

## Draft Guidance on Besifloxacin hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

<b>Active Ingredient:</b>	Besifloxacin hydrochloride
<b>Dosage Form; Route:</b>	Suspension/drops; ophthalmic
<b>Strength:</b>	EQ 0.6% Base
<b>Recommended Studies:</b>	In vitro option

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### I. In vitro option:

To qualify for the in vitro option for this drug product all the following criteria should be met:

- i. The Test and Reference Listed Drug (RLD) formulations are qualitatively (Q1)<sup>1</sup> and quantitatively (Q2)<sup>2</sup> the same (Q1/Q2).
- ii. Acceptable comparative physicochemical characterization of the Test and Reference Standard (RS) products. The comparative study should be performed on at least three batches of both the Test and RS products and should include:<sup>3</sup>
  - Comparable crystalline habit of besifloxacin
  - Comparable appearance, pH, specific gravity, osmolality, surface tension, and viscosity profile
  - Comparable soluble fraction of besifloxacin in the final drug product
  - Comparable drug particle size distribution. The particle size distribution should be compared using population bioequivalence (PBE) (95% upper confidence bound) based on D<sub>50</sub> and SPAN [i.e. (D<sub>90</sub>-D<sub>10</sub>)/D<sub>50</sub>]. The applicant should provide no fewer than ten data sets from three different batches of both the Test and reference products for PBE analysis. Full profiles of the particle size distributions should also be submitted for all samples tested. Refer to the *Guidance on Budesonide* inhalation suspension for additional information regarding PBE.

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<sup>1</sup> Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the reference listed drug product.

<sup>2</sup> Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ±5% of the range used in the reference listed drug product.

<sup>3</sup> The manufacturing process for the exhibit batches should be reflective of the manufacturing process to be utilized for commercial batches.

- iii. Acceptable comparative in vitro drug release of besifloxacin from the Test and RS formulations.
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