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Research

Analytical Method Development And Validation Of Alfuzosin HCL By UV- Spectrophotometer

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Abstract

A specific, precise, accurate, reproducible and robust method was developed for the estimation of Alfuzosin Hcl by UV Spectroscopy using pH 7.4 phosphate buffer as a solvent. Absorption spectrum was obtained by scanning from 200-400nm and the maximum absorbance was found at 350nm. Then the method was optimized and validated with various validation parameters as per ICH guidelines. From the linearity studies correlation coefficient was found to be 0.9995. From precision and intermediate precision studies %RSD was found to be 0.573 and 0.097 respectively. Assay was conducted by using marketed formulation of AlfuzosinHcl and the % purity was found to be 98.5%. Hence the method was suitable for the estimation of AlfuzosinHcl by UV Spectroscopy. carried out at three different levels i.e. at 80%, 100% and 120%. The method was validated statistically.

Keywords: UV- spectroscopy, Alfuzosin hydrochloride, Assay, Method development, Method validation.

INTRODUCTION

Alfuzosin hydrochloride is chemically designated as N-{3-[(4-Amino-6,7-dimethoxyquinazolin-2-yl(methyl)amino] propyl} tetrahydro- 2-furamide hydrochloride (1).Alfuzosin hydrochloride, a selective alpha adrenergic antagonist is used against benign prostatic hypertrophy (BPH) in elderly males(2-4).The prostate gland of the patients enlarges in BPH and prevents urine flow from the bladder which results in urinary retention. The treatments available are surgical removal of excess tissue or drug therapy (5). Two classes of drugs are used, 5-alpha reductase inhibitors and alpha-adrenergic antagonists. The second class includes terazosin, doxazosin, tamsulosin and alfuzosin. Alfuzosin is freely soluble in water, and thus readily absorbed after administration(6-7).Few analytical methods have been reported for the determination of alfuzosin in pharmaceuticals and biological fluids. A review of the literature suggests that there aren't many chromatographic 2–6 Methods that have been published for AFZ estimation. To the best of our knowledge, there hasn't been any research on the

spectrophotometric approach for AFZ analysis in either biological fluids or drug formulations published in the literature. In order to estimate AFZ in bulk pharmaceuticals and pharmaceutical formulations (8). Literature review shows that the UV, HPLC methods have been reported for the estimation of Alfuzosin. In the present work a new spectrophotometric method was developed and validated according to ICH guidelines. The structure of Alfuzosin was shown in Fig.no.1

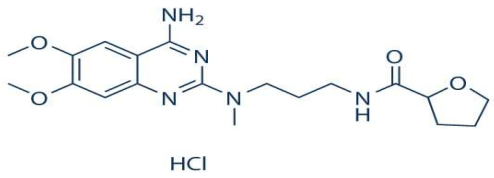

Fig 1: Structure Of Alfuzosin Hcl

MATERIALS AND METHOD

AlfuzosinHcl pure drug was obtained from Dr. Reddy's Laboratories marketed as Alfuzosin tablets (40mg), UV Visible Spectrophotometer (T-60).phosphate buffer was procured from FinarLabs.

Solubility

The drug is insoluble in Dichloromethane and sparingly soluble in Alcohol and Solvents that are soluble in organic solvents are n-hexane, cyclohexane, methanol, water, and ether. As a solvent, we choose a pH 7.4 phosphate buffer because it meets the criteria and is readily available.

Preparation of diluent

Dissolve 1 gm of Alfuzosin in 100 ml of pH 7.4 phosphate buffer to get Alfuzosin.

Determination of λmax of Alfuzosin drug

The 10 mg of drug is solubilised in 10 ml phosphate buffer from the above 1 ml solution it is made up to 10 ml. the above 1 ml solution is diluted to 10 ml and absorbance is measured. Scan the standard solution in 1 cm square cell over the range of 200-400 nm using diluent as blank.

Preparation of Dilutions

Different aliquots of drug solution 0.2 mL, 0.4 mL, 0.6 mL, 0.8 mL, 1.0 mL was taken from 100 µg/mL and was transferred into 10 mL volumetric flask and the volume was made up to 10 mL with phosphate buffer pH 7.4 to give 2µg/mL, 4µg/mL, 6µg/mL, 8µg/mL and 10µg/mL respectively and absorbance of all the solutions were measured at 350 nm.

Linearity

Calibration curve was plotted by taking absorbance of 2µg/mL to 10µg/mL by taking concentration on x -axis and absorbance on y -axis.

Precision

Precision of the method was determined by repeatability (Intraday precision) and intermediate precision (Inter-day precision) for standard solution (6µg/mL) by six replicate absorbance measurements from the homogenous solution and the %RSD was calculated. The results were expressed as % RSD of the measurement.

LOD and LOQ

The detection limit of an individual's analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value. Quantification limit of an individualanalytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy.

LOD =3.3Sa/b (Equation-1)
LOQ=10 Sa/b (Equation-2)
Sa = the standard deviation of the intercept

b = Slope of the calibration curve

Robustness
The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provide an indication of its reliability during normal usage. It was performed by varying λmax value of ±1 nm for 6µg/ml in triplicate.

Accuracy
The accuracy of an analytical method is the closeness of the test results obtained by that method to the true value. Accuracy of the method demonstrated at three different concentration levels 80%, 100% and 120%, by spiking a known quantity of standard drug into analyzed sample in triplicate.

Assay
Marketed formulation of Alfuzosin was selected, 10 tablets were randomly selected and analysed using the newly developed and validated method. Take the tablets in mortar and pestle to crush in powder. 5% solution of Alfuzosin tablet powder is dissolved in 10 mL of pH 7.4 phosphate buffer and it was further diluted to give 1mg/ml or 1000µg/ml. 1mL from the above sample solution was made up to 10ml with pH 7.4 phosphate buffer to give 100µg/ml. Take 0.2 mL solution from the above and made up to 10 mL with phosphate buffer pH 7.4 gives 20 µg/m L after mixing, filter the solution using Whattman filter paper to get clear solution. Measure the absorbance of the solution six replicates at 350nm

RESULTS AND DISCUSSION

Linearity
Five linearity solutions were prepared by using Alfuzosin HCL active pharmaceutical ingredient at concentration levels raising from 50-150% of target concentration of tablets using pH 7.4 phosphate buffer as diluent, measure the absorbance of solutions in 1 square cm cell on a suitable UV Spectrophotometer at about 350 nm using diluents as blank. The Linearity data was shown in table no. 1. And the calibration curve was shown in Fig. no. 2.

Table 1: Linearity

S.No	Concentration	Absorbance
1	2	0.129
2	4	0.198
3	6	0.277
4	8	0.359
5	10	0.488
	Mean	0.289
	Slope	0.0395
	R²	0.9995

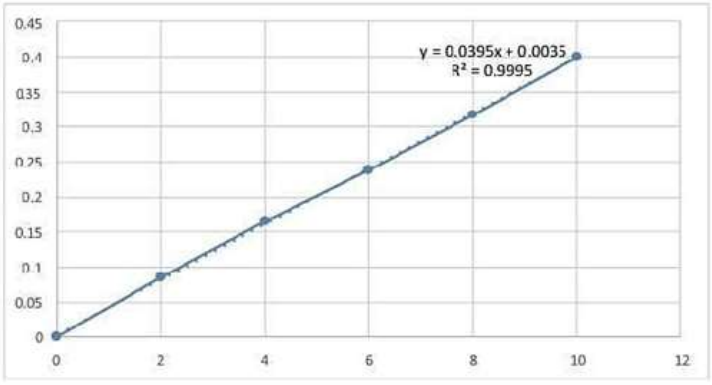

Fig 2: Calibration curve of Alfuzosin HCL

Table 2: Optical Characteristics of Alfuzosin

Parameters	Alfuzosin Hcl
λmax	350nm
Slope	0.0395
Intercept	0.0035
Linearity	2-10 µg/m
Correlation coefficient	0.9995

Calibration curve was plotted and correlation coefficient was found to be 0.9995. So, there was a good correlation between absorbance and concentration.

Precision

Intraday and Inter-day precision data was shown in Table 3 and 4 respectively.

Table 3: Intra Day Precision

Concentration	Absorbance
8	0.513
8	0.511
8	0.509
8	0.516
8	0.512
8	0.514
Mean	0.518601
SD	0.003980
% RSD	0.57471

Table 4: Inter-day Precision

Concentration	Absorbance (Day 1)	Absorbance (Day 2)
8	0.514	0.516
8	0.515	0.517
8	0.511	0.512
8	0.516	0.518
8	0.512	0.513
8	0.513	0.515
Mean	0.514220	0.52311
SD	0.003858	0.001889
%RSD	0.56921	0.57114

The % RSD for Intraday and Inter-day precision was found to be < 2%. It indicates that the method was precise.

Accuracy

Accuracy was performed at 80%, 100% and 120 % of target concentration of Alfuzosin HCL in triplicate as per the test method.The accuracy data was shown in table no. 5

Table 5: Accuracy

S. no	Level of addition %	Amount of pure drug added(mg)	Absorbance	Amount of drug found	%Recovery
1	80	4	0.342	4.14	99.2
	80	4	0.345	4.08	99.8
	80	4	0.349	4.92	99.6
2	100	6	0.426	6.64	100.4
	100	6	0.428	6.45	100.2
	100	6	0.429	6.18	100.5
3	120	8	0.514	8.48	101.6

120	8	0.516	8.26	101.2
120	8	0.518	8.58	101.9

The average % recovery of Alfuzosin HCL was found to be within the limits 98-102%

Table6: LOD & LOQ

S. No	Parameters	Alfuzosin Hcl (ug/ml)
1	LOD	1.849 ug/ml
2	LOQ	2.731 ug/ml

Robustness

Robustness was performed for six sample solutions at different wavelengths. The robustness data was shown in table 7.

Table 7: Robustness

Concentration	Absorbance(348nm)	Absorbance (352nm)
6	0.349	0.364
6	0.346	0.369
6	0.348	0.362

There was no much variation in the absorbance with change in wavelength**.**

Assay

Accurately weigh 10mg of Alfuzosin HCL in a 10ml volumetric flask and make up to 10ml with pH 7.4 phosphate buffer. From the above solution transfer 1ml and make up to 10ml with pH 7.4 phosphate buffer. Pipette out 0.6ml and make up to 10ml with pH 7.4 phosphate buffer andmeasure the absorbance at 350nm.

=0.245/0.255 *50/50*1/100*100/258*50/5*258/10*100
= 98.5%

Alfuzosin HCL was 99.8% which was comparable with the label claim amount. It shows that the developed UV method was successful in determining from Alfuzosin HCL tablet dosage form.

CONCLUSION

A new method was developed and validated for the determination of Alfuzosin Hcl using UV spectroscopy. The proposed method was found to be simple, accurate, precise, reproducible and robust. The developed method can be applied for the assay of commercial tablets containing Alfuzosin Hcl in routine quality control analysis.

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