

Contains Nonbinding Recommendations

Draft Guidance on Sodium Polystyrene Sulfonate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Sodium polystyrene sulfonate

Dosage Form; Route: Powder; oral/rectal

Recommended Studies:

Sodium polystyrene sulfonate powder is a Drug Efficacy Study Implementation (DESI) effective drug for which there are no known or suspected bioequivalence (BE) problems, and as such is rated "AA" in the FDA/CDER's Approved Drug Products with Therapeutic Equivalence Evaluations (i.e., the "Orange Book").

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

Bioequivalence based on (90% CI): N/A

Waiver request of in vivo testing: 453.6 GM/BOT pursuant to 21 CFR 320.22 (c).

Dissolution test method and sampling times: N/A.