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REVIEW ARTICLE

A Review article on QbD Driven Investigation for Simultaneous Estimation of Antidiabetic Drug

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ABSTRACT
According to the review, this drug combination has an analytical method created, but they have not yet studied or produced a bioanalytical method, thus my goal is to use quality by design to develop a good approach method development.
***Keywords**: Glimepiride, Reverse Phase-High Performance Liquid Chromatography, QbD, Metformin, Voglibose.*

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INTRODUCTION

A product of sulfonyl urea is glimepiride. It is [[p-[2-(3ethyl-4-methyl-2-oxo-3-pyrroline-1-Oxamide) ethyl] phenyl] sulfonyl] in its chemical makeup. urea-3-(trans-4-methyl cyclohexyl). It is frequently employed in type 2 diabetes. (1) Chemically metformin hydrochloride is N-dimethylimido dicarbon imidic diamide. Metformin is classified as a biguanide chemically. Patients with type-2 diabetes are treated with anti-diabetic medicines from the biguanide families that also have an antihyperglycemic effect.(2) Voglibose 3,4 Dioxy 4-[2-Hydroxy-1-(Methyl) Ethyl] Due to its extensive spectrum of medicinal and pharmacological qualities, such as its outstanding inhibitory activity against -glucosidase and its action against hyperglycemia and many illnesses caused by hyperglycemia, amino-2-c-(hydroxymethyl)-Depiinositol has garnered significant interest. A brand-new, highly effective glucosidase inhibitor for type 2 diabetes called voglibose has demonstrated substantial anti-obesity and anti-diabetic properties. (3) Quality by Design is Achieving specified predictable characteristics with intended and predetermined requirements is known as quality by design (QbD). Understanding components and the impacts of their interactions through a chosen set of tests is a very useful QbD component. The creation of a thorough science- and risk-based HPLC method for the analysis of zidovudine active pharmaceutical ingredient (API) utilising a quality by design methodology is described in the current study.(4) There are numerous publications on HPLC method development strategy, according to the literature review, but the method development strategies for RP-HPLC specifically focused on pharmaceutical
The creation of a QbD environment has not received much attention.
Throughout the product lifecycle, the quality of the technique is maintained by applying the QbD principles. (4) The current investigations involve the creation of a straightforward, quick, accurate, and affordable high-performance liquid chromatographic approach for the determination of metformin hydrochloride (M-HCl). The experimental settings of the HPLC method were extensively optimized using the Design of Experiments (DoE). To pinpoint the essential technique parameters, a risk assessment was carried out (CMPs). A two-factor, three-level design was used to carry out the factor screening studies. Mathematical models were created using buffer pH and mobile phase composition, two independent variables. The response surface approach and the effects of these independent elements were thoroughly examined using the Central Composite Design (CCD), which evaluated the important analytical attributes (CAAs), namely retention time, peak area, and symmetry factor, as the parameters.(5)

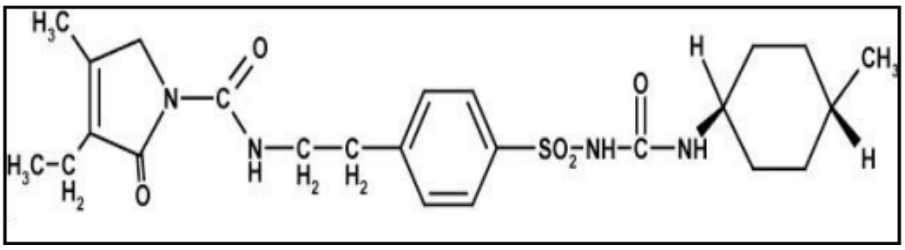


Fig 1: Structure of Glimepiride(3)

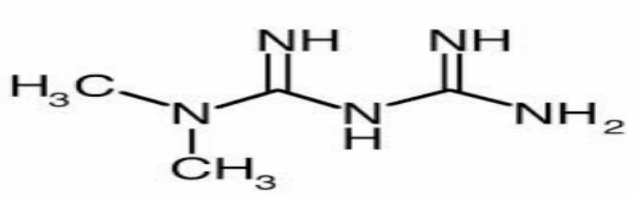


Figure 2: Structure of Metformin (6)

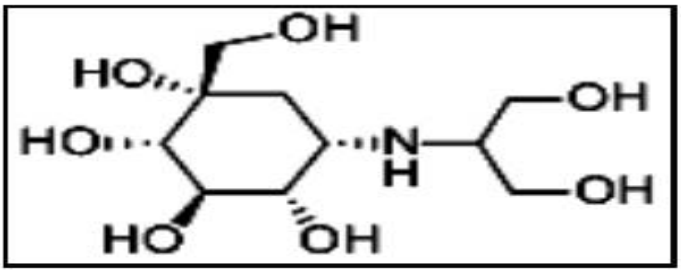
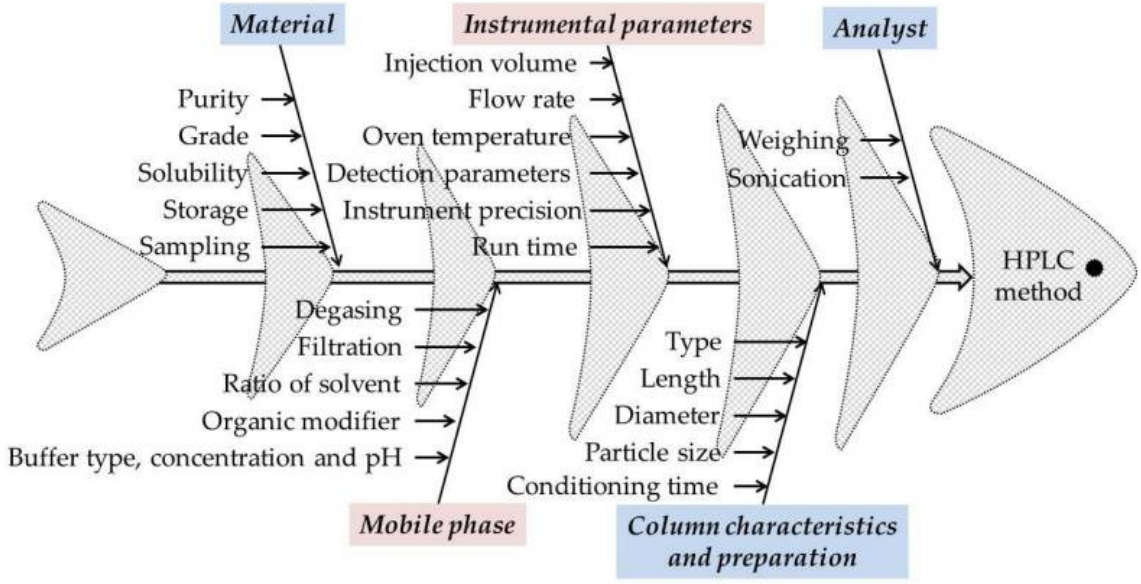


Fig 3: Structure of Voglibose(3)

DRUG PROFILE

DRUG NAME	**Metformin Hydrochloride**	**Glimepiride**	**Voglibose**
IUPAC NAME	3-(diamino methylidene)-1,1-dimethylguanidine; hydrochloride	4-ethyl-3-methyl-*N*-[2-[4-[(4-methylcyclohexyl) carbamoylsulfamoyl] phenyl] ethyl]-5-oxo-2*H*-pyrrole-1-carboxamide	(1,3-dihydroxypropan-2-ylamino)-1-(hydroxymethyl) cyclohexane-1,2,3,4-tetrol
Molecular weight	165.62	490.6	267.28
Molecular Formula	C4H12CLN5	C24H34N4O5S	C10H21NO7
Drug category	Type 2 diabetes	Type 2 diabetes	Diabetes Mellitus
Melting point	135	207	163
Pka	7	6	8.76
Uses	Metformin is an oral diabetes medicine that helps control blood sugar level.	Glimepiride is an oral diabetes medicine that is used together with diet and exercise to improve blood sugar control in adult with type 2 diabetes mellitus.	Voglibose is an alpha glucosidase inhibitor used for lowering post-prandial blood glucose level in people with diabetes mellitus.



MATERIAL AND METHODS

UV – Visible Spectrometer and Analytical Method Development

The UV – Visible Spectrometer study done by the preparing standard stock solution of Antidiabetic Drug Voglibose, Glimepiride, and metformin Hydrochloride was prepared in Methanol. from the standard stock solution further dilution done by using respective Many variable parameters have been investigated for method development by varying different kinds of organic solvents, buffers with various pH levels, HPLC columns, temperature, flow rate, and wave length.(7)

Sl.no	Drug	Method	Description	References
1	Metformin, Losartan and Glimepiride	RP-HPLC method and UV spectroscopy.	1. Column- Luna c18 (250 × 4.6 mm, i.e., 5 µm) 2. Mobile Phase: Methanol (solvent A) and 0.1% Orthophosphoric acid [OPA] (solvent B) 3. Flow rate -0.8mL min -1. 4. Rt- MET, LOS and GLI were found to be 3.11, 7.12 and13.52minsresp.5. Wavelength Photo diode array detector at 284 nm	(1)
2	pioglitazone, glimepiride and metformin hydrochloride	RP-HPLC method and UV spectroscopy	1. Column- Luna c18 (250 × 4.6 mm, i.e., 5 µm) 2. Mobile Phase: Methanol and Water [70:30] 3. Flow rate -0.8mL min -1. 4. Rt- MET, PIO and GLI were found to be 4.4, 5.5 and6.9 mins resp. 5. Wavelength Photo diode array detector at 229 nm	(8)
3	Glimepiride	RP-HPLC method	C-18 column with 150 x 4.6 mm mobile phase Acetonitrile: Disodium hydrogen o phosphate (70: 30) flow rate was maintained at 1.0 ml / min. Detection wavelength 228 nm	(9)
4	Sitagliptin and Metformin	Quality by Design based Development and Validation of RP-HPLC Method	C18 Monolithic column (100mm× 4.5mm i.d., 5µm) connected with an C18 guard cartridge (4mm×3mm i.d., 5µm). The mobile phase consisted of Methanol and Acetonitrile, 0.01mM KH2 PO4 (pH 3.5±0.5), adjusted with freshly prepared 10% orthophosphoric acid. A wavelength of 210 nm was selected for detection.	(10)

5	metformin and gliclazide	analytical HPLC method	The mobile phase for the chromatographic runs was composed of acetonitrile (45:55, v/v) and 20 mM ammonium formate buffer (pH 3.5). On an Alltima CN (250 mm 4.6 mm x 5 m) column, the separation was accomplished using the isocratic mode. Well-separated drug peaks were found using a UV detector at 227 nm.	(11)
6	Glimepiride, Pioglitazone, and Metformin	RP-HPLC method	The chromatographic column's stationary phase, Inertsil ODS-3 V (250 mm, 4.6 mm, 5 m), was used. Tetrahydrofuran, buffer, and buffered acetonitrile were mixed in the following proportions: 40: 50: 10. 7. The buffer was made by dissolving 1 g of dipotassium hydrogen orthophosphate in 1000 mL of water. The pH was raised to 5.0 by using orthophosphoric acid. The volume of the injection was 20 litres. The flow rate of the pump was 1.7 mL/min. At 228 nm and 25 C, the eluent was found to exist.	(12)
7	Linagliptin and Metformin HCl	Quality by Design based Development and Validation of RP-HPLC Method	Chromatographic separation was acquired with column Water C18 (250mm x 4.5mm x 5µm) at flow rate 1.0 ml/min with the mobile phase consists of acetonitrile and methanol (75:25 % v/v). The detection of Linagliptin and Metformin HCl was carried out at 245nm.	(13)

CONCLUSION

Different methods for determination of the Antidiabetic drug have been reported. Some Analytical RP-HPLC method also reported but as per review still there is large gap in the Bioanalytical method. By this review we concluded that still lot of research gap is available in the bio analytical method development using the concept of QbD.

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