

Draft Guidance on Ivacaftor ; Lumacaftor

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Active Ingredient: Ivacaftor; Lumacaftor

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 125 mg Ivacaftor; 200 mg Lumacaftor
(Dose = 2*{125 mg Ivacaftor; 200 mg Lumacaftor})
Subjects: Normal healthy males and females (nonpregnant), general population.

Additional Comments: N/A

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover *in-vivo*
Strength: 125 mg Ivacaftor; 200 mg Lumacaftor
(Dose = 2*{125 mg Ivacaftor; 200 mg Lumacaftor})
Subjects: Normal healthy males and non-pregnant females, general population.

Additional Comments: N/A

Analytes to measure (in appropriate biological fluid): Ivacaftor; Lumacaftor in plasma

Bioequivalence based on (90% CI): Ivacaftor; Lumacaftor

Waiver request of in-vivo testing: N/A

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site, available to the public at the following location: <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 (ANDA).