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SPECTROPHOTOMETRIC METHODS FOR QUANTITATIVE ESTIMATION OF TRAMADOL HYDROCHLORIDE FROM TABLET FORMULATION

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ABSTRACT

Two simple and sensitive visible spectrophotometric methods have been developed for the quantitative estimation of Tramadol Hydrochloride from its tablet formulation. The developed methods are based on formation of chloroform extractable colored complex of drug with metanil yellow and tropaeolin ooo. The chloroform extracted complex of drug with metanil yellow showed absorbance maxima at 410.0 nm and linearity was observed in the concentration range of 3-24 µg/ml (method-I), with tropaeolin ooo showed absorbance maxima at 485.0 nm and linearity was observed in the concentration range of 3-24 µg/ml (method-II). Results of analysis for both the developed methods were validated statistically and by recovery studies.

Key words: Tramadol Hydrochloride, Chloroform extract, Absorbance, Metanil yellow and Tropaeolin ooo.

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INTRODUCTION

Tramadol[1] Chemically it is [2-(dimethylaminomethyl)-1-(3-methoxyphenyl) cyclohexanol] hydrochloride.Tramadol hydrochloride is a centrally acting analgesic, used for treating moderate to severe pain. It 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[2]. It is used to treat moderate to moderately severe pain and most types of neuralgia, including trigeminal neuralgia. Literature survey reveals that , various methods available for estimation of tramadol hydrochloride like UV spectrophotometric[3-8], RP-HPLC[9], LC-MS[10], HPTLC[11], etc. have been reported. However, there is no work in the literature reported about the visible Spectrophotometric estimation of Tramadol Hydrochloride in pharmaceutical dosage forms with Metanil yellow & Tropaeolin ooo reagents. An attempt has been made in the present study to develop two simple & rapid visible Spectrophotometric methods for analysis of Tramadol Hydrochloride in pharmaceutical dosage forms.

EXPERIMENTAL

A Shimadzu UV/Visible spectrophotometer- 1700 with 1 cm matched quartz cells was used for spectral measurement. All the chemicals used were of analytical grade, metanil yellow solution (0.05% w/v) and tropaeolin ooo (0.03% w/v) was prepared in acid buffer[9] pH 1.6 and extracted several times with chloroform so as to remove chloroform soluble impurities. Buffer solutions were prepared in double distilled water. The tablet samples of Tramadol Hydrochloride were procured from the local market.

For method **I**, in a series of 10 ml volumetric flasks aliquots of standard drug solution of Tramadol Hydrochloride (30 μg/ml) in chloroform were transferred and diluted with the same so as to give several dilutions in the concentration range of 3-24 μg/ml of drug. To 10 ml of each dilution taken in a separating funnel, 10 ml of metanil yellow solution was added, shaken and allowed to stand for 10 minutes for the formation of colored complex. The colored chloroform layer was separated out and absorbance was measured at 410.0 nm against a reagent blank. A calibration curve was prepared by plotting concentration versus absorbance.

For method **II**, in a series of 10 ml volumetric flasks aliquots of standard drug solution of Tramadol Hydrochloride (30 μg/ml) in chloroform were transferred and diluted with the same so as to give several dilutions in the concentration range of 3-24 μg/ml of drug. To 10 ml of each dilution taken in a separating funnel, 10 ml of tropaeolin ooo solution was added, shaken and allowed to stand for 10 minutes for the formation of colored complex. The colored chloroform layer was separated out and absorbance was measured at 485.0 nm against a reagent blank. A calibration curve was prepared by plotting concentration versus absorbance.

For analysis of formulation, twenty tablets of Tramadol Hydrochloride were accurately weighed and average weight per tablet was determined. The tablets were powdered and powder equivalent to 100 mg of Tramadol Hydrochloride was accurately weighed and extracted four times with 20 ml portions of chloroform, the combined extract was filtered through Whatmann filter paper No.41 into 100 ml volumetric flask. The residue was washed with chloroform and the washings were added to the filtrate, final volume of filtrate was made up to the mark with chloroform. From the above filtrate 3 ml was further diluted to 100 ml in a volumetric flask to get a tablet sample stock of 30 μg/ml.

For method I, 4 ml of above stock was further diluted to 10 ml with chloroform and for method II, 4 ml of above stock was further diluted to 10 ml with chloroform. This was treated as per the respective procedure for the calibration curve and absorbance was measured at 410.0 and 485.0 nm respectively and the amount of drug present in sample was computed from respective calibration curve.

RESULTS AND DISCUSSION

Both the developed methods were repeated five times for two different strength of tablet formulation. Results of analysis are reported in Table 2.

Recovery studies were carried out for both the developed methods by addition of known quantity of pure drug solution to pre analyzed tablet sample solution at three different concentration levels. The result of recovery studies is reported in Table 2.

The proposed Spectrophotometric methods for determination of Tramadol Hydrochloride from tablet formulations are based on formation of chloroform extractable colored complex of drug with metanil yellow and tropaeolin ooo. The pH required for method I and II was optimized at pH 1.6 . The optical characteristics such as Beer's law limits, sandell's sensitivity, molar extinction coefficient and percent relative standard deviation, (calculated from the eight measurements with in the Beer's law limits) were calculated and the results are summarized in Table-1.

TABLE-I OPTICAL CHARACTERSTICS AND PRECISION OF PROPOSED METHODS I AND II

Parameter	Method-I	Method-II
λ_{max} (nm)	410.0	485.0
Beer's law limits (µg/ml)	3-24	3-24
Molar absorptivity ($Lmole^{-1}cm^{-1}$)	$0.1523x10^6$	$0.1712x10^6$
Sandell's sensitivity (µg cm^{-2}/0.001 absorbance unit)	0.00172	0.00175
Regression equation (Y=a+bC)		
Slope (b)	0.0507	0.0574
Intercept (a)	-0.002	-0.0012
Correlation co efficient (r)	1.0000	1.0000
Relative standard deviation (%)*	0.3106	0.05964
% Range of error (confidence limits)*		
0.05 level	0.2597	0.0499
0.01 level	0.3842	0.0738

Y = a + b C, where C is concentration in µg/ml and Y is absorbance unit.

* Eight replicate samples

TABLE - II ASSASY AND RECOVERY OF TRAMADOL HYDROCHLORIDE IN DOSAGE FORMS

Sample	Labeled amount (mg/tab)	Amount obtained (mg/tab)			% Recovery**	
		Proposed method		Reference* method	I	II
		I	II			
1	50	49.96	49.92	49.94	99.92	99.84
2	50	49.88	49.94	49.96	99.76	99,92
3	50	49.95	49.96	49.92	99.90	99.84

* Reference U.V. Method developed in our lab ** Average of three determination

Regression characteristics like standard deviation of slope (S_b), standard deviation of intercept (S_a), standard error of estimation (S_c), and percentage ranges of error (0.05 and 0.01 confidence limits) were calculated and are shown in Table-1.

Recovery studies were satisfactory which shows that there is no interference of excipients. The developed methods were found to be simple, rapid and accurate and can be used for routine analysis of drug from tablet formulations.

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