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NOTE

UV Spectrophotometric Methods for the Determination of Anti-diabetic Drugs

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Simple and sensitive UV spectrophotometric methods are developed for the determination of pioglitazone hydrochloride and rosiglitazone maleate in pure and pharmaceutical dosage forms. Methods obey Beer's law in the concentration range 5–30 μg/mL and 10–60 μg/mL exhibiting maximum absorption at 270 nm and 318 nm respectively. These methods are extended to pharmaceutical preparations and there is no interference from any common pharmaceutical additives and diluents.

Key Words: Spectrophotometric determination, Anti-diabetic drugs, Pioglitazone hydrochloride, Rosiglitazone maleate.

Pioglitazone hydrochloride (PGH)[1, 2] and rosiglitazone maleate (RGM)[3] are anti-diabetic drugs. Chemically PGH is 2,4-thiazolidine dione, 5-[[4-[2-(5-ethyl-2-Pyridinyl)ethoxy]phenyl]methyl] and RGM is 2,4-thiazolidine dione, 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-(2Z)-2-butenedioate (1 : 1). PGH and RGM are potent and highly selective agonists for peroxisome proliferator-activated receptor-gamma (PPARγ). Few HPLC methods were reported for the estimation of PGH[4–7] and RGM[8, 9] in human plasma and serum. However, spectrophotometric methods are not reported. The present investigation has been undertaken to develop a UV spectrophotometric method for the determination of PGH and RGM.

Instrumentation

Spectral and absorbance measurements were made on Systronics UV-Visible spectrophotometer-117 with 10 mm matched quartz cells.

Preparation of standard solutions

Accurately weighed 100 mg of PGH or RGM and dissolved in 100 mL of 0.1 N hydrochloric acid (HCl) to get 1 mg/mL stock solution. 10 mL of the stock solution was further diluted with the same solvent to obtain a working standard solution of 100 μg/mL.

Preparation of sample solutions

Twenty tablets were accurately weighed and finely powdered. The powder equivalent to 100 mg of PGH or RGM was dissolved in 0.1 N HCl. These

solutions were filtered and the residue was washed with the same solvent and further diluted to 100 mL.

Proposed Method for PGH and RGM

Aliquots of solution 0.5 to 2.5 mL (100 μg/mL) of PGH or RGM were transferred into a series of 10 mL volumetric flasks and the volume was brought to 10 mL with 0.1 N HCl. The absorbance was measured at 270 nm or 318 nm respectively against blank solution. The amount of PGH or RGM present in the sample solution was computed from its calibration curve.

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, per cent relative standard deviation (calculated from the eight measurements containing 3/4th of the amount of the upper Beer's law limits for the drugs), per cent range of error (0.05 to 0.01 confidence limits) were calculated and the results are summarized in Table-1. To evaluate the validity and reproducibility of the methods, known amounts of pure drug were added to the previously analyzed pharmaceutical preparations and the mixtures were analyzed by proposed methods and the results are presented in Table-2. The methods were applied for the analysis of the drugs in their pharmaceutical formulations. Interference studies revealed that the common excipients and other additives usually present in the dosage form did not interfere in the proposed methods.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION OF THE PROPOSED METHODS

Parameters	PGH	RGM
Beer's law limit (μm/mL)	5–25	5–25
Molar extinction coefficient (L mol^{-1} cm^{-1})	1.182×10^4	1.00×10^4
Sandell's sensitivity	0.033	0.047
(μg/cm^2/0.001 absorbance unit)		
Regression equation (Y*)		
Slope (a)	3.0×10^{-2}	2.1×10^{-2}
Intercept (b)	8.0×10^4	6.0×10^4
Correlation coefficient (r)	0.9999	0.9999
% Relative standard deviation (+)	0.291	0.455
% Range of error		
0.05 confidence limits	0.244	0.381
0.01 confidence limits	0.360	0.563

Y* = b + ac, where c is concentration in μg/mL and Y is absorbance unit.
+ Six replicate samples

In conclusion the proposed methods are most economic, simple, sensitive and accurate and can be used for the routine determination of PGH and RGM in bulk as well as in pharmaceutical preparations.

TABLE-2
ESTIMATION OF PGH AND RGM IN PHARMACEUTICAL FORMULATIONS

Sample	Labeled amount (mg)	Amound found (mg) Proposed method	% Recovery
PGH Tablets			
1	15	14.98	99.86
2	30	29.98	99.93
3	45	45.02	100.04
RGM Tablets			
1	2	1.99	99.5
2	4	4.01	100.25
3	8	7.96	99.5

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