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A UV SPECTROPHOTOMETRIC ASSAY OF SUSTAINED RELEASE BRANDS OF TRAMADOL HYDROCHLORIDE

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ABSTRACT

Tramadol hydrochloride is an analgesic used to treat moderate to moderately severe pain. A simple efficient least time consuming spectrophotometric technique for the assay of tramadol hydrochloride has been developed. The Assay is based on Ultraviolet UV absorbance maxima at about 228 nm wavelength of tramadol hydrochloride using water as solvent. A sample of drug was dissolved in water to produce a solution containing 200 ppm tramadol Hydrochloride. Similarly a Sample of different brands were dissolved in water to produce a solution containing 200 ppm solution. The absorbance of sample preparation was measured at 228 nm against the solvent blank. Samples were prepared in the range of 200-12.5 ppm concentration for two different brands. Their % Assay, Regression Equation, Regression line, correlation co-efficient is obtained to predict further availability of drug. Thus we can conclude that the method can be applied for the routine Quality control quantitative analysis of tramadol hydrochloride sustained release formulation.

KEYWORDS: tramadol hydrochloride, Assay, sustained release brands, UV-Spectrophotometer.

INTRODUCTION

T.HCL is centrally acting analgesic. It is used primarily to treat mild severe pain, both acute and chronic. T.HCL possess agonist actions at the μ-opioid receptor and effects reuptake at Nor-adrenergic and serotonergic systems. Tramadol is a compound with μ-agonist activity. It is used to treat neuralgia, including trigeminal neuralgia. For pain moderate in severity its effectiveness is equivalent to that of morphine. Literature survey reveals determination of

tramadol hydrochloride by capillary Electrophoresis method[1], RP- HPLC[2], HPTLC[3], UPLC[4], UV Spectrophotometric methods.[5, 6]

Tramadol hydrochloride and Acelofenac in combination were determined by UV Spectrophotometry using second order derivative method.[7]

Similarly tramadol hydrochloride and paracetamol were also determined by UV spectrophotometry using AUC method.[8] The Photostability studies on (±)-tramadol in a liquid formulation were also done.[9]

The present method can be employed for QC analysis of T.HCL in sustained release formulation. The main aim of the study is to investigate the application of UV – Spectrophotometric method in the determination of T.HCL in pharmaceutical preparation. This method was appropriate, good, accurate, precise, economical and simple assay of this compound in dosage forms.

There are different drugs whose Assay has been performed by using UV – Spectrophotometry.[10-15]

Tramadol Hydrochloride

$C_{16}H_{25}NO_2 \cdot HCl$

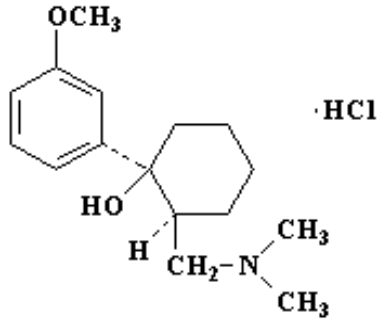

Figure: 1. Drug structure.

MATERIALS AND METHODS

Instruments

A Shimadzu UV – 2600 double beam spectrophotometer with one cm quartz cells was used for measurement of Absorbance. For weighing, a Shimadzu AUX – 220 balance was used. For Sonication of solutions a digital ultrasonic cleaner was also used. The Standard drug is procured from **Swapnroop Drugs and Pharmaceuticals**, **Aurangabad and Maharashtra**. The different brands of drug were obtained from local pharmacy in Trichy. Cost free solvent distilled water was used for the entire analysis.

Selection of wavelength

About 200 ppm of tramadol hydrochloride solution was accurately prepared in water. These solutions were scanned in the range of 200 – 400 nm UV regions. The wavelength of maximum absorbance was observed at 228 nm and this wavelength was adopted for absorbance measurement.

Preparation of standard solution

Accurately weighed 20mg of T.HCL standard was transferred to a volumetric flask and sufficient amount of distilled water was added to produce 100 ml.

Sample preparation

The two different brands (CONTIN – SR and TRAMAZAC – TC) were purchased from different medical store in trichy, Tamilnadu. The all tablets of CON were labelled to contain 100mg of Tramadol hydrochloride per tablet and has shelf life of one year. The TC were labelled to contain 100mg per tablet and has a shelf life of 3 years. 20 tablets of two different brands T.HCL(CONTIN – SR,TRAMAZAC –TC) from the marketed sample were weighed and crushed uniformly with the help of mortar and pestle. By calculating the average weighed sample powder equivalent to 20 mg of T.HCL was transferred into a volumetric flask containing 10 ml water. The solutions were sonicated for about 5 to 7 minutes and then filtered with the help of Whatmann No 1 filter paper. The first 5 ml of filtrate was discarded. The remaining amounts of filtrate of both solutions were made up volume up to 100ml with water.

Dilutions preparation

The dilutions of different brands of T.HCL i.e. CONTIN – SR and TRAMAZAC – TC were prepared from sample solution of each brand.

Four different dilutions of 100 ppm, 50 ppm, 25 ppm, 12.5 ppm of each brand were prepared from 200 ppm sample solutions.

PROCEDURE

After preparation of standard and tablet solutions, strength of solution 200 ppm in 100ml absorbance of sample preparation, standard preparation and different dilutions (100 ppm, 50 ppm, 25 ppm, 12.5 ppm all in 100ml) in 1 cm cell at wavelength of maximum absorbance i.e.

228 nm using the blank solution was measured. Calculate the quantity in mg of T.HCL per tablet.

RESULTS AND DISCUSSIONS

The main objective of the study was to carry out a simple, least time consuming, cost effective and accurate pharmaceutical Assay for the determination of T.HCL in available sustained release dosage form. Among the two brands TC shows % Assay as 102.6947 %and CON – 01 shows % Assay as 102.4023%. This method can be applied for routine analysis of T.HCL. The method showed good linearity in the range of 12.5 – 200 ppm for two brands. The correlation co-efficient of CON – 01 is 0.9938 and for TC – 02 is 0.9948. The table 1 shows absorbance values of T.HCL. Table 2 shows % Assay of two different brands and table 3 shows the Regression equation and R^2 values which should not be less than 0.99. The absorbance was taken to calculate their % Assay, Regression equation, Regression line to predict further availability of drug. From fig.2 and fig.3 we can conclude that concentration and absorbance obey Beers law i.e. absorbance α concentration. The squared correlation co-efficient values are with in limit. The performed Assay would be more beneficial for pharmacist and health professionals. The results are analysed by using the Origin software.

Table 1: Absorbance of T.HCL

CONCENTRATION(ppm)	CON	TC
200	1.822	1.791
100	1.033	1.0.12
50	0.542	0.541
25	0.269	0.270
12.5	0.145	0.141

Table 2: Percentage assay of two different brands

Brands	% Assay
CON	102.4023
TC	102.6947

Table 3: Regression Equation and Squared correlation co-efficient

Brands	R^2	Regression Equation
CON	0.9938	y = 0.008x + 0.068
TC	0.9939	y = 0.008x + 0.071

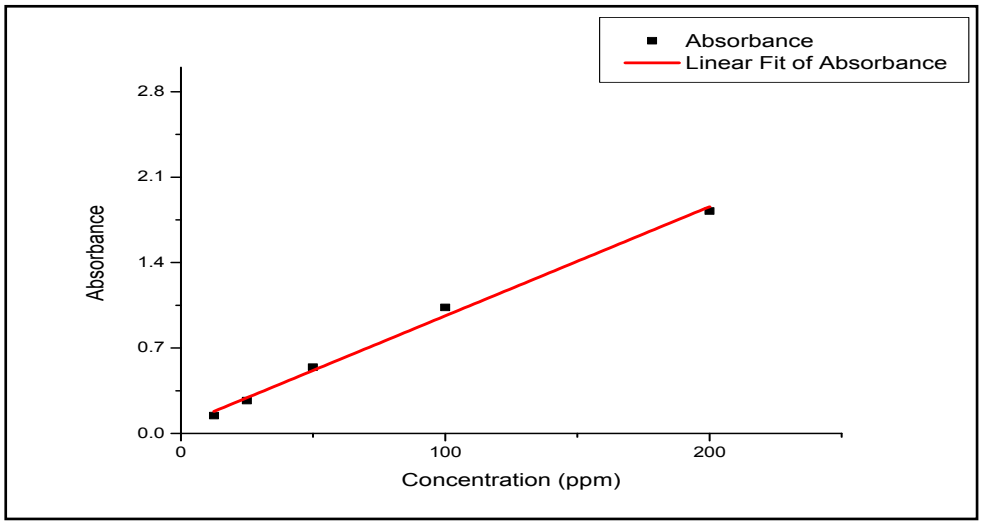

Figure 2: Linearity plot of CON

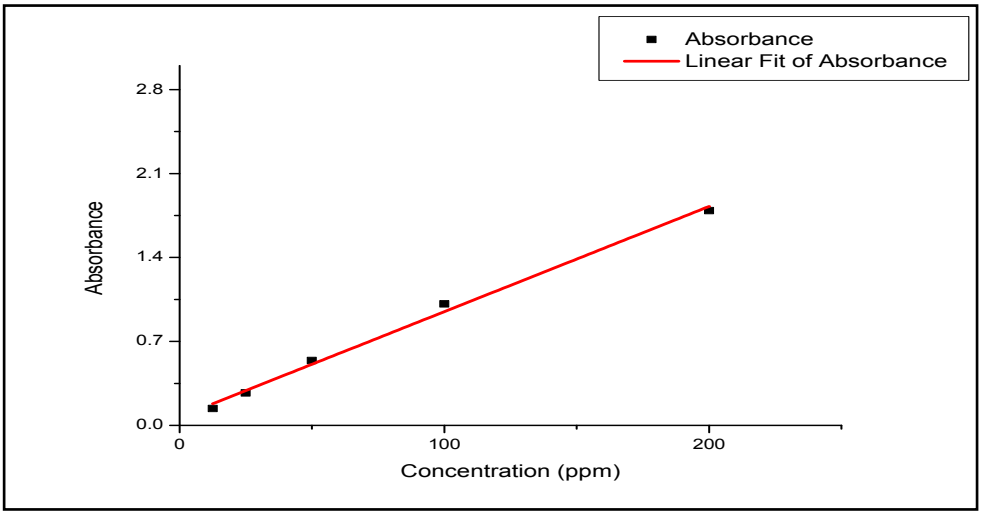

Figure 3: Linearity plot of TC

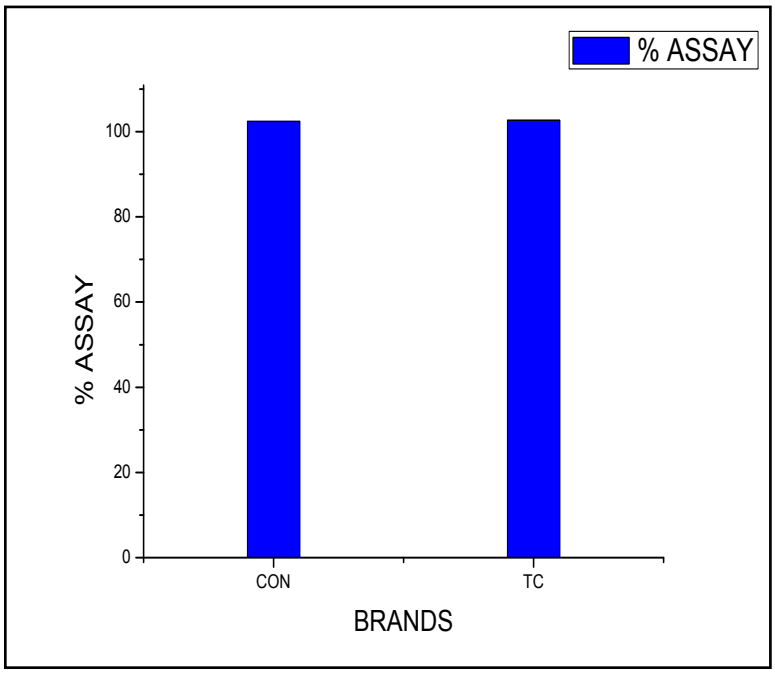

Figure 4: Graph for %Assay of different brands

CONCLUSION

The UV – Spectrophotometric Assay proposed for determination of T.HCL in tablets dosage form. The technique employed effectively for analysis of two brands. It is particularly fast, basic, economical and rough. Proposed method is quick and effective compared to other techniques which are time consuming and costly. The two different brands are having results of assay and linearity with in the specified quality control range. As per IP T.HCL prolonged release tablets should contain NLT 95% and NMT 105% labelled amount of $C_{16}H_{25}NO_2$.HCl. Hence we can conclude both brands are with in specified limit.

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