Contains Nonbinding Recommendations

Draft Guidance on Rolapitant

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Rolapitant

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in vivo*
   Strength: EQ 90 mg base
   Subjects: Normal healthy males and females, general population
   Additional comments: Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.

---

2. Type of Study: Fed
   Design: Single-dose, two-way crossover *in vivo*
   Strength: EQ 90 mg base
   Subjects: Normal healthy males and females, general population
   Additional Comments: Please see comments above.

Analytes to measure (in appropriate biological fluid): Rolapitant in plasma

Bioequivalence based on (90% CI): Rolapitant

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 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).

Information Regarding Long Half-Life Drugs
Rolapitant has a long terminal elimination half-life. Please ensure adequate washout periods between treatments in the crossover studies. Please also consider using a parallel study design due to rolapitant's long half-life. For a long half-life drug product, an AUC truncated to 72 hours may be used in place of AUC0-t or AUC0-inf if the drug demonstrates low intrasubject variability in distribution and clearance.