

Draft Guidance on Barium Sulfate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Paste; oral

Recommended Studies: In vitro study

Additional Comments: The proposed test drug product should be qualitatively (Q1)¹ and quantitatively (Q2)² the same as the Reference Listed Drug (RLD). In addition, test and reference products should have comparable physicochemical properties including but not limited to viscosity at low, medium and high shear rates and pH. Comparative analysis should be performed on at least three batches of both test and reference products.

In Vitro Study: Particle size distribution

Parameters to measure: D₁₀, D₅₀ and D₉₀

Bioequivalence based on (95% upper confidence bound): D₅₀ and SPAN [i.e., (D₉₀-D₁₀)/D₅₀] using the population bioequivalence (PBE) statistical analysis procedure. Refer to the Guidance on Budesonide inhalation suspension for additional information regarding PBE.

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: Not applicable.

¹ Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the reference product.

² Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ±5% of those used in the reference product.