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## Draft Guidance on Migalastat Hydrochloride

May 2025

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<b>Active Ingredient:</b>	Migalastat hydrochloride
<b>Dosage Form:</b>	Capsule
<b>Route:</b>	Oral
<b>Strength:</b>	EQ 123 mg Base
<b>Recommended Studies:</b>	Two options: (1) Biopharmaceutics Classification System (BCS)-based biowaiver or (2) one in vivo bioequivalence study with pharmacokinetic endpoints

### I. Option 1: BCS Class III-based biowaiver option:

A waiver request of in vivo testing for this product may be considered provided that the appropriate documentation regarding high solubility, very rapid dissolution of the test product and reference listed drug (RLD), 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*<sup>a</sup> is submitted in the application. Applicants may use the information contained in the approved labeling of the 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

Type of study: Fasting

Design: Single-dose, two-treatment, two-period crossover in vivo

Strength: EQ 123 mg Base

Subjects: Healthy males and non-pregnant, non-lactating females

Additional comments: None

**Analyte to measure:** Migalastat in plasma

**Bioequivalence based on (90% CI):** Migalastat

**Waiver request of in vivo testing:** Not applicable

**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 the test product and RLD<sup>1</sup>. Specifications will be determined upon evaluation of the abbreviated new drug application.

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<sup>a</sup> 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>.

<sup>1</sup> 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*.