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Current Trends in the Analysis and Bioanalysis of Glimepiride: An In-Depth Review

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ABSTRACT

Glimepiride is a sulfonylurea family antidiabetic drug that is mostly administered to treat type 2 diabetes. The current study's primary focus is on the advancement of analytical methods and the many strategies currently employed for aspirin estimation, whether in pharmaceutical dose form or bulk. Because analytical processes enable us to get both qualitative and quantitative data utilizing the most up-to-date analytical equipment, they are essential for determining compositions. Glimepiride can be analyzed using spectroscopy, electrochemistry, chromatography and other techniques. These techniques help to understand critical process elements and lessen the negative impact they have on precision and accuracy. To satisfy legal criteria and uphold strict standards for the caliber of commercial items, analytical methods must be developed. Following the reference, regulatory agencies in several countries have created policies and processes for authorizing, verifying and registering.

Keywords: Glimepiride; UV-spectroscopy; HPTLC; HPLC

INTRODUCTION

Glimepiride is a N-acylurea, N-sulfonylurea and sulfonamide class of drug. Glimepiride is a second-generation sulfonylurea that received FDA approval in 1995 to use for the improvement of glycemic control in adults with type 2 diabetes mellitus. Because of metformin's proven safety and effectiveness, it is considered a second-line choice. It is advised that glimepiride be used in conjunction with dietary and activity changes. When taken orally, its effects peak in three hours and last for roughly a day [1].

Physicochemical properties

It appears as white solid form of powder. Its molecular wight is 490.62 g/mol. It is the BCS class 2 drug, has solubility in DMSO and is poorly water soluble. Its melting point is 212.2-214.5°C. Its pKa is 4.32 (Figure 1).

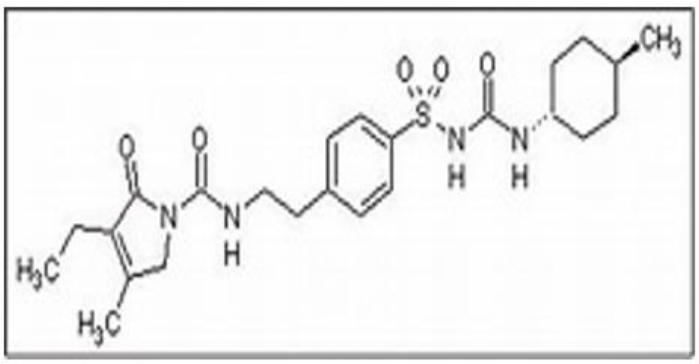

Figure 1: Chemical structure of Glimepiride.

LITERATURE REVIEW

Pharmacokinetics

Glimepiride has a linear pharmacokinetic profile and is fully absorbed when taken orally within an hour of dosing. After two to three hours, the peak plasma concentrations (C_{max}.) were attained. Glimepiride has a plasma protein binding rate of over 99.5%. The CYP2C9 enzyme mediates the oxidative biotransformation of glimepiride, resulting in the creation of a pharmacologically active main metabolite known as cyclohexyl hydroxymethyl derivative (M1). One or more cytosolic enzymes can further break down M1 into the inactive metabolite carboxyl derivative (M2). Glimepiride has an elimination half-life of roughly five to eight hours [2].

Pharmacodynamics

Glimepiride increases peripheral glucose uptake by stimulating the release of insulin granules from the pancreatic beta cells and improving peripheral tissue sensitivity to insulin, which lowers plasma blood glucose and glycated hemoglobin (HbA1C) levels.

Mechanism of action

In order to increase insulin secretion from the beta cell, glimepiride binds non-specifically to the B sites of the sulfonylurea receptor-1 (SUR1) and sulfonylurea receptor-2A (SUR2A) subunits as well as the A site of the SUR1 subunit of the channel, blocking the ATP-sensitive potassium channel [5].

Need of analytical method development

Quality control labs use analytical techniques to evaluate the efficacy, safety, purity, performance and identification of pharmaceutical products. The ICH has published analytical guidance documents on stability testing (Q1), analytical technique validation (Q2), contaminants in drug substances and products (Q3) and specifications for new drug substances and products (Q6). The analytical methods used in manufacturing are among the most important to regulatory bodies. The pharmaceutical must be approved by regulatory bodies once the applicant demonstrates control over the entire drug development process using recognized analytical methods [3-5].

Analytical method development by UV-visible spectroscopy

The study of how electromagnetic energy interacts with materials in the ultraviolet-visible range is known as ultraviolet-visible spectroscopy. Wavelengths in the Ultraviolet (UV) vary from 200 nm to 400 nm. Its foundation is the Beer-Lambert law, which asserts that a solution's absorbance and route length are directly proportional. For a given route length, it can thus be used to calculate the absorber's concentration in a solution. It is crucial to understand how quickly absorbance varies with concentration (Table 1) [6].

Table 1: Analytical method development by UV-visible spectroscopy.

S. No.	Sample	Method/Instrument model	Solvent/ solution	Wavelength (nm)
1	Tablet and bulk	UV-visible spectrophotometer 2501 PC (double beam) of Shimadzu	Methanol	227.6
2	Tablet	Shimadzu UV-visible double beam spectrophotometer (Shimadzu, Japan)	Sodium hydroxide	235, 233 and 237
3	Tablet and bulk	UV-visible spectrophotometer (Elico SL-150 model of Elico Pvt. Ltd, India)	Cresol red dye (method A) and bromophenol blue dye (method B) in methanol and chloroform	450 and 578 for methods A and B.
4	Tablet	Labindia 3000+UV-Visible Spectrophotometer	Methanol	225
5	Tablet and bulk	Elico model SL 159 UV-visible single beam spectrophotometer	Methanol	228
6	Tablet and bulk	Shimadzu UV-1800 spectrophotometer	Methanol	218
7	Tablet	Double-beam Shimadzu (Kyoto, Japan) UV-visible spectrophotometer, Model UV-1601 PC	Methanol	231
8	Tablet and bulk	UV-visible double beam spectrophotometer (Shimadzu-1800 Japan)	Methanol	227

DISCUSSION

Analytical method development by HPLC

The most used separation method and one of the most reputable analytical procedures is High Performance Liquid Chromatography (HPLC). For over 40 years, it has been utilized in labs all over the world for a number of applications, such as synthetic chemistry, clinical chemistry, pharmaceutical sciences, food and environmental evaluations, etc. A liquid or a solid could serve as the stationary phase in this procedure. The

components of a combination can be separated using HPLC and a liquid mobile phase. A form of liquid chromatography known as "High-Performance Liquid Chromatography" (HPLC) involves physically pumping the liquid mobile phase through a stationary phase-containing column. The core of HPLC systems is the column. Accurate certification requires a consistent and symmetrical peak, which is produced by a proper silica and bonding procedure. The RP columns C18 (USP L1), C8 (USPL8), phenyl (USP L11) and Cyno (USP L18) are frequently used (Table 2) [7].

Table 2: Analytical method development by HPLC.

S.No.	Sample	Stationary phase/ column	Mobile phase	Wavelength (nm)	Flow rate (ml/min)	RT (min)
1	Tablet	C-18 column (20 mm × 4 mm)	0.023 M potassium dihydrogen phosphate buffer (pH6.0) and acetonitrile in ratio of 60:40 v/v	230	1	4.5
2	Tablet	LC-18 column (25 cm × 4 mm × 5 µm)	Acetonitrile, methanol and phosphate buffer, pH 3.5 in the ratio of 20:50:30 (v/v/v)	220	1	12.189
3	Tablet	C-18 column (250 x 4.6 mm, particle size 5 µm)	Acetonitrile: 0.1% formic acid in ratio (55:45 v/v)	250	1	-
4	Tablet and bulk	C-18 column (250 mm × 4.6 0 mm, particle size 5 µm)	methanol and 0.5 percent potassium dihydrogen phosphate (pH 4) in ratio 74:26	210	1	-
5	Tablet and bulk	C18 column 150 × 4.6 mm, with 5 µm particle size	Monobasic sodium phosphate and acetonitrile	228	1	9.3
6	Tablet and bulk	C-8 column (250 × 4.6 mm, particle size 5-μm	Acetonitrile: phosphate buffer (60: 40 (v/v), pH 3.0)	235	1	9.39
7	Tablet and bulk	C18, 250 mm × 4.6 mm, particle size 5 μm	70% methanol and 30 % HPLC water	229	0.85	6.8
8	Tablet	C 18 column (125 × 4 mm, particle size 5µm)	Acetonitrile, water and glacial acetic acid (550:450:0.6 v/v)	230	1	-
9	Tablet and bulk	ODS 3V (150 × 4.6 mm, *i.e.*, 5 µm)	0.02 M phosphate buffer, pH 2.5 (solvent A) and acetonitrile (solvent B)	230	1	11.708
10	Tablet and bulk	ODS (250 × 4.6 mm, 5 µm)	Acetonitrile and ammonium acetate (pH 4.5; 20mM) in ratio 60:40 (v/v)	230	1	10.2
11	Tablet	C-18 250 × 4.60 mm, 5 µm	Methanol-phosphate buffer (pH 4.3) in ratio 75:25 v/v	258	1	10.17
12	Tablet	C18 (250 × 4.6 mm, 5.0 µm)	Potassium phosphate buffer (pH 6.5)-methanol in ratio (34: 66, v/v)	228	1	-
13	Tablet	C8 column (5 µm, 2.50 × 4.60 mm)	Methanol: 0.025M potassium dihydrogen phosphate (pH 3.20) in ratio (70: 30, v/v)	235	1	6
14	Tablet and bulk	ODS-3V (250 mm × 4.6 mm, 5 μm)	Phosphate buffer (pH 5), acetonitrile, tetrahydrofuran (40: 50: 10)	228	1.7	5
15	Tablet	Cyano, 250 × 4.6 mm, 5.0	Acetonitrile and water (4:1, v/v)	230	0.8	38.73
16	Tablet	SIL (250 mm × 4.6 mm i.d. 5 µm)	Aqueous phase (20 mM phosphate buffer, adjusted to pH 3.0) and an organic phase (methanol: Acetonitrile; 62.5:37.5) in the ratio of 80:20	230	1	5.87

Analytical method development by HPTLC

The potent analytical technique known as HPTLC is very beneficial for both qualitative and quantitative jobs. Separation may result by partitioning, adsorption or both, depending on the type of adsorbents applied to the plates and the development solvent solution. Principle, theory, instrumentation, implementation, optimization, validation, automation and qualitative and quantitative analysis are just a few of the several facets that make up HPTLC foundations (Table 3) [8].

Table 3: Analytical method development by HPTLC.

S.No.	Sample	Stationary phase/ column	Mobile phase	Wavelength (nm)
1	Tablet and bulk	Silica gel 60 F254	Chloroform: methanol: Ammonia (9:1.5:0.2 v/v/v)	238
2	Tablet	Silica gel 60 F254	Ethyl acetate, benzene and hexane (4:3:1 v/v/v)	238

Bioanalytical method development

Bioanalysis is a key component of medication development. These days, bioanalysis is essential to toxicological evaluation, pharmacokinetic and pharmacodynamics research and drug development. The creation of bioanalytical techniques is one of the drug development hurdles. The quantitative identification of various analyte types in biological matrices also requires the validation of bioanalytical techniques. The steps in the bioanalysis process include sampling, sample preparation, analysis, calibration, data review and reporting (Table 4) [9,10].

Table 4: Bioanalytical method development.

S.No.	Method	Sample	Stationary phase/ column	Mobile phase	Wavelength (nm)	Flow rate (ml/min)	RT (min)
1	HPLC	Tablet and human plasma	C18 column (150 × 4.6 mm, 5 µm)	0.05% Triethylamine (pH-3.5), acetonitrile and methanol in the ratio of 55:15:30	248	1	-
2	HPLC	Bulk and rat plasma	C18 stationary phase (250 × 4.6 mm, 5 µm)	Methanol: water (85:15 v/v)	230	1	2.5
3	UPLC	Bulk powder, tablets and spiked human plasma	1.7 µ C18 100A (2.1-mm × 50-mm)	0.05 M Potassium dihydrogen phosphate buffer pH 5.00 (A) with 0.10M sodium dodecyl sulfate and isopropanol (15.00-25.00%) (B)	230	0.2	-
4	LC-UV	Bulk and human plasma	RP 18e, (125 × 4, 5 µm)	Phosphate buffer (50 mM) with octane sulfonic acid (10 mM), methanol and acetonitrile as a mobile phase (55:10:35, v/v) Solvent A: mixture of	228	1	6.4
5	UPLC	Tablet and human plasma	1.7 µm XB-C18 100 Å (50 × 2.1 mm) column	(85:15 v/v). [0.1 M SDS- 0.3% triethyl amine- 0.1% phosphoric acid (pH 6)]. Solvent B: n-propanol.	225	0.2	-

CONCLUSION

This study's main focus has been on the various analytical methods used to determine how much glimepiride is present in various prescriptions and in the bulk form of those medications. There are numerous dose formulas for glimepiride. The researchers have worked to create analytical methods such as UV spectrophotometry, TLC, RP-HPLC, HPLC, HPTLC and others. Every analytical method developed has a higher sample throughput, is automated, highly sensitive, reproducible and accurate. The literature survey's objective is to compile information on different analytical instrumental methodologies. A new analytical method could be developed with the help of such information.

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