SPECTROPHOTOMETRIC ESTIMATION OF BUSPIRONE HYDROCHLORIDE IN BULK AND ITS PHARMACEUTICAL FORMULATION

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Abstract

Three simple, accurate, rapid and sensitive methods developed for the determination of buspirone hydrochloride in bulk drug and in its tablets by UV Spectroscopy (Method – A – Water as a Solvent), UV Spectroscopy (Method – B – Methanol as a Solvent), and Colorimetry (Method - C). In Method A buspirone hydrochloride estimated at 236 nm using distilled water as a solvent. The linearity was observed in the concentration range of 5 – 25 µg/ml with correlation co efficient of 0.9866. In Method B methanol used as a solvent. The linearity was observed in the concentration range of 10 – 50 µg/ml with correlation co efficient of 0.9905. In Method C buspirone hydrochloride is a colorless compound undergoes oxidation with 0.005M Potassium Permanganate Solution in the presence of 0.5M Sodium Hydroxide gives Pink color. The intensity of color directly proportional to the concentration of buspirone hydrochloride and its found that intensity of color stable for 20mins and the absorbance was measured at 610 nm with different time intervals with the linearity range and correlation co -efficient of 10 – 50 µg/ml and 0.9924. The result of analysis for all the methods was validated statistically and by recovery studies.

Key Words: Uv Spectrphotometry, Colorimetry and Buspirone Hydrochloride

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 to treat anxiety. It helps u to think more clearly, relax, worryless, 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 buspione 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 methods A, B and C for the estimation of Buspirone hydrochloride in bulk drug and its pharmaceutical formulations.

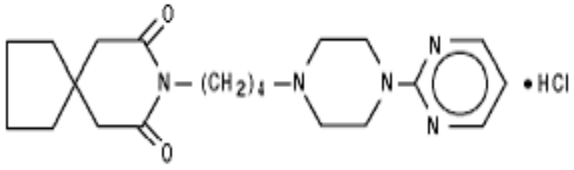


Fig 1: Structure of Buspirone Hydrochloride

EXPERIMENTAL

ELICO 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) sodium hydroxide (iii) potassium permanganate (iv) All Reagents were prepared by using distilled water

ASSAY PROCEDURE

METHOD A: Buspirone hydrochloride stock solution was prepared by weighing 100mg of Buspirone hydrochloride transferred in to 100ml volumetric flask (previously calibrated) and dissolve it in 40ml of solvent by shaking for 10 min and volume was made up to 100ml with distilled water to get a concentration of 1mg/ml (solution A). From this solution an aliquot of 10ml was withdrawn and it was diluted to 100ml with distilled water to get a concentration of 100µg/ml (solution-B). From this aliquots of 0.5ml, 1ml, 1.5ml, 2ml, 2.5ml, were pipetted out in to a 10 ml volumetric flask (Previously Calibrated) and diluted to 10ml using distilled water to get concentrations of 5 µg/ml, 10 µg/ml, 15 µg/ml, 20 µg/ml, 25 µg/ml, respectively. Absorbance of these solutions was measured at 2360nm using UV Spectrophotometer against blank.

Similarly the absorbance of sample solution was measured and amount of Buspirone hydrochloride was determined by using calibration curve.

METHOD B: Buspirone hydrochloride stock solution was prepared by weighing 100mg of Buspirone hydrochloride, transferred in to 100ml volumetric flask (previously calibrated) and dissolve it in 40ml of solvent by shaking for 10 min and volume was made up to 100ml with methanol to get a concentration of 1mg/ml (solution A). From this solution an aliquot of 10ml was withdrawn and it was diluted to 100ml with distilled water to get a concentration of 100µg/ml (solution-B). From this aliquots of 0.5ml, 1ml, 2ml, 3.0ml, 4ml, 5ml were pipetted out in to a 10 ml volumetric flask (Previously Calibrated) and diluted to 10ml using distilled water to get concentrations of 5 µg/ml, 10 µg/ml, 20 µg/ml, 30 µg/ml, 40 µg/ml, 50 µg/ml respectively. Absorbance of these solutions was measured at 241 nm using UV Spectrophotometer against blank.

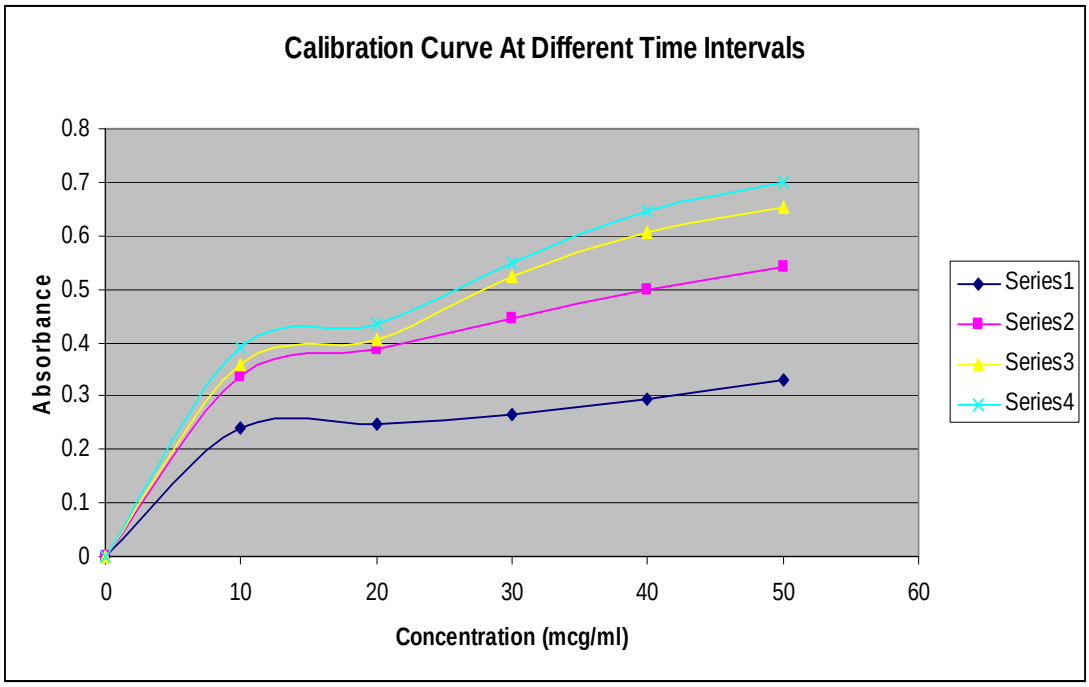
Similarly the absorbance of sample solution was measured and amount of Buspirone hydrochloride was determined by using calibration curve.

METHOD C: Buspirone hydrochloride stock solution was prepared by weighing 100mg of Buspirone hydrochloride, transferred to a 100ml volumetric flask (Previously Calibrated) and volume was made up to 100ml with distilled water to get a concentration of 1mg/ml (**solution-A**). From this solution an aliquot of 10ml was withdrawn and it was diluted to 100ml with distilled water to get a concentration of 100µg/ml (**solution-B**).

From this aliquots of 0.5ml, 1ml, 2ml, 3.0ml, 4ml, 5ml were pipetted out in to a 10 ml volumetric flask (Previously Calibrated) containing 2.5ml of 0.005M potassium permanganate solution, 1ml of 0.5M sodium hydroxide solution and diluted to 10ml using distilled water to get concentrations of 5 µg/ml, 10 µg/ml, 20 µg/ml, 30 µg/ml, 40 µg/ml, 50 µg/ml respectively. Absorbance of these solutions at different time intervals measured at 5min, 10min, 15min and 20min were measured at 610 nm using UV Spectrophotometer against blank. After 20 min the intensity of color has decreased due to oxidation of buspirone hydrochloride in presence alkaline mediun.

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 **Table 1 & Fig 2.**

Fig 2 (Method C): LINEARITY CURVE



It shows the absorbance of Buspirone solution has increased at different time intervals up to 20 mins.

0 mins, 5 mins, 10 mins, 20 mins

Table 1(Method C): CALIBRATION CURVE

SNO	CONCENTRATION (µg/ml)	ABSORBANCE 0MINS	5MINS	10MINS	15MINS	20MINS
1	10	0.241	0.339	0.359	0.392	0.406
2	20	0.249	0.386	0.406	0.434	0.447
3	30	0.267	0.446	0.522	0.548	0.569
4	40	0.295	0.498	0.607	0.646	0.690
5	50	0.331	0.543	0.653	0.699	0.702

ANALYSIS OF FORMULATION

The methods were extended for the determination of buspirone hydrochloride in tablets. 20 tablets of brand buspirone hydrochloride (Buscalm-5) label claim 5mg of buspirone hydrochloride were weighed, average weight determined and finely powdered and equivalent weight calculated based on label claim equal to 100mg, transferred into a 100ml volumetric flask and make up to the mark with suitable solvent. The contents of the flask thoroughly mixed and filtered by using what Mann's filter paper. The sample solution was analyzed as described in the above mentioned methods. The analysis procedure was repeated six times and the results of analysis were shown in **Table 2, 3 &4.**

TABLE 2 (METHOD A): ANALYSIS OF FORMULATION

SNO	SAMPLE	LABELLED AMOUNT (mg)	CONCENTRATION TAKEN FOR ANALYSIS(µg/ml)	AMOUNT OF SUBSTANCE FOUND (µg/ml)	%RECOVERY
1	TABLET	5	5	4.982	99.64
2	TABLET	5	10	10.101	101.01
3	TABLET	5	15	14.668	97.78
4	TABLET	5	20	19.575	97.87
5	TABLET	5	25	24.182	96.72
Mean Recovery					**98.60**

TABLE 3 (METHOD B): ANALYSIS OF FORMULATION

SNO	SAMPLE	LABELLED AMOUNT(mg)	CONCENTRATION TAKEN FOR ANALYSIS(µg/ml)	AMOUNT OF SUBSTANCE (µg/ml)	%RECOVERY
1	TABLET	5	10	10.807	108.07
2	TABLET	5	20	20.175	100.87
3	TABLET	5	30	31.767	105.89
4	TABLET	5	40	40.029	100.07
5	TABLET	5	50	51.729	103.45
Mean Recovery					**103.67**

TABLE- 4 (METHOD C): ANALYSIS OF FORMULATION

SNO	CONCENTRATION(µg/ml) TAKEN FOR ANALYSIS	ABSORBANCE 0mins	5mins	10mins	15mins	20mins
1	10	0.211	0.225	0.282	0.297	0.305
2	20	0.220	0.346	2.383	0.424	0.431
3	30	0.265	0.420	0.505	0.536	0.549
4	40	0.310	0.526	5.605	0.641	0.673
5	50	0.350	0.610	0.720	0.792	0.806
	CONCENTRATION	**AMOUNT FOUND**				
1	10	9.121	9.538	12.909	12.495	12.328
2	20	22.997	22.560	21.479	22.665	22.124
3	30	31.580	30.525	31.830	31.633	31.297
4	40	40.163	41.933	40.315	40.040	40.937
5	50	47.793	50.974	50.073	52.131	51.277

	CONCENTRATION	PERCENTAGE LABEL CLAIM (%)				
1	10	91.21	95.838	129.09	124.95	123.28
2	20	114.9	112.8	107.30	113.32	110.60
3	30	105.26	101.75	106.10	105.44	104.30
4	40	100.40	104.83	100.78	100.10	102.34
5	50	95.586	101.94	100.14	104.26	102.55

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 methods and also performed by recovery experiments. The results of percentage recovery shown in **Table 5, 6 & 7.**

TABLE-5 (METHOD A): RECOVERY STUDIES

SNO	CONCENTRATION OF STANDERD SOLUTION USED (µg/ml)	CONCENTRATION SAMPLE USED (µg/ml)	AMOUNT FOUND (µg/ml)	%RECOVERY
1	5	5	5.030	100.6
2	7.5	7.5	7.495	99.9
3	10	10	10.04	100.4
Mean Recovery				**100.3**

TABLE-6 (METHOD B): RECOVERY STUDIES

SNO	CONCENTRATION OF STANDERD SOLUTION USED (µg/ml)	CONCENTRATION OF SAMPLE SOLUTION USED (µg/ml)	AMOUNT FOUND (µg/ml)	%RECOVERY
1	5	5	5.140	102.8
2	7.5	7.5	7.503	100.0
3	10	10	9.965	99.65
Mean Recovery				**100.81**

TABLE-7 (METHOD C): RECOVERY STUDIES

	CONCENTRATION OF SAMPLE + STD (µg/ml)	ABSORBANCE 0 min	5 min	10 min	15 min	20 min
1	10+10	0.469	0.732	0.789	0.858	0.878
2	15+15	0.532	0.866	1.027	1.084	1.118
3	20+20	0.605	1.024	1.212	1.287	1.363
	CONCENTRATION	**AMOUNT FOUND**				
1	10+10	22.997	22.560	21.479	22.665	22.417
2	15+15	31.580	30.525	31.830	31.633	31.470
3	20+20	40.163	41.933	40.315	40.040	40.983

	CONCENTRATION	PERCENTAGE RECOVERY 0 min	5 min	10 min	15 min	20 min
1	20	114.98	112.80	107.39	113.32	112.08
2	30	105.26	101.75	106.10	105.44	104.90
3	40	100.40	104.83	100.78	100.10	102.45

RESULTS AND DISCUSSION

Estimation of Buspirone hydrochloride in dosage forms by UV and Visible Spectrophotometry methods were 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 tablets was simple, precise, accurate, rapid and sensitive. The methods are linear in the concentration range reported. The developed methods are 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 optical characteristics such as absorption maxima, Beer's law limits, molar absoptivity and sand ell's sensitivity were reported in **Table - 8.**

TABLE 8: VALIDATION AND STATISTICAL PARAMETERS

S.NO	PARAMETERS		RESULTS		
			UV -Water	UV-Methanol	COLORIMETRY
1	λ max		236	241	610
2	Linearity range (µg/ml)		5-25µg/ml	5-50µg/ml	10-50 µg/ml
3	Correlation Coefficient (r)		0.9866	0.9905	0.9924
4	r^2		0.9734	0.9812	0.8509
5	Intercept		0.06438	0.05709	-0.07661
6	Slope		0.03174	0.01803	0.005369
7	Standard Deviation (SD)		0.3010	0.3400	0.2598
8	Standard Error (SE)		0.1229	0.1285	0.1061
9	Limit Of Detection (LOD)		31.294ng/ml	62.22ng/ml	159.68ng/ml
10	Limit Of Quantification (LOQ)		94.83ng/ml	188.57ng/ml	483.88ng/ml
11	Linearity (% RSD)		0.6526	0.6530	55.40
12	Intra Day (%RSD)	5µg/ml	0.4902	0.4900	-
		10µg/ml	0.4900	0.4902	-
		20µg/ml	0.5100	0.4899	-
13	Inter Day (%RSD)	25µg/ml	0.4904	0.5144	-
		30µg/ml	0.4176	0.4899	-
		40µg/ml	0.4251	0.4899	
14	Repeatability (% RSD)		0.4904	0.4899	-
15	Sandell's sensitivity		0.0411mcg/ml	0.0263 mcg/ml	0.052 mcg/ml
16	Accuracy (%)		100.30	100.81	102.45 – 112.08
17	Molar Absorptivity (g/lit/mole)		3.7999×10^4	2.1099×10^4	2.5×10^4

The regression analysis using the method of least squares was made for slope (m), intercept (c) and correlation obtained from the different concentration and the results were shown in **Table – 8.**

The reproducibility and precision of the methods are very good shown by the low values of % RSD. Recovery studies were close to 100% that indicates the accuracy and precision of the proposed methods and also indicates non interference from the formulation excipients. The results of analysis were shown **Table – 8.**

In conclusion the developed methods are simple, accurate, sensitive and economical for the routine estimation of buspirone hydrochloride in bulk drug and its pharmaceutical formulations.

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