

Draft Guidance on Daclatasvir Dihydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: Eq. 90 mg (base)
Subjects: Males and non-pregnant, non-lactating females, general population.
Additional Comments: The bioequivalence study should be conducted without co-administration of sofosbuvir.

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: Eq. 90 mg (base)
Subjects: Males and non-pregnant females, non-lactating general population.
Additional comments: See comment above

Analytes to measure (in appropriate biological fluid): Daclatasvir in plasma

Bioequivalence based on (90% CI): Daclatasvir

Waiver request of in-vivo testing: Eq. 30 mg (base) and Eq. 60 mg (base) strength tablets based on (i) acceptable bioequivalence studies on the Eq. 90 mg (base) strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website 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).