

Guidance on Entecavir

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Active ingredient: Entecavir

Form/Route: Tablets/Oral

Recommended studies: 1 study

Type of study: fasting

Design: single-dose, two-way crossover *in-vivo*

Strength: 1 mg

Subjects: Normal healthy males and females, general population

Additional Comments: As an option, due to the relatively long half-life, the firm may wish to conduct this study using a parallel design. As an additional option for either the crossover or parallel design, the firm may wish to truncate the AUC at 72 hours.

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

Bioequivalence based on (90% CI): Entecavir

Waiver request of in vivo testing: 0.5 mg based on (i) acceptable bioequivalence studies on the 1 mg strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. Please find the dissolution information for this product at this website. Please 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 application.