INTERNATIONAL JOURNAL OF PHARMACEUTICAL, CHEMICAL AND BIOLOGICAL SCIENCES

Available online atwww.ijpcbs.com

Research Article

QUANTITATIVE ESTIMATION OF ATENOLOL INPHARMACEUTICAL DOSAGE FORMS BY USING VISIBLESPECTROSCOPY

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ABSTRACT

A literal and specific visible spectrophotometric method was raised for the estimation for atenolol in solid pharmaceutical dosage form. Method was based on the formation of coloredchromogen (β-napthol). The λ-max of atenolol was found to be 549nm to both crude and marketed sample and is analyzed using Beer-Lamberts law. Beer's law was obeyed at the concentrations ranging 2-10µg/ml. The developed methods were absolute, definite, explicit and consistent and found to be original type for routine determination for atenolol. The method was validated statistically and by recovery studies. The LOD (limit of detection) and LOQ (limit of quantification) for visible spectra were found to be 5.88µg/ml and17.83µg/ml. The correlation coefficient value was found to be 0.999. The purity was found to be 99.5%.

Keywords: Atenolol, Methanol, Validation, Estimation.

INTRODUCTION

Atenolol is a beta-adrenergic receptor antagonist, or a more commonly known as a beta blocker. Atenolol is used to treat angina, hypertension and acute myocardial infarction, supraventricular tachycardia, ventricular tachycardia and alcohol withdrawal symptoms[1]. Atenolol was the main beta blocker identified as carrying a higher risk of provoking type-2 diabetes[2].Atenolol is (figure.1) chemically (RS)-4-(2-hydroxy-3-isopropylaminopropoxy) phenylacetamide.Atenolol is soluble in methanol. Literature survey reported that atenolol individually and combination with other drugs by Spectrophotometry[3-5], HPLC[6-7], HPTLC[8-9] and LC-MS[10-11] methods for estimation of atenolol in its pharmaceutical formulation. The aim of the work is reported a simple, sensitive, rapid, precise and accurate visible spectroscopic method for the estimation of atenolol in pure samples and tablet formulations

MATERIALS AND METHODS

Instrumentation

The present work was carried out on ElicoSL164 UV- Visible spectrophotometer having double beam detector configuration. The absorption spectra of reference and test solution were carried out in a 1 cm quartz cell over the range of 200-800 nm.

Chemicals

All chemicals of analytical grade used as it is.

Preparation of standard solution

Standard stock solution was prepared by dissolving accurately weighed 100 mg of atenolol in methanol and the volume was made up to 100 ml with methanol (Stock solution-I, 1000

mcg/ml). 10 ml of solution took from stock-I and then diluted to 100 ml with water (Stock solution-II, 100 mcg/ml). 1ml of stock solution-II,1 ml of concentrated hydrochloride, 1ml of 1% $NaNo_2$ solution, 1 ml of 0.1% β-napthol in a10 ml volumetric flask were add and diluted to 10 ml with distilled water so that to produce the concentration 10 mcg/ml. This method was done on ice bath and maintain temperature below at 8^0 C was transferred to a 10ml volumetric flask and the final volume was diluted to 10 ml with water, so that to produce the concentration 10 mcg/ml. The absorbance of red chromogen obtained was measured against respective blank solution in the visible region of 400-800 nm, which shows maximum absorbance at 549 nm.

Preparation of sample solutions

20 tablets of one brand of atenololweretook, and all the tablets were crushed to fine powder by using pestle and mortar. Powder equivalent to 25 mg of atenolol wasweighed accurately and transferred into a 25 ml standard volumetric flask. The contents were dissolved in 40ml of ethanol and make up to 100 ml of ethanol. Heating the resulting solution to 60^0c and shake for 15 minutes and cool and sonicated for five minutes. This solution was filtered through 0.45 µm whatsmann filter paper. 10 ml of the filtrate was diluted to 100 ml with distilled water to get the solution of 100 mcg/ml. An aliquot of 1 ml of test solution, 1 ml of concentrated hydrochloride, 1ml of 1% $NaNo_2$ solution, 1 ml of 0.1% β-napthol in a10 ml volumetric flask were add and diluted to 10 ml with distilled water so that to produce the concentration 10 mcg/ml.This method was done on ice bath and maintain temperature below at 8^0 C. The absorbance of red chromogen obtained was measuredagainst respective blank solution in the visibleregion of 490-550 nm, which shows maximumabsorbance at 549 nm.

PROCEDURE

Aliquots of standard solution of atenolol ranging from 0.2-1.0 ml (1 ml = 100 mcg) were transferred into a series of 10 ml volumetric flasks. The volume in each flask was made up to 10 ml with distilled water and the absorbencies were measured at 549 nm against solvent blank. The obtained absorbance values when plotted against the concentration of atenolol give the calibration graph.

VALIDATION[12]

Validation of the developed method was done according to ICH guidelines.

Linearity

The linearity of the method was demonstrated over the concentration range of 2-10 mcg/ml of the target concentration. Accurately weighed 100 mg of pure drug was taken in clean, dry 100 ml volumetric flask and dissolved in small volume of methanol and made up the volume to 100 ml with methanol. This gave 1000 mcg/ml of drug concentration(Stock solution-I). From this 10 ml of solutionwas pipetted out into 100 ml volumetric flaskand volume was made upto the mark with water (Stock solution-II, 100 mcg/ml). Concentrations of 2, 4, 6, 8, and 10 mcg/ml were prepared fromabove prepared Stock solution-II, calibrationcurve was plotted and the correlation coefficientwas calculated.

Precision

Correlation coefficient of the linearity werefound for method and reported in Table No.1. The precision of an analytical method is thedegree of agreement among individual testresults when the method is appliedrepeatedly to multiple samplings ofhomogenous samples. It provides an indicationof random error results and was expressed ascoefficient of variation (CV).

Intra and inter-day precision

A variation of results within the same day (intraday),variation of results between days (interday)was analyzed. Intra-day precision wasdetermined by analyzing atenolol for five times in the same day at 549 nm. Interdayprecision was determined by analyzing thedrug daily once for five days at 549 nm.

Accuracy

Accuracy is the closeness of the test resultsobtained by the method to the true value. The recovery technique was performed to judge theaccuracy of the proposed method. For this,known quantities of the atenololsolution were mixed with definite amounts ofpre-analyzed formulations and the mixtureswere analyzed. The total amount of atenolol was determined by using the proposedmethod and the amount of added drug wascalculated by the difference.

Ruggedness and Robustness

The solutions were prepared and analyzedwith change in the analytical conditions likedifferent laboratory conditions and differentanalysts.

RESULT AND DISCUSSIONS

The optimum conditions for visiblespectroscopy method has been established byvarying the parameters one at a time andkeeping the other parameters fixed andobserving the effects of products on theabsorbance of the sample and colored species.Beer's law limits, molar absorbivity, Sandal'ssensitivity, %range of error and % relativestandard deviation are summarized in Table 1.The regression analysis using the method ofleast squares was made for the slope (b),intercept(a) and correlation coefficient(r)obtained from different concentrations aregiven in Table 1. The results showed that themethod have reasonable precision. To evaluatethe validity and reproducibility of the methods,known amounts of pure drug were added to thepreviously analyzed pharmaceutical dosageforms and the mixtures were analyzed by theproposed methods. The percentage recoveriesare given in Table.3. The interference studiesveiled that the common excipients and otheradditives that are usually present in the tablet dosage forms did not interfere at theirregularly added levels.

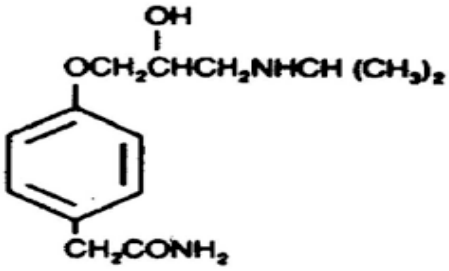

Fig. 1: Structure of Atenolol

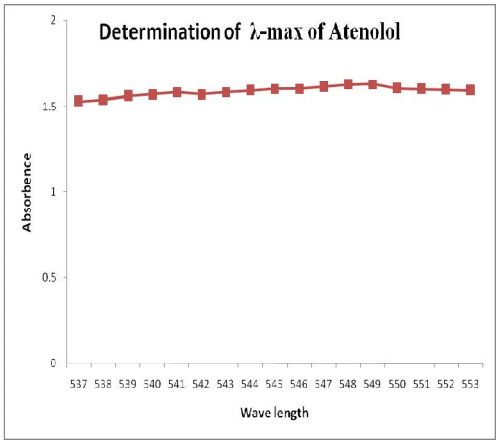

Fig. 2: λmax graph of Atenolol

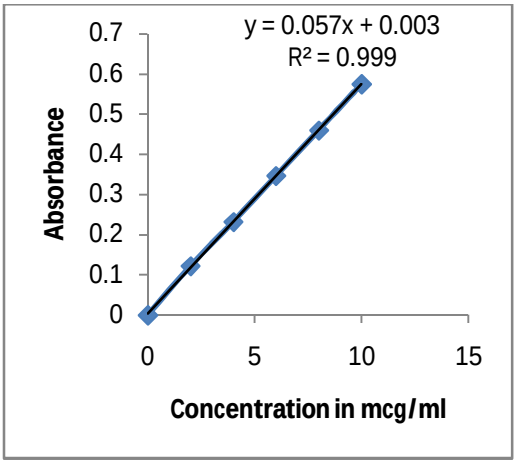

Fig. 3: Calibration curve for Atenolol (2-10 mcg/ml)

Table 1: Optimum conditions, Optical characteristics and Statistical data of the regression equation in visible spectrophotometry

Parameter	Visible spectrophotometry
λmax (nm)	549
Molar extinction coefficient (mol-1 cm-1)	0.0575 X104
Sandell's sensitivity (mcg/cm2-0.001 absorbance units)	0.0173
Regression equation (Y*)	Y= 0.0572 C+ 0 .0033
Slope (b)	0.0572
Intercept (a)	0.0033
Correlation coefficient(r2)	0.999
% RSD**	0.319
Limit of detection (mcg/ml)	5.88
Limit of quantitation (mcg/ml)	17.83

Table 2: Analysis of formulation

Drug	Amount (mg/tablet		% label claim	%RSD
	labelled	Found		
Atenolol	25	24.85	99.5	0.421

Table 3: Recovery Studies

Drug	Labelled clime (mg/Tablet)	Estimated amount (mg/Tablet)	Spike level (%)	Amount of drug added (mg)	Amount of drug recovered (mg)	Percentage recovery ± SD*
Atenolol	25	24.85	50	5	4.89	99.8± 0.251
			100	10	9.97	99.7± 0.327
			150	15	14.92	99.8± 0.293

CONCLUSIONS

From the results the method described in this paper for the determination of atenolol from tablet formulation is simple, accurate, sensitive and reproducible. The proposed method could be applied for routine analysis in quality control laboratories.

ACKNOWLEDGEMENTS

The authors are thankful to management of Sir Vivekananda Group of Institutions educational society for providing laboratory facilities.

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