Contains Nonbinding Recommendations

Draft Guidance on Neratinib Maleate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: Eq 40 mg base at the dose of 240 mg (6 x Eq 40 mg base)
   Subjects: Males and females of non-child bearing potential (post-menopausal or surgically sterile), general population
   Additional Comments: Recommend the use of effective contraception during treatment for 3 months after the last dose for males with a female partner of reproductive potential.

   2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: Eq 40 mg base at the dose of 240 mg (6 x Eq 40 mg base)
   Subjects: Males and females of non-child bearing potential (post-menopausal or surgically sterile), general population
   Additional Comments: See comments above.

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

Bioequivalence based on (90% CI): Neratinib

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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

Recommended Sept 2018