

Draft Guidance on Sodium Polystyrene Sulfonate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Routes: Suspension; oral and rectal

Recommended Studies:

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

Analyte to measure: Not applicable

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: Not applicable

Product-specific testing conditions for in vitro feeding tube studies:

The reference product can be administered via an enteral tube. Therefore, conduct the in vitro feeding tube studies including comparative recovery testing with four repeated administration, particle size distribution study, and sedimentation volume testing (risk assessment). Refer to the Lansoprazole Delayed Release Orally Disintegrating Tablet Guidance for additional information regarding procedures of in vitro feeding tube studies.

Testing tube: Nasogastric tube (8 French), gastric tube (12 French)

Testing strength: 15 g/60 mL

Comparative Recovery Testing: The recovery for the test and reference products should be determined using a validated analytical method that measures the potassium exchange capacity.