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Draft Guidance on Nebivolol Hydrochloride

October 2024

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Active Ingredient: Nebivolol hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 2.5 mg Base, EQ 5 mg Base, EQ 10 mg Base, EQ 20 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 20 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Females, if applicable, should practice abstention or contraception during the study.

Analyte to measure: Racemic nebivolol

Bioequivalence based on (90% CI): Racemic nebivolol

Waiver request of in vivo testing: EQ 2.5 mg Base, EQ 5 mg Base, and EQ 10 mg Base strengths, based on (i) acceptable bioequivalence study on the EQ 20 mg Base strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test and reference listed drug (RLD) products.[1] Specifications will be determined upon review of the abbreviated new drug application.

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[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*