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Draft Guidance on Foscarbidopa; Foslevodopa

February 2026

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Active Ingredients:	Foscarbidopa; Foslevodopa
Dosage Form:	Solution
Route:	Subcutaneous
Strength:	120 mg/10 mL; 2400 mg/10 mL (12 mg/mL; 240 mg/mL)
Recommended Study:	Request for waiver of in vivo bioequivalence study requirements

To qualify for a waiver from the requirement for submission of evidence of in vivo bioequivalence on the basis that bioequivalence is self-evident under 21 CFR 320.22(b)(1), a generic foscarbidopa; foslevodopa subcutaneous solution product should be qualitatively (Q1)¹ and quantitatively (Q2)² the same as the reference listed drug (RLD).

An applicant may seek approval of a drug product that differs from the RLD in preservative, buffer, or antioxidant provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.³

¹ Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the RLD.

² Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ±5% of those used in the RLD.

³ 21 CFR 314.94(a)(9)(iii).

Additional information:

Device:

The RLD is presented in vials for administration with an infusion pump and required accessories. The infusion pump and its supplied accessories constitute the device constituent part, though additional accessories (the vial adapter, syringe, insertion device, cannula, and the infusion set tubing) are required for dose delivery.

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

- Single-patient-use, ambulatory infusion pump format
- Pre-Programmable Delivery Options
- Compatibility with and between required accessories

User interface assessment:

An abbreviated new drug application 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

Document History: Recommended February 2026

Unique Agency Identifier: PSG_216962

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