

Draft Guidance on Selegiline Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Selegiline Hydrochloride

Form/Route: Orally Disintegrating Tablet/ Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 1.25 mg X 2 tablets (Dose = 2.5 mg)
Subjects: Normal healthy males and females, general population.
Additional Comments: Females should not be pregnant, and if applicable, should practice abstinence or contraception during the study. The study tablets should be placed on top of the tongue and allowed to disintegrate. Subjects should avoid ingesting liquids for 5 minutes before, and 5 minutes after dosing. The tablets should not be swallowed. Water may be taken after 5 minutes.

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 1.25 mg X 2 tablets (Dose = 2.5 mg)
Subjects: Normal healthy males and females, general population.
Additional Comments: Please see comments above.

Analytes to measure (in appropriate biological fluid): Selegiline and its active metabolites, desmethylselegiline and methamphetamine, in plasma

Please submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and Cmax.

Bioequivalence based on (90% CI): Selegiline

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.