WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 5.045
Volume 4, Issue 01, 875-881. Research Article ISSN 2277– 7105

SPECTROPHOTOMETRIC DETERMINATION OF TERAZOSIN IN TABLET DOSAGE FORMS

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Article Received on
29 October 2014,

Revised on 20 Nov 2014,
Accepted on 10 Dec 2014

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ABSTRACT

Two simple, accurate, rapid and precise spectrophotometric method has been developed for determination of terazosin in tablet dosage forms. The method A was based on the formation of chloroform extractable complex of Terazosin with wool fast blue. The absorbance of the extractable ion pair complex is measured at the wavelength of maximum absorbance 585 nm against the reagent blank. Method B was based on the the charge transfer reactions of Terazosin as *n*-electron donor with acceptor, 2,5-dichloro-3,6-dihydroxy-1,4-benzoquinone. The absorbance of the highly intensive coloured solution was measured at 455 nm against reagent blank treated similarly.

KEYWORDS: Terazosin, Spectrophotometry, Wool Fast Blue(WFB), 2,5-dichloro-3,6-dihydroxy-1,4-benzoquinone(DDQ), Formulations.

INTRODUCTION

Terazosin, 6, 7-dimethoxy-2-[4-(tetrahydrofuran-2-ylcarbonyl) piperazin-1-yl]quinazolin-4-amine (fig 1) is a selective potent α1 adreno-receptor antagonist. It is an effective drug for hypertension and benign prostatic hyperplasia. It is used in men to treat the symptoms of an enlarged prostate (benign prostatic hyperplasia or BPH), which include difficulty urinating (hesitation, dribbling, weak stream, and incomplete bladder emptying), painful urination, and urinary frequency and urgency. It also is used alone or in combination with other medications to treat high blood pressure. Terazosin is in a class of medications called alpha-blockers. It relieves the symptoms of BPH by relaxing the muscles of the bladder and prostate. It lowers blood pressure by relaxing the blood vessels so that blood can flow more easily through the body.

Literature survey reveals many reported methods for the analysis of terazosin by Spectrophotometric and spectrofluorimetric methods[1], fluorescence determination[2], x-ray fluorescence spectrometry[3], HPLC[4-6], extraction-fluorimetric combined methodology[7], Ionic-Liquid Micro extraction[8], Ultra violet spectrophotometric method. [9]

Spectrophotometry is the technique of choice even today in the laboratories of research, hospitals and pharmaceutical industries due to its low cost and inherent simplicity. This paper describes two rapid, simple, sensitive and economical spectrophotometeric methods for the determination of terazosin in commercial dosage forms. Method A is based on the formation of chloroform extractable complex of terazosin with wool fast blue. The ion association complex is a special form of molecular complex resulting from two components extractable into organic solvents from aqueous phase at suitable pH. One component is a chromogen (wool fast blue) processing charge (Cationic or anionic in nature) & so insoluble in organic solvents. The other is colorless, processing opposite charge to that of chromogen. Method B utilizes the charge transfer reactions of terazosin as *n*-electron donor with acceptor, 2,5-dichloro-3,6-dihydroxy-1,4-benzoquinone. The molecular interactions between electron donors and electron acceptors are generally associated with the formation of intensely colored charge-transfer complexes, which absorb radiation in the visible region. The charge-transfer reaction has not been reported yet for terazosin in pharmaceutical formulations.

Therefore, an attempt has been made to develop two simple, accurate, rapid and reproducible spectrophotometric methods for determination of terazosin in capsule or tablet dosage form.

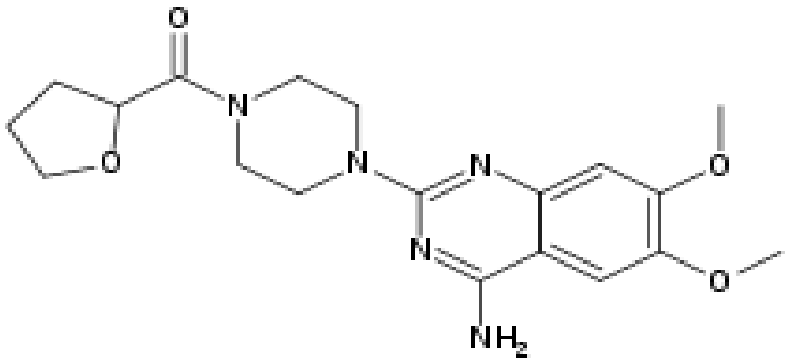

Fig 1: Chemical structure of terazosin

MATERIALS AND METHODS

Wool fast blue solution (0.2%) was prepared in distilled water, freshly prepared. 2,3-dichloro 5,6-dicyano-p-benzoquinone(DDQ; Merck, Schuchardt, Munich, Germany) solution(0.1%) was prepared in methanol and it was prepared a fresh daily. Buffer solutions of required pH were prepared by mixing appropriate volumes of glycine, sodium chloride and 0.1M Hydrochloric acid.

Preparation of solutions: Terazosin standard stock solution (1 mg/ml) was prepared by transferring accurately weighed 100 mg portion of terazosin in 100 ml volumetric flask and volume was made up with methanol. From this a working concentration of 100 µg/ml was prepared for both method A and method B.

Assay procedures

Method A

Aliquots of standard drug solution of terazosin 0.5 – 2.5 ml were taken and transferred into a series of 125 ml of separating funnels. To each funnel 2 ml of 0.2% wool fast blue was added. Reaction mixture was shaken gently for 5 min. Then 10 ml of chloroform was added to each of them. The contents are shaken thoroughly for 5 min and allowed to stand, so as to separate the aqueous and chloroform layer. Colored chloroform layer was separated out and absorbance was measured at 585 nm against reagent blank. Calibration curve was prepared from absorbance values so obtained (fig 2).

Method B

Various aliquots of standard solution of terazosin ranging from 0.2-1.0 ml were transferred into10 ml calibrated flasks. To each flask 1.0 ml hydrochloric acid and 1.0 ml of DDQ solution was added, and the reaction was allowed to proceed at room temperature (25±5oC). The reaction was achieved instantaneously. The solutions were diluted to volume with distilled water. The absorbance of the resulting solutions was measured at the wavelengths of maximum absorption 455 nm against reagent blanks treated similarly. The amount of drug present in sample is read from the calibration graph(fig 3).

Pharmaceutical preparations: Twenty tablets contents were accurately weighed, their mean weight was determined and they were mixed and finely powdered. A portion equivalent to 100 mg of terazosin was accurately weighed and transferred into a 100 ml volumetric flask containing 50 ml methanol, sonicated for 30 min and diluted to 100 ml with methanol. The resulting solution was filtered through Whatmann filter paper no 42. The original stock

solution was further diluted to get sample solution of drug concentration of 100 µg/ml and analyzed as given under the assay procedures for bulk samples. The results are represented in Table 2.

Recovery Studies: To ensure the accuracy and reproducibility of the results obtained, known amounts of pure drug was added to the previously analysed formulated samples and these samples were reanalyzed by the proposed methods and also performed recovery experiments. The percentage recoveries thus obtained were given in Table 2.

RESULTS AND DISCUSSION

The optimum conditions were established by varying one parameter at a time and keeping the others fixed and observing the effect on absorbance of chromogen for method A and method B**.** In the present work method A and B have been developed for the estimation of terazosin from tablet formulations. The developed method A is based on formation of chloroform extractable colored complexes with wool fast blue. Method B based on the reaction of terazosin as *n*-electron donor with acceptor, 2,5-dichloro-3,6-dihydroxy-1,4-benzoquinone. Statistical analysis was carried out and the results were found to be satisfactory. Recovery studies were close to 100 % that indicates the accuracy and precision of the proposed methods. The optical characteristics such as absorption maxima, Beer´s law limits, molar absorptivity and Sandell´s sensitivity are presented in Table 1. The regression analysis using method of least squares was made for the slope (b), intercept (a) and correlation (r) obtained from different concentrations and results are summarized. The percent relative standard deviation, standard deviation and student's't' test values calculated from the five measurements of terazosin are presented in Table 3. Relative standard deviation values and standard deviation were low that indicates the reproducibility of the proposed methods. In the student's't' tests, no significant differences were found between the calculated and theoretical values of both the proposed methods at 95% confidence level. This indicated similar precision and accuracy in the analysis of terazosin in its tablets.

TABLE 1: OPTICAL CHARACTERISTICS OF THE PROPOSED METHODS

Parameters	Method A	Method B
Wavelength (nm)	585	455
Beer's limits, mcg/ml	50-250	20-100
Sandell's , sensitivity, (µg cm^{-2})	0.0197	0.0280
Molar absorptivity, (L mol^{-1} cm^{-1})	$1.9x10^3$	$2.8x10^3$
Regression equation, Y*	Y= 0.0003x+0.001	Y= 0.0005x+0.006
Correlation coefficient, (r)	0.999	0.999
Intercept (a)	0.001	0.006
Slope (b)	0.003	0.00 5

TABLE 2: Assay and Recovery of Terazosin in Tablet Formulations

Tablet formulations	Labeled amount	*Amount found		% Recovery	
		Method A	Method B	Method A	Method B
Tablet 1	5	5.02	4.94	100.24	100.08
Tablet 2	5	4.99	5.01	99.99	99.96

*Average of five determination based on label claim

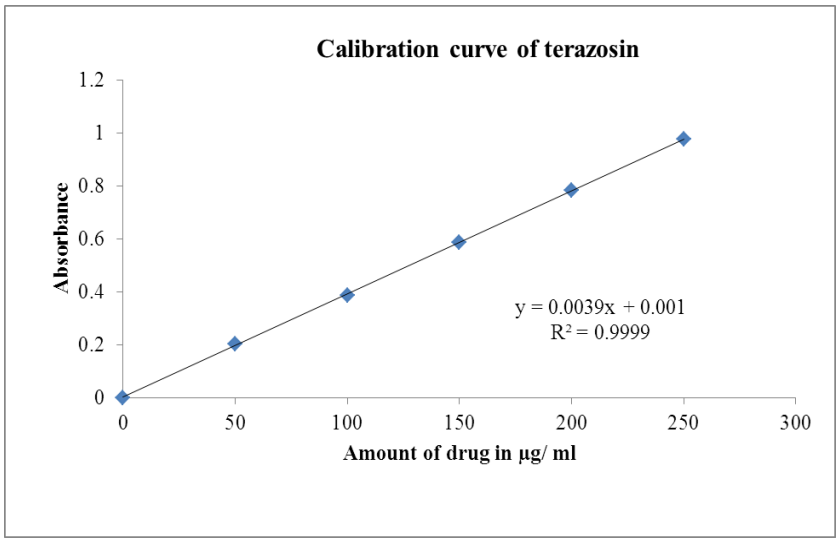

Fig 2: Calibration curve of terazosin for method A

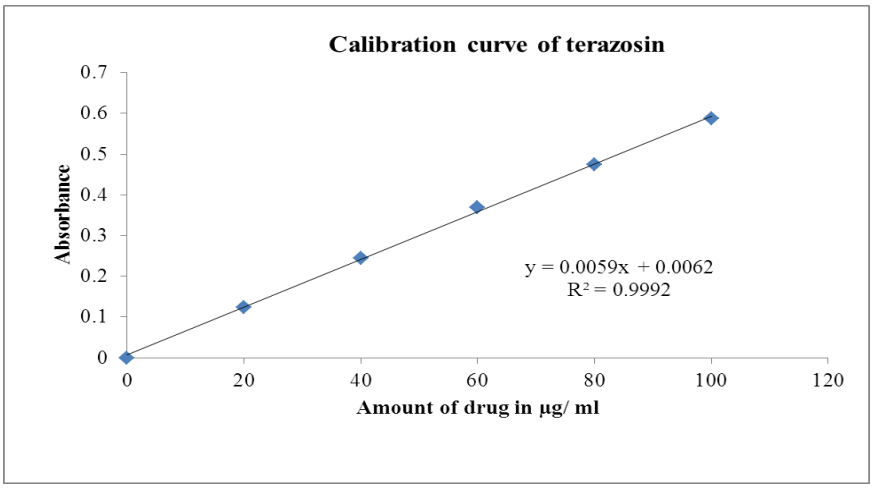

Fig 3: Calibration curve of terazosin for method B

TABLE 3: Results of Statistical Analysis of the Proposed Methods

Tablet formulation	*Standard deviation		% Relative standard deviation*		*t value	
	Method A	Method B	Method A	Method B	Method A	Method B
Tablet 1	0.0782	0.0731	1.557	1.4608	0.5719	0.1223
Tablet 2	0.0601	0.0871	1.204	1.763	0.3721	1.5404

*Average of five determination based on label claim

CONCLUSION

The developed Spectrophotometric method is simple, specific, accurate and precise for the simultaneous determination of terazosin from tablets. The developed method was successfully validated in terms of system suitability, linearity, range, precision, accuracy, specificity in accordance with ICH guidelines. Thus, the described method is suitable for routine analysis and quality control of pharmaceutical preparations either as such or in combination.

ACKNOWLEDGEMENTS

One of the author K. Nagaraja Setty is thankful to principal of the Government Degree College for men Kurnool, for providing required facilities for research work.

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