

**Draft Guidance on Barium Sulfate**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Strength:** 2% (9 g / 450 mL)

**Recommended Studies:** In vitro study

**Additional Comments:** The proposed test drug product should be qualitatively (Q1)<sup>1</sup> and quantitatively (Q2)<sup>2</sup> the same as the reference listed drug (RLD). Test and reference drug products should have comparable physicochemical properties, including but not limited to, viscosity across a range of shear rates (e.g., low, medium, and high), and pH. The comparative analyses should be performed on at least three lots of the test drug product and three lots of the reference drug product.

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**In Vitro Study:** Particle Size Distribution

**Parameters to measure:** D<sub>10</sub>, D<sub>50</sub>, D<sub>90</sub>

**Bioequivalence based on (95% upper confidence bound):** D<sub>50</sub> and SPAN [i.e., (D<sub>90</sub>-D<sub>10</sub>)/D<sub>50</sub>] 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

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

<sup>2</sup> 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.