

Draft Guidance on Sodium Phenylbutyrate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Powder/Oral

Recommended studies: 2 options: In-Vivo Studies or In-Vitro Dissolution testing

I. In-Vivo option:

If the test product is **not** qualitatively (Q1) and quantitatively (Q2) the same as the RLD, the following studies are recommended to establish bioequivalence of the test product:

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 3 gm/teaspoonful
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 3 gm/teaspoonful
Subjects: Healthy males and nonpregnant females, general population.
Additional comments:

Analytes to measure: Phenylbutyrate in plasma

Bioequivalence based on (90% CI): Phenylbutyrate

Waiver request of in-vivo testing: Not Applicable

II. In-Vitro option:

If the test product is qualitatively (Q1) and quantitatively (Q2) the same as the reference listed drug (RLD), the above studies may not be necessary provided that the dissolution testing data is acceptable.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. Please find the dissolution information for this product at this website. Please 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 application.