Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Selumetinib Sulfate

May 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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:	Selumetinib sulfate
Dosage Form:	Granules
Route:	Oral
Strengths:	EQ 5 mg Base | EQ 7.5 mg Base
Reference Listed Drug:	NDA 219943
Recommended Studies:	Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Class of study: Bioequivalence
   Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 5 mg Base
   Dose: EQ 25 mg Base administered as 5 capsules of granules
   Subjects: Healthy males and non-pregnant, non-lactating females
   Safety recommendations:
   - Exclude subjects with history of or risk factors for ophthalmological abnormalities (e.g., retinopathy).
   - Female subjects of reproductive potential should use non-hormonal contraception and male subjects with female partners of reproductive potential should use effective contraception, during the study and for one week after the last dose.

Study design recommendations:

- Prepare oral granules by carefully opening the capsule and sprinkling all of the oral granules on a small amount (about 1 to 3 teaspoons) of smooth yogurt or fruit puree. Follow the administration instructions described in the reference listed drug labeling.

2. Class of study: Bioequivalence
Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 5 mg Base
Dose: EQ 25 mg Base administered as 5 capsules of granules
Subjects: Healthy males and non-pregnant, non-lactating females
Safety recommendations: See recommendations under Study #1.
Study design recommendations: See recommendations under Study #1.

Analyte to measure: Selumetinib in plasma

Bioequivalence based on (90% CI): Selumetinib

Waiver request of in vivo testing of additional strength: EQ 7.5 mg Base strength may be waived based on (i) an acceptable bioequivalence study on the EQ 5 mg Base strength, (ii) acceptable comparative in vitro dissolution studies between the additional strength and the EQ 5 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 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 May 2026

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