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Research Article

Novel spectrophotometric estimation of atenolol using hydrotropic solublizing agent

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Abstract

The Ultraviolet absorption spectrophotometric method for the estimation of poorly water soluble drug like Atenolol in pharmaceutical formulation has been developed aqueous solubility of this selected model drug was in 5M Urea solution. The primary objective of the present investigation was to employ these hydrotropic solutions to improve solubility of poorly soluble drug, without use of costlier organic solvents. The selected wavelength for Atenolol was 275 nm. The hydrotropic solution did not interfere in estimation method development. The result analyses have been validated statistically and recovery studies. The proposed methods are new, simple, economic, accurate safe and precise.

Keywords: Atenolol, Hydrotropic Urea, Spectrophotometric Estimation.

Introduction

Increasing solubility of insoluble and slightly soluble drug is the major importance.varrious techniques have been employed to enhance the aqueous solubility of poorly water soluble drug. Hydrotropic Solublisation is one of them. The term hydrotropy has been used to designate the increase solubility of various substances in water by use of large amount additives such as Urea, Sodium benzoate, sodium acetate, Thiourea have been employed to increase solubility of poorly water soluble drug Various organic solvents like methanol, chloroform, alcohol have been used for solublisation of poorly water soluble drugs for spectrophotometric estimation. Drawbacks of Organic solvents include higher cost, toxicity, pollution and error, in analysis due to volatility. The primary objective of this study was to employ hydrotropic solubilizing agents for Atenolol to preclude the use of organic solvents. These hydrotropic solution did not interfere inthese method development .This method statistically validated

Materials and Methods

Materials

Atenolol pure standards were received as gift samples from micro labs Pharmaceuticals Bangalore (India). All other reagentsused were UV grade.

Apparatus:

UV- Shimadzu 1800, Centrifuge, Cuvette .

Method

Preparation of 5 M Urea Solution

30 gm of urea salts was weighed and dissolved in 100 ml water and centrifuge for 2hrs.

Preparation of Standard Solution

Accurately weigh 100 mg drug transfer into 100 ml volumetric flask dissolved with 5 M urea solution and volume was made up to 100 ml with water to

get concentration 1000 ug/ml (Stock A Solution).
10 ml of Stock A solution was taken in 100 ml volumetric flask and diluted upto 100 ml to given 100 ug/ml (Stock B).
From these stock B Solution of Atenolol prepare different concentration of 200, 250, 300, 350, 400, 500, 1000 ug/ml were selected and scanned at selected wavelength 275 nm.

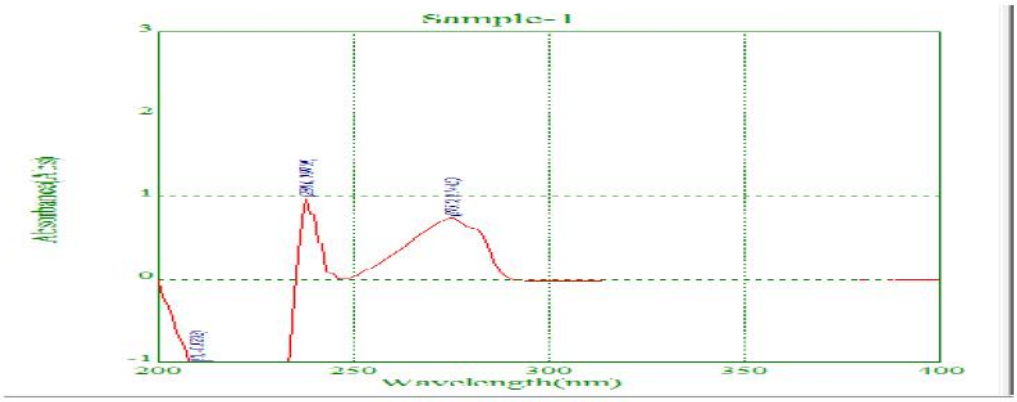

Fig :1Absorption Peak of Atenolol in Urea

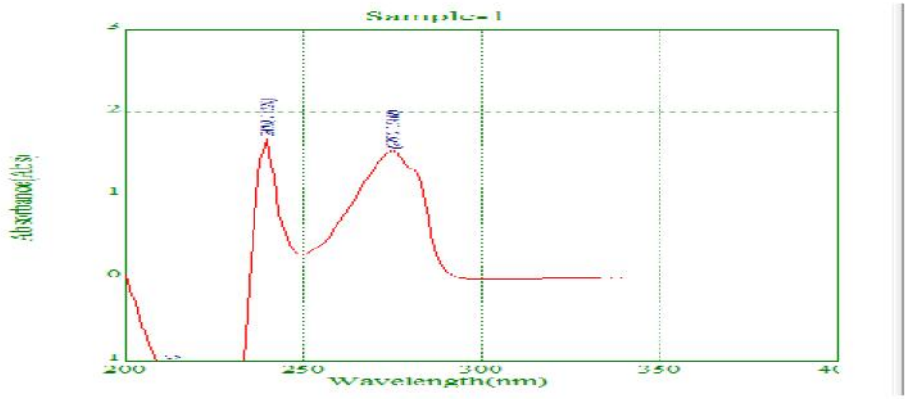

Fig :2 Absorption Peak of Atenolol in Methanol

Validation Parameters

Accuracy

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The method was validated in accordance to ICH guidelines Recovery study was performed by standard addition method by adding the known amount of Atenolol (Reference and standard) to placebo at three different concentration levels i.e. 50%, 100% and 150% of assay concentration and % recovery for drug was calculated.% Recoveries of Atenolol in urea solutionwere found in the range of 96.48% where as in organic solvent(Methanol)97.38%.

Table no.1Accuracy study of Atenolol in Urea

Sr.No	Preanalysed	50% 100ug/ml	100% 200 ug/ml	150% 250 ug/ml
Replicate1	0.1994	0.7289	0.8248	1.1544
Replicate2	0.1998	0.7295	0.8254	1.1532
Replicate3	0.1943	0.7285	0.8230	1.1541
Mean	0.1978	0.7289	0.8244	1.1539
SD	0.00306	0.000503	0.001249	0.000624
RSD	1.5500	0.069008	0.1515	0.0540

Table no. 2 Accuracy study of Atenolol in Methanol

Sr.No	Preanalysed	50% 100ug/ml	100% 200 ug/ml	150% 250 ug/ml
Replicate1	0.2648	0.3704	0.6332	0.9054
Replicate2	0.2672	0.3699	0.6351	0.9092
Replicate3	0.2687	0.3698	0.6353	0.9115
Mean	0.2669	0.3700	0.6345	0.9087
SD	0.001967	0.000321	0.001159	0.0003081
RSD	0.7369	0.00867	0.18266	0.3390

Precision

The system precision was checked by using standard Atenolol to ensure that
the analytical system is precise.

Day to day study

Day was determined by analyzing the combined standard solutions of Atenolol (200,250,300 µg/ml) at three different day. The % RSD of precision study of these drugs was found to be less than 1 %

Table No. 3 Day to Day Variation for(Urea Solution)

Concentration in ug/ml	200	250	300
Day 1	0.477	0.6475	0.9064
Day 2	0.4785	0.6459	0.9087
Day 3	0.4890	0.6618	0,9135
Mean	0.4885	0.6460	0.9095
SD	0.006538	0.00864	0.003568
RSD	1.33707	1.33746	0.39230

Table No.4 Day to Day Variationfor (Methanol Solution)

Concentration in ug/ml	200	250	300
Day 1	0.5757	0.9108	1.2600
Day 2	0.5776	0.9127	1.2610
Day 3	0.5812	0.920	1.2580
Mean	0.5781	0.9145	1.2597
SD	0.003066	0.004837	0.001185
RSD	0.53035	0.53110	0.09136

Analyst to Analyst Study

Analyst to Analyst study 3 Replicates of 200,250,300 µg/ml were selected and scanned at selected wavelength 275nm (λ_{max})

Table No.5 analyst to analyst Study forUrea solution

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Concentration in ug/ml	200	250	300
Analyst 1	0.477	0.6475	0.9063
Analyst 2	0.4747	0.6451	0.9742
Analyst 3	0.4894	0.6521	0.9140
Mean	0.4802	0.6482	0.9715
SD	0.007679	0.003503	0.04504
RSD	1.5991	0.54041	0.49413

Table No.6 analyst to analyst Study for Methanol solution

Concentration in ug/ml	200	250	300
Analyst 1	0.5784	0.9144	1.2578
Analyst 2	0.5781	0.9136	1.2584
Analyst 3	0.5797	0,9131	1.2626
Mean	0.5787	0,9137	1.2596
SD	0.000855	0.000656	0.002615
RSD	0.14688	0.71795	0.20760

Linearity and Range

The solutions for linearity were prepared in the concentrations as follows and absorption peak area was plotted against the concentration of the each drugs. From the data obtained,corelation coefficient, slope and y-intercept were calculated.

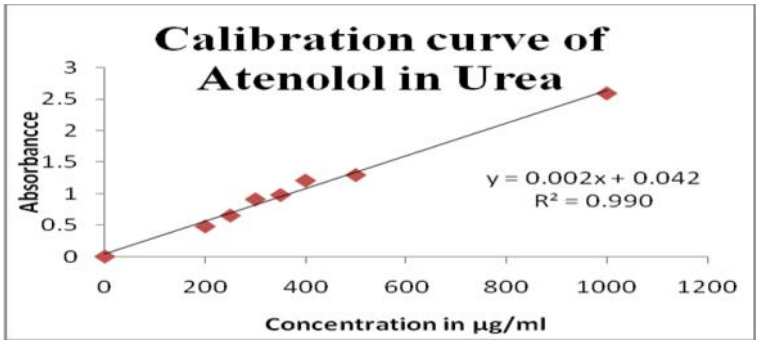

Fig :- 03 Calibration Curve of Atenolol In Urea

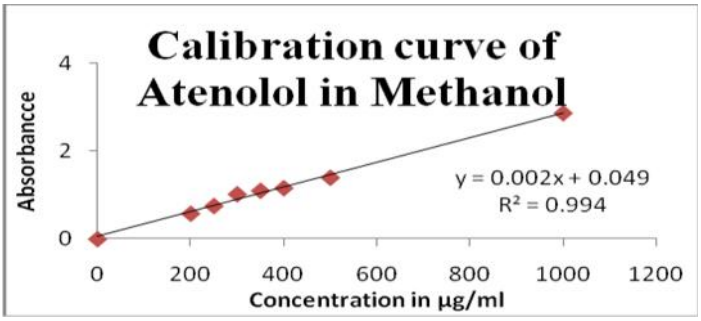

Fig :- 04 Calibration Curve of Atenolol In Methanol

Table No.7 Results of Linearity

Parameters	Result
Linearity and range	200-1000µg/ml
Slope	0.002822
Intercept	0.052494
Correlation coefficient(r^2)	0.994
Regression equation	Y=0.002x+0.049

Limit of Detection and Limit of Quantization

The LOD & LOQ of atenolol by proposed method was determined using calibration standards. LOD & LOQ were calculated as **3.3 σ/s** and 10 **σ/s.**Respectively, where **S** is theslope of the calibration curve and **σ** is the Standard deviation of response.The results of the same are shown in following table.

Table No.8 LOD & LOQ

Sr.No.	In Urea Solution	In Methanol Solution
LOQ	8.79µg/ml	11.32µg/ml
LOD	2.90 µg/ml	3.73 µg/ml

Result and Discussion

The present paper describes application of hydrotropic solublization phenomenon for the simultaneous estimation of Atenolol in bulk dosage form by simultaneous estimation method. The drug showed good regression values at their respective wavelength. The LOD & LOQ indicated good sensitivity of proposed methods. Hence Proposed methods are new, simple, cost effective, accurate, sensitive free from pollution and precise and can be adopted for routine analysis of Atenolol in bulk dosage form .Precision was determined by studying the day to day variation and analyst to analyst variation. The standard deviation, coefficient of variance and standard error were calculated for Atenolol bulk dosage form. The results were mentioned in following table.

Table No. 9 Result Table For Urea

Sr,No	**Parameter**	**Result**
1	λ_{max}	275nm
2	Beer‟s range	200-1000µg/ml
3	Correlation coefficient(r^2)	0.995
4	Regression equation	Y=0.002x+0.042
5	Intercept	0.052494
6	Slope	0.002822
7	LOQ	8.79µg/ml
8	LOD	2.90 µg/ml
9	% Recovery	96.48%

Table No.10 Result Table for Methanol

Sr.No.	Parameter	Result
1	λ_{max}	275
2	Beer‟s range	200-1000ug/ml
3	Correlation coefficient(r^2)	0.994
4	Regression equation	Y=0.002x+0.049
5	Intercept	0.052494
6	Slope	0.002822
7	LOQ	11.32µg/ml
8	LOD	3.73µg/ml
9	% Recovery	97.38%

Conclusion

Thus, it may be concluded that the proposed method of analysis, using Urea as the hydrotropic solubilizing agent is new, simple, cost-effective, environmentally friendly, safe, accurate and reproducible. Urea commonly used tablet excipients did not interfere in Spectrophotometric estimation at 275 nm. Decided advantage is that organic solvents are precluded but not at the expense of accuracy. The proposed method is worth adopting in pharmacopoeia. By proper choice of hydrotropic agents, the use of organic solvents in analysis may be discouraged to a large extent. The proposed method shall prove equally effective to analyze Atenolol in the corresponding drug sample and may prove to be of great importance in pharmaceutical analysis.

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