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Sulfasalazine Delayed-Release Tablets

DEFINITION

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

IDENTIFICATION

• **A.**

Standard solution and **Sample solution:** Proceed 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**

Standard solution: 7.5 µg/mL of USP Sulfasalazine RS in the same medium as the *Sample solution*

Sample stock solution: Nominally 1.5 mg/mL of sulfasalazine prepared as follows. Dissolve an appropriate amount of sulfasalazine from finely powdered Tablets (NLT 20) in 0.1 N sodium hydroxide in a suitable volumetric flask.

Sample solution: Nominally 7.5 µg/mL of sulfasalazine prepared as follows. Transfer 5.0 mL of the *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.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

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 the labeled amount of sulfasalazine ($C_{18}H_{14}N_4O_5S$) 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⟩**:** Proceed as directed in the *Procedure* for *Method B* in *Apparatus 1 and Apparatus 2, Delayed-Release Dosage Forms*.

Acid stage

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 1: 100 rpm

Time: 120 min

At the end of 120 min, determine the amount of sulfasalazine ($C_{18}H_{14}N_4O_5S$) dissolved by using the following method.

Mobile phase: Isopropanol, acetonitrile, water, and glacial acetic acid (11:7:22:0.4)

Standard solution: 55.6 µg/mL of USP Sulfasalazine RS in 0.1 N sodium hydroxide

Sample solution: Pass about 7 mL of the solution under test through a membrane filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for sulfasalazine is about 7.7 min.]

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sulfasalazine ($C_{18}H_{14}N_4O_5S$) dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NMT 10% of the labeled amount of sulfasalazine ($C_{18}H_{14}N_4O_5S$) is dissolved.

Buffer stage

Medium: pH 7.5 phosphate buffer; 900 mL

Apparatus 1: 100 rpm

Time: 60 min

At the end of 60 min, determine the amount of sulfasalazine ($C_{18}H_{14}N_4O_5S$) dissolved by using the chromatographic method as described in *Acid stage*.

Tolerances: NLT 85% (*Q*) of the labeled amount of sulfasalazine ($C_{18}H_{14}N_4O_5S$) 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 DELAYED-RELEASE 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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