Contains Nonbinding Recommendations

Draft Guidance on Erythromycin

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Ointment; ophthalmic

Recommended Studies: Acceptable comparative physicochemical characterization of the test and reference listed drug (RLD) formulations. The comparative study should be performed on at least three exhibit batches[1] of both test and reference products and should include:

- Comparative solid state form of erythromycin.
- Comparative appearance.
- Comparative acidity and alkalinity of the extracted ointment base.
- Comparative rheological properties including yield stress and viscosity. The applicant should characterize viscosity over a range of shear rates.
- Comparative drug particle size and size distribution. Full profiles of the particle size distribution should also be submitted for all samples tested.
- Comparative in vitro drug release rates of erythromycin from the test and RLD formulations. The methodology used for in vitro drug release testing should be able to discriminate the effect of process variability in the production of the test formulation.

The test and RLD formulations should be qualitatively[2] and quantitatively[3] the same (Q1/Q2)[4].

Analytes to measure (in appropriate biological fluid): Not applicable

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: Not applicable

[1] All 3 exhibit batches should be at least 1/10 the size of the commercial batch and the manufacturing process used for the 3 exhibit batches should be reflective of the process used for the commercial batch.
[2] Q1 (qualitative sameness) means that the test product uses the same inactive ingredient(s) as the reference product.
[3] Q2 (quantitative sameness) means that the concentrations of the inactive ingredient(s) used in the test product are within ±5% of those used in the reference product.
[4] No changes (source, grade, etc.) should be made to the structure forming excipient in the product for commercial batches unless adequate supporting data and risk assessment are provided to demonstrate that the changes will not affect the product performance and quality.