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Draft Guidance on Bimatoprost

August 2026

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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:	Bimatoprost
Dosage Form:	Gel
Route:	Ophthalmic
Strength:	0.01%
Reference Listed Drug:	NDA 217307
Recommended Study:	One in vitro bioequivalence study with supportive characterization studies

Eligibility: To demonstrate bioequivalence by this option, the test 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 intended for ophthalmic use that differs from the RLD in preservative, buffer, substance to adjust tonicity, or thickening agent 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] FDA has determined that any qualitative or quantitative deviations from the RLD regarding the inactive ingredients specified in 21 CFR 314.94(a)(9)(iv) necessitate scientific justification. This justification should address the potential impact on bioequivalence of the proposed test product and inform the determination of whether appropriate in vivo bioequivalence studies are required. Prospective applicants are advised to submit a pre-Abbreviated New Drug Application (ANDA) development meeting request to discuss the justification for any such deviations and the intended approach to demonstrate bioequivalence.

1. Class of study: Bioequivalence
   Type of study: Comparative in vitro release (IVR) testing of bimatoprost
   Design: In vitro bioequivalence study should be performed on three batches of both test product, and three batches of the RS, if available[4], using at least 12 units from each batch
   Strength: 0.01%
   Study design recommendations:
   - The applicant should identify relevant critical quality attributes of the drug product that can impact product performance in terms of drug release and develop the in vitro release methodology to discriminate meaningful differences in these attributes (e.g., viscosity).
   - A complete IVR method development and validation report should be provided.
   - Comparative analysis of release profiles should be established using an appropriate statistical method (e.g., model independent approach using similarity factor (f_2)). For more information on calculation of f_2 factor, refer to the guidance for industry *Dissolution Testing of Immediate Release Solid Oral Dosage Forms*.[a]

2. Class of study: Characterization
   Type of study: Supportive physicochemical characterization
   Design: Comparative analyses performed on three exhibit batches of both test product[5] and RS, if available[6]
   Strength: 0.01%
   Parameters to measure:
   - Appearance
   - pH
   - Specific gravity
   - Osmolality
   - Viscosity profile as a function of applied shear

Device: The RLD is presented in a single-dose vial with a dropper tip. The vial with dropper tip 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.

[4] It may be acceptable to evaluate fewer than three batches of the RS if a prospective applicant provides adequate justification and supporting evidence demonstrating the unavailability of RS lots. Data from a minimum of three batches of the test product should be submitted in the ANDA.
[5] The manufacturing process for the exhibit batches should be reflective of the manufacturing process to be utilized for commercial batches.
[6] Evaluating fewer than three lots of the RS may be acceptable if the prospective applicant provides sufficient justification and supporting evidence demonstrating that additional RS lots are unavailable. However, data from a minimum of three batches of the test product must be included in the ANDA.

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 guidance for industry *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.[a]

Quality assessment: For quality-related recommendations for supporting drug product development, refer to the guidance for industry *Quality Considerations for Topical Ophthalmic Drug Products*.[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.