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Draft Guidance on Givinostat Hydrochloride

November 2025

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

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Active Ingredient: Givinostat hydrochloride

Dosage Form: Suspension

Route: Oral

Strength: EQ 8.86 mg Base/mL

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 8.86 mg Base/mL at a dose of EQ 44.3 mg Base (5 mL)
   Subjects: Healthy males and healthy females not of reproductive potential
   Additional comments: Exclude subjects with abnormal complete blood counts.

Analyte to measure: Givinostat in plasma

Bioequivalence based on (90% CI): Givinostat

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 reference listed drug (RLD).[1] Specifications will be determined upon evaluation of the abbreviated new drug application (ANDA).

Additional information:

Device:
The RLD is presented in a bottle with pre-inserted syringe adaptor and co-packaged with one 5 mL graduated oral syringe. The device constituent part is the oral dosing syringe.

FDA recommends that prospective applicants examine the size and shape, the external critical design attributes, and the external operating principles of the RLD device when designing the test device including:

- Volume markings
- Visibility and contrast of plunger gasket within the syringe

User interface assessment:
An ANDA for this product should include complete comparative analyses so FDA can determine whether any differences in design for the user interface of the proposed generic product, as compared to the RLD, are acceptable and whether the product can be expected to have the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling. For additional information, refer to the most recent version of the guidance for industry *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.[a]

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Unique Agency Identifier: PSG_217865

[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.

[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*.