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Draft – Not for Implementation

Draft Guidance on Sunitinib Malate

December 2025

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Active Ingredient:	Sunitinib malate
Dosage Form:	Capsule
Route:	Oral
Strengths:	EQ 12.5 mg Base, EQ 25 mg Base, EQ 37.5 mg Base, EQ 50 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 50 mg Base
Subjects: Healthy males and healthy females not of reproductive potential
Additional comments:
 - Exclude subjects with abnormal liver function tests or with risk factors for prolonged QTc interval and Torsades de Pointes. Exclude subjects who have undergone or plan to undergo surgery for at least 2 weeks prior to and at least 3 weeks after the study. Monitor liver function tests prior to dosing in each period. Monitor electrocardiograms during the study. Males with female partners of reproductive potential should use effective contraception during the study and for 7 weeks after the last dose.
 - $AUC_{(0-72h)}$ may be used in place of $AUC_{(0-t)}$ for comparing the extent of absorption, due to sunitinib’s long half-life. Ensure an adequate washout period between treatments in the crossover study. Alternatively, a parallel study design may be considered.

Analyte to measure: Sunitinib in plasma

Bioequivalence based on (90% CI): Sunitinib

Waiver request of in vivo testing: EQ 12.5 mg Base, EQ 25 mg Base, and EQ 37.5 mg Base strengths based on (i) an acceptable bioequivalence study on the EQ 50 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 for each of all strengths 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*.