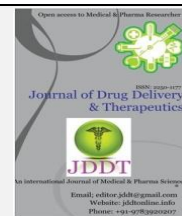


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Research Article

Area Under Curve UV Spectrophotometric Method for Determination of an Opioid Analgesic in Bulk

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ABSTRACT

The aim of this work is to establish rapid, simple, precise and economical methods viz., area under curve were developed and validated for estimation of tramadol hydrochloride in pharmaceutical dosage forms. Further, this study is designed to validate the developed methods as per ICH guidelines. The work was carried out to for estimation of Tramadol in bulk pharmaceutical form by utilizing area under curve (AUC) method using UV-Visible Spectrophotometry. For this purpose the wavelength range 200-400 nm was selected. Distilled water was used as a solvent throughout the work. Linearity was observed in concentration range 5-25 $\mu\text{m/ml}$ ($r^2 = 0.9992$) for the method. The developed method was found to be simple, linear, precise, accurate and sensitive which can be used for routine quality control analysis for spectrophotometric estimation of Active Pharmaceutical Ingredient.

Keywords: Tramadol HCL, Distilled water

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INTRODUCTION

Tramadol hydrochloride is a centrally acting synthetic opioid analgesic binding to specific opioid Receptors. It is a non-selective, pure opioid agonist at μ , delta and kappa opioid receptors with a higher affinity for μ receptors. Tramadol chemically, (1R,2R)-2-((dimethyl-amino)methyl)-1-(3-methoxyphenyl) cyclohexanol hydrochloride (Fig. 1), is a typical opioid which is a centrally acting analgesic used for treating moderate to severe pain. Tramadol Hydrochloride can be estimated by UV spectrophotometry¹⁻⁸, RP-UPLC [9-12] and GC-MS⁹ alone or in combination with other drugs. Accordingly, the objective of this study was to develop and validate the simple spectrophotometric method for the estimation of tramadol hydrochloride in bulk and tablets as per ICH guidelines. Drug was found to be freely soluble in water which was chosen for solvent proceeding studies.

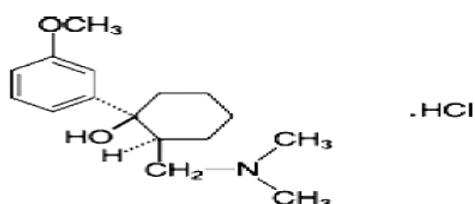


Figure 1: Chemical Structure of Tramadol Hydrochloride.

MATERIALS AND METHODS

Chemicals

Tramadol hydrochloride was a gift sample from Flamingo Pharmaceutical, Taloja, Navi Mumbai, India. All chemicals and reagents used were of analytical reagent (AR) grade and purchased from Qualigens Fine Chemicals, Mumbai, India.

Instrumentation

Shimadzu (Kyoto, Japan) model UV- 1800 double beam UV-Visible spectrophotometer attached with computer operated software UV probe 2.33 with spectral width of 2 nm, wavelength accuracy of 0.5 nm and pair of 1 cm matched quartz cells was used to measure absorbance of the resulting solutions. Analytical balance of make Mettler Toledo (Model JL 1503- C) was used for weighing purpose.

METHOD

Experimental Work

A) To check the solubility of Tramadol Hydrochloride

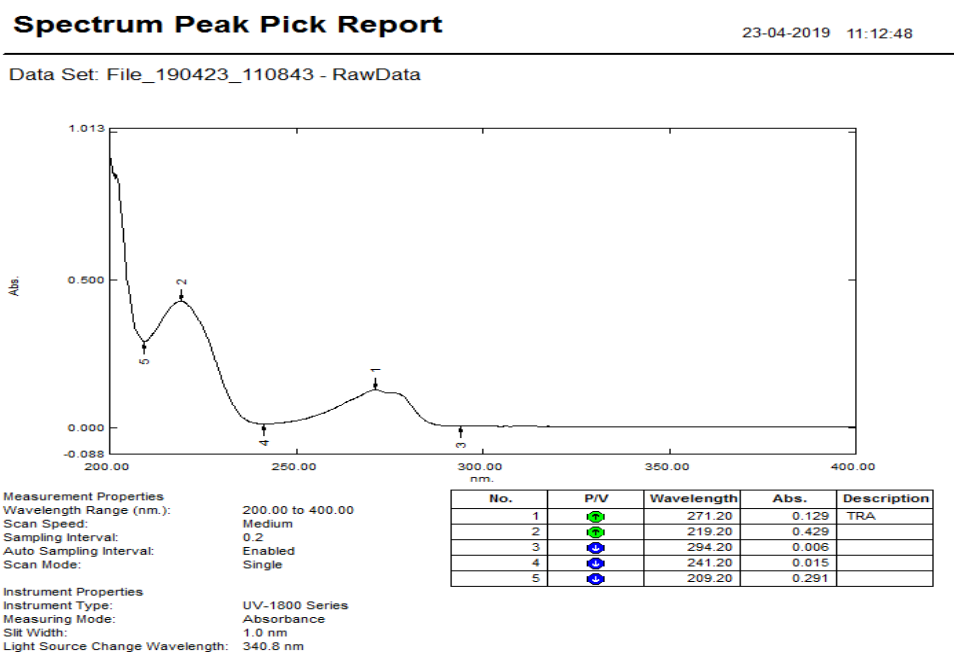
25 mg of Tramadol was weighed and solubility of this sample was checked in 25 ml distilled water, methanol, ethanol.

B) To identify the λ max of Tramadol Hydrochloride:

Weigh 10mg of the pure drug and dissolve it in small portion of distilled water and make up the volume upto 10 ml using distilled water to give a standard stock solution of 1000 μ m/ml. From above solution 2.5 ml of the standard solution was withdrawn in volumetric flask and diluted to 25 ml to prepare 100ppm solution. Suitable dilutions were made with distilled water to get standard solutions of concentrations: 5, 10, 15, 20, 25 μ m/ml. Spectrum peak details are shown in Figure 2 Spectrum peak pick.

Table 1: Calibration curve of Tramadol Hydrochloride

Concentration	Absorbance
5	0.068
10	0.076
15	0.085
20	0.093
25	0.101

**Figure 2: Spectrum Peak Pick.****C) Area Under Curve Method:**

In case of AUC (Area under Curve) method is applicable where there is sharp peak or broad spectra are obtained. It involves the calculation of integrated value of absorbance with respect to the wavelength between the two selected wavelengths λ_1 and λ_2 . Area calculation processing item calculates the area bound by the curve and the horizontal axis. The horizontal axis is selected by the entering the wavelength ranges over which area has to be calculated. This wavelength range is selected on the basis of repeated observation so as to get the linearity between area under curve and concentration. The above mentioned spectrums were used to calculate AUC. Thus, the calibration curve can be constructed by plotting concentration versus AUC.

D) Analytical Method Development and Validation:**Linearity:**

The linearity of an analytical procedure is the interval between the upper and lower concentration of analyte in the sample. For which demonstrated that the analytical procedure is of linearity. The standard solution of Tramadol (5, 10, 15, 20, and 25 μ m/ml) was pipette out in a separated series of 10ml volumetric flask. Make up the volume with distilled water and mixed well. The absorbance maxima and area under curve for the solutions was measured at 271 nm and range of 200 - 400 nm for two methods respectively against distilled water as blank. Calibration Curve table of

tramadol is shown in Table. 1. Calibration curve of Tramadol.

RESULTS AND DISCUSSION**A) Calibration Curve for Drug:****Absorbance maxima method:**

In the Experimental conditions described, the graph obtained for the absorbance maxima for pure drug showed linear relationship (Figure 3). Regression analysis was made for the slope, intercept and correlation coefficient values. The regression equations of calibration curve were $y = 0.0016x + 0.0603$ ($r^2 = 0.9992$) at 271.00 nm for absorption maxima the range was found to be 5 - 25 μ m/ml for the UV spectrophotometric analysis. Calibration Curve is shown in Table. 1. Calibration Curve of Tramadol. Calibration curve of Tramadol is shown in Figure. 3.

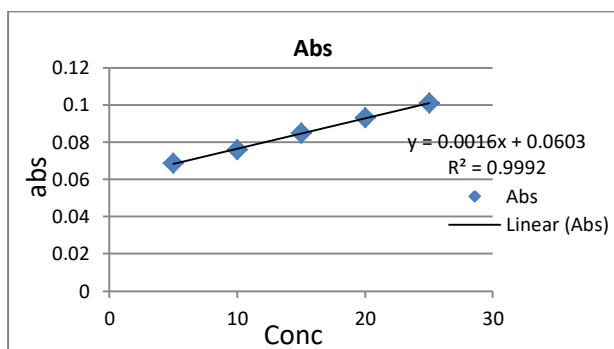


Figure 3: Calibration Curve of Tramadol.

A) Area Under Curve Method :

In the Experimental conditions described, the graph obtained for the Area Under Curve (AUC) spectra showed linear relationship (Figure 4). Regression analysis was made for the slope, intercept and correlation values. The equation is $y = 0.0016x + 0.0603$ ($r^2 = 0.9992$) at 200 - 400 nm for Area Under Curve spectrophotometry analysis. The range was found to be 5 - 25 $\mu\text{m}/\text{ml}$ for the Area Under Curve UV spectrophotometric analysis.

Spectrum Peak Area Report

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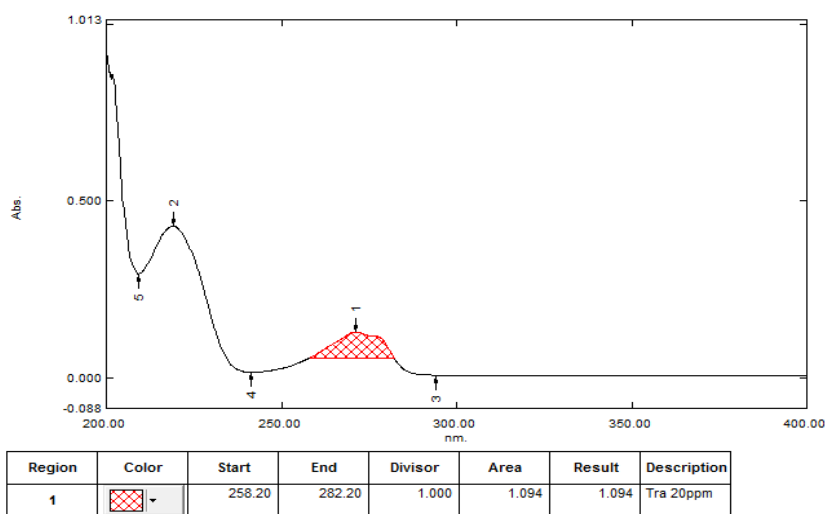


Figure 4: Area Under Curve Of Tramadol.

Table 2: Area Under curve of Tramadol.

Parameter	AUC
Wavelength Range (nm)	200 - 400
Concentration Range ($\mu\text{m}/\text{ml}$)	5 - 25
Slope (m)	0.0016
Intercept (c)	0.0603
Correlation Coefficient (r^2)	0.9992

CONCLUSION

The simple and economic UV spectrophotometric AUC methods have been developed for the determination of Tramadol. Because of cost-effective and minimal maintenance, the present UV spectrophotometric methods can be preferred at small scale industries and successfully applied and suggested for the qualitative analysis of Tramadol in pharmaceutical formulations for QC, where economy and time are essential and to assure therapeutic efficacy. The results show the UV spectrophotometric method was found to be accurate, precise and sensitive.

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