Draft Guidance on Rasagiline Mesylate

Active ingredient: Rasagiline Mesylate
Form/Route: Tablets/Oral
Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 1 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comment:

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 1 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comment: Tyramine-rich foods, beverages, or dietary supplements and amines (from over-the-counter cough/cold medications) should be avoided to prevent a possible hypertensive crisis/“cheese reaction” during rasagiline ‘fed’ study.

Analytes to measure: Rasagiline in plasma

Bioequivalence based on (90% CI): Rasagiline

Waiver request of in-vivo testing: 0.5 mg tablet, based on (i) acceptable bioequivalence studies on the 1 mg strength tablet, (ii) proportional similarity of the formulations across the strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

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.

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