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RESEARCH ARTICLE

A Simple Spectrophotometric Estimation of Tramadol Hydrochloride in Pharmaceutical Formulations

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Abstract: A simple, accurate, rapid and sensitive spectrophotometric method has been developed for the determination of tramadol hydrochloride in pharmaceutical formulations. The method was based on the formation of chloroform extractable complex of tramadol hydrochloride with wool fast blue, which shows absorbance maxima at 590 nm against the reagent blank treated similarly. The method obeys Beer's law in the concentration ranges of 50-250 µg/mL. Validation studies are statistically significant as all the statistical parameters are within the acceptance range (% RSD< 2.0 and S.D. < 2.0) for both accuracy and precision study. High recovery and low % RSD reveals the reliability of the method for quantitative study of the proposed method in tablet formulation. The proposed method is simple, rapid accurate, precise, reproducible and economic and can be used for routine quantitative analysis of tramadol hydrochloride in pure and tablet dosage form.

Keywords: Ultraviolet-visible spectrophotometry, Tramadol hydrochloride, Wool fast Blue, (WFB), Formulations

Introduction

Tramadol hydrochloride is a centrally acting analgesic, used for treating moderate to severe pain. Tramadol hydrochloride possesses agonist actions at the μ-opioid receptor and effects reuptake at the noradrenergic and serotonergic systems. Tramadol is a compound with μ-agonist activity. Chemically it is [2-(dimethylaminomethyl)-1-(3-methoxyphenyl) cyclohexanol]. It is used to treat moderate to moderately severe pain and most types of neuralgia, including trigeminal neuralgia. Literature survey reveals that, several spectrophotometric method[1-3] TLC- densitometry[4], UV spectrophotometric and HPLC-DAD

methods[5]**,** HPLC method[6-8] High Performance thin layer chromatography-densitometry[9], have been reported for the estimation of tramadol in pharmaceutical formulations. Few analytical methods were reported in literature for the determination of tramadol and other combination drugs which includes spectrophotometric method[10-16], spectrophotometric and spectrofluorimetric method[17]**.**

Experimental

All absorbance measurements were made on a Spectronic 1001 plus spectrophotometer (Milton Roy Company, USA) with 1 cm matched quartz cells**.** Glasswares used in each procedure were soaked overnight in a mixture of chromic acid and sulphuric acid rinsed thoroughly with double distilled water and dried in hot air oven.

Chemicals and reagents

All the solutions were freshly prepared. All solvents and other chemicals used through this study were of analytical grade. Wool fast blue solution (0.2%) was prepared in distilled water. Buffer solutions of required pH were prepared by mixing appropriate volumes of glycine, sodium chloride and 0.1 M hydrochloric acid. The chemical structure of tramadol hydrochloride is shown in Figure 1.

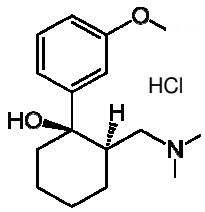

Figure 1. Chemical structure ot tramadol hydrochloride

Preparation of standard stock solution

A standard stock solution containing 1 mg/mL was prepared by dissolving 100 mg of tramadol hydrochloride in 100 mL of distilled water. From this, a working standard solution containing 100 µg/mL was prepared for the proposed method.

Assay procedure

Aliquots of standard drug solution of tramadol hydrochloride 0.5 - 2.5 mL were taken and transferred into a series of 125 mL of separating funnels. To each funnel 1.0 mL buffer solution and 0.5 mL of 0.2% wool fast blue was added. Reaction mixture was shaken gently for 5 min. Then 5 mL of chloroform was added to each of them. The contents were shaken thoroughly for 5 min and allowed to stand, so as to separate the aqueous and chloroform layer. Colored chloroform layer was separated out and absorbance was measured at 590 nm against reagent blank. Calibration curve was plotted from absorbance values against concentration of drug (Figure 2).

Preparation of sample solution

Twenty tablets of tramadol hydrochloride were accurately weighed and powdered. Tablet powder equivalent to 100 mg of tramadol hydrochloride was dissolved in 50 mL of distilled water, sonicated for 15 min, filtered and washed with distilled water. The filtrate and washings were combined and the final volume was made to 100 mL with distilled water. The solution was suitably diluted and analyzed as given under the assay procedure for bulk samples. The results are represented in Table 1. None of the excipients usually employed in the formulation of tablets interfered in the analysis of tramadol hydrochloride, by the proposed methods.

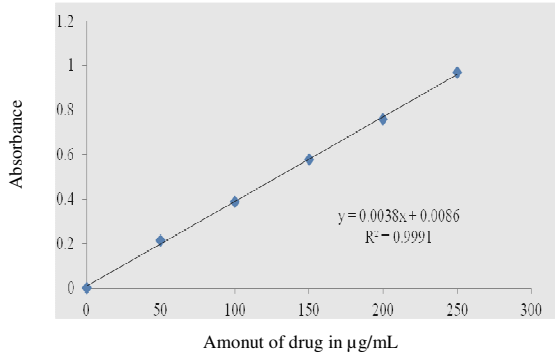

Figure 2. Calibration curve of tramadol hydrochloride

Recovery studies

To ensure the accuracy and reproducibility of the results obtained, known amounts of pure drug was added to the previously analysed formulated samples and these samples were reanalyzed by the proposed method and also performed recovery experiments. The percentage recoveries thus obtained were given in Table 1.

Table 1. Optical characteristics of proposed method

Statistical parameters	Proposed method
λ_{max}, nm	590
Beer's law limit, µg/mL	50-250
Molar absorptivity, l mole^{-1} cm^{-1}	3.51x10^3
Sandell's sensitivity (µg cm-2 / 0.001 absorbance unit)	0.0281
Regression equation (Y = a + bC)	Y=0.003x+0.008
Slope (b)	0.003
Intercept (a)	0.008
Correlation coefficient (r)	0.999

**Y = a+bC, where Y is the absorbance and C concentration in µg / mL*

Results and Discussion

The optimum conditions were established by varying one parameter at a time and keeping the others fixed and observing the effect on absorbance of chromogen**.** In the present work the method was developed for the estimation of tramadol hydrochloride from tablet formulation. The developed method is based on formation of chloroform extractable colored complexes with wool fast blue. The conditions required for the formation of colored complexes were optimized. Recovery studies were close to 100% that indicates the accuracy and precision of the proposed methods. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sand ell's sensitivity are presented in Table 1. The regression analysis using the method of least squares was made for slope (b), intercept (a) and correlation obtained from different concentrations and the results are summarized in Table 1. The high molar absorptivities of the resulting colored complexes indicate the high sensitivity of the methods. The percent relative standard deviation, standard deviation and student's 't' test values calculated from the five measurements of tramadol hydrochloride are presented in Table 2. Relative standard deviation values and standard

deviation were low that indicates the reproducibility of the proposed methods. In the student's 't' tests, no significant differences were found between the calculated and theoretical values of both the proposed methods at 95% confidence level. This indicated similar precision and accuracy in the analysis of tramadol hydrochloride in its tablets.

Table 2. Assay and recovery of tramadol hydrochloride in tablet formulations

Tablets	Labeled amount, mg	*Amount found, mg±S.D*	% Recovery	%RSD*	*t value
Tablet 1	100	99.94±0.35	100.2	0.3509	0.3826
Tablet 2	100	100.12±0.3	100.02	0.3021	0.8875
Tablet 3	100	100.18±0.46	99.98	0.4649	0.8641
Tablet 4	100	99.96±0.23	100.4	0.2397	0.3731

**Average of five determinations based on label claim*

Conclusion

The proposed methods are simple, sensitive, accurate and economical for the routine estimation of tramadol hydrochloride in bulk and in its tablet dosage form.

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