

Draft Guidance on Bimatoprost

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Active Ingredient:	Bimatoprost
Dosage Form; Route:	Solution/drops; topical
Strength:	0.03%
Recommended Study:	Request for waiver of in vivo bioequivalence study requirements

Additional Comments: Bimatoprost topical solution products should have comparable physicochemical properties to the Reference Standard (RS) including but not limited to pH, specific gravity, buffer capacity, osmolality, and viscosity, if applicable. Comparative analysis should be performed on three exhibit batches, if available, of both test and RS products.

I. Waiver:

To qualify for a waiver of the in vivo bioequivalence (BE) study requirement, a generic bimatoprost topical solution 0.03% product must be qualitatively (Q1)¹ and quantitatively (Q2)² the same as the Reference Listed Drug (RLD).

An in vivo BE study is requested for any bimatoprost topical solution 0.03% product that has a different inactive ingredient from the RLD, a difference of more than 5% in the amount of any inactive ingredient compared to that of the RLD, or differences in comparative physicochemical characterization data.

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

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 reference product.