Glibenclamide (Glibenclamidum)

**Molecular formula.** C\textsubscript{23}H\textsubscript{28}ClN\textsubscript{3}O\textsubscript{5}S

**Relative molecular mass.** 494.0

**Graphic formula.**

![Graphic formula of Glibenclamide](image)


**Other name.** Glyburide.

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

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

**Category.** Antidiabetic agent.

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

**Requirements**

**Definition.** Glibenclamide contains not less than 98.5% and not more than 101.0% of C\textsubscript{23}H\textsubscript{28}ClN\textsubscript{3}O\textsubscript{5}S, calculated with reference to the dried substance.

**Identity tests**

• Either test A alone or tests B and C may be applied.

  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 glibenclamide RS or with the reference spectrum of glibenclamide.

  B. The absorption spectrum of a 0.10 mg/mL solution in hydrochloric acid/ methanol (0.01 mol/l) VS, when observed between 230 nm and 350 nm, exhibits a maximum at about 300 nm and a less intense maximum at about 275 nm; the absorbance of a 1-cm layer at 300 nm is about 0.63.

  C. Melting temperature, about 172 °C.

**Heavy metals.** Use 1.0 g for the preparation of the test solution as described under 2.2.3 Limit test for heavy metals, Procedure 3; not more than 20 μg/g.

**Sulfated ash.** Not more than 1.0 mg/g.

**Loss on drying.** Dry to constant weight at 105°C; it loses not more than 10 mg/g.

**Related substances.** Carry out the test as described under 1.14.1 Thin-layer chromatography, using silica gel R4 as the coating substance and a mixture of 45 volumes of chloroform R, 45 volumes of cyclohexane R, 5 volumes of ethanol (~750 g/l) TS, and 5 volumes of glacial acetic acid R as the mobile phase. Apply separately to the plate 10 μl of each of 2 solutions in chloroform R containing (A) 10 mg of the test substance per mL and (B) 0.05 mg of the test substance per mL. After removing the plate from the chromatographic chamber, allow it to dry in air 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 about 0.5 g, accurately weighed, in 100 mL of hot neutralized ethanol TS, and titrate with carbonate-free sodium hydroxide (0.1 mol/l) VS, using phenolphthalein/ethanol TS as indicator. Repeat the operation without the substance being examined and make any necessary correction. Each mL of carbonate-free sodium hydroxide (0.1 mol/l) VS is equivalent to 49.40 mg of C\textsubscript{23}H\textsubscript{28}ClN\textsubscript{3}O\textsubscript{5}S.