Contains Nonbinding Recommendations

Guidance on Rifampin

Active ingredient: Rifampin

Form/Route: Capsule/Oral

Recommended studies: 1 study

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:

Analytes to measure (in appropriate biological fluid): Rifampin in plasma.

Bioequivalence based on (90% CI): Rifampin

Waiver request of in-vivo testing: 150 mg based on (i) acceptable bioequivalence studies on the 300 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Please submit separate applications for each strength. You may cross-reference the study submitted in the application for the higher strength to request waivers of *in-vivo* testing for the lower strength.

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 USP method.