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RP-HPLC method development for determination of pioglitazone hydrochloride from tablets

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ABSTRACT

A simple, rapid and precise reversed-phase HPLC method has been developed for the quantitation of pioglitazone in tablet on a C-8 (mm) column using a mobile phase consisting acetonitrile-water(60:40 %v/v) adjusted to ph 6.0 with 0.1 % v/v glacial acetic acid solution at a flow rate of 1 ml/min and detection at 266 nm. The retention time of pioglitazone have been found to be 6.40 min and recoveries were between 98.82-101.21 %. Validation of the proposed method has also been done.

Keywords: Pioglitazone (Pio), Metformin (Met), HPLC,CAN, glacial acetic acid

INTRODUCTION

Pioglitazone is a thiozolidinedione class of antidiabetic agents. It is a selective agonists for nuclear peroxide proliferator-actived receptor-gamma. It also reduces the insulin resistance in periphery and in the liver of patients. It increases glucose transport into muscle and adipose tissue by enhancing the synthesis and translocation of specific forms of the glucose transporter proteins. Pioglitazone is not official in any pharmacopoeia. Literature survey revealed only two HPLC methods for its determination in pharmaceuticals and two in human serum. The present work describes a simple, precise and accurate reversed-phase HPLC method for the estimation of pioglitazone in tablet dosage form.

MATERIAL AND METHODS:

All chemicals/solvents used were of AR/HPLC grade. Standard pioglitazone was provided by Zydus Cadila. A Shimadzu HPLC system was used for the analysis. The method was carried out at Hypersil C-8 (250) column as a stationary phase and acetonitrile-water(60:40 %v/v) adjusted to ph 6.0 with 0.1 % v/v glacial acetic acid solution as a mobile phase at a flow rate of 1 ml/min. Detection was done at 266 nm. The mobile phase was filtered through a 0.45 µ membrane filter and degassed. The analysis was carried out at room temperature.

Standard stock solution was prepared containing 1 mg/ml of pioglitazone in methanol. Subsequently dilutions were made to get the concentrations about 20 µg/ml in mobile phase. Sample solution was prepared in 50 ml volumetric flask by shaking tablet powder equivalent to 15 mg of pioglitazone in methanol. This solution was filtered (0.22µ membrane filter) and further dilution was made with mobile phase. A steady baseline was recorded with optimized chromatographic conditions. Chromatographs of standard solution (six replicates) and sample solution (three replicates of each) were recorded (one of which is depicted in Fig.1.). The retention time of pioglitazone was found to be 6.40 min. The concentrations of pioglitazone in sample solution were obtained by comparing with the standard solution.

RESULTS AND DISCUSSION:

Accuracy of the method was studied by recovery experiments. Reference standard drug at the level of 80, 100 and 120 % of the label claim was added to the tablet powder equivalent to 15 mg of pioglitazone. These were analysed by injecting three replicates each of sample solution and the percent recovery was calculated. Precision of the method was demonstrated by reproducibility studies. This was done analyzing six samples prepared from a homogeneous sample. Linearity and range of the method was determined analyzing standard solutions containing 1 to 20 mcg/ml. The calibration curve was plotted using area under curve Vs concentration of the standard solution. Ruggedness of the method was evaluated by carrying out the experiment by different conditions. Stability of standard and sample solution was ascertained by analyzing it periodically. Robustness of the method was demonstrated by variation in composition of mobile phase (± 2 %), pH of the mobile phase (±1) and temperature(± 1).

The chromatographic parameters were validated by system suitability studies and peak asymmetry and column efficiency were determined (Table 1). The precision data shows that reproducibility of the assay procedure is satisfactory and % RSD was found to be

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Table 1 : System suitability studies

Parameters	Results
Mean Peak Area	123523.33
% R.S.D	
Inter-day	0.0255
Intra-day	0.0549
Tailing Factor	0.7
Theoretical Plates	2513.4426
Retention Time	6.40 +_ 0.55

Table 2 : Analysis of formulations

Brand Name	Amount present (mcg/ml)	Amount found (mcg/ml)	Label Claim (mg/ tablet)	Label Claim found* (mg/tab)	*%Recovery	*%R.S.D	S.E*
PIOZ*-15(USV)	10	10.03	15	15.05	100.36	0.2316	0.1342

***n=6**

Table 3: Recovery studies

Amount Present (mcg/ml)	Level of Recovery	Amt Present (mg/tab)	Amt of Std added (mg)	*Total Amt Recovered	* % Recovery	*% R.S.D	S.E*
10	80	15	12	26.66	98.82	0.6586	0.3756
	100	15	15	30.24	100.84	0.4423	0.2553
	120	15	18	33.38	101.21	0.2830	0.1633

***n=3**

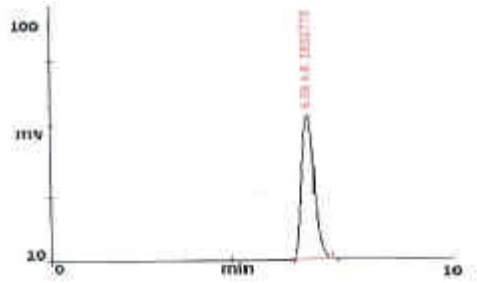

Fig 1 : HPLC Chromatogram of Pioglitazone

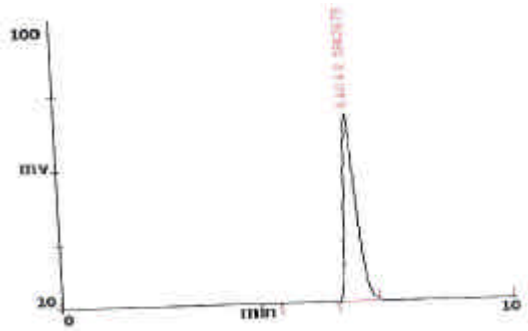

Fig 1 : HPLC Chromatogram of Pioglitazone Tablet

0.0255 and 0.0549 (Table 1). Accuracy studies indicated that the mean percent recovery of the added standard was found to be 100.36 % with a mean % R.S.D of 0.2316 (Table 2). A linear relationship was obtained in the concentration range of 1-20 µg/ml with the equation y = 280218x - 291763and correlation coefficient 0.9996. Ruggedness study signified the reproducibility of the method for different stress conditions. The method was found to be robust with respect to theoretical plates and retention time. Limit of detection and limit of quantitation was found to be 0.0319 µg/ml and 0.0968 mcg/ml, respectively. Accuracy of the method was studied by recovery experiments. Reference standard drug at the level of 80, 100 and 120 % (Table 3) of the label claim was studied. The proposed HPLC method was fond to be simple, accurate, precise, linear, rugged and rapid. Hence this method can be applied for the routine analysis of tablet formulations.

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