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NOTE

Simultaneous spectrophotometric estimation of rosiglitazone maleate and glimepiride in tablets

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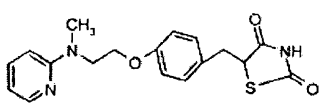
Abstract : A new, simple, sensitive, accurate and reproducible spectrophotometric method was developed for the simultaneous estimation of rosiglitazone maleate and glimepiride in combine dosage form.

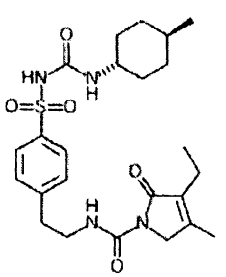
Keywords : Rosiglitazone, glimepiride.

Rosiglitazone maleate ($C_{18}H_{19}N_3O_3S$; Mol. wt. =357.42; ROSI) is chemically (±)-5-{*p*-[2-(methyl-2-pyridylamino)-ethoxy]benzyl}-2,4-thiazolidinedione. It is selective against



Structure of rosiglitazone

for paroxisome proliferator-activated receptor gamma (ppar-γ)[1,2]. Literature survey revealed that several methods including spectrophotometric[3], HPLC[4,5], liquid chromatography[6] have been reported for the estimation of rosiglitazone. Glimepiride ($C_{24}H_{34}N_4O_5S$; Mol. wt. = 490.61 ; GLIM) is a sulfonylurea antidiabetic drug. Chemically it is 1-({[2-(3-ethyl-4-methyl-2-oxo-3-pyrroline-1-carboxamido)ethyl]phenyl}sulfonyl-3-(trans-4-methylcyclohexyl) urea[7,8]. A number of spectrophotometric[9] and HPLC[10,11] liquid chromatography[12] methods have been reported in the literature for the estimation of GLIM.



Structure of glimepiride

The combination of rosiglitazone maleate (ROSI) and glimepiride (GLIM) is available only in tablet form in the market. In the present communication a simple, rapid, selective and reproducible spectrophotometric method has been developed for simultaneous estimation of ROSI and GLIM.

Results and discussion

The proposed method for simultaneous estimation of ROSI and GLIM was found to be simple, accurate, economical and rapid for routine simultaneous analysis of drugs from the formulation without prior separation. Mean of absorptivity for rosiglitazone at 248.5 nm and 228.5 nm was 555.04 and 576.35 respectively and for glimepiride as 192.38 and 558.63 at 248.5 nm and 228.5 nm respectively. Quantity of rosiglitazone and glimepiride in formulation A was found to be 2.0147 mg/tab (label claim 2 mg/tab) and 1.0039 mg/tab (label claim 1 mg/tab) respectively. In this method, once absorptivity coefficients were determined, very little time is required for analysis, as it would only require determination of absorbances of the sample solutions at the selected wavelengths and few calculations. The values of coefficient of variation were satisfactorily low and recovery was close to 100% for both the drugs. Hence, it can be employed for routine analysis in quality control laboratories.

Experimental

A GB Cintra-10 double beam UV-Visible spectrophotometer (Australia) equipped with 10 mm matched quartz cells was used in the present investigation. The spectropho-

tometer was run at a spectral band width of 5 nm with a scan speed of 24 ~ 1400 nm/min. Methanol A.R. grade (Qualigens, Mumbai) was used in the present study. Gift samples of ROSI and GLIM were obtained from M/s Aristo Pharmaceutical Ltd., Mumbai, and M/s Synmedic Lab, Faridabad respectively. A combination of both drugs, rosiglitazone maleate 2 mg and glimepiride 1 mg in each tablet dosage form is obtained from market. Standard stock solutions of individual compounds were prepared by dissolving accurately weighed amount of each drug in methanol to make final concentration of 1000 μg/ml. The absorbance was measured at 24.5 nm for ROSI and 228.5 nm for GLIM against methanol. Both the drugs obey Beer's law individually and in mixture within the concentration range of 2-16 μg/ml. Fig. 1 represents the overlain spectra of both the drugs in methanol.

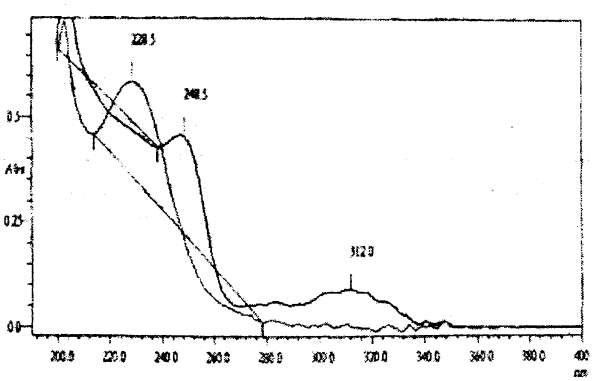


Fig. 1. Overlain spectra of rosiglitazone and glimepiride.

The average weight of each tablet was calculated by weighing 20 tablets. Tablets were powdered finely in a glass mortar. The tablet powder equivalent to 100 mg of ROSI and 50 mg of GLIM was accurately weighed and extracted with 4 successive 20 ml portions of methanol and transferred quantitatively into 100 ml volumetric flask after filtering through Whatman filter paper. The required volume was made up with methanol. Further dilutions were made to get the required concentration.

Two wavelengths selected for the generation of simultaneous equations were 248.5 nm and 228.5 nm. Absorption was determined at these two wavelengths for both the drugs separately. The molar absorptivity for the two drugs is presented in Table 1.

Table 1. Absorptivity values for rosiglitazone maleate and glimepiride

Concentration (μg/ml)		Absorptivity at 248.5 nm		Absorptivity at 228.5 nm	
ROSI	GLIM	ROSI	GLIM	ROSI	GLIM
2	2	564	199	608	575
4	4	575	200	600	582
6	6	545	210	534	594
8	8	546	207	507	552
10	10	545	185	593	546
12	12	551	181	561	535
14	14	545	181	610	546
16	16	532	176	598	539
	Mean	555.04	192.38	576.38	558.63

Molar absorptivity values of ROSI is 2.6279×10^4 L/mol cm at 248.5 nm and 2.7274×10^4 L/mol cm at 228.5 nm, while molar absorptivity values for GLIM is 9.4199×10^3 L/mol cm at 248.5 nm and 2.7426×10^4 L/mol cm at 228.5 nm.

The simultaneous equations formed were

$$\text{At } 248.5 \text{ nm} : A_1 = 0.0555C_X + 0.0192C_Y \quad (1)$$

$$\text{At } 228.5 \text{ nm} : A_2 = 0.0576C_X + 0.0559C_Y \quad (2)$$

where A_1 and A_2 are absorbances of sample solution at 248.5 nm and 228.5 nm respectively. C_X and C_Y are the concentrations of ROSI and GLIM respectively (μg/ml) in sample solution. By substituting the value of C_Y from eq. (2) into eq. (1), the value of C_X can be obtained. Similarly C_Y can also be obtained.

Estimation of marketed preparation : An aliquot of sample stock solution (0.4 ml) was transferred to 100 ml volumetric flask and volume was made up to the mark with methanol. This solution was scanned in the range 200-400 nm against methanol as blank. Absorbances of these solutions were measured at 248.5 nm and 228.5 nm as A_1 and A_2 respectively. The concentration of each drug was then calculated using eqs. (1) and (2). Results of analysis of the tablet formulation are reported in Table 2.

Table 2. Statistical analysis for rosiglitazone maleate and glimepiride

Tablet brand	Tablet component	Label claim[a] (mg/tab)	Amount found (mg/tab)[a]	S.D.[a]	%RSD[a]	SE[a]
FORMUL	ROSI	2	2.0147	0.0093	0.4619	0.0038
ATION A	GLIM	1	1.0039	0.0080	0.7971	0.0033

[a]Average of six determinations.

Table 3. Recovery study of rosiglitazone maleate and glimepiride

Tablet brand	Tablet component	Label claim (mg/tab)[a]	Amount added (mg/tab)[a]	Percent recovery ± S.D.[a]
FORMUL	ROSI	2	2	100.61 ± 0.0155
ATION A	GLIM	1	1	100.38 ± 0.0192

[a]Average of six determinations.

The experiment was repeated six times to get reproducibility .

To study accuracy, reproducibility and precision of the method, recovery studies were carried out by adding known amount of pure drugs to the analyzed sample of tablet powder and mixture was reanalyzed for the drug content using the proposed method. Results of recovery was found to be satisfactory and presented in Table 3.

Acknowledgement

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