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## Draft Guidance on Ensartinib Hydrochloride

December 2025

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|---------------------------|---|
| <b>Active Ingredient:</b> | Ensartinib hydrochloride  |
| <b>Dosage Form:</b>       | Capsule   |
| <b>Route:</b>             | Oral  |
| <b>Strengths:</b>         | EQ 25 mg Base, EQ 100 mg Base                                   |
| <b>Recommended Study:</b> | One in vivo bioequivalence study with pharmacokinetic endpoints |

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: EQ 100 mg Base  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments:
  - Exclude subjects with abnormal liver function tests. Subjects should be advised to limit sun exposure and use appropriate sun protection during the study to prevent dermatologic adverse reactions. Females of reproductive potential should use non-hormonal contraception during the study and for one week after the last dose. Males with female partners of reproductive potential should use effective contraception during the study and for one week after the last dose.
  - Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of ensartinib. Alternatively, a parallel study design may be considered.

**Analyte to measure:** Ensartinib in plasma

**Bioequivalence based on (90% CI):** Ensartinib

**Waiver request of in vivo testing:** EQ 25 mg Base strength based on (i) an acceptable bioequivalence study on the EQ 100 mg Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test product and reference listed drug (RLD).<sup>1</sup> Specifications will be determined upon review of the abbreviated new drug application.

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**Unique Agency Identifier:** PSG\_218171

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<sup>1</sup> If the RLD is not available, refer to the most recent version of the guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.