

Draft Guidance on Tetracaine hydrochloride 0.5%

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Active Ingredient:	Tetracaine hydrochloride
Dosage Form; Route:	Solution/drops; ophthalmic
Strength:	0.5%
Recommended Studies:	Request for waiver of in vivo bioequivalence study requirements

Additional Comments: Tetracaine hydrochloride (0.5%) ophthalmic 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, tetracaine hydrochloride (0.5%) ophthalmic solution 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 tetracaine hydrochloride (0.5%) ophthalmic solution product that has a different inactive ingredient from the RLD,³ 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 RLD 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 RLD product.

³ For ophthalmic drug products, FDA has determined that, as a scientific matter, any qualitative or quantitative deviations from the RLD, even in inactive ingredients listed in 21 CFR 314.94(a)(9)(iv), should be accompanied by an appropriate in vivo BE study or studies. Guidance for industry *ANDA Submissions – Refuse-to-Receive Standards*.