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Development and validation of UV-Visible spectrophotometric method for the determination of Tapentadol hydrochloride from tablet dosage form

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ABSTRACT

An accurate, rapid, highly sensitive, economic and reproducible UV-Visible spectrophotometric method was developed and validated for the estimation of Tapentadol Hydrochloride in its pharmaceutical formulation. The method was validated as per International Conference on Hormonization (ICH) Q2A and Q2B guidelines. Tapentadol Hydrochloride was monitored at 275nm with UV detection; there is no interference of diluents at 275nm for Tapentadol Hydrochloride. The method was linear (r2=0.9992) at concentration ranging from 20-100µgmL-1, precise (intra and inter-day% RSD values<2%), accurate (mean recovery=101.3%) specific and robust. The proposed method was successfully applied for the quantification of bulk and active pharmaceutical present in tablet dosage form.

Keywords: Tapentadol Hydrochloride, UV-Visible spectrophotometry, validation.

INTRODUCTION

Tapentadol is a centrally acting synthetic analgesic. The analgesic efficacy is due to opiod receptor activation and the inhibition of norepinephrine reuptake. Tapentadol is indicated for the treatment of moderate to severe pain for both acute (following injury, surgery, etc.) and chronic musculoskeletal pain[1-2]. The chemical name of Tapentadol is3-[(1*R*,2*R*)-3-(dimethylamino)-1-ethyl-2-methylpropyl]phenol hydrochloride, Fig I.Its molecular formula is $C_{14}H_{23}NO$.HCL and its molecular weight is 257.80.It appears as a white crystalline powder. It is Soluble in water, acetonitrile, methanol and ethanol. It is not official in any pharmacopoeia, few Spectrometric andliquid chromatography methods have been reported for the determination of Tapentadol[3-6].The author have developed a spectrophotometric method which would serve as a rapid and reliable method for the determination of Tapentadol in Bulk and pharmaceutical dosage forms. The statistical analysis proved that the method is reproducible and selective for the analysis of Tapentadol in bulk drug and tablet formulation.

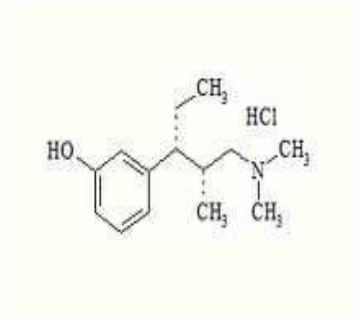

Figure I: Tapentadol Hydrochloride

MATERIALS AND METHODS

Instrumentation:
The analysis of the drug was carried out onJasco UV 630-Visible spectrophotometer.Weighing was done on digital electronic balance made by Shimadzu instruments.

Chemicals and reagents:
Milli-Q water (Millipore Corporation, USA) was used and Methanol was purchased from Merck (Mumbai, India).Tapentadol Hydrochloride was obtained as a gift from MSN laboratories, Hyderabad.

Optimizationofexperimentalconditions:
Selectionofsolvent
Solubility of drug was checked in solvents like methanol,ethanol and water. UV-spectra of drug in these solutions were recorded. Among these solvents, methanol gave good response. Hence methanol was selected as solvent for further studies, Fig III.

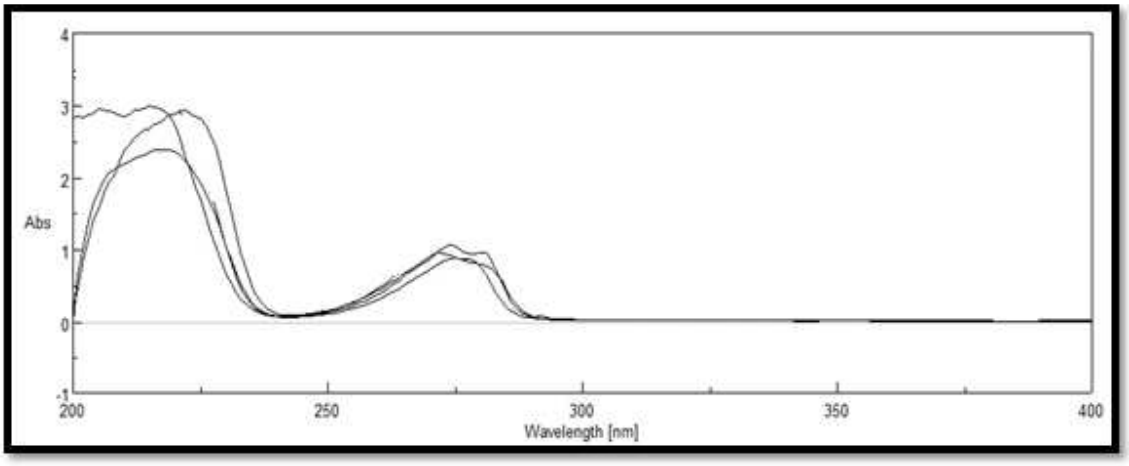

Figure II: Selection of solvent

Selectionofwavelength:
A solution containing tapentadol hydrochloride (10µg/mL) was prepared in methanol and scanned in the UV region,from which a wavelength of 275 nm was selected for further studies, Fig III.

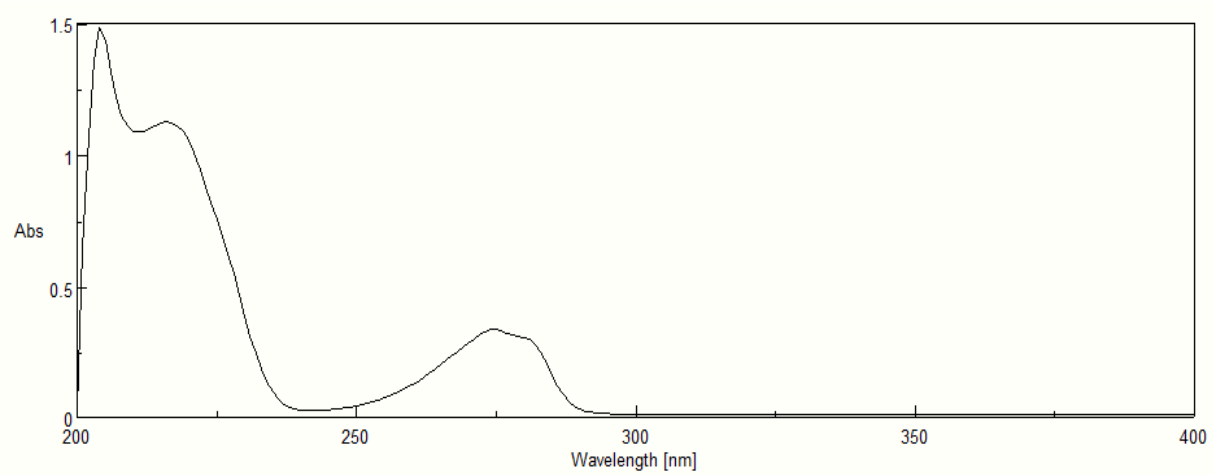

Figure III: Selection of wavelength

Preparation of standard solutions

The stock solution of Tapentadol hydrochloride 100 µg/mLwas prepared in methanol. Suitable aliquots of drug solution were transferred into 10 *mL* volumetric flask and diluted with methanol to get concentration ranging from 20-100 *µg/mL.*These solutions were scanned in the uv region and absorbance of these solutions were noted at 275 nm, Fig IV.

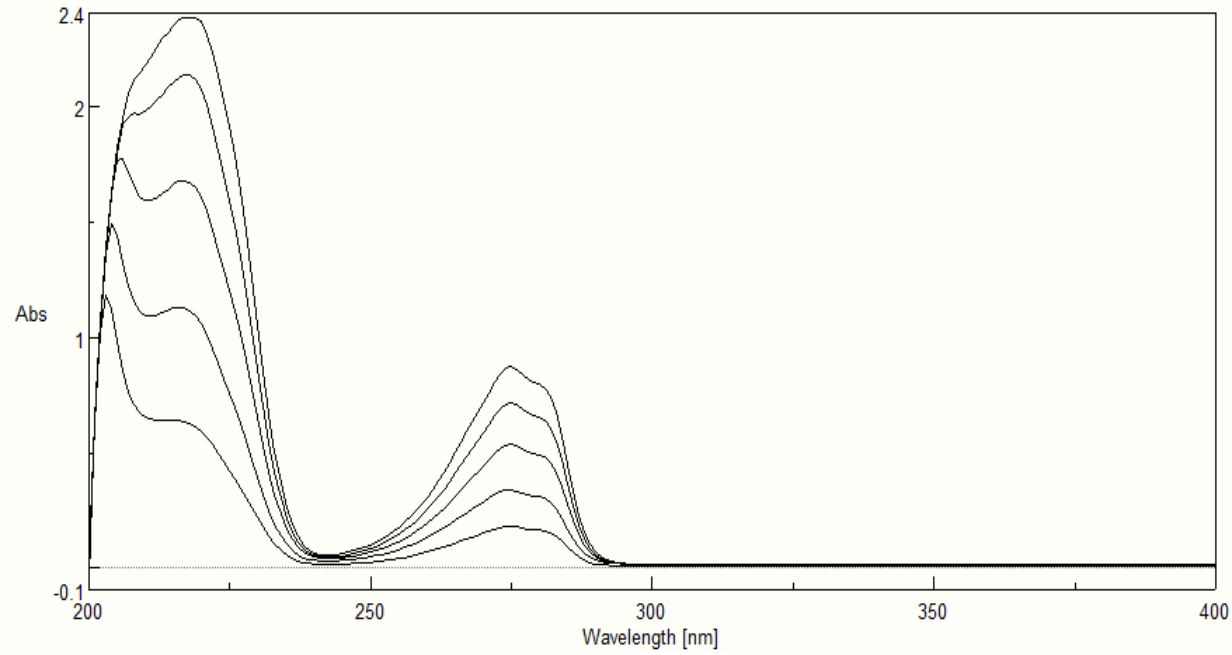

Figure IV: Overlain UV spectra of Tapentadolhydrochloride (20-100 µg/mL)

Preparation of test solution:

For the estimation of tapentadol hydrochloride in tablets formulation, 20 tablets were weighed and triturated to fine powder. Weigh accurately weight equivalent to 5mg of tapentadol hydrochloride powder and transferred to 50 ml of volumetric flask and made up to volume with methanol (100 µg/mL). From the above solution, 4 ml was pipetted into 10 ml standard flask, and the volume made upto the mark with methanol, scanned in uv region, and absorbances were noted at selected wavelength, Fig. V. The results of formulation analysis are given in table

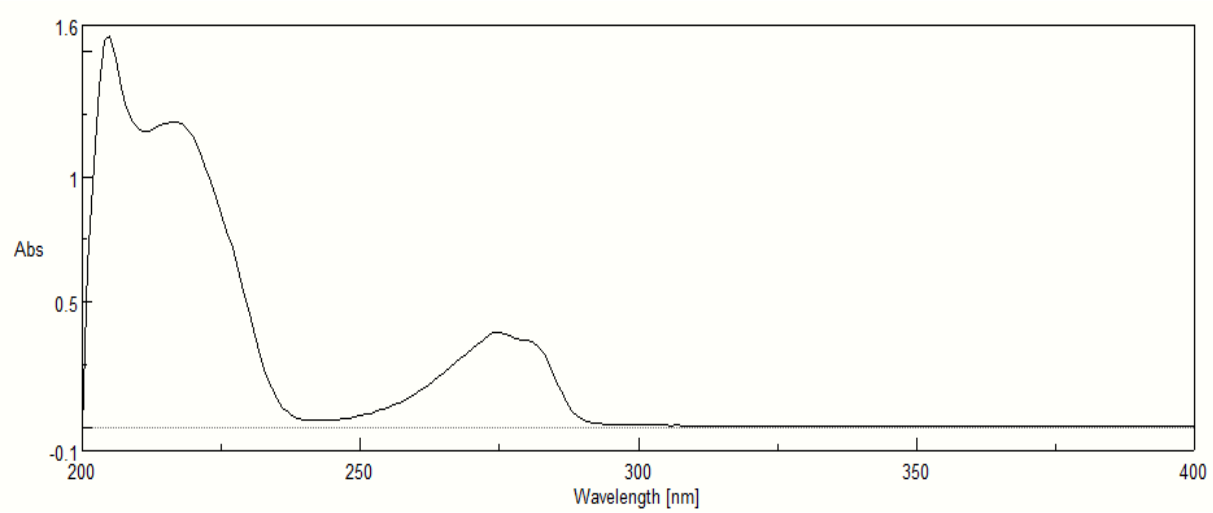

Figure V: UV spectrum of formulation(40 µg/mL)

Table I: Analysis of formulation

Drug	Amount (mg/tablet)		% Label claim	% RSD*
	Labeled	Found		
Tapentadol Hydrochloride	50	4.16	96.32	1.32

RSD of six observations

Validation:

The objective of method validation is to demonstrate that the method is suitable for its intended purpose as it is stated in ICH guidelines [7-10] Q2A & Q2B. Recommended validation characteristics depend on the type of analytical procedure. Method validation characteristics were tested in accordance with ICH guidelines for each method [10]. Linearity (correlation coefficient) was tested in the given range for each method. Repeatability and intermediate precisions were obtained as % Relative Standard Deviation (% RSD) using six replicates per day. Limits of detection and quantification were provided for Tapentadol Hydrochloride using standard deviation of intercept. To establish ruggedness of the proposed methods, assay for Tapentadol Hydrochloride was performed at 275 nm. The polynomial regression data for the calibration plots showed good linear relationship in the concentration range of 20-100 µg/ml and given in table1. Recovery studies were carried out at three different levels i.e. 80%, 100%, and 120% by adding the pure drug to the previously analyzed tablet powder sample. Percentage recovery for Tapentadol Hydrochloride was determined by all the methods and they were found to be under acceptance criteria which are 98.62%, 96.04%, and 99.23% according ICH guidelines. The percentage recovery value indicates non interferon from excipients used in formulation. The result of analysis of marketed formulation is shown in table3. The reproducibility and accuracy of the method was found to be good, which was evidenced by low standard deviation.

RESULTS AND DISCUSSION

Linearity:

The Linearity for spectrophotometric method was determined at five concentration levels ranging from 20-100 µg/mL for Tapentadol Hydrochloride. The calibration curve was constructed by plotting absorbance against concentration of drug. The slope and intercept value for calibration curve were y=0.0088 X +0.0051, were y represents absorbance of analyte and Xrepresents analyte concentration. The results were satisfactory, because there is significant correlation between absorbance and concentration of drug within the concentration range. The calibration curves for Tapentadol Hydrochloride are given in the fig VI.

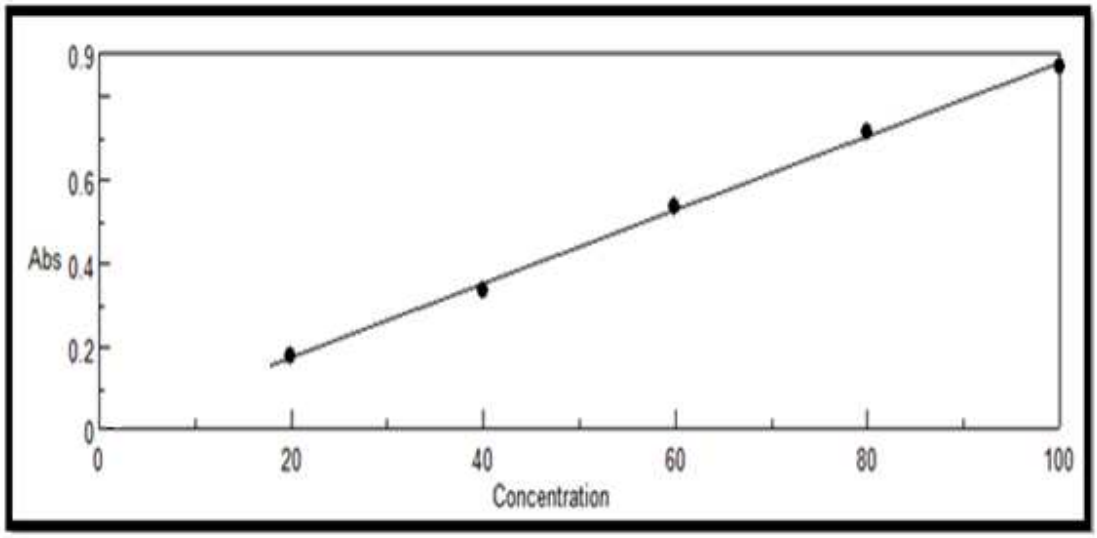

Figure VI: showing calibration curve ofT a pentadol Hydrochloride (20-100µg/ml).

Precision

The Precision of the analytical method were determined by repeatability (within - day) and intermediate precision (Between – day). Intradayprecision was found out by carrying out of the analysis of the standard drug for two different concentrations in linearity range of the drug for three times on the same day and % RSD was calculated, table II

TableII:Intradayprecision

Concentration(µg/mL)	Absorbance	% RSD
20	0.1868	0.704
	0.1889	
	0.1893	
40	0.3498	1.371
	0.3408	
	0.3426	

Interday precision was found out by carrying out the analysis of the standard drug for two different concentrations in the linearity range of the drug for three days over a period of one week and % RSD was calculated, table III. The results shown indicate that the method was precise.

Table III: Inter day precision

Concentration (µg/ml)	Day	Absorbance	% RSD
20	1	0.1781	1.227
	2	0.1751	
	3	0.1740	
40	1	0.3343	0.774
	2	0.3384	
	3	0.3392	

Recovery

Recovery was determined by spiking the formulation with standards of drug equivalent to 80%, 100% and 120% of the amount originally present. The percentage recovery and relative standard deviation in the formulation were calculated and given in table IV. The results of analysis showed that the amount of drug was found in good agreement with label claim of the formulation.

Table IV: Recovery studies

Analyte	Level	% Recovery	% RSD*
Tapentadol Hydrochloride	80%	98.62	0.723
	100%	96.04	0.504
	120%	99.23	0.635

**RSD of six determinations*

Stabilitystudies

When the prepared solution is exposed to atmosphere, the analytes are likely to decompose. Hence it is necessary to conduct stability studies.The stability of the analyte in the solution was studied at different time intervals and absorbances were compared with the freshly prepared solution. The solution was found to be stable for about 6 hours as reduction of absorbances was within limits, table V.

Table V: Stability of the analyte

Concentration (µg/ml)	Time (Hours)	Absorbance
40	1	0.3284
	2	0.3308
	3	0.3227
	4	0.3295
	5	0.3242
	6	0.3296
	7	0.3336

CONCLUSION

The proposed method is rapid, accurate, precise and reproducible and hence can be used for routine analysis of Tapentadol Hydrochloride in bulk and tablet dosage forms. The sample recoveries from the formulation were in good agreement with their respective label claims which suggested non-interference of excipients and blank in the estimation. The most striking features of the method is simplicity and rapidity, not requiring tedicious sample preparation techniques such as extraction degassing which are may needed for HPLC procedures and getting the results meeting all requirements. All the above results indicate that the method is simple, accurate, economic and rapid for routine analysis of Tapentadol hydrochloride.

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