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Add the following:

^Sodium Phenylbutyrate Oral Powder

DEFINITION

Sodium Phenylbutyrate Oral Powder contains NLT 90.0% and NMT 110.0% of the labeled amount of sodium phenylbutyrate ($C_{10}H_{11}NaO_2$).

IDENTIFICATION

- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Mobile phase: [Methanol](#), [water](#), and [glacial acetic acid](#) (49:50:1)

Diluent: [Methanol](#) and [water](#) (20:80)

Standard solution: 2.5 mg/mL of [USP Sodium Phenylbutyrate RS](#) in *Diluent*. Sonicate, if necessary, to dissolve.

Sample solution: Nominally 2.5 mg/mL of sodium phenylbutyrate in *Diluent* prepared as follows. Transfer an amount of Oral Powder equivalent to about 500 mg of sodium phenylbutyrate to a 200-mL volumetric flask. Add about 140 mL of *Diluent*, and sonicate for 10 min with intermittent shaking. Dilute with *Diluent* to volume. Pass through a suitable filter of 0.45-μm pore size.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 260 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Flow rate: 1.2 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sodium phenylbutyrate ($C_{10}H_{11}NaO_2$) in the portion of Oral Powder 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 [USP Sodium Phenylbutyrate RS](#) 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%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: [Simulated intestinal fluid](#) without enzyme; 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Mobile phase: [Methanol](#), [water](#), and [glacial acetic acid](#) (49:50:1)

Standard solution: ($L/900$) mg/mL of [USP Sodium Phenylbutyrate RS](#), where L is the label claim of sodium phenylbutyrate in milligrams for each dosage strength prepared as follows. Transfer the appropriate amount of [USP Sodium Phenylbutyrate RS](#) to a volumetric flask. Add 40% of the final volume of [methanol](#), and sonicate, if necessary, to dissolve. Dilute with *Medium* to volume.

Sample solution: Transfer carefully an amount of Oral Powder equivalent to each dosage strength, based on the label claim, to the dissolution vessel containing the *Medium*. Perform the dissolution test and pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 245 nm

Column: 4.6-mm $\times$ 15-cm; 5- μ m packing [L1](#)

Flow rate: 1.7 mL/min

Injection volume: 10 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sodium phenylbutyrate ($C_{10}H_{11}NaO_2$) dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Sodium Phenylbutyrate RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/dosage strength)

V = volume of *Medium*, 900 mL

Tolerances: NLT 85% (Q) of the labeled amount of sodium phenylbutyrate ($C_{10}H_{11}NaO_2$) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meets the requirements

IMPURITIES

• ORGANIC IMPURITIES

Mobile phase: [Methanol](#), [water](#), and [glacial acetic acid](#) (44:55:1)

Diluent: [Methanol](#) and [water](#) (20:80)

System suitability stock solution A: 0.08 mg/mL of [USP Phenylbutyrate Related Compound A RS](#) in *Diluent*. Sonicate to dissolve, if necessary.

System suitability stock solution B: 0.06 mg/mL of [USP Phenylbutyrate Related Compound B RS](#) in *Diluent*. Sonicate to dissolve, if necessary.

System suitability solution: 4 mg/mL of [USP Sodium Phenylbutyrate RS](#), 0.008 mg/mL of [USP Phenylbutyrate Related Compound A RS](#), and 0.006 mg/mL of [USP Phenylbutyrate Related Compound B RS](#) prepared as follows. Dissolve a suitable amount of [USP Sodium Phenylbutyrate RS](#) with 50% of the total flask volume of [methanol](#) and sonicate, if necessary, to dissolve. Add suitable volumes of *System suitability stock solution A* and *System suitability stock solution B* to the same flask and dilute with *Diluent* to volume.

Sensitivity solution: 1.5 μ g/mL each of [USP Phenylbutyrate Related Compound A RS](#) and [USP Phenylbutyrate Related Compound B RS](#) from *System suitability stock solution A* and *System suitability stock solution B* in *Diluent*

Standard solution: 0.008 mg/mL of [USP Phenylbutyrate Related Compound A RS](#) and 0.006 mg/mL of [USP Phenylbutyrate Related Compound B RS](#) from *System suitability stock solution A* and *System suitability stock solution B* in *Diluent*

Sample solution: Nominally 4 mg/mL of sodium phenylbutyrate in *Diluent* prepared as follows. Transfer an amount of Oral Powder equivalent to about 200 mg of sodium phenylbutyrate to a 50-mL volumetric flask. Add about 35 mL of *Diluent* and sonicate for 10 min with intermittent shaking. Dilute with *Diluent* to volume. Pass through a suitable filter of 0.45- μ m pore size.