Asian Journal of Chemistry; Vol. 24, No. 8 (2012), 3487-3489

ASIAN JOURNAL OF CHEMISTRY

www.asianjournalofchemistry.co.in

Fading Spectrophotometric Determination of Pioglitazone Hydrochloride with Eosine B

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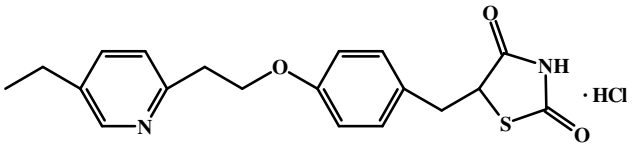
(*Received*: 16 July 2011; *Accepted*: 12 March 2012) AJC-11172

A fading spectrophotometric method for the determination of pioglitazone hydrochloride was carried out based on the reaction between pioglitazone hydrochloride and eosine B to form ion-association complex with the fading absorption peak at 518 nm, where the absorbance ΔA was correlated with its concentration. Linear relationship with good correlation coefficient (0.9996) was found between the absorbance ΔA and the concentration of pioglitazone hydrochloride in a concentration range of 3-27 μg mL^{-1}. The proposed method was successfully applied to the determination of the investigated drug in tablets or capsules in agreement with the results of ultraviolet spectrophotometry.

Key Words: Pioglitazone hydrochloride, Eosine B, Fading spectrophotometry, Tablets, Capsules.

INTRODUCTION

Pioglitazone hydrochloride[1], chemical name (±)-5-{*p*-[2-(5-ethyl-2- pyridyl)ethoxy]benzyl}-2,4-thiazolidinedione hydrochloride (**Scheme-I**), is an oral antidiabetic agent, which acts primarily by decreasing insulin resistance and was developed by Takeda chemicals[2]. It is used both as monotherapy and in combination with sulfonylurea or insulin in the management of type 2 diabetes mellitus (non-insulin-dependent diabetes mellitus, NIDDM)[3,4].



Scheme-I: Structure of pioglitazone hydrochloride

Several procedures have been reported in the literature for the determination of pioglitazone hydrochloride. These methods are high-performance liquid chromatography[5-8], LC-MS method[6], solid phase extraction HPLC[7], classical potentiometric sensor[8], electrochemical method[9], ultraviolet spectrophotometry[10], fading spectrophotometry with eosin Y[11] and acidic triphenylmethane dyes[12-14] and extractive spectrophotometry[15].

Spectrophotometric method has been widely applied to the determination of compounds of pharmaceutical preparations for faster and cheaper than liquid chromatography. In this work, a new fading spectrophometric method for the assay of pioglitazone hydrochloride was developed, which was based on the fading reaction between pioglitazone hydrochloride and eosine B to form ion-association complex with the fading absorption peak at 518 nm. In the proposed method, there are no complicated sample separation and extraction steps with satisfactory analytical results in agreement with those of ultraviolet spectrophotometry.

EXPERIMENTAL

A Shimadzu UV-250pc model UV-Visible spectrophotometer (Tokyo, Japan) with 1 cm matched quartz cells was used for the absorbance measurements.

Pioglitazone hydrochloride stock solution (1000 μg mL^{-1}) was prepared by dissolving 0.5000 g of pioglitazone hydrochloride in 500 mL volumetric flask and filling it up with water. 60 μg mL^{-1} pioglitazone hydrochloride standard working solution was obtained by diluting the stock solution with water. 5×10^{-4} mol L^{-1} eosine B solution was prepared by dissolving 0.1560 g of eosine B and diluting the solution to 500 mL with the distilled water. Clark-Lubs solutions were prepared at pH range from 2.20 to 4.00 based on the described procedure[16]. The water used was distilled water and all the reagents were of analytical grade.

A suitable amount of sample solution or standard pioglitazone hydrochloride working solution and 1.50 mL of

5.0×10^{-4} mol L^{-1} eosine B solution as well as 2 mL of Clark-Lubs solution with pH value of 3.8 were transferred into a 10 mL colourimetric tube, diluted to the mark with water. After lying aside for 20 min at room temperature, the absorbance A, A_0 of the complex solution and the reagent blank were measured with 1 cm cell at 518 nm against water, respectively. The absorbance difference was defined as $\Delta A = A_0 - A$

RESULTS AND DISCUSSION

Absorption spectra: In the experimental condition, pioglitazone hydrochloride can react with eosine B to form ion-association complex, the absorption spectra were shown in Fig. 1, it was found that the absorption peaks of the reagent blank and the solution containing pioglitazone hydrochloride were all at 518 nm, which indicated that it was a fading reaction. Hence, 518 nm was selected for further studies.

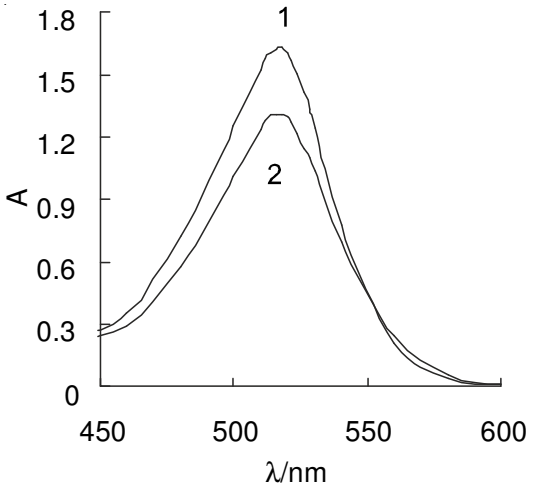


Fig. 1. Absorption spectra: (1) the reagent blank *vs.* water; (2) the solution containing pioglitazone hydrochloride *vs.* water; [pioglitazone hydrochloride] = 12 μg mL^{-1}, [eosine B] = 7.5×10^{-5} mol L^{-1}, pH = 3.8

Effect of reaction time: The effect of reaction time for the reaction between pioglitazone hydrochloride and eosine B was studied. As shown in Fig. 2, pioglitazone hydrochloride reacted with eosine B within at most 15 min at room temperature. The formed complex remained steady at least 75 min. Therefore 20 min of reaction time was chosen in the experiments.

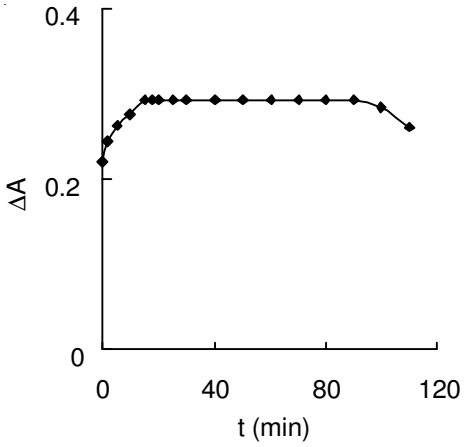


Fig. 2. Effect of reaction time: [pioglitazone hydrochloride] = 12 μg mL^{-1}, [eosine B] = 7.5×10^{-5} mol L^{-1}, pH = 3.8

Effect of pH: The effect of various pH values in Clark-Lubs solution was investigated on the reaction of pioglitazone hydrochloride and eosine B and the results were given in the Fig. 3. It was obvious from Fig. 3 that pH value at 3.8 was the best medium with the maximum absorbance ΔA. Further study shows that 1.00-3.50 mL pH 3.8 Clark-Lubs solution will give the maximum absorbance ΔA. Therefore 2.00 mL pH 3.8 Clark-Lubs solution was chosen for further studies.

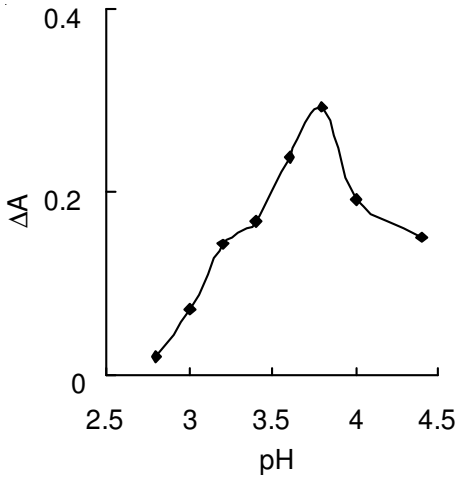


Fig. 3. Effect of pH: [pioglitazone hydrochloride]=12 μg mL^{-1}, [eosine B] =7.5×10^{-5} mol L^{-1}

Effect of eosine B solution: From Fig. 4, 1.00-1.75 mL eosine B solution could give the maximum absorbance ΔA for the system, so 1.50 mL 5.0×10^{-4} mol L^{-1} eosine B solution was chosen in the experiments.

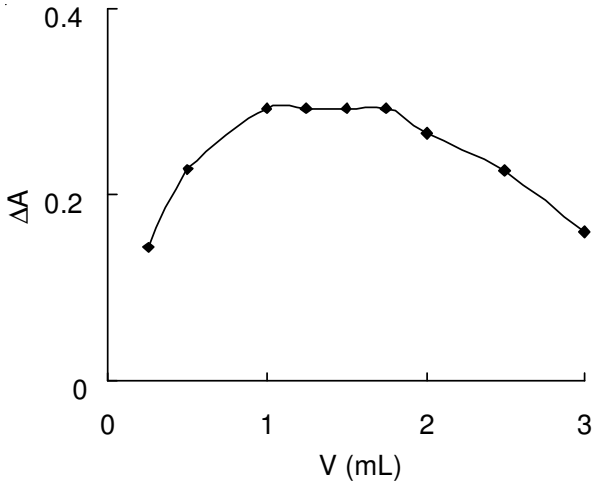


Fig. 4. Effect on volume of eosine B solution: [pioglitazone hydrochloride] = 12 μg mL^{-1}, pH = 3.8

Working curve and detection limit: A series of standard pioglitazone hydrochloride solutions with different concentration were prepared. Under the chosen experimental conditions, ΔA of these solutions was measured. The working curve was drawn and shown in Fig. 5. The results showed that Beer's law was obeyed in the concentration range of 3-27 μg mL^{-1} for pioglitazone hydrochloride. The linear regression equation was $\Delta A = 0.0134C + 0.131$ with the regression coefficient $\gamma = 0.9996$.

TABLE-1
ANALYTICAL RESULTS OF PIOGLITAZONE HYDROCHLORIDE

Sample	Labeled mount (mg)	This method			Ultraviolet spectrophotometric method[15]		
		Determined amount[a] (mg)	Percentage of labeled value[a] (w/ %)	RSD (%)	Determined amount[a] (mg)	Percentage of labeled value[a] (w/ %)	RSD (%)
Tablets[b]	15	14.92	99.47	1.3	14.92	99.47	1.60
Tablets[c]	15	14.89	99.27	1.7	14.87	99.13	2.10
Tablets[d]	15	15.10	100.7	1.6	15.21	101.4	1.70
Capsules[e]	15	14.96	99.73	1.9	14.91	99.40	1.80

[a]Each value is the mean of five measurements; [b]Tablets from Jiangsu Hengrui Medicine Co. Ltd.; [c] Tablets from Beijing Taiyang Medicine Co. Ltd. [d]Tablets from Zhijian Kangenbei Medicine Co. Ltd. [e]Capsules from Sichuan Baoguang Medicine Co. Ltd

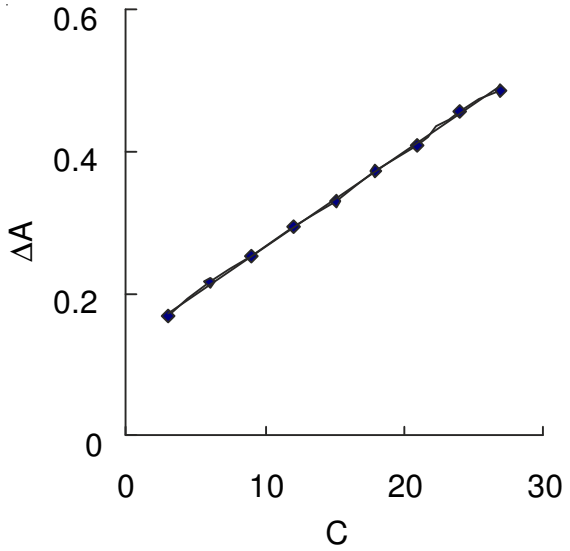


Fig. 5. Working curve: [eosine B] = 7.5×10^{-5} mol L^{-1}, pH = 3.8

Application: The proposed method was applied to the determination of pioglitazone hydrochloride in commercial tablets and commercial capsules. Twenty weighed commercial tablets, which were obtained from local drug store, were ground to a fine powder. Twenty weighed commercial capsules were discard of nappe shell. The amount of powder equivalent to 60 mg of the active compound was dissolved in 1000 mL water and centrifuged. Then 2.00 mL of the centrifuged solution was analyzed in five replicate determinations by the proposed method. Satisfactory results were obtained as shown in Table-1 in agreement with the results of ultraviolet spectrophotometry[15].

Conclusion

Fading reaction of pioglitazone hydrochloride with eosine B, can be utilized as a useful method for the spectrophotometric determination of pioglitazone hydrochloride. The proposed method has the advantages of being simple, cheap, accurate and requires minimum equipments and chemicals. These advantages encourage the application of the proposed method in routine quality control of the investigated pioglitazone hydrochloride in industrial laboratories.

ACKNOWLEDGEMENTS

The authors thank Jiangsu Hengrui Medicine Co. Ltd., China for supplying gift sample of pioglitazone hydrochloride. Thanks are also due to Education Bureau of Jiangsu Province (China) for the financial support.

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