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Draft Guidance on Nebivolol Hydrochloride; Valsartan

October 2024

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Active Ingredients: Nebivolol hydrochloride; Valsartan

Dosage Form: Tablet

Route: Oral

Strength: EQ 5 mg Base; 80 mg

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 5 mg Base; 80 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Females, if applicable, should practice abstention or contraception during the study. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

Analytes to measure: Racemic nebivolol and valsartan in plasma

Bioequivalence based on (90% CI): Nebivolol and valsartan

Waiver request of in vivo testing: Not applicable

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 product and reference listed drug (RLD).[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.*