RESEARCH ARTICLE

Estimation of Imeglimin in Pharmaceutical Tablets by RP-HPLC

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ABSTRACT

Objective: This study's primary goal is to create a novel, sensitive and comprehensive reverse phase-high performance liquid chromatography (RP-HPLC) procedure. The computation of Imeglimin's dose and dosage is the primary goal.

Method: Chemicals and impurities were separated chromatographically using a C18 (AGILENT) chromatographic column. Methanol and 0.1% OPA are present in the mobile phase in a 40:60 v/v ratio. A 240 nm ultraviolet light detector was employed for the purpose of detection. With a retention time of 4.718 minutes, the results demonstrated the effectiveness of meglimin. After adjusting the flow rate to 0.7 mL/min, there was good separation. There are several imeglimin doses planned, ranging from 10 to 50 µg/mL. 101.46 to 101.12% in yield.

Results: This method's validation has good accuracy, sensitivity, precision, linearity, specificity, and robustness, and it satisfies the requirements of the International Conference on Harmonization.

Conclusion: In conclusion, imeglimin was predicted and the construction method was isolated. In conclusion, it's feasible for daily use.

Keywords: Estimation, Imeglimin, RPHPLC, Validation.

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INTRODUCTION

The development of analytical methods and their use in reverse phase-high performance liquid chromatography (RP-HPLC) isessential to ensure product accuracy and reliability. A unique and reliable method was developed and parameters such as flow rate, cell level and wavelength detection were optimized for good separation and detection of analytes. Research is important in many fields in business and science to advance knowledge, ensure product quality and safety, and contribute to education and health.[1] Imeglimin works by stimulating insulin secretion in diabetics and is primarily used to reduce type 1 diabetes. Worldwide, there is an increase in the prevalence of diabetes. Recent years have seen a global rise in the prevalence of type 2 diabetes as a result of risk factors like obesity, poor metabolism, and sedentary lifestyles.[2,3] Over 380 million people worldwide suffer from type 2 diabetes, and by 2035, that number is predicted to rise to over 592 million. Imeglimin is a new way to treat type 2 diabetes mellitus (T2DM) by targeting different aspects of glucose metabolism, including mitochondrial function, insulin secretion, and insulin sensitivity. Mitochondrial bioenergetics affects various mechanisms suchas glucose-dependent insulin secretion, insulin sensitivity and reduced glucose secretion, improving glucose homeostasis in patients with T2DM.[4,5] When the literature was examined, it was seen that many analytical methods such as UV spectroscopy.[6,7] ultra-high-performance liquid chromatography (UHPLC).[8] Rp HPLC.[9,10] have been developed and published for the prediction of igliflozin. Figure 1 depicts the imeglimin structure.

MATERIALS AND METHODS

Materials

Chemicals and reagents

The supplier of imeglimin (API) were to be Swapnaroop Drugs and Pharmaceuticals, Sambhajinagar, among others solvents utilized were HPLC quality, and chemicals and reagents used were analytical grade.

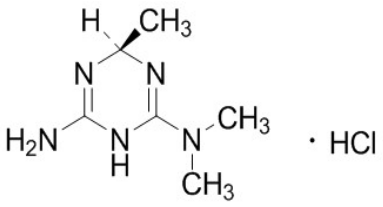

Figure 1: Structure of imeglimin

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Instruments

The HPLC system utilized was Analytical Technologies Ltd's. HPLC Workstation Software and UV-DAD detector.

Chromatographic conditions

The C18 (250 x ID 4.6 mm, particle size: 5 µm), wavelength 331 nm, and ambient temperature, chromatography column was used. Methanol and orthophosphoric acid were used as the mobile phase, with a 40:60 ratios and a flow rate of 0.8 mL/min.

Method

Mobile phase optimization

Optimization of the cell in chromatography is essential to achieve the best separation and analysis; different solvents such as acetonitrile, methanol, and HPLC grade water have been selected in vacuum, but there is no difference between them. openness relationship. The difference between methanol and buffer (0.1% OPA) was mixed and the final ratio of methanol and 0.1% OPA was 40:60% v/v. Symmetry is good and there are no significant effects.

Standard preparation

About 50 mg of imeglimin should be weighed, transferred to a 100 mL volumetric flask, and diluted with 100 mL of solvent to yield 500 mcg/mL of concentration. To get concentrations of 10 to 50 µg/mL, serially dilute 0.2, 0.4, 0.6, 0.8, and 1-mL into a 10 mL flask.

Sample preparation

20 tablets are weighed, 50 mg of imeglimin powder is measured and added with 30 mL methanol in a volumetric flask. The solution was mixed with sonication for 20 minutes and the final volume was treated with methanol to give a volume of 1000 µg/mL. Filter the solution through a 0.45 membrane filter. After further dilution, final concentration is of 10 µg/mL. After injection of 20 mL of each test and drug, chromatograms were recorded for 10 minutes. The formulation was found to be accurate and unaffected by excipients in the tablet formulation. The optimized chromatogram is shown in Figure 2.

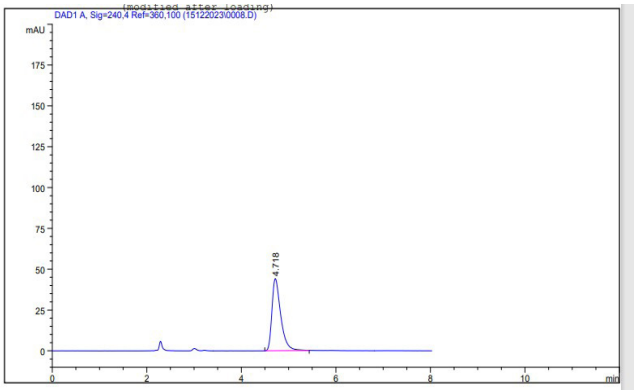

Figure 2: Chromatogram of conditions optimized with imeglimin

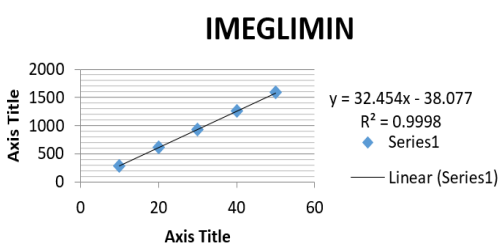

Figure 3: Imeglimin calibration curve

RESULT AND DISCUSSION

Linearity and Range

The linearity of the formulations was tested at five concentration levels. The equation of the regression line is y = 32.454x - 38.077, where R2 = 0.9998. The results are shown in Figure 3.

Precision

For precision studies, three different concentrations of 10, 30, 50 µg/mL were selected and tested for both intraday and interday precision. Duplicate solutions were injected with

Table 1: Intraday precision study (Method precision).

Conc. (mcg/mL)	*Conc. found (mcg /mL)*	*%Amount*	*STD Deviation*	*%Relative standard deviation*
10	10.2200	102.2300	0.9600	0.2300
30	30.1471	100.4900	4.3443	0.4621
50	49.8123	99.6246	8.1229	0.5146

Table 2: Interday precision study (Method precision).

Conc. (mcg/mL)	*Conc. found (mcg /mL)*	*%Amount*	*STD Deviation*	*%Relative standard deviation*
10	10.2260	102.2619	5.6530	0.6434
30	29.8237	99.4124	1.3318	0.0209
50	49.2144	98.4289	2.2742	0.1694

Table 3: Recovery studies of imeglimin

%	*Conc. (mcg/mL)*	*Conc. added (mcg/mL)*	*Conc. found (mcg/mL)*	*%Recovery*	*Standard deviation*	*%Relative standard deviation*
80	10	8	18.2302	102.3825	0.0569	0.3119
100	10	10	19.9952	99.97	0.0776	0.3879
120	10	12	22.16	101.36	0.0141	0.0638

Table 4: Robustness studies

Parameters	*Utilised*	*SD*	*%RSD*
Flow rate	0.9	1.44	0.17
	1.1	1.83	0.21
Wavelength	239	1.38	0.14
	241	1.5	0.19

intraday precision in the morning and evening. Intraday accuracy is assessed by analyzing two separate daily solutions, also in a dual format. The resulting areas and percentage of relative standard deviation (RSD) were calculated for each set of experiments. The results of the intraday and intraday accuracy studies are shown in Tables 1 and 2.

Accuracy

Research accuracy was used to assess the accuracy of the method by measuring back at three different levels (80–120%). Use 10 mcg/mL in this stable solution and add three different standard solutions of 80, 100 and 120% to ensure the accuracy of the method. Table 3 shows the regression analysis at three different levels.

Robustness

Robustness is measured by consciously making small changes to the test procedure. In this way, pH, wavelength, and flow rate are intentionally different and appear to occur. This method has demonstrated robustness by demonstrating its ability to withstand changes in temperature, pH, and flow rate without significantly affecting its effectiveness. Table 4 represents robustness.

Limits of Detection and Limits of Quantification

The values are 0.2583 to 0.7827 mcg/mL. Together, results confirm the sensitivity and specificity of this method.

DISCUSSION

Good separation and resolution are achieved with this method. Methanol and 0.1% OPA (TEA pH 4.2) in a 40:60% by volume ratio was the mobile phase utilized. A retention time of 4.718 was discovered. A steady 0.7 mL/min flow rate was maintained. Studies on day and intraday exposure were carried out. In the intraday study, it recovered from 99.62 to 102.23%, but in the intraday study, it recovered from 98.42 to 102.26%. In accordance with ICH guidelines, exposure studies were conducted at three different levels, resulting in a recovery rate of 98.102%. Through the manipulation of current and wavelengths, performance studies were conducted.

CONCLUSION

The suggested RP-HPLC method exhibits good sensitivity, simplicity, accuracy, and precision when measuring a single dose of imeglimin. As a result, it is thought that the RP-HPLC method is appropriate for regular raw material and product analysis.

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