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A Sensitive Spectrophotometric method for the Quantitative Determination of *Buspirone Hydrochloride* in Pharmaceutical Formulations

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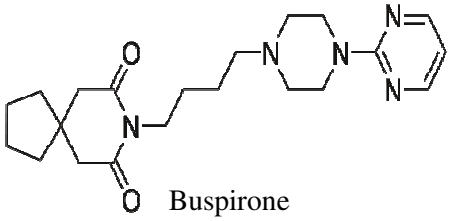
Abstract

***Plan**: An analytical method for the estimation of Buspirone hydrochloride in bulk drug and tablet formulation is described.*
***Methodology**: The developed method is based on the formation of red colored chromogen due to the reaction of Buspirone hydrochloride with Thiobarbituric acid reagent, which exhibits λmax at 531nm against reagent blank. The color was stable for more than 6 hrs for method. Beer's law is obeyed over the concentration range of 10-100 µg /ml. All the variables were studied to optimize the reaction conditions. The calculated molar absorptivity value is 2.29 × 10^6 lit.mol^{-1}.cm^{-1}.*
***Outcome**: The proposed method was successfully applied to the determination of Buspirone hydrochloride in formulations. Good recoveries were obtained and the results were statistically compared with the official method, showed good agreement and indicated no significant difference in precision. No interference was observed in the presence of common pharmaceutical excipients. The proposed method does not require any extraction.*
***Key Words**: Buspirone Hydrochloride, Thiobarbituric acid, Spectrophotometric method.*

1. Introduction

Buspirone HCl is chemically 8-[4-(4-pyrimidin-2-ylpiperazin-1-yl) butyl]-8-azaspiro [4,5] decane-7,9-dione hydrochloride. It is a non sedating antianxiety agent.



Buspirone

It has dopaminergic, adrenergic and serotonin modulating properties. The USP describes the assay of Buspirone either in pure form or in tablets by HPLC. Several analytical methods have been reported for the determination of Buspirone in raw material, dosage forms and biological fluids. These methods include spectrophotometry,[6-9] HPLC,[2,3] polarography,[4,5] GC[10] and capillary zone electrophoresis[11,12].UV visible Spectrophotometric procedures are popular for their sensitivity in the assay of drugs and have received considerable attention for the quantitative determination of many pharmaceutical compounds.

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The official HPLC methods[1] for the determination of Buspirone are time consuming with laborious procedures or costly equipments for routine analysis. Therefore, development of simple and accurate method for the analysis of Buspirone in raw material and dosage forms, which can be used in quality control laboratory, is a necessity.

The aim of the present study was to develop and validate a simple method for determination of Buspirone using Spectrophotometric method which can be used as an alternative to the official method or other recommended procedures in quality control laboratories.

2. Experimental

2.1. *Apparatus:*

Shimadzu UV-visible recording spectrophotometer (UV-240 Graphicord, Shimadzu Corporation, Japan) with 1cm quartz cells was used for the studies. The pH values of all buffers were adjusted using a Metrohm 692 pH meter.

2.2. *Reagents:*

All chemicals were of analytical reagent grade (Merck, Germany) unless otherwise specified. Double distilled water was used to prepare all solutions. Freshly prepared solutions were always used. Buspirone HCl was obtained from Alidac Genetics and Pharmaceuticals, Ahmadabad.

i) *Acid citrate buffer:*

It was prepared by dissolving 37g of sodium citrate dihydrate in 32ml of hydrochloric acid and diluting to 250ml with water.

ii) *Thiobarbituric acid reagent:*

The reagent is prepared by dissolving 5g of thiobarbituric acid in 5ml of 4N sodium hydroxide solution and diluted with water to 500ml. The solution was mixed with 250ml of the acid citrate buffer and was adjusted to pH 2.

iii) *Standard Drug Solution:*

500 mg/ml stock solution of Buspirone HCl in water was used.

iv) *Reagent blank***:**

To 3ml of water in a boiling tube 15ml of thiobarbituric acid reagent was added and the solution was heated on a boiling water bath for 30 minutes. Cooled and the solution was transferred to a 25ml standard flask and the volume was made with water.

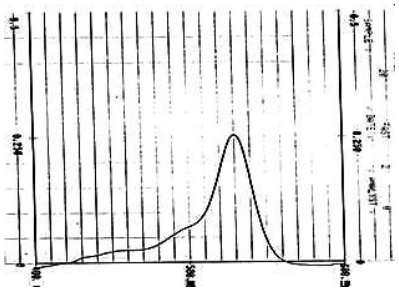

Fig. 2 Spectral Scan of Buspirone-Thiobarbituric acid Complex

2.3. *General Procedure for the Determination of Pure Drug:*

Different aliquots the Buspirone HCl stock solution ranging from 0.5-5ml portions were pipetted out using a 1.0 ml graduated pipette (1×200) into 10 boiling tubes to get a concentration of 10-100µg/ml. 15ml of thiobarbituric acid reagent was added to each tube. The solutions were heated on a boiling water bath for 30 minutes. Tubes were cooled and the contents were transferred to 25ml standard flasks. The volume was made with water. The absorbance of the resulting solutions were measured at 531nm using the reagent blank. The standard calibration curve was prepared by plotting absorbance versus concentration.

2.4. *Assay Procedure for Tablets:*

i) *Extraction of Buspirone HCl tablets*

20 tablets were accurately weighed and powdered in a glass mortar. A quantity of tablet powder equivalent to 25mg of Buspirone HCl was accurately weighed and transferred to a small conical flask. 20ml of water was added and swirled gently for 10 minutes. This aqueous solution was filtered into a 50ml standard flask through a whatmann filter paper. The residue was extracted again with 10ml of water and passed through the filter and the final volume was made upto 50ml with water.

ii) *Development of the color:*

The color complex was developed by heating 2ml and 3ml each of the extract with 15ml of thiobarbituric acid reagent in a boiling water bath for 30 minutes. The solutions were cooled and the volume was made upto 25ml with water. The absorbance of the solution was measured as described under pure drug. Three different samples of Buspirone HCl tablets were analysed by this method. The results are furnished in the table 2. Using the data in the table 2 the content of Buspirone HCl per tablet was determined from the Beer's law plot.

Table 1. Data for Beer's law Plot for Buspirone HCl.

Concentration (µg/ml)	*Absorbance* at 531nm*
10	0.051
20	0.106
30	0.160
40	0.214
50	0.262
60	0.326
70	0.376
80	0.431
90	0.488
100	0.541

*Average of 5 determinations.

Table 2. Data for the analysis of Buspirone HCl Tablets.

Tablet Sample	*Absorbance at 531nm*	*Amount of Buspirone HCl (mg/tablet)*		*%Label Claim*
		Labelled	Found	
Tamspar	0.260	10	9.96 ± 0.98	99.68%
Buspar	0.258	10	9.935 ± 0.82	99.35%
Anxipar	0.261	10	9.988 ± 0.78	99.88%

3. Results and Discussion

3.1. *Spectral Characteristics*:

Absorption spectra of the red colored Buspirone-thiobarbituric acid complex is shown in Fig.2 with a maximum absorbance (λmax) at 531nm. The color complex was stable for about 6 hours.

3.2. *Optimization of variables and method development:*

A number of preliminary experiments were performed to optimize the necessary conditions for rapid and quantitative formation of color complex to achieve the maximum stability and sensitivity. Optimum conditions were fixed by varying one parameter at a time while keeping other parameter constant and observing its effect on the absorbance at 531nm.

3.3. *Effect of pH:*

The influence of pH of buffer solution on the development and stability of color complex was tested using different systems as acid citrate, phthalate, phosphate and acetate buffers. The acid citrate buffer solution was the buffer of choice which did not interfere and gave the highest sensitivity for complex formation. The absorbance of Buspirone-thiobarbituric acid complex was examined at different pH values range of 1-5. The maximum color intensity was observed at pH of 2 and maximum absorbance was achieved with 15ml of buffer solution. This condition was applied throughout the experiment.

3.4. *Analytical data:*

Under the optimized experimental condition, calibration curve was constructed by plotting the absorbance at λmax against the concentration of Buspirone HCl. Beer's law range, molar absorptivity, Sandell's sensitivity, regression equation, and correlation co-efficient were determined for the proposed method . A linear relationship was found between the absorbance at λmax and the concentration of the drug in the range of 10-100µg/ml for Buspirone HCl in the final measured volume with molar absorption coefficients of 2.29×10^6 $l.mol^{-1}.cm^{-1}$. Regression analysis of the Beer's law plot at λmax revealed a good correlation (r^2 =0.999).

The graph showed negligible intercept and were described by the regression equation, y = 0.0015 C + 0.00122; where y is the absorbance of 1cm layer, 0.0015 is the slope, 0.00122 is the intercept and C is the concentration of the measured solution in µg/ml obtained by the least squares method. The high molar absorptivity of the resulting color complex indicates high sensitivity of the method.

3.5. *Sensitivity:*

The limit of quantification that can be determined with RSD<3.76% was found to be 10 µg/ml. The limit of detection that can be reliably detected with a S/N ratio of 3 was found to be 5µg/ml.

3.6. *Validation of the method:*

Samples of pure Buspirone HCl at two different concentrations were prepared and tested in 5 replicates using the proposed procedure. The complete set of validation assays was performed. The accuracy of the method is indicated by the good recovery (98.15-99.85%) and the precision is supported by the low relative standard deviation.

3.7. *Application to dosage forms:*

The proposed method was successfully applied to the determination of Buspirone HCl in commercial tablets. The applicability of the proposed method for assay of Buspirone HCl in formulations was examined by analysing various formulations and the results are tabulated in table 2. Five replicate determinations were made. Satisfactory results were obtained and were in a good agreement with the label claims. The results were reproducible with low RSD values (1.65%).

3.8. *Comparison with Official method:*

The reliability and validity of the proposed method was established by parallel determination against HPLC method described in United States Pharmacopoeia (2008).The results of analysis of the commercial formulation and the recovery study of drug suggested that commonly used additives and excients do not interfere with the assay procedure. The proposed method is sufficiently sensitive to permit determination of low concentration of Buspirone HCl (10µg/ml).

Different methods have been reported for determination of Buspirone HCl in pharmaceutical preparations. Nevertheless, most of these techniques utilize sophisticated instruments and reagents that are not available in many laboratories or need well trained personnel. A significant advantage of this Spectrophotometric technique is that it can be applied for the determination of individual compounds in a multi-component mixture.

The importance of this technique lies in the chemical reaction upon which the procedure based rather than upon the sophistication of the instrument. It offers the assay of a specific component in a complex dosage formulation. Slight variation in experimental conditions such as temperature, reagent concentration or pH do not affect significantly on this method.

The overall advantages of the present method are its simplicity, sensitivity and no need for expensive instruments in comparison to reported techniques. This method can be used for routine determination of Buspirone HCl in bulk drug as well as in pharmaceutical preparations.

4. **Conclusion**

In the present study, a visible Spectrophotometric method is described for determination of Buspirone HCl. This method is simple, accurate and applicable in different dosage forms in comparison to official method and complicated and costly techniques such as GC and HPLC. These advantages encouraged the application of the proposed method in routine quality control laboratories for determination of Buspirone in bulk drug and pharmaceutical preparations.

Acknowledgement

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