

Draft Guidance on Bisacodyl; Polyethylene Glycol 3350; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Bisacodyl; Polyethylene Glycol 3350; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride

Dosage Form; Route: Delayed-release tablet for solution; oral

Strength: 5 mg; 210 gm; 0.74 gm; 2.86 gm; 5.6 gm

Recommended Studies: Request for Waiver of *In vivo* Bioequivalence Study Requirements

Bioequivalence study recommendations:

Bisacodyl Delayed-release Tablets are classified as a Category I (GRASE: generally recognized as safe and effective) over the counter (OTC) product. It is therefore eligible for a waiver of *in-vivo* bioequivalence (BE) testing based on the OTC monograph and acceptable comparative dissolution testing provided that the test product is in the same dosage form and strength as the reference standard (RS).

To qualify for a waiver of *in vivo* BE study requirements under 21 CFR 320.22(b)(3), the generic Polyethylene Glycol 3350, Potassium Chloride, Sodium Bicarbonate, and Sodium Chloride for Oral Solution products must contain the same active ingredients in the same concentration and dosage form as the RS and should not contain an inactive ingredient or other change in formulation from the RS that may significantly affect local availability for the product.

Analytes to measure (in appropriate biological fluid): Not applicable

Bioequivalence based on (90% CI): 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).