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Sulfasalazine Tablets

DEFINITION

Sulfasalazine Tablets contain NLT 95.0% and NMT 105.0% of the labeled quantity of sulfasalazine ($C_{18}H_{14}N_4O_5S$).

IDENTIFICATION

• PROCEDURE

Standard solution: Use the *Standard solution*, prepared as directed in the Assay.

Sample solution: Use the *Sample solution*, prepared as directed in the Assay.

Acceptance criteria: The visible absorption spectrum of the *Sample solution* corresponds to that of the *Standard solution*, as prepared in the Assay.

ASSAY

• PROCEDURE

Sample stock solution: 1.5 mg/mL of sulfasalazine, from finely powdered Tablets (NLT 20 tablets), in 0.1 N sodium hydroxide

Sample solution: Transfer 5.0 mL of *Sample stock solution* to a 1000-mL volumetric flask containing 750 mL of water, mix, add 20.0 mL of 0.1 N acetic acid, and dilute with water to volume.

Standard solution: 7.5 µg/mL of [USP Sulfasalazine RS](#) in the same medium as the *Sample solution*

Spectrometric conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: Maximum at about 359 nm

Blank: Water

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Concomitantly determine the absorbances of the *Samples*. Calculate the percentage of $C_{18}H_{14}N_4O_5S$ in the portion of Tablets taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Sulfasalazine RS](#) in the *Standard solution* (µg/mL)

C_U = nominal concentration of sulfasalazine in the *Sample solution* (µg/mL)

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: pH 7.5 Phosphate Buffer (see [Reagents, Indicators, and Solutions—Buffer Solutions](#)); 900 mL

Apparatus 1: 100 rpm

Time: 60 min

Detector: UV 358 nm

Standard solution: [USP Sulfasalazine RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary, to a concentration that is similar to the *Standard solution*.

Tolerances: NLT 85% (Q) of the labeled amount of $C_{18}H_{14}N_4O_5S$ is dissolved.

- **UNIFORMITY OF DOSAGE UNITS** (905): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS** (11).
[USP Sulfasalazine RS](#)

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

Topic/Question	Contact	Expert Committee
SULFASALAZINE 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](#)

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