

Draft Guidance on Valganciclovir Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablets; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way, crossover in-vivo
Strength: 450 mg (900 mg dose)
Subjects: Healthy males and females (nonpregnant and non-lactating)
Additional Comments:
Valganciclovir may cause fetal toxicity and impaired fertility; therefore:
 - Females of reproductive potential should be advised to use effective contraception during treatment and for at least 30 days following treatment with valganciclovir.
 - Males should be advised to practice barrier contraception during and for at least 90 days following treatment with valganciclovir.

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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.
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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: 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).