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Draft Guidance on Metoprolol Tartrate

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Solution

Route: Oral

Strength: 10 mg/mL

Reference Listed Drug: NDA 219373

Recommended Study: Request for waiver of in vivo bioequivalence study requirements

Waiver request of in vivo bioequivalence study: To qualify for a waiver of in vivo bioequivalence study requirements under 21 CFR 320.22(b)(3), the test product must contain the same active ingredient in the same concentration and dosage form as the reference listed drug (RLD)[1] and must not contain any inactive ingredient or other change in formulation from the RLD that may significantly affect absorption of the active ingredient.

Device: The RLD is presented in a bottle co-packaged with a bottle adapter and an oral syringe. The oral syringe is 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:

- Volume markings

[1] If the RLD is not available, refer to the most recent version of the guidance for industry *Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application.*

User interface assessment: An abbreviated new drug application (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 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 May 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.