Contains Nonbinding Recommendations

Guidance on Entacapone

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Entacapone

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 200 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: Due to the high inter- and intra-subject variability observed with this product, you may want to consider using a replicate study design. Since the drug product is to be used predominantly in the elderly, please include as many subjects of 60 years of age or older as possible.

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2. Type of study: Fed
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 200 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: Please see comments above.

Analytes to measure: 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.fda.gov/cder/ogd/index.htm. 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.