Journal of Applied Pharmaceutical Science 01 (06); 2011: 159-161

Journal of Applied Pharmaceutical Science

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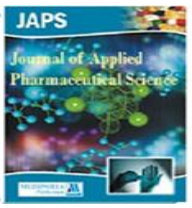

ISSN: 2231-3354
Received: 16-07-2011
Accepted: 29-07-2011

Analytical method development and validation for the simultaneous estimation of pioglitazone and glimepiride in tablet dosage form by multiwavelength spectroscopy

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ABSTRACT

One simple, accurate, economical and reproducible UV spectrophotometric method for simultaneous estimation of two component drug mixture of pioglitazone and glimepiride in combined tablet dosage form has been developed. The developed method employs multiwavelength spectroscopy using 280 nm and 238 nm as two wavelengths for estimation. Results of analysis were validated statistically and by recovery studies.

Key words: Pioglitazone, glimepiride, multiwavelength spectroscopy, recovery study.

INTRODUCTION

Pioglitazone (PIO) is a thiazolidinedione antidiabetic agent. It is one of the PPAR-alpha agonist, insulin sensitizer used to reduce the insulin resistance. Chemically Pioglitazone (Fig.1) is [(+) - 5- [[4- [2- (5-ethyl- 2-pyridinyl) ethoxy] phenyl] methyl] - 2, 4-]thiazolidinedione monohydrochloride.Glimepiride (GLI) is a sulfonyl urea antidiabetic agent. Chemically glimepiride(Fig.1) is 1- [[p- [2- (3- ethyl-4- methyl- 2- oxo- 3- pyrroline- 1- carboxamido)ethyl] phenyl] sulfonyl] - 3- (trans- 4-methylcyclohexyl) urea(The Merck index,2001).Pioglitazone and Glimepiride in combined tablet dosage form are available in the market. The literature reveals that there are some of the methods have been reported for pioglitazone and glimepiride in single dosage forms(Zhong et al., 1989),(Kenji et al.,1996),(Xue et al.,2003),(Mubeen Ahmad et al.,2005),(Yannis et al.,2005) and only few reports were found in combined dosage forms by UV(Shveta et al.,2005) , HPLC(Sane et al.,2004) ,(Karthik et al.,2008) and HPTLC (Sane. et al.,2004). Even though various methods were reported in the literature for estimation of glimepiride and pioglitazone individually or in combination with other drugs no method had been reported for simultaneous estimation of these two drugs using Multiwavelength spectroscopy method in bulk drug and pharmaceutical dosage forms.

The present study was aimed at the simultaneous estimation of pioglitazone and glimepiride by Multicomponent mode of analysis. Developed spectrophotometric method was found to be simple, accurate, reproducible and economical in comparison to routine extractive or colorimetric methods used for analysis of single drug and have been used successfully for determination of two components from combined tablet dosage form.

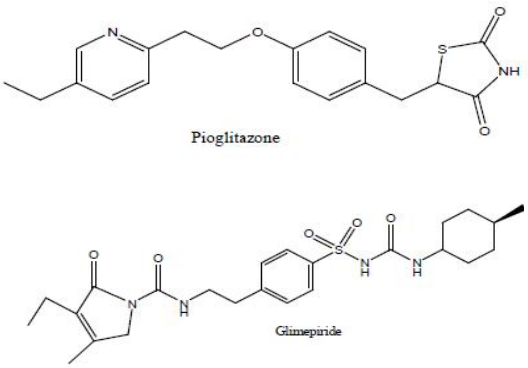

Fig 1: Structure of Pioglitazone and Glimepiride.

MATERIALS AND METHODS

Reagents and Materials

All the reagents used were of analytical grade for spectrophotometric methods.

Instrument

A Shimadzu UV/Visible double beam spectrophotometer (Model 1700) with 1 cm matched quartz cells were used in present study for spectral and absorbance measurements.

Method

The wavelength maxima of two drugs (Pioglitazone and Glimepiride) i.e. 280.0 nm and 238.0 nm were selected as two sampling wavelengths for this method.

Five mixed standards of two drugs in 0.1 N NaOH were prepared so as to contain 10-50 mcg/ml of pioglitazone and 1-5 mcg/ml of glimepiride. All mixed standard solutions were scanned over the range of 400 nm to 200 nm in multicomponent mode of spectrophotometer using 280.0 nm and 238 nm as two sampling wavelengths. An overlain spectrum of mixed standard solutions is shown in (Fig.2). The spectral data from these scans were used to determine the concentration of the two drugs in the sample solution.

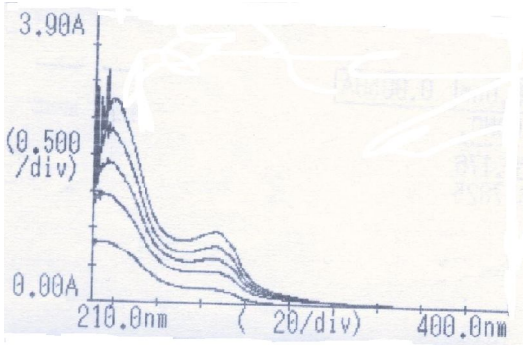

Fig.2: Overlain spectra of mixed standards of Pioglitazone and Glimepiride.

Analysis of commercial formulation

Twenty tablets were accurately weighed and average weight per tablet was determined. Tablets were crushed to fine powder and tablet powder equivalent to 15 mg of pioglitazone was accurately weighed and extracted four times with 20 ml portions of 0.1 N NaOH solution and filtered through Whatman filter paper No. 41 into a 100 ml volumetric flask, filter paper was washed with 0.1 N NaOH solution added washings to the filtrate and volume was made up to the mark with the same. From the above filtrate 1 ml was further diluted to 10 ml with 0.1 N NaOH solution.

The sample solution was scanned over the range of 400 nm to 200 nm in multicomponent mode and concentration of each component was estimated by analysis of spectral data of sample solution with respect to that of mixed standards by the instrument. The spectra of sample solution is given in (Fig.3). Results of analysis are reported in Table-1.

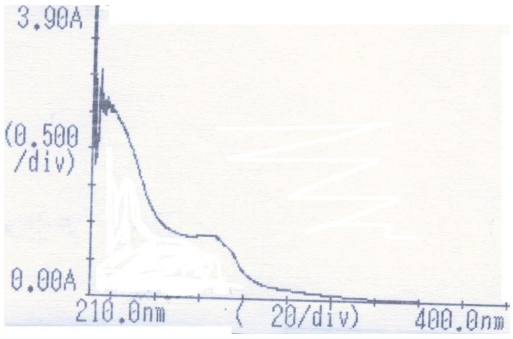

Fig.3: Spectra of sample solution.

Table-1: Result of analysis.

Brand	Label Claim(mg/tab)		% Label Claim Estimated*		Standard deviation		% Recovery**	
	Pio	Gli	Pio	Gli	Pio	Gli	Pio	Gli
I	15	1	101.04	100.93	0.743	0.968	101.00	100.92
II	15	2	98.54	100.37	0.812	1.235	97.84	99.31

*Average of six determinations
** Average of Recovery Studies at three different concentration levels

Recovery Study

Recovery studies were carried out by addition of pure drug to previously analysed tablet sample at three different concentration levels. The results of recovery studies are reported in Table 1. The results of recovery studies reflect that there is no interference of excipients in the analysis of Pioglitazone and glimepiride from tablet formulation.

RESULT AND DISCUSSION

The proposed method for simultaneous estimation of pioglitazone and glimepiride in combined tablet dosage form was found to be simple, accurate, rapid and economical. The values of standard deviation are satisfactorily low and recovery was close to 100% indicating reproducibility of the method.

The proposed method involving multiwavelength spectroscopy is specific to instrument having software for provision of such determination. Selection of proper sampling wavelength and concentration of components in mixed standard is critical. Since calculations are done by the instrument itself chances of manual error are nil.

CONCLUSION

The developed method was validated in terms of accuracy, reproducible for simultaneous estimation of two component drug mixture of pioglitazone and glimepiride in combined tablet dosage form. The assay experiment showed that the contents of PIO and GLI estimated in the tablet dosage form were free from the interference of excipients. This demonstrated that the developed multiwavelength spectroscopy method was simple, economical, accurate and reproducible and could be conveniently adopted for the routine quality control analysis of PIO and GLI simultaneously, from its pharmaceutical formulations and bulk drug.

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