Contains Nonbinding Recommendations

Draft Guidance on Cabozantinib S-Malate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

Active Ingredient: Cabozantinib S-malate

Dosage Form; Route: Tablets; oral

Recommended Studies: One study

Type of study:	Fasting
Design:	Single-dose, two-way crossover in vivo
Strength:	EQ 60 mg BASE
Subjects:	Males and non-pregnant, non-lactating females, general population

Additional comment: Cabozantinib has a long terminal elimination half-life. Please refer to *the Guidance for Industry: Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA* for additional information regarding long half-life drugs.

Analytes to measure (in appropriate biological fluid): Cabozantinib, in plasma

Bioequivalence based on (90% CI): Cabozantinib

Waiver request of in vivo testing: EQ 20MG BASE and EQ 40MG BASE strengths based on (i) acceptable bioequivalence studies on the EQ 60MG 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 on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. 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 abbreviated new drug application (ANDA).