Contains Nonbinding Recommendations

Draft Guidance on Fostamatinib Disodium

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: EQ 150 mg Base
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional Comments: Females of reproductive potential should be advised to use effective contraception during treatment with and for at least 1 month after the last dose.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: EQ 150 mg Base
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional Comments: See comments above

Analytes to measure (in appropriate biological fluid): Fostamatinib's active metabolite R406 in plasma

Bioequivalence based on (90% CI): Fostamatinib's active metabolite R406

Waiver request of in-vivo testing: EQ 100 mg Base strength based on (i) acceptable bioequivalence studies on the EQ150 mg Base strength, (ii) proportionally similar formulation 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 website 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).