route: Oral

Strengths: EQ 71 mg Base, EQ 95 mg Base

Recommended Studies: Three in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 95 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with risk factors for prolonged QTc interval and Torsades de Pointes. Monitor electrocardiograms during the study. Exclude subjects with abnormal liver function tests or blood counts. Subjects should avoid consuming dietary supplements, fruits (e.g., grapefruit, Seville oranges), and products containing these fruits that may affect the exposure of nilotinib for a sufficient time prior to and during the study. Female subjects of reproductive potential should use effective contraception during the study and for 14 days after the last dose. Male subjects of reproductive potential and their female partners should use effective contraception during the study and for 14 days after the last dose.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 95 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See comments above.

3. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 71 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See comments above.

Analyte to measure: Nilotinib in plasma

Bioequivalence based on (90% CI): Nilotinib

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

Document History: Recommended November 2025

Unique Agency Identifier: PSG_219293

[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*.