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Dapsone Tablets

DEFINITION
Dapsone Tablets contain NLT 92.5% and NMT 107.5% of the labeled amount of dapsone ($C_{12}H_{12}N_2O_2S$).

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**

Sample solution: Transfer a quantity of finely powdered Tablets, equivalent to 100 mg of dapsone, to a suitable container, add 5 mL of acetone, shake for 5 min, filter, and evaporate the filtrate to dryness. Dry this residue at 105° for 1 h.

Acceptance criteria: Meets the requirements

• **B. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*:** 197U

Sample solution: Triturate a quantity of finely powdered Tablets, equivalent to 100 mg of dapsone, with 50 mL of methanol, and filter. Dilute a portion of the filtrate with methanol to make approximately a 1 in 200,000 solution.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Mobile phase: Transfer 100 mL of isopropyl alcohol, 100 mL of acetonitrile, and 100 mL of ethyl acetate to a 1000-mL volumetric flask. Add hexane to volume without mixing, then mix, and allow the mixture to cool to room temperature.

Standard solution: 25 µg/mL of USP Dapsone RS in *Mobile phase*

Sample solution: Nominally 25 µg/mL of dapsone prepared as follows. Weigh and finely powder NLT 20 Tablets. Transfer a portion of the powder, nominally equivalent to 50 mg of dapsone, to a 200-mL volumetric flask. Add 150 mL of methanol, and place the flask in an ultrasonic bath at a temperature of 35° for 15 min, with occasional shaking. Allow to cool to room temperature, and add methanol to volume. Centrifuge a portion of the mixture until clear. Transfer 5.0 mL of the clear supernatant to a 50-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; 10-µm diameter, packing L3

Injection volume: 10 µL

System suitability

Sample: *Standard solution* (chromatograph a sufficient number)

Suitability requirements

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dapsone ($C_{12}H_{12}N_2O_2S$) 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 Dapsone RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 92.5%–107.5%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

Medium: Dilute hydrochloric acid (2 in 100); 1000 mL

Apparatus 1: 100 rpm

Time: 60 min

Standard solution: ▲(*L*/1000) mg/mL of USP Dapsone RS in *Medium*, where *L* is the label claim in mg/Tablet. Transfer a portion of this solution containing 0.2 mg of dapsone to a 25-mL volumetric flask, add 5 mL of 1 N sodium hydroxide, and dilute with water to volume.▲ (ERR 1-May-2024)

Sample solution: Withdraw and filter a portion of the *Sample solution*. Transfer a portion of the filtrate estimated to contain 0.2 mg of dapsone to a 25-mL volumetric flask, add 5 mL of 1 N sodium hydroxide, and dilute with water to volume.

Instrumental conditions

Mode: UV

Analytical wavelength: 290 nm

Tolerances: NLT 75% (*Q*) of the labeled amount of dapsone ($C_{12}H_{12}N_2O_2S$) is dissolved.

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

Procedure for content uniformity

Standard solution: 8 µg/mL of USP Dapsone RS in methanol

Sample solution: Nominally 8 µg/mL of dapsone prepared as follows. To 1 Tablet in a 100-mL volumetric flask add 2.0 mL of water, and allow to stand for 30 min, swirling occasionally. Add 70 mL of methanol, and place the flask in an ultrasonic bath until the specimen is completely dispersed. Add methanol to volume, and centrifuge a portion of the mixture. Quantitatively dilute a measured volume of the clear supernatant with methanol.

Instrumental conditions

Mode: UV

Analytical wavelength: 296 nm

Cell: 1 cm

Blank: Methanol

Analysis

Samples: *Standard solution* and *Sample solution*.

Calculate the percentage of the labeled amount of dapsone ($C_{12}H_{12}N_2O_2S$) in the Tablet 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 Dapsone RS in the *Standard solution* (µg/mL)

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

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Dapsone RS

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

Topic/Question	Contact	Expert Committee
DAPSONE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable
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