*Contains Nonbinding Recommendations*

**Guidance on Valacyclovir Hydrochloride**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

**Active ingredient:** Valacyclovir Hydrochloride

**Form/Route:** Tablets/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 1000 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments:

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 1000 mg
   Subjects: Normal healthy males and females, general population
   Additional comments:

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**Analytes to measure (in appropriate biological fluid):** Valacyclovir and its metabolite, acyclovir, in both studies. If valacyclovir plasma concentrations can be reliably measured and its pharmacokinetic parameters accurately determined, you should analyze the valacyclovir data using the confidence interval approach. The acyclovir data can be used to provide supportive evidence of comparable therapeutic outcome..

**Bioequivalence based on (90% CI):** Valacyclovir

If valacyclovir cannot be reliably measured, you should analyze the acyclovir data obtained from these studies using the confidence interval approach

**Waiver request of in-vivo testing:** 500 mg based on (i) acceptable bioequivalence studies on the 1000 mg strength, (ii) proportional similarity of the formulations 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.