Research Article

UV Spectrophotometric Method for Estimation of Tramadol in Bulk and Tablet Formulation by area Under Curve Method

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ABSTRACT

A new, simple, rapid, precise and novel spectrophotometric method has been developed for estimation of Tramadol hydrochloride (TMD). TMD is an antipyretic and analgesic drugs. Literature revealed that several methods have been reported for the quantification of tramadol·HCl but area under curve method was not available. For this Area under Curve Method is used. The method involved measurement of AUC at wavelengths at 266 and 279 nm. The solutions of standard and the sample were prepared in water. Beer's law obeyed in concentration range of 5 to 25 µg/ ml and correlation coefficient 0.9991. This method was validated for precision, reproducibility, linearity and accuracy as per ICH guidelines. The method was found to be simple, accurate and precise

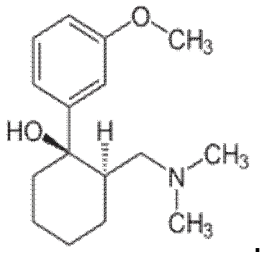
Keywords: Area under curve, Tramadol hydrochloride, ICH guidelines.

1. 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. Tramadol hydrochloride [cis-2-((dimethylamino) methyl)-1-(3-methoxyphenyl) cyclohexanol hydrochloride] (Figure. 1), is a centrally acting analgesic, used in the treatment of moderate to severe acute and chronic pain[1-2].Different methods have been reported for the determination of TMD in the bulk drug, in the dosage forms with other drugs in cough-cold products and in biological samples.

Literature survey revealed, different methods have been reported for the determination of TMD in bulk drug and in dosage forms in combination with other drugs. HPLC have been reported[3] UV spectrophotometry[4], atomic absorption and conductometric titration[5], capillary electrophoresis[6], Gas chromatography[7] and thin layer chromatography[8].

Among the various methods available for the determination of drugs, spectrophotometry continues to be very popular, because of their simplicity, specificity and low cost. This study presents new spectrophotometric method for the determination of tramadol. HCL in bulk.



. HCl

Fig. 1: Structure of Tramadol. HCl

2. MATERIAL AND METHODS

2.1 Instrumentation

Shimadzu UV 1800 double beam UV-visible spectrophotometer was used along with 1.0 cm path length matched pair of quartz cell for spectrophotometric method. Digital Balance: Shimadzu ATX224. Calibrated glassware was used for the study.

2.2 Reagents and chemicals

TMD reference standards was purchased from Balaji chemicals Pvt. Ltd,. Analytical grade methanol was purchased from Suvidhanath laboratories Pvt Ltd. All the reagents were of analytical grade. Glass double distilled water was used throughout the experiment.

2.3 Preparation of standard stock solutions and calibration curve

Standard stock solution of pure drug containing 1000 µg/ml of TMD prepared in distilled water. The working standard solutions of the drug were obtained by dilution of the

stock solution in the distilled water. Series of solutions with conc. 5, 10, 15, 20, 25 µg/ml of TMD were used to prepare calibration curve. Solutions were scanned and proposed methods were applied. Water was used as a blank solution.

2.4 Preparation of sample stock solution

A drug equivalent to 50 mg was transferred into a 50 ml volumetric flask (1000 µg/ml). From this 10 ml was withdrawn and and diluted upto 100 ml with water. From this further 1.5 ml was diluted upto 10 ml.

2.5 Method: Area under curve (AUC)

It involves the calculation of integrated value of absorbance with respect to the wavelength between two selected wavelengths. Area calculation processing item calculates the area bound by the curve and the horizontal axis. The horizontal axis is selected by entering the wavelength range over which the area has to be calculated. The wavelength range is selected on the basis of repeated observations so as to get the linearity between area under curve and concentration.

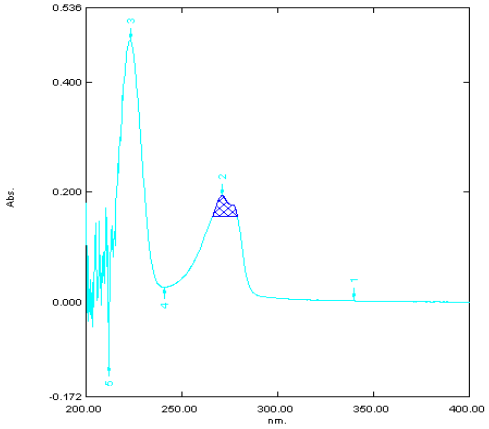


Fig. 2: Selection of AUC wavelength

2.5 a Preparation of calibration curve

Aliquots of working standard solution (0.5 – 25 ml) were transferred into a series of 10 ml volumetric flask, diluted up to mark with distilled water and scanned in the spectrum mode from the wavelength range 200-400 nm. A calibration curve was prepared by plotting the area versus concentration. The calibration curve was linear in concentration range of 5 – 25 µg/ml.

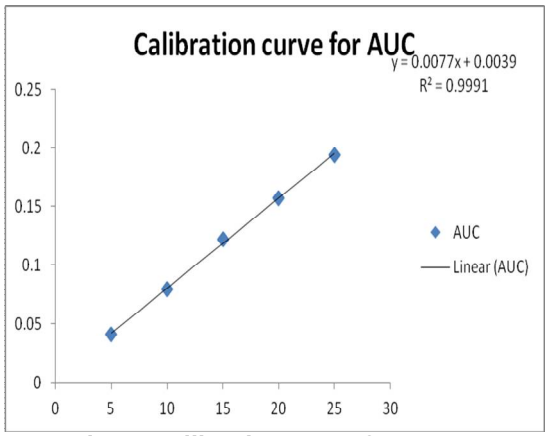


Fig. 3: Calibration curve for AUC

3. RESULTS AND DISCUSSION

3.1 Method validation

The Method was validated as per ICH guidelines using different parameter.

3.1.1 Linearity

The linearity was evaluated by analyzing different concentration of standard solution of TMD. The Beer Lambert's law was obeyed in the concentration range of 5-25 µg/ mL with regression coefficient of 0.9991.

3.1.2 Ruggedness

Ruggedness of the proposed method is determined by analysis of aliquots from homogenous slot by two analyst using same operational and environmental conditions.

3.1.3 Accuracy (% recovery)

The accuracy of the methods was performed by calculating recovery of TMD by the standard addition method. Known amounts of standard solutions of TMD were added at 80%, 100% and 120% levels to pre quantified TMD sample solutions of 15 µg/ml. The amount of tramadol was estimated by applying obtained values to the respective regression equations.

3.1.4 Precision

To determine the precision of the method, Tramadol solutions at linear concentration were analyzed each three times. Solutions for the standard curves were prepared fresh everyday.

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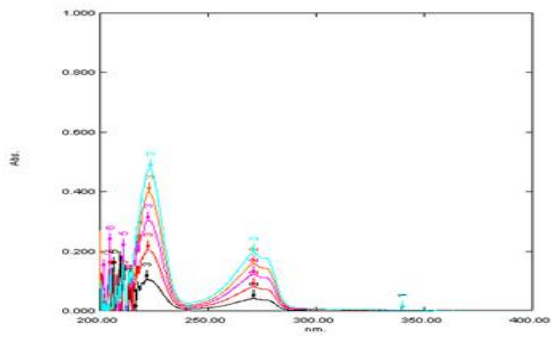

Fig. 4: Overlay spectra for Tramadol HCl

Table 1: Spectrophotometric characteristics and statistical data of the regression equations

Parameters	Results
λmax (nm)	250-295
Beer`s range (µg/ mL)	5-25
Regression equation	Y=0.0077X + 0.0039
Correlation coefficient	0.9991
Intercept	0.0039
Slope	0.0077

Table 2: Results of Analysis of Tablet Formulation

S. No	Label claim	Amount in test solution	Amount found
Sample-1	50 mg	15 µg/mL	14.50 µg/mL

Table 3: Intra and interday Precision

Label Claim	Amount in solution	Intraday Prescision			Interday Prescision
		Set 1	Set 2	Set 3	
50 mg per Tab	15µg/mL	99.74%	99.77%	99.64%	99.56%

Table 4: Recovery data of Tramadol

Level of % Recovery	Concentration Taken (µg/ mL)	Concentration estimated(µg/ mL)	% Analytical Recovery
80 %	18	17.56	97.55 %
100 %	20	19.86	99.30 %
120 %	22	21.73	98.77 %

CONCLUSION

No Area Under Curve spectrophotometric methods have been described for the determination of Tramadol. The present study was undertaken with an objective of developing simple, sensitive and reliable analytical method like UV-Visible spectrophotometry for estimation of Tramadol. The results of our study indicate that the proposed UV spectroscopic methods are simple, rapid, precise and accurate.

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