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# Sodium Phenylbutyrate Compounded Oral Suspension

**DEFINITION**

Sodium Phenylbutyrate Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of sodium phenylbutyrate ($C_{10}H_{11}O_2Na$).

Prepare Sodium Phenylbutyrate Compounded Oral Suspension 200 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

| | |
|---|---|
| Sodium Phenylbutyrate powder[a] | 20 g |
| Vehicle: a 1:1 mixture of Ora-Sweet[b] (regular or sugar-free) and Ora-Plus,[b] a sufficient quantity to make | 100 mL |

[a] Ucyclyd Pharma, Inc., Scottsdale, AZ.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the *Sodium Phenylbutyrate powder* in a suitable mortar, and comminute to a fine powder with a pestle. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a sodium phenylbutyrate liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.



**ASSAY**

• **Procedure**

**Mobile phase:** Acetonitrile and 5 mM phosphoric acid (40:60). Filter and degas.

**Standard solution:** 0.1 mg/mL of sodium phenylbutyrate in *Mobile phase*. [Note—The *Standard solution* should be prepared from the appropriate reference material.]

**Sample solution:** Shake thoroughly by hand each bottle of Oral Suspension. Prepare 0.1 mg/mL of sodium phenylbutyrate from Oral Suspension and *Mobile phase*.

**Chromatographic system**

(See *Chromatography* ⟨621⟩, *System Suitability*.)

**Mode:** LC

**Detector:** UV 218 nm

**Column:** 4.6-mm × 25-cm; 5-µm packing L1

**Column temperature:** 60°

**Flow rate:** 1.0 mL/min

**Injection volume:** 5 µL

**System suitability**

**Sample:** *Standard solution*

[Note—The retention time for sodium phenylbutyrate is about 3.0 min.]

**Suitability requirements**

**Relative standard deviation:** NMT 2.0% for replicate injections

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sodium phenylbutyrate ($C_{10}H_{11}O_2Na$) in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

$r_U$ = peak response from the *Sample solution*

$r_S$ = peak response from the *Standard solution*

$C_S$ = concentration of sodium phenylbutyrate in the *Standard solution* (mg/mL)

$C_U$ = nominal concentration of sodium phenylbutyrate in the *Sample solution* (mg/mL)

**Acceptance criteria:** 90.0%–110.0%

**SPECIFIC TESTS**

• **pH** ⟨791⟩**:** 7.0–8.0

**ADDITIONAL REQUIREMENTS**

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| SODIUM PHENYLBUTYRATE COMPOUNDED ORAL SUSPENSION | Brian Serumaga<br>Science Program Manager | CMP2020 Compounding 2020 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | CMP2020 Compounding 2020 |

**Chromatographic Database Information:** Chromatographic Database



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