Contains Nonbinding Recommendations

Draft Guidance on Olopatadine Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Active Ingredient: Olopatadine hydrochloride

Dosage Form; Route: Solution/drops; ophthalmic

Strength: EQ 0.2% base

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

Additional Comments: Olopatadine hydrochloride 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, a generic olopatadine hydrochloride 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 olopatadine hydrochloride 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 reference product.
[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 reference 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. *ANDA Submissions –Refuse-to-Receive Standards: Guidance for Industry.* https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm370352.pdf