Active ingredient: Entacapone

Form/Route: Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 200 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: Applicants may consider using a reference-scaled average bioequivalence approach for entacapone. Please refer to the Progesterone Draft Guidance for additional information regarding this bioequivalence approach.

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 200 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: See comments above. Please refer to the Amantadine Hydrochloride Draft Guidance for additional information regarding fed studies.

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

Bioequivalence based on (90% CI): Entacapone

Waiver request of in-vivo testing: Not Applicable

Dissolution test method and sampling times:

Please note that a Dissolution Methods Database is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please 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 application.