Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-3EEF1AC3-8A28-4A7D-B074-5824ABC17E37_4_en-US
DOI: https://doi.org/10.31003/USPNF_M78930_04_01
DOI Ref: 1kal3

Sulfadiazine Tablets

DEFINITION
Sulfadiazine Tablets contain NLT 95.0% and NMT 105.0% of the labeled quantity of $C_{10}H_{10}N_4O_2S$.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

• **B.** Melting Range or Temperature, *Class Ia* ⟨741⟩

Sample solution: Equivalent to 100 mg/mL of sulfadiazine from finely powdered Tablets in chloroform

Analysis: Transfer the *Sample solution* to a small filter. Wash with 5 mL of chloroform, and discard the filtrate. Triturate the residue with 10 mL of 6 N ammonium hydroxide for 5 min, add 10 mL of water, and filter. Warm the filtrate until most of the ammonia is expelled, cool, and add 6 N acetic acid until the reaction is distinctly acid: a precipitate of sulfadiazine is formed. Collect the precipitate on a filter, wash it with cold water, and dry at 105° for 1 h.

Acceptance criteria: The sulfadiazine melts at 250°–254°.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, glacial acetic acid, and water (12:1:87)

Standard solution: 1 mg/mL of USP Sulfadiazine RS in 0.025 N sodium hydroxide

Sample solution: 1 mg/mL of sulfadiazine from powdered Tablets in 0.025 N sodium hydroxide. [Note—Weigh NLT 20 Tablets, shake the solution for 30 min, and centrifuge, if necessary.]

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5 for sulfadiazine

Relative standard deviation: NMT 2.0% (five replicate injections)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{10}H_{10}N_4O_2S$ in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 75 rpm

Time: 90 min

Detector: UV, 242 nm

Analysis: Determine the quantity of $C_{10}H_{10}N_4O_2S$ dissolved by using UV absorption on filtered portions of the solution under test, in comparison with a Standard solution having a known concentration of USP Sulfadiazine RS in the same medium. Use *Medium* as the blank and cells with a path length of 0.1 cm.

Tolerances: NLT 70% (Q) of the labeled amount of $C_{10}H_{10}N_4O_2S$ is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Sulfadiazine RS

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

Topic/Question	Contact	Expert Committee
SULFADIAZINE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 35(3)

Current DocID: GUID-3EEF1AC3-8A28-4A7D-B074-5824ABC17E37_4_en-US

DOI: https://doi.org/10.31003/USPNF_M78930_04_01

DOI ref: 1kal3