Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Vancomycin Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: For solution; oral

Strengths: EQ 25 mg/mL Base and EQ 50 mg/mL Base

Recommended Study: Request for Waiver of in vivo Bioequivalence Study Requirements

Waiver option:

To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of vancomycin hydrochloride oral solution kit must contain the same active drug ingredient in the same concentration and dosage form as the reference listed drug. The fruit-flavored diluent must contain no inactive ingredient or other changes in its formulation that may significantly affect its systemic or local availability.

Analyte to measure: Not applicable

Bioequivalence based on (90% CI): Not applicable

Dissolution test method and sampling times: Not applicable