

Guidance on Dicloxacillin Sodium

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Active ingredient: Dicloxacillin Sodium

Form/Route: Capsules/Oral

Recommended studies: 1 study

Type of study: Fasting

Design: Single-dose, two-way crossover *in-vivo*

Strength: 500 mg

Subjects: Normal healthy males and females, general population

Additional Comments:

Analytes to measure: Dicloxacillin in plasma

Bioequivalence based on (90% CI): Dicloxacillin

Waiver request of in-vivo testing: 125 mg and 250 mg based on (i) acceptable bioequivalence study on the 500 mg, (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.