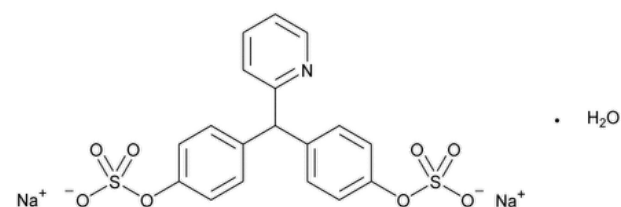


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Sodium Picosulfate

Change to read:



$C_{18}H_{13}NNa_2O_8S_2 \cdot H_2O$ 499.42

4,4'-(2-Pyridylmethylene)diphenyl bis(hydrogen sulfate) disodium salt, monohydrate;

▲Sodium 4,4'-(Pyridin-2-ylmethylene)bis(4,1-phenylene) disulfate monohydrate CAS RN®: 1307301-38-7; UNII: LR57574HN8.▲ (USP 1-Aug-2023)

Anhydrous

$C_{18}H_{13}NNa_2O_8S_2$ ▲481.40▲ (USP 1-Aug-2023) CAS RN®: 10040-45-6; UNII: VW106606Y8.

Change to read:

DEFINITION

Sodium Picosulfate contains NLT ▲98.0%▲ (USP 1-Aug-2023) and NMT ▲102.0%▲ (USP 1-Aug-2023) of sodium picosulfate ($C_{18}H_{13}NNa_2O_8S_2$), calculated on the anhydrous basis.

IDENTIFICATION

• A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A, 197K, or 197M

Change to read:

• B. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests](#),▲ (USP 1-Aug-2023) [Sodium](#): Meets the requirements ▲ (USP 1-Aug-2023)

Add the following:

▲• C. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2023)

ASSAY

Change to read:

• PROCEDURE

▲**Buffer:** 2.3 g/L of [dibasic sodium phosphate dihydrate](#) in [water](#). To each liter of solution, add 200 mg of [cetyltrimethylammonium bromide](#), and adjust with [phosphoric acid](#) to a pH of 7.5.

Mobile phase: [Acetonitrile](#) and *Buffer* (45:55)

[NOTE—If necessary, vary the buffer/acetonitrile proportion in 10-mL increments per liter of *Mobile phase* in order to fulfill the resolution requirement.]

Standard solution: 0.05 mg/mL of [USP Sodium Picosulfate RS](#) in *Mobile phase*

Sample solution: 0.05 mg/mL of Sodium Picosulfate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 263 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 40 µL

Run time: NLT 2 times the retention time of sodium picosulfate

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sodium picosulfate in the portion of Sodium Picosulfate taken:

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

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

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

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

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

▲ (USP 1-Aug-2023)

Acceptance criteria: ▲98.0%–102.0%▲ (USP 1-Aug-2023) on the anhydrous basis

IMPURITIES

Change to read:

• [CHLORIDE AND SULFATE \(221\)](#), *Chloride*

Sample: 1.0 g

Acceptance criteria: ▲The turbidity in the *Sample* does not exceed that produced in▲ (USP 1-Aug-2023) 0.30 mL of 0.020 N [hydrochloric acid](#) (NMT 0.02%).

Change to read:

• [CHLORIDE AND SULFATE \(221\)](#), *Sulfate*

Sample: 500 mg

Acceptance criteria: ▲The turbidity in the *Sample* does not exceed that produced in▲ (USP 1-Aug-2023) 0.20 mL of 0.020 N [sulfuric acid](#) (NMT 0.04%).

Change to read:

• **ORGANIC IMPURITIES**

▲**Buffer, Mobile phase, and Chromatographic system:** Proceed as directed in the Assay.▲ (USP 1-Aug-2023)

System suitability solution: 0.5 mg/mL of ▲[USP Sodium Picosulfate RS](#)▲ (USP 1-Aug-2023) and 0.5 µg/mL of [USP Sodium Picosulfate Related Compound A RS](#)▲ (USP 1-Aug-2023), in *Mobile phase*

▲**Standard solution:**▲ (USP 1-Aug-2023) 0.5 µg/mL of ▲[USP Sodium Picosulfate RS](#)▲ (USP 1-Aug-2023) in *Mobile phase*▲ (USP 1-Aug-2023)

Sensitivity solution: 0.25 µg/mL of ▲[USP Sodium Picosulfate RS](#) from the *Standard solution*,▲ (USP 1-Aug-2023) in *Mobile phase*▲ (USP 1-Aug-2023)

Sample solution: ▲500 µg/mL▲ (USP 1-Aug-2023) of Sodium Picosulfate in *Mobile phase*

▲ (USP 1-Aug-2023)

System suitability

Samples: *System suitability solution*, ▲*Standard solution*,▲ (USP 1-Aug-2023) and *Sensitivity solution*

Suitability requirements

Resolution: NLT 4 between sodium picosulfate related compound A and sodium picosulfate, *System suitability solution*

▲**Relative standard deviation:** NMT 5.0%, *Standard solution*▲ (USP 1-Aug-2023)

Signal-to-noise ratio: NLT 10, *Sensitivity solution*