Edition: BP 2025 (Ph. Eur. 11.6 update)

# Glipizide Tablets

General Notices

**Action and use**

Inhibition of ATP-dependent potassium channels (sulfonylurea); treatment of diabetes mellitus.

## DEFINITION

Glipizide Tablets contain Glipizide.

*The tablets comply with the requirements stated under Tablets and with the following requirements.*

**Content of glipizide $C_{21}H_{27}N_5O_4S$**

90.0 to 110.0% of the stated amount.

## IDENTIFICATION

A. The *light absorption*, Appendix II B, in the range 210 to 320 nm of the final solution obtained in the Assay exhibits maxima at 226 nm and 274 nm.
B. Shake a quantity of the powdered tablets containing 25 mg of Glipizide with 10 mL of *dichloromethane* for 5 minutes, filter, dry the filtrate with *anhydrous sodium sulfate*, filter again and evaporate the filtrate to dryness. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of glipizide *(RS 169)*.

## TESTS

**Related substances**

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Extract a quantity of the powdered tablets containing 0.1 g of Glipizide with four 10-mL quantities of *acetone*, evaporate the combined extracts to dryness under reduced pressure at a temperature not exceeding 30° and dissolve the residue in sufficient of a mixture of equal volumes of *dichloromethane* and *methanol* to produce 5 mL.
(2) Dilute 1 volume of solution (1) to 200 volumes with a mixture of equal volumes of *dichloromethane* and *methanol*.
(3) Dilute 1 volume of solution (1) to 500 volumes with the same solvent mixture.
(4) 0.010% w/v of *glipizide impurity A EPCRS* (5-methyl-*N*-[2-(4-sulfamoylphenyl)ethyl]pyrazine-2-carboxamide) in a mixture of equal volumes of *dichloromethane* and *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel $F_{254}$* (Merck silica gel 60 $F_{254}$ plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 20 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

20 volumes of *ethyl acetate*, 20 volumes of *anhydrous formic acid* and 40 volumes of *dichloromethane*.

LIMITS

In the chromatogram obtained with solution (1);

any spot corresponding to glipizide impurity A is not more intense than the spot in the chromatogram obtained with solution (4) (0.5%);

any other *secondary spot* is not more intense than the spot in the chromatogram obtained with solution (2) (0.5%);

and not more than two such spots are more intense than the spot in the chromatogram obtained with solution (3) (0.2%).

## ASSAY

Weigh and powder 20 tablets. To a quantity of the powder containing 15 mg of Glipizide add 30 mL of *methanol*, heat gently on a water bath whilst shaking, cool and add sufficient *methanol* to produce 50 mL. Filter and dilute 5 mL of the filtrate to 50 mL with *methanol*. Measure the *absorbance* of the resulting solution at the maximum at 274 nm, Appendix II B, using *methanol* in the reference cell. Calculate the content of $C_{21}H_{27}N_5O_4S$ taking 237 as the value of A(1%, 1 cm) at the maximum at 274 nm.