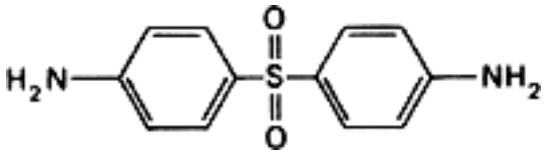
Dapsone (Dapsonum)

Molecular formula. $C_{12}H_{12}N_2O_2S$

Relative molecular mass. 248.3

Graphic formula.



Chemical name. 4,4'-Sulfonyldianiline; 4,4'-sulfonylbis[benzenamine]; 4,4'-diaminodiphenylsulfone; CAS Reg. No. 80-08-0.

Description. A white or creamy white, crystalline powder; odourless.

Solubility. Soluble in 7000 parts of water and in 30 parts of ethanol (~750 g/l) TS; soluble in acetone R.

Category. Antileprotic.

Storage. Dapsone should be kept in a tightly closed container, protected from light.

Additional information. Even in the absence of light, Dapsone is gradually degraded on exposure to a humid atmosphere, the decomposition being faster at higher temperatures.

Requirements

Definition. Dapsone contains not less than 99.0% and not more than 101.0% of $C_{12}H_{12}N_2O_2S$, calculated with reference to the dried substance.

Identity tests

A. The absorption spectrum of a 5.0 µg/mL solution in methanol R, when observed between 230 nm and 350 nm, exhibits maxima at about 260 nm and 295 nm; the absorbances of a 1-cm layer at the maximum wavelength of 260 nm and 295 nm are about 0.72 and 1.20, respectively.

B. See the test described below under "Related substances". The principal spot obtained with solution A corresponds in position, appearance, and intensity with that obtained with solution B.

C. About 0.1 g yields the reaction described for the identification of primary aromatic amines under 2.1 General identification tests, producing a vivid red precipitate.

D. Melting temperature, about 178°C.

Sulfated ash. Not more than 1.0 mg/g.

Loss on drying. Dry to constant weight at 105°C; it loses not more than 15 mg/g.

Related substances. Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography, but using an unlined chamber, silica gel R3 as the coating substance, and a mixture of 8 volumes of toluene R and 4 volumes of acetone R saturated with water as the mobile phase. Apply separately to the plate 10 µl of each of 5 solutions in methanol R containing (A) 10 mg of the test substance per mL, (B) 10 mg of dapsone RS per mL, (C) 0.15 mg of the test substance per mL, (D) 20 µg of the test substance per mL and (E) 0.10 mg of 4,4'-thiodianiline RS per mL. The solution of 4,4'-thiodianiline RS should be freshly prepared. Pour the mobile phase into the chamber and insert the plate immediately, to avoid prior saturation of the chamber. After removing the plate from the chromatographic chamber, spray it with 4-dimethylaminocinnamaldehyde TS2. Heat the plate at 100°C and examine the chromatogram in daylight. The spot obtained with solution C is more intense than any spot obtained with solution A, other than the principal spot, and in addition, not more than 2 among those secondary spots are more intense than the spot obtained with solution D. Moreover, there is no visible spot corresponding in position and appearance with that obtained with solution E.

Assay. Carry out the assay as described under 2.7 Nitrite titration, using about 0.25 g, accurately weighed, dissolved in a mixture of 15 mL of water and 15 mL of hydrochloric acid (~70 g/l) TS and titrate with sodium nitrite (0.1 mol/l) VS. Each mL of sodium nitrite (0.1 mol/l) VS is equivalent to 12.42 mg of $C_{12}H_{12}N_2O_2S$.