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Draft – Not for Implementation

Draft Guidance on Acyclovir

August 2021

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

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This is a new draft product-specific guidance for industry on generic acyclovir.

Active Ingredient:	Acyclovir
Dosage Form; Route:	Ointment; ophthalmic
Strength:	3%
Recommended Study:	In vitro option

In vitro option

The proposed test drug product should be qualitatively (Q1)[1] and quantitatively (Q2)[2] the same as the Reference Listed Drug (RLD). Bioequivalence may be established based on comparative

[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.

in vitro testing of three exhibit batches of both the test product and designated Reference Standard (RS) product include:[3]

- Appearance.
- Polymorphic form of acyclovir.
- Acidity and alkalinity of the extracted ointment base.
- Rheological properties including yield stress and viscosity. The applicant should characterize viscosity over a range of shear rates.
- Drug particle size and size distribution.
- In vitro drug release tests of acyclovir from the test and RS products. Detailed information on development and validation of a proposed in vitro drug release testing method should be provided.

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[3] The manufacturing process for the exhibit batches should be reflective of the manufacturing process to be utilized for commercial batches.