

Draft Guidance on Taltrectinib Adipate

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:	Taltrectinib adipate
Dosage Form:	Capsule
Route:	Oral
Strength:	EQ 200 mg Base
Reference Listed Drug:	NDA 219713
Recommended Study:	One in vivo bioequivalence study with pharmacokinetic endpoints

1. Class of study: Bioequivalence
Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 200 mg Base
Subjects: Healthy males and healthy females not of reproductive potential
Safety recommendations:
 - Exclude subjects with abnormal liver function tests.
 - Males with female partners of reproductive potential should use effective contraception during the study and for 3 weeks after the last dose.

Study design recommendations:

- Subjects should avoid consuming dietary supplements, fruits (e.g., grapefruit or grapefruit-containing products) that may affect the exposure of taletrectinib for a sufficient time prior to and during the study.
- $AUC_{(0-72h)}$ may be used in place of $AUC_{(0-t)}$ for comparing the extent of absorption due to taletrectinib'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: Taletrectinib in plasma

Bioequivalence based on (90% CI): Taletrectinib

Dissolution: Dissolution test(s) should be included for quality control. Provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method¹ 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>