Contains Nonbinding Recommendations

Draft Guidance on Nebivolol Hydrochloride

Active Ingredient: Nebivolol hydrochloride

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 20 mg Base
   Subjects: Normal healthy males and females, general population.
   Additional comments: Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 20 mg Base
   Subjects: Normal healthy males and females, general population.
   Additional comments: Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.

Analytes to measure (in appropriate biological fluid): Racemic nebivolol

Bioequivalence based on (90% CI): Racemic nebivolol

Waiver request of in vivo testing: 2.5 mg, 5 mg, and 10 mg based on (i) acceptable bioequivalence studies on the 20 mg strength, (ii) proportional similarity of the 2.5 mg, 5 mg, 10 mg, and 20 mg strengths, and (iii) acceptable in vitro dissolution testing of the 2.5 mg, 5 mg, 10 mg, and 20 mg strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).