

Draft Guidance on Trimipramine Maleate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Capsule; oral

Recommended Studies: Two in vivo studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: EQ 50 MG BASE
Subjects: Healthy males and nonpregnant females, general population
Additional comments: None

-
2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: EQ 50 MG BASE
Subjects: Healthy males and nonpregnant females, general population
Additional comments: None
-

Analytes to measure (in appropriate biological fluid): Trimipramine in plasma

Bioequivalence based on (90% CI): Trimipramine

Waiver request of in vivo testing: EQ 25 MG BASE and EQ 100 MG BASE strengths based on (i) acceptable bioequivalence studies on the EQ 50 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 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).