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Draft Guidance on Rasagiline Mesylate

May 2023

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Active Ingredient: Rasagiline mesylate

Dosage Form; Route: Tablet; Oral

Recommended Studies: Two options: (1) Biopharmaceutics Classification System (BCS) III-based biowaiver or (2) two in vivo bioequivalence studies with pharmacokinetic endpoints

I. Option 1: BCS Class III-based biowaiver

A waiver request of in vivo testing for this product may be considered provided that the appropriate documentation regarding high solubility, very rapid dissolution, and the test product formulation is qualitatively the same and quantitatively similar as detailed in the most recent version of the FDA guidance for industry on *M9 Biopharmaceutics Classification System-Based Biowaivers*[a] is submitted in the application. A decision regarding the acceptability of the waiver request will be made upon assessing the data submitted in the application.

II. Option 2: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 1 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 1 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

Analyte to measure: Rasagiline in plasma

Bioequivalence based on (90% CI): Rasagiline

Waiver request of in vivo testing: EQ 0.5 mg Base strength based on (i) acceptable bioequivalence studies on the EQ 1 mg Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of both strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

Revision History: Recommended November 2009; Revised May 2023

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[a] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.