

Guidance on Eprosartan Mesylate

This guidance represents 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: Eprosartan mesylate

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way, crossover in vivo
Strength: EQ 600 mg base
Subjects: Healthy males and non-pregnant, non-lactating females, general population
Additional comments: Females should not be pregnant or lactating, and, if applicable, should practice abstention or contraception during the study.
2. Type of study: Fed
Design: Single-dose, two-way, crossover in vivo
Strength: EQ 600 mg base
Subjects: Healthy males and non-pregnant, non-lactating females, general population
Additional comments: Please see comment above.

Analyte(s) to measure (in appropriate biological fluid): Eprosartan in plasma

Bioequivalence based on (90% CI): Eprosartan

Waiver request of in vivo testing: EQ 400 mg base, based on (i) acceptable bioequivalence studies on the EQ 600 mg base strength, (ii) acceptable 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 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 all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).