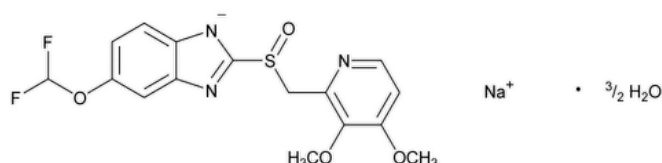


Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Dec-2023
 Document Type: USP Monographs
 DocId: GUID-E8EC33EC-F64B-4BE0-9108-AA79C86FB11F_10_en-US
 DOI: https://doi.org/10.31003/USPNF_M2631_10_01
 DOI Ref: iy4ok

© 2025 USPC
 Do not distribute

Pantoprazole Sodium

Change to read:



$C_{16}H_{14}F_2N_3NaO_4S \cdot \frac{3}{2}H_2O$ 432.37

▲ 1*H*-Benzimidazole, 5-(difluoromethoxy)-2-[[[(3,4-dimethoxy-2-pyridinyl)methyl]sulfinyl]-,▲ (USP 1-Dec-2023) sodium salt, hydrate (2:3);

5-(Difluoromethoxy)-2-[[[(3,4-dimethoxy-2-pyridyl)methyl]sulfinyl]benzimidazole, sodium salt, sesquihydrate CAS RN®: 164579-32-2; UNII: 6871619Q5X.

▲ Anhydrous

$C_{16}H_{14}F_2N_3NaO_4S$ 405.35 CAS RN®: 138786-67-1; UNII: S9363155XL.

Pantoprazole (free acid)

$C_{16}H_{15}F_2N_3O_4S$ 383.37 CAS RN®: 102625-70-7; UNII: D8TST40562.▲ (USP 1-Dec-2023)

DEFINITION

Pantoprazole Sodium contains NLT 98.0% and NMT 102.0% of pantoprazole sodium ($C_{16}H_{14}F_2N_3NaO_4S$), calculated on the anhydrous basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A or 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Change to read:

- **C. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Sodium:** Meets the requirements ▲▲ (USP 1-Dec-2023)

ASSAY

Change to read:

• PROCEDURE

[NOTE—Protect solutions containing pantoprazole sodium from light.]

Buffer: 1.32 g/L of [dibasic ammonium phosphate](#) in [water](#), adjusted with [phosphoric acid](#) to a pH of 7.5

▲ **Solvent**▲ (USP 1-Dec-2023) **mixture:** [Acetonitrile](#) and [methanol](#) ▲(70:30)▲ (USP 1-Dec-2023)

Solution A: ▲ **Solvent**▲ (USP 1-Dec-2023) **mixture** and ▲ **Buffer**▲ (USP 1-Dec-2023) (15:85)

Solution B: ▲ **Solvent**▲ (USP 1-Dec-2023) **mixture**

Mobile phase: See [Table 1](#). ▲▲ (USP 1-Dec-2023)

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	86	14
10	86	14



14 Documents

Document Sharing Hub

Time (min)	Solution A (%)	Solution B (%)
35	42	58
▲40	86	14
50	86	14

Diluent 1: [Acetonitrile](#) and [water](#) (50:50)▲ (USP 1-Dec-2023)

Diluent ▲2:▲ (USP 1-Dec-2023) Dilute 25 mL of [ammonium hydroxide](#) with [water](#) to 500 mL.

▲▲ (USP 1-Dec-2023)

Standard stock solution: 0.4 mg/mL of [USP Pantoprazole Sodium RS](#) ▲prepared as follows. Transfer a suitable amount of [USP Pantoprazole Sodium RS](#) to a suitable volumetric flask containing 10%–20% of the final volume of *Diluent 1*,▲ (USP 1-Dec-2023) and dilute with *Diluent* ▲2▲ (USP 1-Dec-2023) to volume.

Standard solution: 0.06 mg/mL of [USP Pantoprazole Sodium RS](#) from the *Standard stock solution* in *Diluent* ▲2▲ (USP 1-Dec-2023)

Sample stock solution: ▲0.4 mg/mL of Pantoprazole Sodium prepared as follows.▲ (USP 1-Dec-2023) Transfer about 20 mg of Pantoprazole Sodium to a 50-mL volumetric flask. Dissolve in ▲*Diluent 1* at 10%–20% of the final volume,▲ (USP 1-Dec-2023) and dilute with *Diluent* ▲2▲ (USP 1-Dec-2023) to volume.

Sample solution: 0.06 mg/mL of Pantoprazole Sodium from the *Sample stock solution* in *Diluent* ▲2▲ (USP 1-Dec-2023)

Chromatographic system

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

Mode: LC

Detector: UV 285 nm

Column: 3.9-mm × 15-cm; 4-μm packing [L1](#)

Temperatures

Autosampler: 4°

Column: 30°

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Sample: ▲▲ (USP 1-Dec-2023) *Standard solution*

▲▲ (USP 1-Dec-2023)

Suitability requirements

▲**Tailing factor:** NMT 2.0▲ (USP 1-Dec-2023)

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pantoprazole sodium ($C_{16}H_{14}F_2N_3NaO_4S$) in the portion of Pantoprazole Sodium taken:

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

r_U = peak response ▲of pantoprazole▲ (USP 1-Dec-2023) from the *Sample solution*

r_S = peak response ▲of pantoprazole▲ (USP 1-Dec-2023) from the *Standard solution*

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

C_U = concentration of Pantoprazole Sodium in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis