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Draft Guidance on Solriamfetol Hydrochloride

October 2024

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Active Ingredient:	Solriamfetol hydrochloride
Dosage Form:	Tablet
Route:	Oral
Strengths:	EQ 75 mg Base, EQ 150 mg Base
Recommended Studies:	Two options: (1) Biopharmaceutics Classification System (BCS)-based biowaiver or (2) one in vivo bioequivalence study with pharmacokinetic endpoints

I. Option 1: BCS Class I-based biowaiver

A waiver request of in vivo testing for all the strengths of this product may be considered provided that the appropriate documentation regarding high solubility, high permeability and rapid dissolution 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. Applicants may use the information contained in the approved labeling of the reference listed drug (RLD). Peer reviewed articles may not contain the necessary details of the testing for the Agency to make a judgment regarding the quality of the studies. A decision regarding the acceptability of the waiver request can only be made upon assessment of the data submitted in the application.

II. Option 2: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 150 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Exclude subjects receiving concomitant treatment with monoamine oxidase inhibitors, or who are within 14 days following discontinuation of monoamine oxidase inhibitor. Subjects should be normotensive before enrollment in the study. Monitor blood pressure and heart rate during the study.

Analyte to measure: Solriamfetol in plasma

Bioequivalence based on (90% CI): Solriamfetol

Waiver request of in vivo testing: EQ 75 mg Base strength based on (i) acceptable bioequivalence study on the EQ 150 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 for each of both strengths of the test product and RLD.¹ Specifications will be determined upon review of the abbreviated new drug application.

If any strength of the tablet product has a functional score, additional dissolution profile testing should be conducted for each segment of the split tablet after manual and mechanical splitting as per the most recent version of the FDA guidance for industry on *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation*.^a

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^a For the most recent version of a guidance, check the FDA guidance website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.