Guidance on Acyclovir

Active ingredient: Acyclovir

Form/Route: Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 800 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: 800 mg
   Subjects: Normal healthy males and females, general population
   Additional comments:

Analytes to measure: Acyclovir in plasma.

Bioequivalence based on (90% CI): Acyclovir

Waiver request of in-vivo testing: 400 mg based on (i) acceptable bioequivalence studies on the 800 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 conduct comparative dissolution testing on 12 dosage units of all strengths of the test and reference products using the following USP method.