

Draft Guidance on Palbociclib

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Capsules; oral

Recommended Studies: Two studies

Type of study: Fasting

Design: Single dose, two-way crossover in vivo

Strength: 125 mg

Subjects: Healthy males and females (non-pregnant), general population

Additional Comments: Female subjects should not be pregnant or lactating, and if applicable, should practice abstinence or contraception during the study. Applicants may consider using a reference-scaled average bioequivalence (BE) approach for palbociclib for the study under fasting condition provided high within-subject variability of $\geq 30\%$ can be shown for the BE parameters of AUC and/or C_{max} in the bioequivalence study. For details on the method for statistical analysis using the reference-scaled average bioequivalence approach, please refer to the Guidance on Progesterone Oral Capsules.

Type of study: Fed

Design: Single dose, two-way crossover in vivo

Strength: 125 mg

Subjects: Healthy males and females (non-pregnant), general population

Additional Comments: Female subjects should not be pregnant or lactating, and if applicable, should practice abstinence or contraception during the study.

Analytes to measure (in appropriate biological fluid): Palbociclib in plasma

Bioequivalence based on (90% CI): Palbociclib

Waiver request of in vivo testing: 75 mg and 100 mg capsule based on (i) acceptable bioequivalence study on the 125 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: 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).