

Draft Guidance on Triamcinolone Acetonide

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Active ingredient: Triamcinolone Acetonide

Form/Route: Suspension/Injectable

Recommended studies: 1 study

1. Type of study: Fasting
Design: Single-dose, two-way, parallel *in-vivo* (*Intramuscular administration*)
Strength: Single-dose of 10 mg (0.25 mL x 40 mg/mL)
Subjects: Healthy males, general population.
Additional Comments: As per 21 CFR § 314.94, the proposed parenteral drug product should be qualitatively (Q1) and quantitatively (Q2) the same as the RLD.

Analytes to measure (in appropriate biological fluid): Triamcinolone Acetonide in plasma.

Bioequivalence based on (90% CI): Triamcinolone Acetonide.

Waiver request of *in-vivo* testing: 10 mg/mL based on (i) acceptable bioequivalence study on the 40 mg/mL strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all strengths, (iv) the formulation of the 10 mg/mL strength is qualitatively (Q1) and quantitatively (Q2) identical to the 10 mg/mL strength of the RLD.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.