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Draft Guidance on Dabrafenib Mesylate

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Tablet, for suspension

Route: Oral

Strength: EQ 10 mg Base

Recommended Study: 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 10 mg Base
   Subjects: Male and female adult patients who are receiving a stable dose of dabrafenib mesylate tablet for suspension as monotherapy or combination therapy based on the approved indications
   Additional comments:
   - Females of reproductive potential should use non-hormonal contraception during the treatment and for two 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 two weeks after the last dose. Implement safety precautions and monitoring during treatment as recommended in the reference listed drug (RLD) labeling.
   - 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. For the purpose of a bioequivalence study, both the test product and RLD should be prepared and administered following instructions specified in the labeling.

Analyte to measure: Dabrafenib in plasma

Bioequivalence based on (90% CI): Dabrafenib

Waiver request of in vivo testing of additional strength: Not applicable

Dissolution test method and sampling times: 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 method[1] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

Product-specific testing conditions for in vitro feeding tube studies: The approved labeling for the RLD states that the product may be administered by a nasogastric (NG) or gastrotomy (G) tube. Conduct the in vitro feeding tube studies, including comparative recovery, sedimentation volume and redispersibility testing, and in-use stability in designated dispersion media, and particle size distribution study. For general procedures of in vitro feeding tube studies, refer to the most recent version of the guidance for industry *Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations*.[a]

1. Comparative recovery testing
    - Three different configurations for both 10 French NG and 10 French G tubes, defined by materials (e.g., polyvinylchloride, silicone, polyurethane) and/or designs (e.g., number of ports/eyes, open or closed distal end)
        - At least one G tube should be tested with an inflated balloon design
    - Holding times of 0 and 15 minutes
    - Repeated administration
2. Sedimentation volume and redispersibility testing
3. In-use stability in designated dispersion media (i.e., water)
4. Particle size distribution study

Additional information:

Device:
The RLD is presented in a bottle co-packaged with two oral dosing cups. The oral dosing cup is the device constituent part.

FDA recommends that prospective applicants examine the size and shape, the external critical design attributes, and the external operating principles of the RLD device when designing the

Test device including:

- Calibrated volume markings
- Number of co-packaged oral dosing cups

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

User interface assessment:
An abbreviated new drug application for this product should include complete comparative analyses so FDA can determine whether any differences in design for the user interface of the proposed generic product, as compared to the RLD, are acceptable and whether the product can be expected to have the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling. For additional information, refer to the most recent version of the guidance for industry *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.[a]

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[a] For the most recent version of a guidance, refer to the FDA guidance website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents