

Draft Guidance on Tolcapone

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablets; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 100 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Due to safety concerns of the risk of potential fatal and acute fulminant liver failure, subjects exhibiting clinical evidence of liver disease should not be recruited into this study

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 100 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Same as above

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

Bioequivalence based on (90% CI): Tolcapone

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 all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).