

## Draft Guidance on Aprepitant

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** For suspension; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting

Design: Single-dose, two-way crossover in-vivo

Strength: 125 mg

Subjects: Healthy males and non-pregnant, non-lactating females, general population.

Additional Comments: Follow the preparation and administration instructions as described in the approved drug label.

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2. Type of study: Fed

Design: Single-dose, two-way crossover in-vivo

Strength: 125 mg

Subjects: Healthy males and non-pregnant, non-lactating females, general population.

Additional Comments: Follow the preparation and administration instructions as described in the approved drug label.

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**Analytes to measure (in appropriate biological fluid):** aprepitant in plasma

**Bioequivalence based on (90% CI):** aprepitant

**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).