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).