Contains Nonbinding Recommendations

Guidance on Zidovudine

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: Zidovudine

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover *in-vivo*
   Strength: 300 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: 300 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 comparative dissolution testing on 12 dosage units of all strengths of the test and reference products using the following USP method.