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UV Spectrophotometric Method for the Estimation of Atenolol In Bulk and Pharmaceutical Formulations

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ABSTRACT

In this study, a simple, sensitive and highly accurate ultraviolet spectrophotometric method has been developed and validated for determination of atenolol in bulk and pharmaceutical formulations. The method is based on the measurement of the absorbance of atenolol solution in methanol: phosphate buffer pH 6.8 (10:90) at 224 nm in the wavelength range of 200 - 400 nm. Beer's law was obeyed in the concentration range of 5-25 µg/mL. The slope, intercept and correlation coefficient were also calculated. Results of percentage recovery shows that the method was not affected by the presence of common excipients in tablets. The developed method was validated in terms of accuracy, precision, linearity, limit of detection, limit of quantification which proves suitability of proposed method for routine estimation of atenolol in bulk and pharmaceutical formulations.

Keywords: Atenolol, Spectrophotometry, Estimation, Tablets.

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INTRODUCTION

Atenolol is β-receptor selective antagonist and is mainly used in treating hypertension, angina, heart failure, and myocardial infarction; chemically, it is 4-(2-hydroxyl-3-isopropyl aminopropoxy) phynylacetamide.[1] The physicochemical properties of atenolol are slight water solubility, low molecular weight (266.33), and suitable elimination half-life (6-7h).[2, 3] Atenolol competes with sympathomimetic neurotransmitters such as catecholamine for binding at beta1-adrenergic receptors in the heart and vascular smooth muscle, inhibiting sympathetic stimulation. This results in a reduction in resting heart rate, cardiac output, systolic and diastolic blood pressure, and reflex orthostatic hypotension[4] Hypertension may be treated with this drug because of their ability to increase the diameter of the blood vessels. Atenolol is available in oral dosage forms viz. tablet, syrups and capsules. In the tablet dosage this drug is commonly available in three different strengths that is 25, 50 and 100 mg[5.]

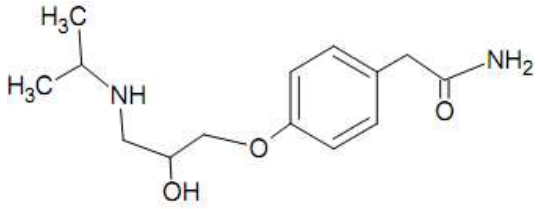

Figure 1: Structure of Atenolol

Literature survey reveals that several spectrophotometry[6], LC- MS [7], HPTLC [8], HPLC [9], RP-HPLC [10,11], and methods have been reported for the estimation of atenolol in pure and tablet dosage form. The scope of present investigation was to develop and validate UV spectroscopic method for quantification of atenolol in bulk and pharmaceutical formulations.

MATERIALS AND METHOD

Materials

Atenolol was obtained as a gift sample from BlueCross Ltd., Nashik, India. All analytical grade chemicals and solvents were supplied by S.D. Fine Chemicals, Mumbai, India. Distilled water was used to prepare all solutions. Freshly prepared solutions were always employed.

Equipment

The UV-Visible Spectrophotometer (Jasco-V630) with data processing system was used. The sample solution was recorded in 1cm quartz cells against solvent blank over the range 200-400nm. A Citizen electronic analytical balance was used for weighing the sample. An ultrasonicator bath (PCI Analytics Pvt. Ltd.) was used for sonicating the tablet powder.

Development of Method

Accurately weighed 10 mg of atenolol was solubilized by 1 ml of methanol in a 10 ml volumetric flask, and phosphate buffer pH 6.8 was added to make up the volume so as to give stock solution of concentration 100 µg/ml. The standard solutions were diluted with phosphate buffer pH 6.8 to obtain various dilutions (5, 10, 15, 20, 25 µg/ml) in standard volumetric flasks (10 ml). The dilutions were scanned in the wavelength range of 200-400 nm. The maximum of atenolol was found at 224 nm. The linear relationship was observed over the range of 5-25 µg/ml. Absorbances were noted at 224 nm against pH 6.8 phosphate buffer as a blank. A calibration graph of the absorbance versus the concentration of the drug was plotted and represented in figure 2.

Procedure for dosage forms

For analysis of commercial formulations, twenty tablets were taken and powdered. Tablet powder equivalent to 10 mg of atenolol was dissolved in small quantity of methanol into a 100 mL volumetric flask and final volume was made up to 100 ml with pH 6.8 phosphate buffer and sonicated for 30 minutes. Then the absorbance of the solution (after suitable dilution) was measured at 224 nm using UV/visible spectrophotometer (Jasco-V630) against pH 6.8 phosphate buffer as a blank. The % drug content was calculated with the help of calibration curve (n=3).

VALIDATION OF THE PROPOSED METHOD

The proposed method was validated according to the (ICH) guidelines [12,13.]

Linearity (Calibration curve)

The developed method validates as per ICH guidelines. The plot of absorbance verses concentration is shown in figure 1. It can be seen that plot is linear in the concentration range of 5-25 µg/ml with correlation coefficient (R^2) of 0.996.

Precision (repeatability)

Intraday and interday precision was determined by measurement of the absorbance for three times on same day and on three different days. The relative standard deviation for replicates of sample solution was less than 2% which meet the acceptance criteria for established method. The obtained results are presented in table 1.

Accuracy (recovery study)

Recovery studies were carried out by adding a known quantity of pure drug to the preanalysed formulations and the proposed method was followed. From the amount of drug found, percentage recovery was calculated as per ICH guidelines. The data were presented in table 2.

LOD and LOQ

The limit of detection (LOD) and limit of quantification (LOQ) of the drug were separately determined based on method of the intercept and the average value of slope. (i.e. 3.3 for LOD and 10 for LOQ) ratio using the following equations designated by ICH guideline.

$LOD = 3.3\ \sigma/S$ $LOQ = 10\ \sigma\ /S$

Where, σ = the standard deviation of the response, S = slope of the calibration curve.

RESULTS AND DISCUSSION

Beer's law is obeyed over the concentration range of 5-25 µg/ml, using regression analysis the linear equation y = 0.0338 x + 0.0218 with a correlation coefficient of 0.996. The limit of detection was found to be 0.49685 µg/mL. The limit of quantification was found to be 1.5056 µg/mL. The percentage purity of atenolol in Brand I (ATECARD), Brand II (ATEN-50) was found to be 100.5, 98.5 % respectively. Precision was calculated with intra and interday variation. Recovery study was performed on formulations and % RSD was found. The optical parameters such as Beer's law limit, slope, and intercept values were calculated and given in table 3. Method was validated for accuracy and precision. The accuracy of method was proved by performing recovery studies in commercially available formulations. The results were given in table 2 and shows relative standard deviation of less than 2 % was observed for analysis of three replicate samples, indicating precision and reproducibility. The percentage recovery value indicates that there is no interference from the excipient present in the formulation. The applicability of the proposed method for the assay of atenolol in tablet formulation was examined by analyzing commercial formulations and the results are tabulated in table 4. The result obtained were good agreement with the label claims of marketed products. The results of analysis of the commercial tablets and the recovery study of the drug suggested that there is no interference from any excipient such as starch, lactose, magnesium stearate which are commonly present in tablets.

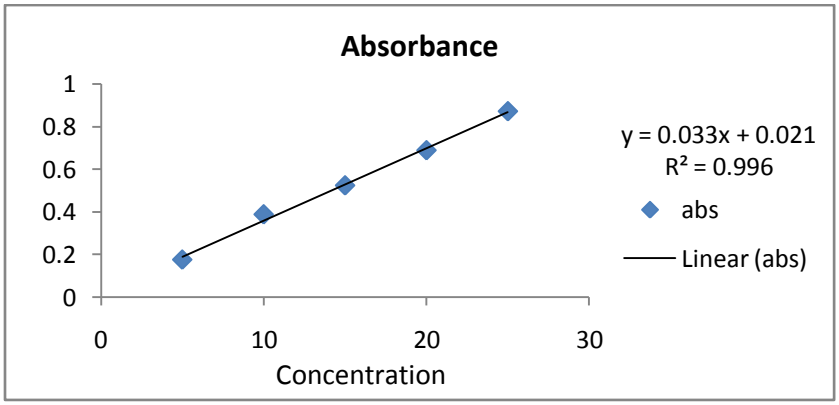

Figure 2: Calibration curve of atenolol at 224 nm

Table 1: **Precision study for proposed method**

Concentration µg/ml	Absorbance Mean	Standard deviation	% Relative standard deviation
Intraday Precision (n= 3)			
5	0.199267	0.003004	1.507471
10	0.41523	0.004261	1.026195
15	0.483667	0.008001	1.654333
Interday Precision (n= 3)			
5	0.146	0.002452	1.67913
10	0.2789	0.005537	1.984662
15	0.4191	0.008388	2.001452

Table 2: Recovery study

Sr. No	Label claim, mg/tablet (ATEN-50)	Amount of standard added, mg	Total amount recovered, mg	% Recovery	Standard deviation	% Relative standard deviation
1	50	5	54.95	99.90%	0.001212	0.6275
2	50	10	60.16	100.2%	0.00075	0.3519
3	50	15	66.42	102.1%	0.00361	0.6056

Table 3: **Optical parameters for determination of atenolol**

Sr no.	Parameter	Data
1	λ-Max	224 nm
2	Beer's law limit	5-25 µg/mL
3	Regression equation	Y = 0.0338x +0.0218
4	Correlation coefficient	R^2 = 0.996
5	Slope	0.0338
6	Intercept	0.0218
7	Limit of detection	0.49685 µg/mL
8	Limit of quantification	1.5056 µg/mL

Table 4: **Results of assay**

Formulation	Label claim, mg/tablet	Amount found*, mg/tablet	% Amount found	% Coefficient of variance
Brand I (ATECARD)	50	50.25 mg	100.5 %	4.65
Brand II (ATEN 50)	50	49.25 mg	98.5 %	5.99

*Mean of three determinations.

CONCLUSION

The simple spectrophotometric method for determination of atenolol have been developed and validated as per ICH guidelines. The developed method is found to be sensitive, accurate and reproducible and can be used for the routine quality control analysis of atenolol in bulk and pharmaceutical formulations.

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