Contains Nonbinding Recommendations

Draft Guidance on Dolutegravir Sodium; Rilpivirine Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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 Ingredients: Dolutegravir sodium; Rilpivirine hydrochloride

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 50 mg Base; EQ 25 mg Base
   Subjects: Males and females, general population
   Additional comments: Exclude females of reproductive potential due to the risk of embryo-fetal toxicity. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of rilpivirine. Alternatively, a parallel study design may be considered.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 50 mg Base; EQ 25 mg Base
   Subjects: Males and females, general population
   Additional comments: See comments above

Analytes to measure: Dolutegravir and rilpivirine in plasma

Bioequivalence based on (90% CI): Dolutegravir and rilpivirine

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