Contains Nonbinding Recommendations

**Guidance on Dicloxacillin Sodium**

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:** 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:**

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**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.

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