

## **Draft Guidance on Medroxyprogesterone Acetate**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Suspension; intramuscular injection

**Recommended Studies:** One study

1. Type of study: Fasting  
Design: Single-dose, parallel, in vivo  
Strength: 150 mg/mL  
Subjects: Healthy nonpregnant females  
Additional Comments: Females should not be pregnant and if applicable, should practice abstinence or contraception during the study.

Both sites of injection (gluteal and deltoid) should be included in the study design. Subjects should be randomized into the following four (4) groups: Test treatment at gluteal site, Test treatment at deltoid site, Reference treatment at gluteal site, and Reference treatment at deltoid site. In addition, if more than one dosing date is planned, approximately equal number of subjects representing each of the 4 groups should be included in each of the dosing dates.

Demonstration of BE at each of the injection sites is not recommended, only demonstration of BE between the test and reference formulations, with the effect of the two injection sites taken into account and analyzed; i.e., the factor, injection site, should be included in the statistical analysis model.

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The formulation of test and reference products should be qualitatively (Q1) and quantitatively (Q2) same per CFR 21 314.94 (a)(9)(iii).

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**Analytes to measure:** Medroxyprogesterone acetate in plasma

**Bioequivalence based on (90% CI):** Medroxyprogesterone acetate

**Waiver request of in vivo testing:** (Not Applicable)

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>.

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 abbreviated new drug application (ANDA).