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# Sulfadiazine Sodium

$C_{10}H_9N_4NaO_2S$  272.26  
 Benzenesulfonamide, 4-amino-*N*-2-pyrimidinyl-, monosodium salt;  
*N*<sup>1</sup>-2-Pyrimidinylsulfanilamide monosodium salt CAS RN<sup>®</sup>: 547-32-0; UNII: 84CS1P306F.

## DEFINITION

Sulfadiazine Sodium contains NLT 99.0% and NMT 100.5% of sulfadiazine sodium ( $C_{10}H_9N_4NaO_2S$ ), calculated on the dried basis.

## IDENTIFICATION

**Change to read:**

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197K▲ (USP 1-Dec-2021)

**Sample:** 1.5 g

**Analysis:** Dissolve the *Sample* in 25 mL of [water](#), and add 3 mL of 6 N acetic acid. A white precipitate of sulfadiazine is formed. Collect the precipitate on a filter, wash it well with cold water, and dry at 105° for 1 h.

**Acceptance criteria:** Meets the requirements

▲▲ (USP 1-Dec-2021)

- **B.** [IDENTIFICATION TESTS—GENERAL \(191\), Sodium](#)

**Sample:** 500 mg

**Analysis:** Ignite the *Sample* and use the residue.

**Acceptance criteria:** Meets the requirements

**Add the following:**

- ▲• **C.** [MELTING RANGE OR TEMPERATURE \(741\)](#)

**Sample:** Use the residue from *Identification A*.

**Acceptance criteria:** The melting range of the residue as determined by the method for *Class 1a* is 250°–254°.▲ (USP 1-Dec-2021)

## ASSAY

- **PROCEDURE**

**Analysis:** Proceed as directed in [Nitrite Titration \(451\)](#). Each milliliter of 0.1 M sodium nitrite is equivalent to 27.23 mg of sulfadiazine sodium ( $C_{10}H_9N_4NaO_2S$ ).

**Acceptance criteria:** 99.0%–100.5% on the dried basis

## IMPURITIES

**Delete the following:**

- ▲• [SELENIUM \(291\)](#)

**Sample:** 200 mg

**Acceptance criteria:** NMT 30 ppm▲ (USP 1-Dec-2021)

## SPECIFIC TESTS

- [LOSS ON DRYING \(731\)](#)

**Analysis:** Dry at 105° for 2 h.

**Acceptance criteria:** NMT 0.5%

## ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°.
- [USP REFERENCE STANDARDS \(11\)](#)

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

| Topic/Question             | Contact                                                                     | Expert Committee          |
|----------------------------|-----------------------------------------------------------------------------|---------------------------|
| SULFADIAZINE SODIUM        | <a href="#">Documentary Standards Support</a>                               | SM12020 Small Molecules 1 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br><a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a> | SM12020 Small Molecules 1 |

**Chromatographic Database Information:** [Chromatographic Database](#)

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