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Research Article

DEVELOPMENT OF AN ANALYTICAL METHOD AND ITS VALIDATION FOR THE ANALYSIS OF ATENOLOL IN TABLET DOSAGE FORM BY UV- SPECTROPHOTOMETRY

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ABSTRACT

Objective: There is no analytical method yet reported for estimation of Atenolol using ammonium acetate solution as a solvent pH6 either in single dosage form or in combination by UV spectroscopy. So, the present work is aimed to develop a simple, precise, accurate and new spectrophotometric method in ultra violet region for the estimation of Atenolol in its tablet dosage form. Atenolol exhibited maximum absorbance at 273.2nm in ammonium acetate solution. It obeys Beer's law in the concentration range of 2-30mcg/ml.

Method: The absorbance was found to increase linearly with increasing concentration of Atenolol, which is corroborated by the calculated correlation coefficient value of 0.9976 (n=10). The slope of the Atenolol was found to be 0.0348. The limit of detection and limit of quantification was found to be 0.05 µg mL-1 & 0.17 µgmL-1. The validity of the described procedure was assessed. Statistical analysis of the result has been carried out revealing high accuracy and good precision. The proposed method was successfully applied to the determination of Atenolol in pharmaceutical formulations without any interference from common excipients.

Results: The relative standard deviations were ≤0.055%, with reproducibility values of 98.75% -100.16%. Results were validated for its repeatability, reproducibility studies and validated statistically.

Conclusion: The proposed method of analysis is novel, simple, accurate and reproducible. This method can be routinely employed in the analysis of Atenolol in tablet formulations precluding using ammonium acetate solution as a solvent.

Keywords: Analytical Method, Atenolol, UV-Spectrophotometry

INTRODUCTION

Atenolol designated chemically as (RS)-4-(2-hidroxy-3-isopropylaminopropoxy) phenylacetamide, is commercially available as a racemic mixture (Fig. 1), it is found in the form of tablets, oral solution, and sterile solution for injectable. Atenolol (ATN) is a selective (cardioselective) adrenergic receptor-blocking agent without membrane-stabilizing or intrinsic sympathomimetic (partial agonist) activities [1]. ATN is also used to treat myocardial infarction (heart attack), arrhythmias (rhythm disorders), angina (chest pains), and disorders arising from decreased circulation and vascular constriction, including migraine [2]. Other described methods in literature has revealed that several methods such as capillary electrophoresis[3], Ultra-performance liquid chromatography (UPLC)[4], Titrimetric, spectrophotometric and kinetic methods[5,6] and high performance liquid chromatography (HPLC) have been reported for the analysis of ATN either in pharmaceutical preparations [7-11] ,or in biological fluids [12-16].

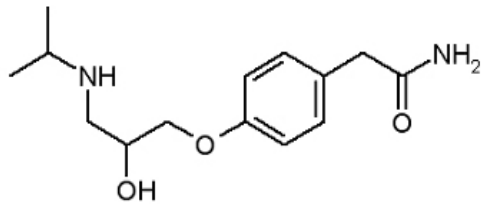

Fig. 1: Chemical Structure of Atenolol

MATERIALS AND METHODS

Single pan electronic balance- sartorious GE412, UV visible spectrophotometer, UV visible double beam spectrophotometer, Systronics2203(smart), Matched quartz cells corresponding to 1 cm path length. Pure samples of Atenolol were obtained from kaushik therapautics pvt Ltd., gurrcumbakkam, Chennai, India. Ammonium acetate solution pH6 of analytical grade were purchased from Arun pharmaceuticals Pvt Ltd., Kadapa, India.

Reagents: Ammonium Acetate solution pH 6, Reference standard Atenolol.

Procedure

Preparation of standard stock solutions

The standard stock solution of drug was prepared by dissolving 25mg of the drug in 25 ml standard flask using Ammonium acetate as a solvent to give a concentration of 1000 µg/ml.

This stock solution on further dilutions are used for establishing following parameters. The final concentrations were made from 1 to30 µg/ml.

Preparation of Ammonium acetate solution pH6

Dissolve 100mg of Ammonium acetate in 300ml of water, add 4.1ml of glacial acetic acid and adjust the pH 6 If necessary using 10M ammonia or 5M acetic acid and dilute with water to 500ml.

Wavelength Selection

Concentrations of solution from 10-12mcg/ml were prepared and were subjected to scanning from 200-400nm using ammonium acetate solution as solvent. From obtained absorbances values, 273.2 nm was selected as λmax for the present work.

Analysis of Tablet Formulation

Twenty tablets were finely powdered. An accurately weighed quantity of powder equivalent to about 100mg of Atenolol was transferred to a 100ml standard flask. The contents of the flask were mixed with the ammonium acetate solution and dissolve the active ingredients and then make up to the volume with the same solvent. The solution was filtered and the filtrate was further diluted with ammonium acetate solution to give a final drug concentration of 1 to 30µg/ml. Absorbance values of sample solution were recorded at 273.2nm.

The proposed method is validated for the following parameters.

Repeatability studies

Reproducibility studies

Determination of Repeatability

Repeatability can be defined as the precision of the procedure when repeated by same analyst under the same operating conditions

(same reagents equipments, settings and laboratory) over a short interval of time. It is normally expected that at least six replicates be carried out and a table showing each individual result provided from which the mean, standard deviation and co-efficient of variation should be calculated for set of n value. The RSD values are important for showing degree of variation expected when the analytical procedure is repeated several time in a standard situation. (RSD below 2% for built drugs, RSD below 2% for assays in finished product).

The ICH documents recommend that repeatability should be assessed using a minimum of nine determinations covering the specified range for the procedure (i.e. three concentrations and three replicates of ach concentration or using a minimum of six determinations at 100% of the test concentration).

Determination of Reproducibility

Reproducibility means the precision of the procedure when it is carried out under different conditions-usually in different laboratories-on separate, putatively identical samples taken from the same homogenous batch of material. Comparison of results obtained by different analysts, by the use of different equipments, or by carrying out the analysis at different times can also provide valuable information [17, 18].

RESULTS AND DISCUSSION

The UV spectra of Atenolol were presented. The absorption maxima was observed at 273.2nm. Obeyance to beers law was confirmed by the linearity of the calibration curve of Atenolol. Atenolol showed linearity in the concentration range of 2-30 µg/ml. Linearity data was given in table 1 and the curve was shown in Figure 1.

Table 1: Data for Linearity of Atenolol

S. No.	Concentration(µg/ml)	Absorbance
1	2	0.057
2	4	0.189
3	6	0.200
4	8	0.258
5	10	0.368
6	12	0.410
7	14	0.457
8	16	0.500
9	18	0.505
10	20	0.510

Linearity Curve

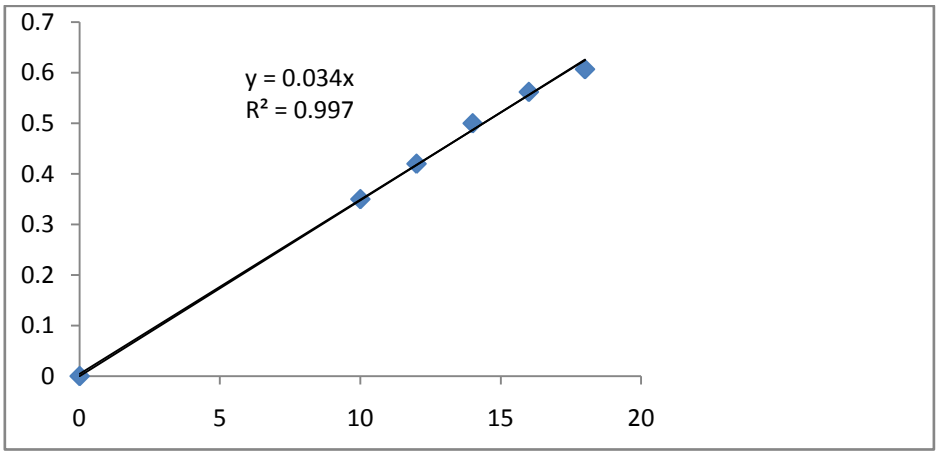

Fig. 2: Absorbance Vs Concentration

Table 2: Results of the Marketed Atenolol

S. No	Concentration (µg/ml)	Label claim (mg)	Amount present (mg/tab)	Amount present (mg/tab)	Percentage Deviation (%w/w)
1	10	25	24.38	99.2	±0.8
2	12	25	24.48	100.2	±0.2
3	14	25	24.33	99.3	±0.7
4	16	25	24.44	101.6	±0.4

The quantitative estimation was carried out in tablet formulations by taking concentrations of 2-30 µg/ml. The brands of formulation shows the percentage purity values range from 99.2 to 101.6 the percentage deviation values were found to be between +0.2 to 0.8 and the values shown in table 3.

Repeatability

The repeatability of the method was confirmed by the assay procedures with same concentrations of 3 replicates each. The data is given in tables 4. The results obtained in repeatability test expresses the precision of the given method.

Table 3: Results for Statistical Data of Atenolol

S. No.	Drug Name	%Assay Mean	Standard Deviation (S.D.)	Relative Standard Deviation(R.S.D)
1	Atenolol	99.87	0.57	0.055

Table 4: Results of Repeatability Studies of Atenolol

S. No.	Concentration(µg/ml)	Assay (%)	Assay Mean	Standard Deviation(S.D)
1	12	100.16		
2	12	100.2	100. 2	0.289
3	12	100.0		

Table 4: Results of Reproducibility Studies of Atenolol

S. No.	Concentration(µg/ml)	Amount Present (Day 1)	%Found (Day 1)	Standard Deviation (Day 1)	Amount Present (Day 2)	%Found (Day 2)	Standard Deviation (Day 2)
n1	6	5.95	99.16	0.0014	5.93	98.83	0.0041
2	6	6.02	100.3	0.0013	6.02	100.3	0.0041
3	6	6.04	100.6	0.0012	6.01	100.2	0.0039
4	8	8.09	101.10	0.0021	8.06	100.7	0.0014
5	8	8.03	100.3	0.0022	8.07	100.8	0.0013
6	8	7.9	98.75	0.0023	8.03	100.3	0.0039
7	10	10.05	100.5	0.0014	10.05	100.5	0.0014
8	10	10.10	101.5	0.0013	10.10	100.0	0.0014
9	10	10.5	100.0	0.0015	10.11	101.1	0.0014
10	12	12.02	100.16	0.0007	12.11	100.9	0.0028
11	12	12.05	100.4	0.0006	12.11	100.9	0.0028
12	12	12.03	100.25	0.0007	12.05	100.4	0.0027

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