Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Miglustat

August 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient:	Miglustat
Dosage Form:	Capsule
Route:	Oral
Strength:	65 mg
Reference Listed Drug:	NDA 215211
Recommended Studies:	Two options: (I) Biopharmaceutics Classification System (BCS)-based biowaiver or (II) one in vivo bioequivalence study with pharmacokinetic endpoints.

Option I: BCS Class III-based biowaiver

BCS-III waiver: 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),[1] and the test product formulation is qualitatively the same and quantitatively very similar as detailed in the guidance for industry *M9 Biopharmaceutics Classification System-Based Biowaivers*[a] 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 judgement 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.

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

Option II: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Class of study: Bioequivalence
   Type of study: Fasting
   Design: Single-dose, two-treatment, two-period, two-sequence, crossover in vivo
   Strength: 65 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Safety recommendation:
   - Females of reproductive potential should use effective contraception during the study.

Analyte to measure: Miglustat in plasma

Bioequivalence based on (90% CI): Miglustat

Dissolution: Dissolution test(s) should be included for quality control. Provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[2] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

For drug products containing high solubility drug substances that meet the rapidly dissolving criteria, demonstration of discriminating ability may not be needed. For additional information, refer to the guidance for industry *Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances.*[a]

Document History: Recommended August 2026

[a] We update guidances periodically. For the most recent version of a guidance, refer to the FDA guidance webpage at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[2] Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm