

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:

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 Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

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