

Contains Nonbinding Recommendations
Draft Guidance on Sunitinib Malate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Sunitinib Malate

Form/Route: Capsules/Oral

Recommended studies: 1 study

Type of study: Steady-state

Design: two-period, two-treatment, two-way crossover *in-vivo* OR parallel *in-vivo*

Strength: 50 mg

Subjects: Cancer patients for whom sunitinib is indicated and who are already receiving a stable dose of Sunitinib Malate capsules.

Additional comments: Individuals with hypertension and cardiac risk factors (e.g., known congestive heart failure, low left ventricular ejection fraction, or prolonged QT interval) should be excluded. Individuals with hepatic or renal dysfunction or those who are on drugs with known or likely interactions with sunitinib should also be excluded unless the objective of the study is to study sunitinib in such individuals. Pregnant women, women of childbearing potential without adequate contraception and breast feeding women should be excluded—see the product label for more information.

Analytes to measure (in appropriate biological fluid): Sunitinib in plasma

Bioequivalence based on (90% CI): Sunitinib

Waiver request of in-vivo testing: 12.5 mg, 25 mg and 37.5 mg based on (i) acceptable bioequivalence studies on the 50 mg strength, (ii) acceptable in vitro dissolution testing of all strengths and (iii) proportional similarity 12.5 mg and 25 mg formulations to the 50 mg strength.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm> . Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application