ISSN: 0974-2115
Journal of Chemical and Pharmaceutical sciences

SPECTROPHOTOMETRIC ESTIMATION OF TAPENTADOL IN BULK AND ITS PHARMACEUTICAL FORMULATION

***B.PAVAN ADITHYA, J.MAHESH, M.VIJAYALAKSHMI**
Dept.of Pharmaceutical Analysis & Quality Assurance, Bapatla College of Pharmacy, Bapatla-522101, Andhra Pradesh, India.
***Correspondingauthor:Email:pavanadithyapharma@gmail.com,Mobileno:+919492707226**

ABSTRACT

A simple, sensitive, accurate, precise, reproducible and inexpensive UV Spectrophotometric method has been developed and subsequently validated for the determination of Tapentadol in bulk and its pharmaceutical formulation. Water was used as a solvent in the present investigation. The UV spectrum was scanned between 200 to 400 nm and 272 nm was selected as maximum wavelength for absorption. Beer's law was obeyed in the concentration range of 25-150 µg/ml with correlation coefficient r= 0.9999. The percent recoveries of Tapentadol were found to be 99.75 to 100.29.The intra and inter day precision percent relative standard deviation values in the range of 0.23 to 0.68 and 0.33 to 0.84.The LOD and LOQ were found to be 1.40038 µg/ml and 4.243 µg/ml. The method has been successfully utilized to determine the Tapentadol in tablets and can be extended for routine analysis in bulk drugs. Results of the analysis were validated as per ICH guidelines.

KEY WORDS: Tapentadol, UV Spectrophotometric method, Water, Validation.

1.INTRODUCTION

Tapentadol (3-[(1*R*,2*R*)-3-(dimethylamino)-1-ethyl-2-methylpropyl]phenol hydrochloride)is a centrally acting analgesic with a dual mode of action as an agonist of the µ-opioid receptor and as a nor epinephrine reuptake inhibitor. It is also an agonist of the σ_2 receptor, though the function of this orphan receptor remains controversial. It has opioid and nonopioid activity in a single compound. In the US, Tapentadol is FDA approved for the treatment of moderate to severe acute pain. Due to the dual mechanism of action as an opioid agonist and nor epinephrine reuptake inhibitor, there is potential for off label use in chronic pain. Its dual mode of action provides analgesia at similar levels of more potent narcotic analgesics such as hydrocodone, oxycodone, and pethidine(meperidine) with a more tolerable side effect profile (wikipedia).

Literature survey revealed few HPLC (Ramesh,2012), Spectrophotometric (Kanzariya,2012) and pharmacological methods (Terlinden,2007;Kneip,2008) have been reported for the estimation of Tapentadol. The aim of the study was to develop simple, sensitive, accurate, precise, reproducible and in expensive UV Spectrophotometric method (Skoog,2004) for the estimation of Tapentadol in bulk and its pharmaceutical formulation and validate as per ICH guidelines.

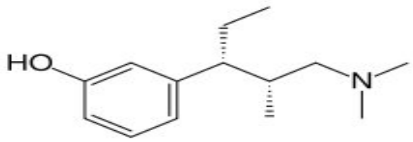


Fig.1 Structure of Tapentadol

2.MATERIALS AND METHODS

Instruments used: An Elico model SL 159 UV-Visible Single beam spectrophotometer with 1cm matched quartz cells were used for recording spectra and absorbance measurements. A schimadzu electronic analytical balance (AX-200) was used for weighing the sample. An ultrasonic 3.5L 100H (Pci) was used for sonicating the sample solution.

Reagents: The pure sample of Tapentadol was supplied by Ami Life sciences, Vadodara. All reagents used were of analytical grade and were obtained from Qualigens fine chemicals, Mumbai. Tapentadol tablets (Tapal 50 mg) were purchased from local market.

Preparation of standard stock solution: Tapentadol hydrochloride, equivalent to 100 mg of Tapentadol was accurately weighed and transferred to 100 ml volumetric flask. 20 ml of Water was added and sonicated for 30 min. The volume was made up to the mark with water to give 1000 µg/ml solution.

Preparation of standards for calibration curve: To prepare calibration standards, 0.25,0.5,0.75,1,1.25,1.5 ml of working standard solutions were diluted to 10ml to obtain drug concentrations of 25,50,75,100,125,150 µg/ml and linearity was studied. Linearity relationship was observed in the range 25 to 150 µg/ml against a reagent blank as reference at 272 nm (Table 1).

Analysis of marketed formulations: For the estimation of Tapentadol in marketed formulation, 20 tablets were weighed and triturate to fine powder. Tablet powder equivalent to 100 mg of Tapentadol was weighed and transfer into 1000ml volumetric flask. 20 ml of water was added and sonicated for 30 min. The final volume was made up to the mark with water to give 1000 µg/ml solution. From this stock solution, various dilutions of the sample solution were prepared and analysed (Table 4).

Method validation: The optimized Spectrophotometric method was completely validated according to the procedures described in ICH guidelines Q2 (R1) for the validation of analytical methods (ICH, 2005).

Accuracy: For the accuracy of proposed method, recovery studies were performed by standard addition method at three different levels (50%, 100% and 150% of final concentration). A known amount of Tapentadol pure drug was added to pre-analyzed tablet powder and the sample was then analyzed by proposed method. Results of recovery studies were found to be satisfactory and reported in Table 3.

Precision: The precision of the method was determined by repeatability and intermediate precision (intra-day and inter-day).

Repeatability: The Repeatability of the proposed method was ascertained by actual determination of six replicates of fixed concentration of the drug within the Beer's range and finding out the absorbance by the proposed method. From this absorbance %RSD was calculated (Table 2).

Intra-day precision: Intra–day precision was determined by analyzing the three different concentration of drug (50 µg/ml, 75µg/ml and 100µg/ml) for three times in the same day. %RSD was calculated (Table 2).

Inter-day precision: Inter-day precision was determined by the three different concentration of drug (50µg/ml, 75µg/ml and 100µg/ml) for three days in a week. %RSD was calculated (Table 2).

Ruggedness: Ruggedness of the proposed method was determined by analysis of aliquots from slot in different laboratories using similar operational and environmental condition. The readings were shown in Table 5.

Limit of detection and Limit of quantification: Limit of detection (LOD) and Limit of Quantification (LOQ) were determined by using the formula based on the standard deviation of the response and the slope. LOD and LOQ were calculated by using equations, LOD=3.3 xσ/s and LOQ=10 x σ/s, where σ=standard deviation, S= slope of the calibration curve (Table 2).

3.RESULTS AND DISCUSSION

The present study describes a highly sensitive, economic, accurate, precise and reproducible method for the determination of Tapentadol. The Beer's law was obeyed in the concentration range 25-150 µg/ml with correlation coefficient r=0.9999.The linear regression equation was found Y=0.0078x–0.0261.The percentage recovery values of pure drug from the analyzed formulation were in between 99.75% - 100.29%.The precision of the proposed method was checked in terms of the repeatability, inter-day and intra-day time periods and %RSD was found to be less than 2%.LOD and LOQ were found to be 1.40038 µg/ml, 4.243 µg/ml respectively. The assay values for marketed formulation were found to be within limit. Hence the results of the analysis were validated and recovery studies were carried out as per ICH guidelines. Therefore the newly developed method was successfully applied in tablet dosage form.

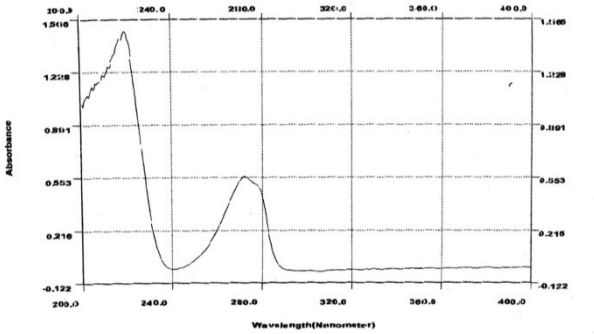
4.CONCLUSION

The proposed analytical method is rapid, accurate, precise and reproducible and hence can be used for the routine analysis of Tapentadol in bulk, tablet dosage forms. High percentage recovery showed that the method was free from interference of excipients used in the formulation. The most striking features of the

method is its simplicity and rapidity, not requiring tedious sample preparations such as extraction of solvents, heating, degassing which are many needed for HPLC procedure. Values of LOD and LOQ showed that the proposed method was sensitive enough to analyze the drug in bulk as well as in its pharmaceutical formulation. All the above result indicates that, the method employed here is very simple, accurate, economic and rapid for routine analysis of the Tapentadol.

5.ACKNOWLEDGEMENTS

Authors are thankful to Department of Pharmaceutical Analysis & Quality Assurance, Bapatla College of Pharmacy, Bapatla for providing laboratory facilities to carry out this research work.



Conc.(µg/ml)	Absorbance
25	0.163
50	0.365
75	0.561
100	0.756
125	0.948
150	1.136

Fig.2 UV spectra of Tapentadol in Water **Table 1.Calibration curve data for Tapentadol**

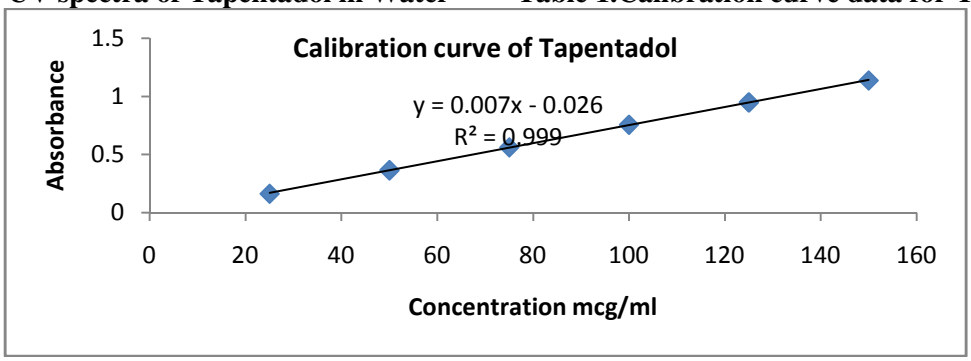


Fig.3 Calibration curve of Tapentadol

Table 2.Optical characteristics and validation parameters of the proposed method

Parameters	**Result**
Measured wavelength(λmax)	272 nm
Beers law limit(µg/ml)	25-150
Molar absorptivity(lit/mole/cm)	$0.16234x10^4$
Specific absorbance $A^{1\%}_{1cm}$	73.361
Sandell's sensitivity (µg/cm^2/0.001 absorbance unit)	0.128205
Regression equation (y=mx+c)	0.0078x-0.0261
Slope(b)	0.0078
Intercept(a)	-0.0261
Correlation coefficient(r)	0.9999
Validation parameters	
Repeatability (%RSD, n=6)	0.49
Inter-day precision(%RSD, n=6)	0.33-0.84
Intra-day precision(%RSD, n=6)	0.23-0.68
LOD(µg/ml)	1.40038
LOQ(µg/ml)	4.243

Table 3.Results of % recovery data (accuracy) for tablet

Levels	Amount of drug (tablet)taken(µg/ml)	Amount of pure drug added(µg/ml)	Amount of drug recovered(µg/ml)	% Recovery
50%	20	17.5	37.406	99.75
100%	20	55.0	75.217	100.29
150%	20	92.5	112.68	100.16
			Mean %recovery 100.06 SD 0.281	

Table 4. Analysis of marketed formulations

Formulation	Labeled Amount(mg)	Amount obtained(mg)	%Drug present	%RSD
Tapal 50	50	49.95±0.3391	99.898	0.46

(*each value is average of six determinations ± standard deviation)

Table 5.Ruggedness data

Amount taken (µg/ml)	ELICO SL 159		SHIMADZU PHARMA SPEC 1700	
	Amount found(µg/ml)	%RSD	Amount found(µg/ml)	%RSD
75 75 75	74.95 74.89 74.80	0.10	74.87 74.96 74.85	0.08

REFERENCES

ICH, Q2 (R1), Validation of Analytical Procedures: text and methodology, 2005.

Kanzariya R.P, Kapuriya K.G, Faldu S.D, Method development and validation of Tapentadol hydrochloride in bulk drug and pharmaceutical dosage form, Inventi Rapid: Pharm. Ana&Qual.Assur, 2012, Article ID-Inventi:ppaqa/309/12, 2012.

Kneip C, Terlinden R, Beier H, Chen G, Investigations into the drug-drug interaction potential of Tapentadol in human liver microsomes and fresh human hepatocytes, Drug Metab.Lett., 2(1), 2008, 67-75.

Ramesh P Kanzariya, Tejash P Patel, Kaushik G Kapuriya, Shital D Faldu, Method development and validation of Tapentadol hydrochloride by RP-HPLC method, Inventi Rapid: Pharm.Ana&Qual.Assur.,2012,ArticleIDInventi:ppaqa /340/12, 2012.

Skoog, Holler, Nieman, Principles of Instrumental Analysis, 5 th Edition, Saunders College Publishing, Harcourt Brace college, Singapore, 2004, 299-326.

Terlinden R, Ossig J, Fliegert F, et al., Absorption, metabolism, and excretion of 14C-labeled Tapentadol HCl in healthy male subjects, Eur.J.Drug Metab.Pharmacokinetic, 32(3), 2007, 163-169.

www.en.wikipedia.org/wiki/Tapentadol.