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Draft Guidance on Sodium Phenylbutyrate

February 2024

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Active Ingredient: Sodium phenylbutyrate

Dosage Form: For suspension

Route: Oral

Strengths: 2 gm/packet, 3 gm/packet, 4 gm/packet, 5 gm/packet, 6 gm/packet, 6.67 gm/packet

Recommended Studies: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 5 gm/packet (at a dose of 5 gm)
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 5 gm/packet (at a dose of 5 gm)
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Phenylbutyrate in plasma

Bioequivalence based on (90% CI): Phenylbutyrate

Waiver request of in vivo testing: 2 gm/packet, 3 gm/packet, 4 gm/packet, 6 gm/packet, and 6.67 gm/packet unit-dose strengths based upon (i) acceptable bioequivalence studies on the 5 g/Packet unit-dose strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Note that a dosage unit for suspension is the labeled strength (packet). Specifications will be determined upon review of the abbreviated new drug application.

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