*Contains Nonbinding Recommendation*

**Draft Guidance on Lidocaine; Prilocaine**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 the 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:** Lidocaine; Prilocaine

**Dosage Form; Route:** Cream; topical

**Recommended Studies:** One study

1. Type of study: Fasting
   Design: Single-dose, two-way crossover, in vivo
   Strength: 2.5%; 2.5%
   Subjects: Normal healthy males and females, general population.
   Additional comments: The comparability of local skin reactions for the test and reference products should be evaluated during the bioequivalence study. Observations of local skin reactions should note the following: pallor or blanching, erythema, alteration in temperature sensation, edema, and skin rash. The parameters measured should include intensity and time to resolution. The parameters should be tabulated with respect to formulation.

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**Analytes to measure (in appropriate biological fluid):** Lidocaine and prilocaine in plasma

**Bioequivalence based on (90% CI):** Lidocaine and prilocaine

**Waiver request of in vivo testing:** Not applicable (N/A)

**Dissolution test method and sampling times:** N/A