Research Article

Development and Validation of Tramadol Hydrochloride in Bulk and Pharmaceutical Dosage form by Ultraviolet Spectroscopy

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ABSTRACT

A simple, rapid, accurate, precise and economic spectrophotometric technique for estimation of tramadol hydrochloride in 0.1N HCl have been developed. Tramadol Hydrochloride exhibit absorbance most 270nm when 0.1N HCl used as solvent proportion, so absorbance was once measured at the identical wavelengths for the determination of Tramadol Hydrochloride obeys Beer Lambert's law in the concentration range of 20-180µg/ml. The present study describes development and validation of simple and economic UV spectrophotometric method for the estimation of Tramadol Hydrochloride in bulk and injection dosage form using absorbance maxima method. Solubility studies indicated that a Tramadol Hydrochloride shows better solubility in proposed diluents i.e., 0.1N HCl solution the λ max of Tramadol Hydrochloride was found to be 270nm. Because of cost effective and minimal maintenance, the present UV spectrophotometric methods can be preferred at small scale industries as compared to other reported methods.

Keywords: Validation, Tramadol Hydrochloride, injection, 0.1N HCL, UV spectrophotometric.

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INTRODUCTION

Tramadol HCl is an certified drug in Indian Pharmacopoeia 2010-15, British Pharmacopoeia 2009-16 and United State Pharmacopoeia Tramadol may be a synthetic analog of the phenanthrene alkaloid codeine. Tramadol is converted to O-desmethyltramadol, Opioids are chemical compounds which work leading one or more of the human opiate receptors. O-desmethyl tramadol is significantly more effective µ-opioid agonist then tramadol. The euphoria and respiratory depression are mainly caused by the µ1 and µ2 receptors; the addictive nature of opioids, is due to these effects, but tramadol's serotonergic and noradrenergic effects may contribute to possible dependence likewise. [1,2]

Tramadol may be a potent drug which is use in the treatment of moderate to severe pain in together with Paracetamol. Most of analytical work has been done using UV spectroscopy[3-8], RP- H.P.L.C. method[9-14], HPTLC method[15] and LC-MS method[16]. I've got tried to develop a replacement method which is simpler, reliable, cheaper, accurate and which might be easily performed in laboratory using simple instrument like UV Spectrophotometer.

MATERIALS AND METHODS

Materials

Tramadol Active Pharmaceutical Ingredient was provided as gift tester by Windlass Biotech Dehradun Uttarakhand. Tramadol (Marketed formulation) is manufactured by Consern Pharma limited.

Instruments

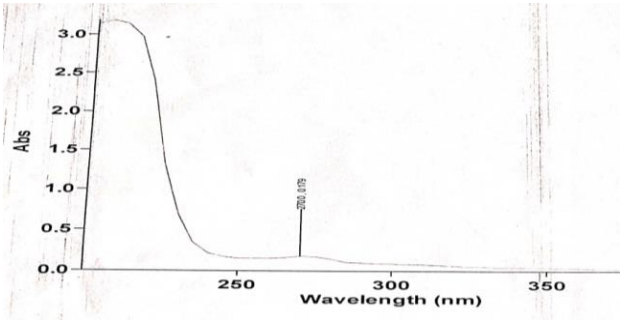
The Ultra Violet-Spectroscopy were conceded out with a Cary 60Single Beam UV spectrometer manufacturer by Agilent Tech, Digital Weight Balance: TX323L, Shimadzu was used.

Preparation of Standard Stock Solution of Tramadol

Accurately weigh about 50mg of the drug and transferred to 50ml of volumetric flask and dissolved it in 50ml of 0.1N HCl. Then volume was made up to the mark with 0.1N HCl. The 10ml of previously set solution was diluted with 50ml of HCl. This standard solution contained 100µg of drug per ml.

Determination of wavelength of maximum absorbance (λ max)

1ml of standard stock solution was pipette out and transferred to a 10ml of volumetric flask. The volume was made up to the mark with 0.1N HCl. The solution contained 100µg/ml of the drug. Then 1ml of the solution is taken in a 10ml volumetric flask was added to it then volume was made up to the mark with 0.1N HCl. This solution contain 10µg/ml of the drug. The absorbance of this solution was scanned in the range of 200-400nm against 0.1N HCl as a blank.



The absorbance of the Tramadol Hydrochloride in 0.1 N HCl by UV Spectrophotometric method.

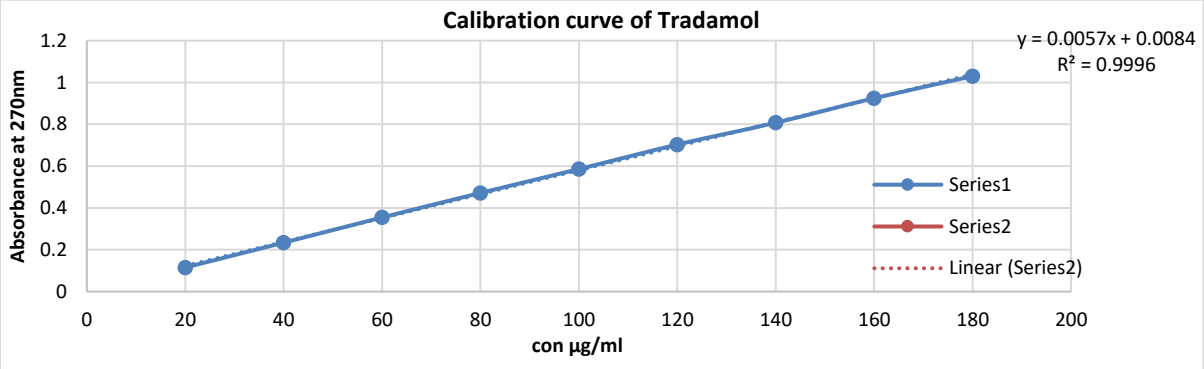
Preparation of calibration curve for Tramadol at 270nm

1,2,3,4,5,6,7 and 8ml standard stock solution (200µg/ml) were pipette out into a series of 10ml volumetric flask. Then the volumes were made up to the mark with 0.1N HCl and mixed to obtain the solutions in the concentration range of 20, 40, 60, 80, 100, 120, 140, 160µg/ml of drug.

The absorbance of these resultant solutions were measured at 270nm against 0.1N HCl as a blank and graph was plotted between absorbance obtained and the concentration of the solution. (Table 1).

Table 1: Linearity, Range, E 1% 1CM, Absorptivity (L gm^{-1} cm^{-1}), and Molar Absorptivity (L mol^{-1}cm^{-1})

Concentration (µg/ml)	Absorption			Mean	E1%	Absorptivity	Molar Absorptivity
	A1	A2	A3				
0	0	0	0	0			
20	0.1152	0.1151	0.1151	0.1151	57.55	5.755	1515.867
40	0.2340	0.2340	0.2362	0.2340	58.5	5.85	1540.89
60	0.3545	0.3546	0.3548	0.3546	59.1	5.91	1556.694
80	0.4718	0.4718	0.4716	0.4718	58.97	5.897	1553.2698
100	0.5862	0.5861	0.5863	0.5861	58.61	5.861	1543.7874
120	0.7036	0.7038	0.7028	0.7032	58.6	5.86	1543.524
140	0.8081	0.8074	0.8076	0.8077	57.69	5.769	1519.5546
160	0.9241	0.9246	0.9254	0.9247	57.79	5.779	1522.1886
180	1.0299	1.0298	1.0296	1.0297	57.42	5.742	1512.4428



Repeatability

Pipetted out 1ml of standard solution shifted into a series of nine 10ml analytical flask and diluted with 0.1N HCl to get the concentration of 20µg/ml. Optical density of the resultant solutions was dignified at 270nm 0.1N HCl used as a blank. The results were obtained and concise in the (Table 2).

Table 2: Study of Repeatability

Repeatability					
Nominal Con µg/ml	Absorbance	Observed Con(µg/ml	Mean Con µg/ml	SD	%RSD
20	0.1111	17.2	17.2	0.00293	0.01704
20	0.1157	18.1			
20	0.1096	17.0			
20	0.1115	17.2			
20	0.1067	16.4			
20	0.1113	17.2			

Accuracy

The accuracy was assessed by the standard addition method of three replicate determinations of three different solutions containing 80,100,120µg/ml of Tramadol Hydrochloride. The average % recoveries for three different concentrations was found to be 99.79 using proposed UV spectrophotometric method. The higher values indicated that the proposed UV spectrophotometric method was accurate for the determination of Tramadol Hydrochloride in pharmaceutical dosage form. Results of recovery studies are summarized in (Table 3).

Table 3: Accuracy

Accuracy				
Recovery	**Nominal Conc. (µg/ml)**	**Absorbance**	**Observed conc. (µg/ml)**	**% Recovery**
80%	90=50+40	0.5043	89.9	99.89
80%	90=50+40	0.5203	89.9	99.89
80%	90=50+40	0.5248	90.0	100.00
100%	100=50+50	0.6096	99.8	99.80
100%	100=50+50	0.5866	99.9	99.90
100%	100=50+50	0.5868	99.9	99.90
120%	110=50+60	0.6450	109.4	99.45
120%	110=50+60	0.6523	109.6	99.64
120%	110=50+60	0.6449	109.9	99.91
Mean				99.82

Specificity

Specificity study was carried out by observing any interference in absorbance of drug in the existence of conjoint excipients like Starch, Talc, Lactose, Magnesium Stearate etc. Absorbance of 100µg/ml drug solution with and without excipients was measured at 270nm. The results obtained were summarized in the (Table 4).

Table 4: Study of Specificity

Specificity					
Nominal con(µg/ml)	**Without Excipients**		**With Excipients**		**% Interference**
	Absorbance	**Observed Conc. (µg/ml)**	**Absorbance**	**Observed Conc. (µg/ml)**	
100	0.5856	101.1	0.5567	96.2	0.95
100	0.5822	100.5	0.5795	100.2	1.00
100	0.5814	100.6	0.5721	98.7	0.98
100	0.5601	96.6	0.5563	96.1	0.99
100	0.5613	96.8	0.5716	98.6	1.02
				Mean	0.987811

% Assay of Tramadol injection two different brands

The injection were in liquid and amount of liquid containing 2ml of Tramadol was transferred into 100ml of volumetric flasks and make up the volume up to the mark with 0.1N HCl. The absorbance of this resultant solution was estimated at 270nm.

Table 5: Brand A (TRAMASURE-100) Mankind Pharma LTD

Sr. No	Absorbance	Conc.(µg/ml)	Dil. Factor	Content (ml)	Label claim(ml)	%Assay
1	0.6059	104.8	100	97.9	100	97.9
2	0.6053	103.6	100	98.7	100	98.7
3	0.6062	105.7	100	97.9	100	97.9
					Mean	98.16

Table 6: Brand B (Supridol IV) Neon laboratories LTD

Sr. No	Absorbance	Conc.(µg/ml)	Dil. Factor	Content (ml)	Label claim(ml)	%Assay
1	0.5470	94.4	100	101.10	100	101.1
2	0.5466	94.6	100	101.90	100	101.9
3	0.5479	94.5	100	102.60	100	102.6
					Mean	101.86

CONCLUSION

A simple UV spectrophotometric method have been developed and validated for the determination of Tramadol Hydrochloride in bulk, tablet and injection dosage form. The results of the validation parameters show that the UV spectrophotometric methods were found to be accurate, precise and sensitive. 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 quantitative analysis of Tramadol Hydrochloride in pharmaceutical formulations for QC, where economy and time are essential and to assure therapeutic efficacy.

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