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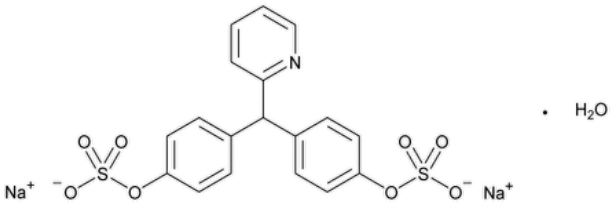
Sodium Picosulfate

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*

Analysis

Samples: *Sample solution* and ▲*Standard solution*▲ (USP 1-Aug-2023)

Calculate the percentage of any impurity in the portion of Sodium Picosulfate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of any impurity from the *Sample solution*

r_S = peak response of sodium picosulfate from the ▲*Standard solution*▲ (USP 1-Aug-2023)

C_S = concentration of ▲USP Sodium Picosulfate RS▲ (USP 1-Aug-2023) in the ▲*Standard solution* (µg/mL)▲ (USP 1-Aug-2023)

C_U = concentration of Sodium Picosulfate in the *Sample solution* (▲µg/mL▲ (USP 1-Aug-2023))

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*. ▲The reporting threshold is▲ (USP 1-Aug-2023) 0.05%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, (%)
▲Bisacodyl related compound A[a]▲ (USP 1-Aug-2023)	0.5	2.0	0.2
▲▲ (USP 1-Aug-2023) Sodium picosulfate related compound A	0.7	1.4	0.2
Sodium picosulfate	1.0	—	—
Any ▲unspecified▲ (USP 1-Aug-2023) impurity	—	1.0	0.10
Total impurities	—	—	0.5

[a] 4,4′-(Pyridin-2-ylmethylene)diphenol.

SPECIFIC TESTS

Delete the following:

▲• **Color of Solution**▲ (USP 1-Aug-2023)

Delete the following:

▲• **Acidity and Alkalinity**▲ (USP 1-Aug-2023)

• **Water Determination** ⟨921⟩, *Method I, Method Ia*: 3.0%–5.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers. Store at room temperature.

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Sodium Picosulfate RS

USP Sodium Picosulfate Related Compound A RS

▲Sodium 4-((4-hydroxyphenyl)(pyridin-2-yl)methyl)phenyl sulfate.▲ (USP 1-Aug-2023)

$C_{18}H_{14}NNaO_5S$ 379.36

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

Topic/Question	Contact	Expert Committee
SODIUM PICOSULFATE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 48(1)

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