Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Nevirapine

October 2024

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Nevirapine

Dosage Form: Tablet

Route: Oral

Strength: 200 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, one-period parallel in vivo
   Strength: 200 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Due to safety concerns of severe life-threatening skin reactions and hepatotoxicity, single dose parallel study designs in healthy subjects are recommended.

Analyte to measure: Nevirapine in plasma

Bioequivalence based on (90% CI): Nevirapine

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 reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended November 2007; Revised May 2017, October 2024

Unique Agency Identifier: PSG_020636

[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*.