

Contains Nonbinding Recommendations
Draft Guidance on Sitagliptin Phosphate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Sitagliptin Phosphate

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 100 mg (base equiv)
Subjects: Normal healthy males and nonpregnant females, general population.
Additional Comments: Females should not be lactating, and if applicable, should practice abstinence or contraception during the study.

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 100 mg (base equiv)
Subjects: Normal healthy males and nonpregnant females, general population.
Additional Comments: Please see Additional Comments above.

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

Bioequivalence based on (90% CI): Sitagliptin

Waiver request of *in-vivo* testing: 25 mg (base equiv) and 50 mg (base equiv) based on (i) acceptable bioequivalence studies on the 100 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable *in vitro* dissolution testing of all strengths.

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.