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*Draft – Not for Implementation*

## **Draft Guidance on Dabrafenib Mesylate**

**December 2025**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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<b>Active Ingredient:</b>	Dabrafenib mesylate
<b>Dosage Form:</b>	Capsule
<b>Route:</b>	Oral
<b>Strengths:</b>	EQ 50 mg Base, EQ 75 mg Base
<b>Recommended Study:</b>	One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting  
Design: Multiple-dose, two-treatment, two-period crossover in vivo  
Strength: EQ 75 mg Base  
Subjects: Male and female patients who are receiving a stable dose of 150 mg (2 x EQ 75 mg Base) twice daily of dabrafenib mesylate capsules as monotherapy or combination therapy based on the approved indications  
Additional comments: Exclude patients who require dosage modification or with expected changes in concomitant medications (e.g., trametinib) that may potentially affect the pharmacokinetics of dabrafenib during the study. Females of reproductive potential should use non-hormonal contraception during treatment and for 2 weeks after the last dose. Males (including those who have had vasectomies) with female partners of reproductive potential should use condoms during treatment and for 2 weeks after the last dose. Implement safety precautions and monitoring during treatment as recommended in the labeling.

**Analyte to measure:** Dabrafenib in plasma

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

**Waiver request of in vivo testing:** EQ 50 mg Base strength based on (i) an acceptable bioequivalence study on the EQ 75 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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**Document History:** Recommended June 2015; Revised December 2025

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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*.