Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Bosutinib Monohydrate

August 2026

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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: Bosutinib monohydrate

Dosage Form: Capsule

Route: Oral

Strengths: EQ 50 mg Base | EQ 100 mg Base

Reference Listed Drug: NDA 217729

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Class of study: Bioequivalence
   Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 100 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Safety recommendations:
   - Females of reproductive potential should use non-hormonal contraception during the study and continue to use effective contraception for at least two weeks after the last dose.
   - Exclude subjects with abnormal liver function tests or complete blood counts**.**
   - Subjects should avoid consuming dietary supplements or fruits (e.g., grapefruit or grapefruit-containing products) that may affect the exposure of bosutinib for a sufficient time prior to and during the study.

Analyte to measure: Bosutinib in plasma

Bioequivalence based on (90% CI): Bosutinib

Bioequivalence of additional strength: Waiver request of in vivo testing of additional strength based on (i) an acceptable bioequivalence study on the EQ 100 mg Base strength, (ii) acceptable comparative in vitro dissolution studies between the additional strength and the EQ 100 mg Base strength using 12 units per strength, and (iii) proportional similarity of the formulations between both strengths

Dissolution: Dissolution tests should be included for quality control and to support a waiver request of in vivo testing of the additional strength. For the quality control dissolution method, provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[1] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

Document History: Recommended August 2026

[1] Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm