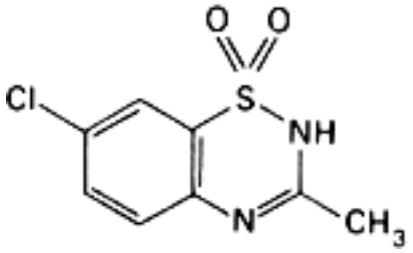
## Diazoxide (Diazoxidum)

**Molecular formula.** $C_8H_7ClN_2O_2S$

**Relative molecular mass.** 230.7

**Graphic formula.**




**Chemical name.** 7-Chloro-3-methyl-2*H*-1,2,4-benzothiadiazine 1,1-dioxide; CAS Reg. No. 364-98-7.

**Description.** A white, or almost white, crystalline powder; odourless.

**Solubility.** Practically insoluble in water and ether R; freely soluble in dimethylformamide R; slightly soluble in ethanol (~750 g/l) TS.

**Category.** Antihypertensive.

**Storage.** Diazoxide should be kept in a well-closed container.

### Requirements

**Definition.** Diazoxide contains not less than 98.0% and not more than 101.0% of $C_8H_7ClN_2O_2S$, calculated with reference to the dried substance.

### Identity tests

A. Carry out the examination as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from diazoxide RS or with the *reference spectrum* of diazoxide.

B. See the test described below under "Related substances". The principal spot obtained with solution B corresponds in position, appearance, and intensity with that obtained with solution 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 5.0 mg/g.

**Related substances.** Carry out the test as described under 1.14.1 Thin-layer chromatography, using silica gel R2 as the coating substance and a mixture of 17 volumes of ethyl acetate R, 4 volumes of methanol R, and 3 volumes of ammonia (~260 g/l) TS as the mobile phase. Apply separately to the plate 10 µl of each of 3 solutions in sodium hydroxide (0.1 mol/l) VS containing (A) 15 mg of the test substance per mL, (B) 0.15 mg of the test substance per mL and (C) 0.15 mg of diazoxide RS per mL. After removing the plate from the chromatographic chamber, allow it to dry in air until the odour of ammonia is no longer detectable, and examine the chromatogram in ultraviolet light (254 nm). Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution B.

**Assay.** Dissolve 0.45 g, accurately weighed, in 100 mL of a mixture of 2 volumes of dimethylformamide R and 1 volume of water, and titrate with sodium hydroxide (0.1 mol/l) VS, determining the end-point potentiometrically. Each mL of sodium hydroxide (0.1 mol/l) VS is equivalent to 23.07 mg of $C_8H_7ClN_2O_2S$.