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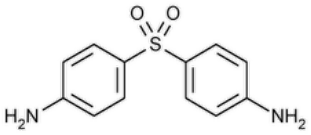
Dapsone



$C_{12}H_{12}N_2O_2S$ 248.30

Benzenamine, 4,4'-sulfonylbis-;

4,4'-Sulfonyldianiline CAS RN®: 80-08-0; UNII: 8W5C518302.

DEFINITION

Dapsone contains NLT 98.0% and NMT 102.0% of dapsone ($C_{12}H_{12}N_2O_2S$), calculated on the dried basis.

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

- **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: 25 µg/mL of Dapsone in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

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

Flow rate: 1 mL/min

Injection volume: 10 µL

Run time: ▲NLT▲ (USP 1-Dec-2021) 2 times the retention time of dapsone

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dapsone ($C_{12}H_{12}N_2O_2S$) in the portion of Dapsone taken:

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

r_U = peak response of dapsone from the *Sample solution*

r_S = peak response of dapsone from the *Standard solution*

C_S = concentration of USP Dapsone RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

Delete the following:

▲• **Selenium ⟨291⟩**

Sample: 100-mg sample mixed with 100 mg of magnesium oxide

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

• **Organic Impurities**

Standard solution A: 12.5 mg/mL of USP Dapsone RS in methanol

Standard solution B: 62.5 µg/mL of USP Dapsone RS in methanol from *Standard solution A*

Sample solution: 12.5 mg/mL of Dapsone in methanol

Chromatographic system

(See *Chromatography ⟨621⟩, General Procedures, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 150- to 200-µm layer of chromatographic silica gel

Application volume: 4 µL

Developing solvent system: Acetone, chloroform, *n*-butyl alcohol, and formic acid (15:60:15:10). Prepare the solvent system fresh daily. Equilibrate the chromatographic chamber with the solvent system for 30 min prior to developing the chromatographic plate.

Spray reagent: 0.1% (w/v) solution of 4-dimethylaminocinnamaldehyde in glacial acetic acid and water (1:1)

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Position the plate in a chromatographic chamber, and develop the chromatograms in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber and air-dry. Spray the plate lightly with *Spray reagent.* Examine the spots that are developed immediately, and compare the intensities of any secondary spots observed in the *Sample solution* with those of the principal spots of the *Standard solutions*.

Acceptance criteria: No secondary spot from the chromatogram of the *Sample solution* is larger or more intense than the principal spot of *Standard solution B* (0.5%), and the sum of the intensities of all the secondary spots of the *Sample solution* corresponds to NMT 1.0%.

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 1.5%

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	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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