

Draft Guidance on Nebivolol Hydrochloride and Valsartan

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Nebivolol hydrochloride; Valsartan

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 5 mg base/80 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: Females should not be pregnant or lactating, and if applicable, should practice abstinence or contraception during the study. Drugs, including BYVALSON, that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 5 mg base/80 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: See comments above

Analytes to measure (in appropriate biological fluid): 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 on the FDA-Recommended Dissolution Methods web site, 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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).