

Sodium Phenylbutyrate Suspension 200 mg/mL

INGREDIENTS:

Sodium phenylbutyrate powder	24 g
Ora-Plus/Ora-Sweet*	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, pharmaceutical analytical scale, glass mortar and pestle, graduated cylinder

PREPARATION DETAILS:

1. Weigh out powder and add to a mortar.
2. Triturate contents to a fine powder.
3. Levigate powder with a small amount of vehicle to form a paste.
4. Add vehicle in increasing amounts while mixing thoroughly.
5. Transfer contents of the mortar to a graduated cylinder.
6. Rinse the mortar and pestle with vehicle and pour into graduated cylinder.
7. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
8. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
9. Shake well to mix.

Special Instructions — *Mix 60 mL of Ora-Plus with 60 mL of Ora-Sweet. Use mixture as vehicle or use Ora-Blend.

Alternatives — May substitute vehicle with 60 mL of Ora-Plus mixed with 60 mL of Ora-Sweet SF or Ora-Blend SF.

Quality-Control Procedures — Visually inspect for physical appearance of formulation and container closure integrity (no leakage, cracks in container, or improper seals).

Labeling Requirements — Extemporaneously compounded preparation. For oral use only. Store at room temperature. Shake well before use.

Storage Conditions/Stability — Store at room temperature. Stable for 90 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic bottle with child-resistant cap

Referenced Manufacturers — Sodium phenylbutyrate powder (Ucyclyd Pharma, Inc); Ora-Plus, Ora-Sweet, Ora-Sweet SF (Paddock Laboratories, LLC).

Stability-Indicating Study — Yes

REFERENCE

1. Caruthers RL, Johnson CE. Stability of extemporaneously prepared sodium phenylbutyrate oral suspensions. *Am J Health Syst Pharm.* 2007;64:1513-1515.