

## **Draft Guidance on Rimexolone**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Suspension/Drops; ophthalmic

**Recommended Studies:** One study

1. Type of study: Bioequivalence study with pharmacokinetic (PK) endpoints  
Design: Single-dose, crossover or parallel design in vivo in aqueous humor  
Strength: 1%  
Subjects: Patients undergoing indicated cataract surgery and scheduled to receive ophthalmic steroid just prior to their eye surgery  
Additional comments: Specific recommendations are provided below.

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**Analytes to measure (in appropriate biological fluid):** Rimexolone in aqueous humor

**Bioequivalence based on (90% CI):** Rimexolone

**In vitro dissolution test method:** Please develop an in vitro drug release testing method for this drug product for stability and quality controls. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

**Additional comments regarding the in vivo pharmacokinetic study in aqueous humor:**

Please refer to the Guidance on Loteprednol Etabonate Ophthalmic Suspension/Drops for additional information on the bioequivalence study.

A pilot PK study is recommended to determine if the sensitivity of the assay is adequate and sampling time points are appropriate for the pivotal PK bioequivalence study.