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Add the following:

▲Sodium Benzoate Compounded Oral Solution

DEFINITION

Sodium Benzoate Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of sodium benzoate ($C_7H_5NaO_2$).

Prepare Sodium Benzoate Compounded Oral Solution 100 mg/mL and 300 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Sodium Benzoate Compounded Oral Solution 100 mg/mL

Sodium Benzoate powder	10 g
Purified Water, a sufficient quantity to make	100 mL

Sodium Benzoate Compounded Oral Solution 300 mg/mL

Sodium Benzoate powder	30 g
Purified Water, a sufficient quantity to make	100 mL

In an appropriately size calibrated container, dissolve the *Sodium Benzoate powder* in about 80 mL of *Purified Water*. Stir until dissolved. Bring to final volume with *Purified Water* and mix well.

ASSAY

• **Procedure**

Solution A: 30 mM of potassium phosphate monobasic buffer adjusted with phosphoric acid to a pH of 3

Mobile phase: Methanol and *Solution A* (50:50)

Standard solution: 0.1 mg/mL of USP Sodium Benzoate RS in *Mobile phase*

Sample solution

For Oral Solution 100 mg/mL: Transfer 1 mL of Oral Solution into a 100-mL volumetric flask, add approximately 80 mL of *Mobile phase*, and vortex. Dilute with *Mobile phase* to volume. Transfer 1 mL of this solution to a 10-mL volumetric flask, add approximately 8 mL of *Mobile phase*, and vortex. Dilute with *Mobile phase* to volume.

For Oral Solution 300 mg/mL: Transfer 1 mL of Oral Solution into a 100-mL volumetric flask, add approximately 80 mL of *Mobile phase*, and vortex. Dilute with *Mobile phase* to volume. Transfer 7 mL of this solution to a 200-mL volumetric flask, add approximately 150 mL of *Mobile phase*, and vortex. Dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 2-mm × 15-cm; 3-µm packing L1

Flow rate: 0.2 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for sodium benzoate is about 6.5 min.]

Suitability requirements

Tailing factor: NMT 2.0

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 benzoate ($C_7H_5NaO_2$) in the portion of Oral Solution taken:

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

r_U = peak response of sodium benzoate from the *Sample solution*

r_S = peak response of sodium benzoate from the *Standard solution*

C_S = concentration of USP Sodium Benzoate RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩

For Oral Solution 100 mg/mL: 6.7–7.7

For Oral Solution 300 mg/mL: 7.3–8.3

ADDITIONAL REQUIREMENTS

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

• **Beyond-Use Date:** NMT 90 days from the date on which it was prepared when stored at controlled room temperature or in a refrigerator.

• **Labeling:** Label it to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Sodium Benzoate RS▲ (USP 1-May-2020)

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

Topic/Question	Contact	Expert Committee
SODIUM BENZOATE COMPOUNDED ORAL SOLUTION	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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