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Draft Guidance on Norgestrel

May 2025

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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Active Ingredient:	Norgestrel
Dosage Form:	Tablet
Route:	Oral
Strength:	0.075 mg
Recommended Study:	Two options: (1) Biopharmaceutics Classification System (BCS)-based biowaiver or (2) one in vivo bioequivalence study with pharmacokinetic endpoints

I. Option 1: BCS Class I-based biowaiver option:

A waiver request of in vivo testing for this product may be considered provided that the appropriate documentation regarding high solubility, high permeability and rapid dissolution of the test product and reference listed drug (RLD)[1] as detailed in the most recent version of the FDA guidance for industry on *M9 Biopharmaceutics Classification System-Based Biowaivers*[a] is submitted in the application. Applicants may use information contained in the approved labeling of the RLD. Peer-reviewed articles may not contain the necessary details of the testing for the FDA to make a judgment regarding the quality of the studies. A decision regarding the acceptability of the waiver request will be made upon assessment of the data submitted in the application.

[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*

II. Option 2: One in vivo bioequivalence study with pharmacokinetic endpoints

Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 0.075 mg
Subjects: Healthy non-pregnant, non-lactating females
Additional comments: None

Analyte to measure: Norgestrel in plasma

Bioequivalence based on (90% CI): Norgestrel

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of the test product and RLD.[1] Specifications will be determined upon review of the abbreviated new drug application.

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[a] For the most recent version of a guidance, check the FDA guidance website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.