

Draft Guidance on Terazosin Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Capsule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 1 mg BASE
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Due to safety concerns, the studies should be conducted using the Eq 1 mg base strength.

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 1 mg BASE
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: See comment above

Analyte to measure (in appropriate biological fluid): Terazosin in plasma

Bioequivalence based on (90% CI): Terazosin

Waiver request of in vivo testing: EQ 2, EQ 5, and EQ 10 mg BASE based on (i) acceptable bioequivalence studies on the EQ 1 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in 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.