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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**Active Ingredient:** Ivacaftor

**Dosage Form; Route:** Granule; Oral

**Recommended Studies:** Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. **Type of study:** Fasting
   **Design:** Single-dose, two-treatment, two-period crossover in vivo
   **Strength:** 75 mg/packet
   **Subjects:** Healthy males and non-pregnant, non-lactating females
   **Additional comments:** Mix granules with 1 teaspoon (5 mL) of soft food or liquid. Conduct bioequivalence study according to the reference product labeling.

2. **Type of study:** Fed
   **Design:** Single-dose, two-treatment, two-period crossover in vivo
   **Strength:** 75 mg/packet
   **Subjects:** Healthy males and non-pregnant, non-lactating females
   **Additional comments:** See comments above.

**Analyte to measure:** Ivacaftor in plasma

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

**Waiver request of in vivo testing:** 25 mg/packet and 50 mg/packet strengths based on (i) acceptable bioequivalence studies on the 75 mg/packet strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all 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/](http://www.accessdata.fda.gov/scripts/cder/dissolution/). Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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**Revision History:**
Recommended April 2016; Revised May 2023

**Unique Agency Identifier:** PSG_207925