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Draft Guidance on Apomorphine Hydrochloride

December 2025

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Active Ingredient:	Apomorphine hydrochloride
Dosage Form:	Solution
Route:	Subcutaneous
Strength:	98 mg/20 mL (4.9 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 apomorphine hydrochloride 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 $\pm 5\%$ of those used in the RLD.

³ 21CFR 314.94(a)(9)(iii).

Additional information:

Device:

The RLD is presented in a prefilled cartridge for administration with the infusion pump, cartridge holder, and infusion set. The infusion pump and cartridge holder are the device constituent part.

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:

- Compatibility of the prefilled cartridge with the cartridge holder, infusion pump, and infusion set
- Dose delivery profile
- Needle gauge and length

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 FDA guidance for industry on *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.^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>.