

Draft Guidance on Medroxyprogesterone Acetate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Medroxyprogesterone Acetate

Form/Route: Suspension/Intramuscular

Recommended studies: 1 study

1. Type of study: Fasting
Design: Single-dose, parallel, in vivo
Strength: 400 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 site 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 as a variation contributing factor; i.e., injection site factor should be included in the statistical analysis model.

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

Analytes to measure: Medroxyprogesterone in plasma

Bioequivalence based on (90% CI): Medroxyprogesterone

Waiver request of in vivo testing: (Not Applicable)

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.accessdata.fda.gov/scripts/cder/dissolution/>. 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.

Please note that a dosage unit for a suspension is the labeled strength (mg/mL). A total of 12 units from 12 different bottles should be used. Specifications will be determined upon review of the application.