Guidance on Zidovudine

Active ingredient: Zidovudine

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 100 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: 100 mg
   Subjects: Normal healthy males and females, general population
   Additional comments:

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

Bioequivalence based on (90% CI): Zidovudine

Waiver request of in-vivo testing: Not Applicable

Dissolution test method and sampling times:

Please conduct dissolution testing on 12 dosage units each of the test and reference products using the USP method.