**Contains Nonbinding Recommendations**

**Draft Guidance on Mexiletine Hydrochloride**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Mexiletine hydrochloride

**Dosage Form; Route:** Capsule; oral

**Recommended Studies:** Two studies

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 250 mg  
   **Subjects:** Males and non-pregnant, non-lactating females, general population  
   **Additional comments:** None

2. **Type of study:** Fed  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 250 mg  
   **Subjects:** Males and non-pregnant, non-lactating females, general population  
   **Additional comments:** None

**Analyte to measure (in appropriate biological fluid):** Mexiletine in plasma

**Bioequivalence based on (90% CI):** Mexiletine

**Waiver request of in vivo testing:** The 150 mg and 200 mg strengths based on (i) acceptable bioequivalence studies on the 250 mg strength, (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:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: [http://www.accessdata.fda.gov/scripts/cder/dissolution/](http://www.accessdata.fda.gov/scripts/cder/dissolution/). Conduct comparative dissolution testing on 12 dosage units for each strength of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

*Recommended Mar 2020*