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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF BUSPIRONE HYDROCHLORIDE IN BULK AND ITS PHARMACEUTICAL FORMULATION BY UV SPECTROMETRY

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ABSTRACT

Simple, accurate, rapid and sensitive method developed for the determination of buspirone hydrochloride in bulk drug and in its tablets by UV Spectroscopy. In mmethod, buspirone hydrochloride estimated at 244 nm using distilled water as a solvent. The linearity was observed in the concentration range of 2-12 µg/ml with correlation co efficient of 0.998. The result of analysis for the method was validated statistically and by recovery studies. Validation was performed according to ICH guidelines for Linearity, accuracy, precision, LOD and LOQ. The proposed method may be suitable for the analysis of Buspirone in tablet formulation for quality control purposes.

KEYWORDS: UV Spectrphotometry, and Validation, Precision, Accuracy, LOQ, LOD, ICH guidelines, Buspirone Hydrochloride.

1. INTRODUCTION

Buspirone hydrochloride is chemically 8[4-[4-{2-pyrimidyl}1-piperazinyl]butyl]- 8- azospiro (4,5)decane-7,9-dione monohydrochloride Fig. 1, used to treat anxiety. It helps to think more clearly, relax, worry less, to feel less jittery and less irritable and may control symptoms such as trouble sleeping, sweating, and pounding heart beat. It is used in treating hyperactivity in the autistic and may decrease the symptoms of obsessive-compulsive disorder (OCD). Buspirone hydrochloride may help in decreasing the urge for nicotine.[1] Survey of literature reveals that the buspirone hydrochloride reported on stability study and in-vitro- in-vivo evaluation[2-5], has been reported, so far no spectrophotometry method reported. The present study describes simple, sensitive, accurate, rapid and economical spectrophotometric method for the estimation of Buspirone hydrochloride in bulk drug and its pharmaceutical formulations.

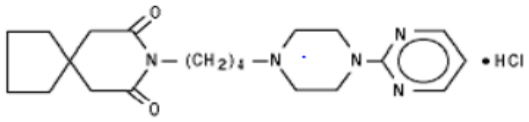

Fig. 1: Structure of Buspirone Hydrochloride.

2. MATERIALS AND METHODS

Libra UV Spectrophotometer SL 150 with 1cm matched quartz cells was used for the spectra measurements. All the chemicals used were of analytical reagent grade: (i) Methanol (ii) Acetronitrile (iii) water (iv) Dilutions were prepared by using distilled water. Buspirone (Gift sample by University college of pharmaceutical sciences (kakatiya university, India), Methanol A.R grade were purchased from Qualigens Fine Chemicals, New Delhi. UV-Visible double beam spectrophotometer (UV-1800, Libra, Limited, India) with1cm matched quartz cells, Micropipette of Variable volume 10-1000 µL (Gene Pete Co.) and Digital balance (Samson).

2.1. Methods

Buspirone hydrochloride stock solution was prepared by weighing 10mg of Buspirone hydrochloride transferred in to 10ml volumetric flask (previously calibrated) and dissolve it in 5ml of solvent by shaking for 10 min and volume was made up to 10ml with distilled water to get a concentration of 1mg/ml (solution A). From this solution an aliquot of 1ml was withdrawn and it was diluted to 10ml with distilled water to get a concentration of 100µg/ml (solution-B). From these aliquots of 0.2ml, 0.4ml, 0.6ml, 0.8ml, 1ml, and 1.2ml were pipetted out in to a 10 ml volumetric flask (Previously Calibrated) and diluted to 10ml using distilled water to get concentrations of 2µg/ml, 4µg/ml, 6µg/ml, 8µg/ml, 10µg/ml, and12µg/ml respectively. The absorbance of the solutions containing Buspirone at 10µg/mL was determined in the UV range 200 - 400 nm using an appropriate blank. Absorbance of these solutions was

measured at 244nm using UV Spectrophotometer against blank. The λ max was found to be 244nm (Table 1).

At this wavelength maxima, calibration curve was drawn by plotting graph between absorbance and concentrations (Fig.2). Similarly the absorbance of sample solution was measured and amount of buspirone hydrochloride was determined by using calibration curve. Results and the linearity curve were shown in (Fig.3).

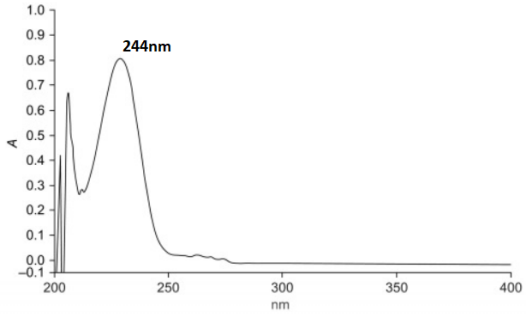

Figure 2: Absorption Maxima of Standard Buspirone.

Table 1: Calibration Curve Parameter.

S.No	Concentration µg/mL	Absorbance at 244nm
1	2	0.152
2	4	0.332
3	6	0.489
4	8	0.634
5	10	0.775
6	12	0.931

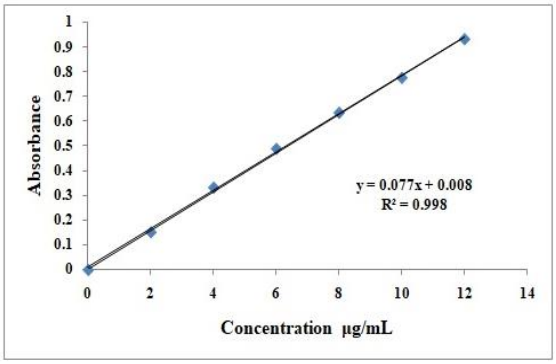

Figure 3: The Linear Curve for Buspirone.

2.1.1. Analysis of Formulation

The method was extended for the determination of buspirone hydrochloride in tablets. 20 tablets of brand buspirone hydrochloride (Buscalm-10), label claim 10mg of buspirone hydrochloride were weighed, average weight determined and finely powdered and equivalent weight calculated based on label claim equal to 10mg, transferred into a 10ml volumetric flask and make up to the mark with suitable solvent.

The contents of the flask thoroughly mixed and filtered, by using Allpure NY (0.45µm). The sample solution was analyzed as described in the above mentioned method. The analysis procedure was repeated six times and the results of analysis were shown in Table 2.

Table 2: Analysis of Formulation.

SNO	Sample	Labeled Amount (mg)	Concentration Taken for Analysis(µg/ml)	Amount of Substance Found (µg/ml)	%Recovery
1	Tablet	10	2	2.028	101.4
2	Tablet	10	4	4.045	101.125
3	Tablet	10	6	6.066	101.1
4	Tablet	10	8	8.085	101.06
5	Tablet	10	10	10.150	101.5
6	Tablet	10	12	12.123	101.025
Mean recovery				**101.23**	

2.1.2. Precision and Recovery Studies

To ensure the accuracy and reproducibility of the results obtained, adding known amounts of pure drug to the previously analyzed formulated samples and reanalyzed by the proposed method and also performed by recovery experiments. The results of percentage recovery were depicted in Table 3, respectively, and the precision of the assay was determined by repeatability (intraday) and intermediate precision (inter-day) and reported as RSD %. For this, 4.8µg/mL, 6µg/mL and 7.2µg/mL concentration solution was measured three times in day and RSD% was calculated and shown in Table 3.

Table 3: Results of Recovery and Precision Studies.

SNO	Concentration of Standered Solution Used (µg/ml)	Concentration Sample Used (µg/ml)	Amount found (µg/ml)	% Recovery	Precision (Intra Day)*	Precision (Inter Day)*
1	4.8	4.8	4.7998	99.99	0.139	0.231
2	6	6	5.997	99.833	0.130	0.134
3	7.2	7.2	7.198	99.72	0.125	0.289
	Mean recovery			**99.84**	**0.131**	**0.218**
*** %RSD of Three Samples.**						

3. RESULTS AND DISCUSSION

Estimation of Buspirone hydrochloride in dosage forms by UV and Visible Spectrophotometric method was carried out using optimized conditions, the percentage recovery of drug found in formulations and the results of analysis shows that the amount of drug was in good agreement with the label claim of the formulation. The proposed method for quantification of Buspirone hydrochloride in tablet was simple, precise, accurate, rapid and sensitive. The method is linear in the concentration range reported. The developed method is free from interference due to the excipients present in the tablets and can be used for quantitative estimation of buspirone hydrochloride in tablets. Statistical analysis was carried out and the result of which satisfactory.

The data was statistically validated by means of least square regression method. The detection and quantization limits as LOD and LOQ were calculated and these were found to be 0.029µg/mL and 0.089µg/mL respectively.

Table 4: Validation Parameters.

S.NO	PARAMETERS	UV -Water
1	Absorption Maxima(nm)	244nm
2	Linearity Range (µg/mL)	2-12µg/ml
3	Standard Regression Equation	Y=0.077x+0.008
4	Correlation Coefficient (r2)	0.998
5	Accuracy(% Recovery ±SD)	99.84±0.2
9	LOD	0.029 µg/ mL
10	LOQ	0.089 µg/ mL

The precision (measurements of intraday and interday) results showed good reproducibility with percentage relative standard deviation (% RSD) is below 2.0. This indicated that method is highly precise. All the validation parameters of results were showed in Table.4

4. CONCLUSION

From the results and discussion the method described in this paper for the determination of Buspirone from tablet formulation is simple, accurate, sensitive and reproducible. The proposed method can be successfully applied for Buspirone assay in tablet dosage forms without any interference in quality control. Analysis of the tablets by this method was reproducible reliable and in good agreement with label claim of the drug.

5. ACKNOWLEDGEMENTS

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