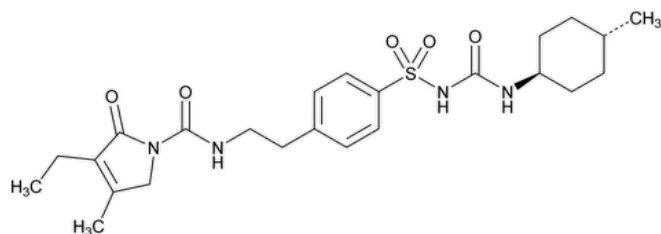


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Glimepiride



$C_{24}H_{34}N_4O_5S$ 490.62

1*H*-Pyrrole-1-carboxamide, 3-ethyl-2,5-dihydro-4-methyl-*N*-[2-[4-[[[(4-methylcyclohexyl)amino]carbonyl]amino]sulfonyl]phenyl]ethyl]-2-oxo-, *trans*-;

1-[[4-[2-(3-Ethyl-4-methyl-2-oxo-3-pyrroline-1-carboxamido)ethyl]phenyl]sulfonyl]-3-(*trans*-4-methylcyclohexyl)urea CAS RN®: 93479-97-1;
 UNII: 6KY687524K.

DEFINITION

Glimepiride contains NLT 98.0% and NMT 102.0% of glimepiride ($C_{24}H_{34}N_4O_5S$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020) [NOTE—Methods described in [\(197K\)](#) or [\(197A\)](#) may be used.]
- **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

PROCEDURE

Mobile phase: Dissolve 0.5 g of [monobasic sodium phosphate](#) in 500 mL of [water](#). Adjust with [phosphoric acid](#) to a pH of 2.1–2.7, and add 500 mL of acetonitrile.

Diluent: Acetonitrile and [water](#) (4:1)

Standard solution: 0.2 mg/mL of [USP Glimepiride RS](#) in *Diluent*

System suitability stock solution: 0.1 mg/mL each of [USP Glimepiride Related Compound B RS](#), [USP Glimepiride Related Compound C RS](#), and [USP Glimepiride Related Compound D RS](#) in *Diluent*

System suitability solution: Dilute 1 mL of the *System suitability stock solution* with the *Standard solution* to 50 mL.

Sample solution: 0.2 mg/mL of Glimepiride in *Diluent*. [NOTE—Keep the *Sample solution* at a temperature not exceeding 12°, and store it no longer than 15 h.]

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 228 nm

Column: 4-mm × 25-cm or 4.6-mm × 25-cm; 4- or 5-μm packing L1

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Samples: *Standard solution* and *System suitability solution*

[NOTE—See [Table 1](#) for relative retention times.]

Suitability requirements

Resolution: NLT 4.0 between glimepiride related compound B and glimepiride related compound C, *System suitability solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of glimepiride ($C_{24}H_{34}N_4O_5S$) in the portion of Glimepiride taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Glimepiride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Glimepiride in the *Sample solution* (mg/mL)

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

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

• **LIMIT OF *cis*-ISOMER (GLIMEPIRIDE RELATED COMPOUND A)**

Mobile phase: Transfer 100 mL of [isopropyl alcohol](#) to a 1-L volumetric flask, add 1 mL of [glacial acetic acid](#), and dilute with [hexane](#) to volume.

System suitability stock solution: Dissolve 1 mg of [USP Glimepiride Related Compound A RS](#) in 1 mL of [methylene chloride](#). Add 3 mL of *Mobile phase*, and mix.

System suitability solution: Transfer 10 mg of [USP Glimepiride RS](#) into a 20-mL volumetric flask, dissolve in 5 mL of [methylene chloride](#), and dilute with *Mobile phase* to volume. Transfer 5 mL of this solution to a separate flask, add 50 μ L of the *System suitability stock solution*, and mix.

Sample solution: Transfer 10 mg of Glimepiride into a 20-mL volumetric flask, dissolve in 5 mL of [methylene chloride](#), and dilute with *Mobile phase* to volume.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 228 nm

Column: 3-mm $\times$ 15-cm; 5- μ m packing L20

[NOTE—The analyses could also be performed with 4.6-mm $\times$ 15-cm, 4.6-mm $\times$ 25-cm, 4-mm $\times$ 12.5-cm, or 4-mm $\times$ 25-cm columns containing packing L20. It is recommended that the flow rate be adjusted to about 1.1 mL/min for a 4.6-mm column and to about 0.8 mL/min for a 4.0-mm column.]

Flow rate: 0.5 mL/min

Injection volume: 10 μ L

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for glimepiride *cis*-isomer and glimepiride are 0.9 and 1.0, respectively.]

Suitability requirements

Signal-to-noise ratio: NLT 15 for the glimepiride *cis*-isomer peak

Peak-to-valley ratio: NLT 2.0 for glimepiride *cis*-isomer and glimepiride

Analysis

Sample: *Sample solution*

Calculate the percentage of glimepiride *cis*-isomer in the portion of Glimepiride taken:

$$\text{Result} = r_{cis} / (r_{cis} + r_G) \times 100$$

r_{cis} = peak area of glimepiride *cis*-isomer from the *Sample solution*

r_G = peak area of glimepiride from the *Sample solution*

Acceptance criteria: NMT 0.8%

• **ORGANIC IMPURITIES**