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Development of Rapid UV Spectrophotometric Method for the Estimation of Pioglitazone Hydrochloride in Bulk and Formulations

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A B S T R A C T

Simple, sensitive, accurate, precise and rapid ultraviolet (UV) Spectrophotometric method was developed for the estimation of Pioglitazone HCl in pure form, formulations and stability samples. For the estimation of Pioglitazone HCl, solvent system employed was acetate buffer pH 2 and wavelength of detection (λ_{det}) was 269nm.The developed method was used to estimate the total drug content in two commercially available oral formulations of Pioglitazone HCl and recovery studies were also carried out. Sample recovery in both the formulations using the above method was in good agreement with their respective label claims, thus suggesting the validity of the method and noninterference of formulation excipients in the estimation. The developed method was found to be stability specific and were validated as per ICH guidelines-2005, USP-2000 and statistical methods.

Keywords: Spectrophotometric determination, Methanol, acetate buffer pH 2, Pioglitazone HCl

A R T I C L E I N F O

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1. Introduction

Pioglitazone HCL is an oral antidiabetic agent that acts primarily by decreasing insulin resistance. Pioglitazone HCL is used in the management of type 2 diabetes mellitus also known as noninsulin dependent diabetes mellitus [NIDDM] or adult onset diabetes. Chemically Pioglitazone HCl is [(±)-5-[[4-[2-(5-ethyl-2-pyridinyl) ethoxy] phenyl]

methyl]-2, 4-] thiazolidinedione monohydrochloride. Pioglitazone HCL is an odourless, white crystalline powder. It is soluble in N, N-dimethyl formamide, slightly soluble in anhydrous ethanol and methanol, very slightly soluble in acetone and acetonitrile, practically insoluble in water and insoluble in ether.

Literature survey revealed that only few methods available for the estimation of Pioglitazone HCl alone, in combination with other drugs, in its dosage form and in plasma. The present investigation undertaken to develop simple UV spectrophotometric method for the estimation of Pioglitazone HCl in bulk and its formulations.

2. Experimental

A Hitachi-U2000 spectrophotometer with a pair of matched quartz cells was used to measure absorbance of the resulting solutions. Pioglitazone HCl was gifted by Aarti drugs Ltd Mumbai. All the other reagents used were of analytical grade and obtained from S.D Fine chem, Mumbai.

Preparation of standard curve:

A 100µg/ml stock solution of Pioglitazone HCl was prepared in acetate buffer pH 2 by first dissolving 10 mg of the drug in 10ml of methanol and then, making up the final volume with acetate buffer pH 2. The λ_{max} of Pioglitazone HCl was determined by scanning suitable dilutions with high correlation coefficient.From the stock solution, various standard dilutions were made to obtain solutions of 2,4,6,8 and 10µg/ml and their respective absorbance values were measured at fixed λ_{max} with parameter set at 0.5nm for bandwidth as well as data pitch. Average absorbance values, standard deviation and % coefficient of variance for each concentration were calculated. One way ANOVA test for linearity was carried out by picking five sets of calibration curves on random basis.

Sample preparation (Bulk drug)

Pioglitazone HCl 50mg was accurately weighed and taken into 100ml volumetric flask containing 10ml of methanol and further it was made upto the volume 100ml with acetate buffer pH 2 solution. This solution was further serially diluted with acetate buffer pH 2 solution to get 2, 4, 6, 8, 10 µg/ml solution. The Pioglitazone HCl content was further determined by measuring the absorbance at 269nm.

Sample preparation (Dosage forms)

Twenty capsules were weighed the powder equivalent to 50mg of Pioglitazone HCl was taken in 100ml volumetric flask containing 50ml of methanol. The contents were shaken well for 30 minutes and made upto the volume with 100ml with methanol. This solution was further suitably diluted with acetate buffer pH 2 solutions and determined the Pioglitazone HCl content by measuring the absorbance at 269nm.

Recovery experiments: To keep an additional check on the accuracy of the developed method and to study the interference of formulation additives, analytical recovery experiments were performed by adding known amount of pure drug to the previously analyzed pharmaceutical preparation and analyzed by the developed method. The concentration levels used were 10µg/ml.

3. Results and Discussion

Method development: To develop accurate, precise and sensitive UV spectrophotometric method for Pioglitazone HCl various solvent systems such as water, methanol etc. were tried alone and in combinations or in the presence of surfactants at different proportions. Selection of acetate buffer pH 2 was based on sensitivity, minimal interference, ease of preparation, suitability for drug content estimation, stability, analysis time and cost. The λ_{max} for Pioglitazone HCl in acetate buffer pH 2 (Figure 1) showed linear relationship (with correlation coefficient of 0.9944) in the concentration range of 2-10 µg/ml (Table 1and 2).

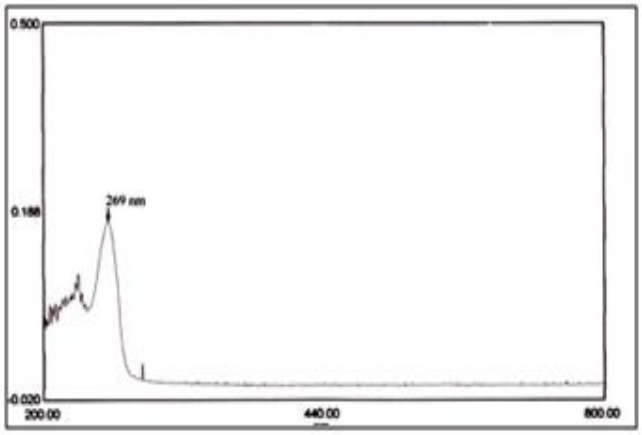

Figure 1: Scan of 10µg/ml solution of Pioglitazone HCl in acetate buffer pH

Table 1: Calibration curve points of the proposed method for the estimation of Pioglitazone HCl

Concentration (µg/ml)	Absorbance*±SD	CV (%)
2	0.052±0.0025	1.20
4	0.101±0.003	1.23
6	0.154±0.0025	1.38
8	0.207±0.001	1.52
10	0.255±0.0015	1.21

Sample solution stability studies

Overlay scans obtained at zero time, 12, 24, and 48 h revealed no degradation upto 48h in the selected solvent at controlled (25±2oC; 65±5%RH) and accelerated (40±2oC; 75±5 %RH) conditions . Drug was stable for more than 48 hours, thus there can be time lap between collection of the sample and analysis of the same.

Recovery studies

The method developed for the estimation of Pioglitazone HCl in bulk and in its dosage forms was found to be simple, accurate, economical and rapid. Table 3, 4, 5 clearly indicate that drug content was uniform ranging from **98 to 99.99%** and SD, CV values were found to be satisfactorily low. Recovery studies were also carried out and found to be **98.89 to 99.89%** for the both batches of capsules. The method requires only measuring the absorbance of sample solution at the selected wavelength followed by simple calculations. Hence, it was further employed for our study.

Table 2: Results of least square regression analysis of UV methods for the estimation of Pioglitazone HCl

Absorption maxima	269
Beers law limit(µg/ml)	1-20
Molar absorptivity (1 $mole^{-1}/cm^{-1}$)	2.96×10^{-2}
Coefficient of correlation	0.9939
Best-fit values	
Slope	0.006643 ± 0.02321
Y-intercept when X=0.0	0.1816 ± 0.1406
X-intercept when Y=0.0	-27.24
1/slope	150.5
95% Confidence Intervals	
Slope	0.05779 to 0.07108
P value	< 0.0001

Table 3: Pioglitazone HCl estimation in bulk by proposed method

Tablet sample	Label Claim (mg/capsule)	Actual content Found mg±S.D	Percent Actual content found ±S.D	CV
Sample-1 **Pioglitazone HCl Cap**.(Generic)	20	19.75±0.153	99.00±0.153	0.939
Sample-2 **Pioglitazone HCl Cap**.(Generic)	40	39.50±2.04	99.35±0.74	0.669

Table 4: Pioglitazone HCl estimation in dosage form by developed method

S.NO	Pioglitazone HCl taken(µg/ml)	Pioglitazone HCl found(CV)	% of Pioglitazone HCl found(CV)
1	10	9.89(0.935)	98.9(0.76)
2	20	19.88(0.884)	99.40(0.85)
3	40	39.56(0.845)	98.9(1.12)
4	50	49.50(0.765)	99.1(0.99)
5	100	98.0 (0.928)	98.0(0.10)

Table 5: Pioglitazone HCl estimation in dosage form in recovery studies by developed method

Tablet Sample	Concentration of added amount of drug in the final dilution (µg/ml ±S.D)	Recovery (µg/ml ±S.D)	Percent Recovery ±S.D	CV
Sample-1 **Pioglitazone HCl** Cap (Generic)	10	9.87 ±0.0123	98.7 ±0.989	0.979
Sample-2 **Pioglitazone HCl Cap**. (Generic)	10	9.9 ±0.0142	99.1 ±0.975	0.918

Method validation

The developed estimation method proved to be accurate (accuracy varies between 10.2-5.5%) and precise (Intra day precisions were less than 4.5%).The method has was validated in the range 2-10µg/ml using acetate buffer pH 2 solution. The method was linear over this concentration range as indicated by the F-test for lack of fit. Analyte recovery was better than 90% at all points on the standard curve, Intraday precision was better than 5% CV while accuracy was between 98-100% of nominal over this range of the estimation.

4. Conclusion

The developed UV spectrophotometric method for the estimation of Pioglitazone HCl was found to be simple and useful with high accuracy, precision, and reproducible. Sample recoveries in all formulations using the above method was in good agreement with their respective label claim or theoretical drug content, this suggesting the validity of the method and non interference of formulation excipients in the estimation. In the selected solvent system, drugs were stable for more than 48 hours, thus suggesting that samples need not be estimated immediately after collection. The developed method was found to be stability specific and were validated as per ICH guidelines (2005) and statistical method.

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