Contains Nonbinding Recommendations

Draft Guidance on Valganciclovir Hydrochloride

Active ingredient: Valganciclovir Hydrochloride

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 450 mg (900 mg dose)
   Subjects: Normal healthy males and females, general population
   Additional Comments: Females must have a negative baseline pregnancy test prior to receiving the drug. Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.

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2. Type of study: Fed
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 450 mg (900 mg dose)
   Subjects: Normal healthy males and females, general population
   Additional comments: Please see comments above.

Analytes to measure (in appropriate biological fluid): Valganciclovir and ganciclovir in plasma in both studies. .

Bioequivalence based on (90% CI): Valganciclovir

Waiver request of in-vivo testing: Not Applicable

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.