ISSN : 0974-7419 Volume 12 Issue 3

Trade Science Inc.

Analytical CHEMISTRY

An Indian Journal

Full Paper

ACAIJ, 12(3) 2013 [98-102]

Development and validation of UV spectrophotometric method for estimation of tapentadol hydrochloride in bulk drug and pharmaceutical formulation

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Received: 7th July, 2012 ; Accepted: 9th October, 2012

ABSTRACT

A novel, simple, sensitive and rapid spectrophotometric method has been developed for estimation of tapentadol hydrochloride. The linearity of tapentadol hydrochloride was found in the range of 5-30µg/ml in water and 0.1N hydrochloric acid with correlation coefficient 0.9981 and 0.9996 respectively. The mean recovery percentage was 99.323±0.396% from water and 99.99443±1.357 from 0.1N hydrochloric acid. There were no interferences observed from the common excipients present in the formulations. The amount of drug estimated by proposed method was in excellent agreement with label claimed. The developed spectrophotometric method was simple, linear, ecoifriendly, precise, accurate and can be conveniently adopted for the routine quality control analysis of the tapentadol hydrochloride in tablet dosage form. © 2013 Trade Science Inc. - INDIA

KEYWORDS

Tapentadol hydrochloride;
Validation;
UV spectroscopy.

INTRODUCTION

Tapentadol hydrochloride [(-)-(1*R*, 2*R*)-3-(3-Dimethylamino-1-ethyl-2-methyl-propyl)-phenol-hydrochloride]. Tapentadol is a new, potent, centrally acting analgesic with a dual mode of action and broad analgesic efficacy. Tapentadol hydrochloride demonstrates the efficacy of a strong centrally acting analgesic with improved gastrointestinal tolerability compared with strong opioid analgesics and its activity is due to both µ-receptor agonism and norepinephrine reuptake inhibition[1-5]. It is a novel µ opioid receptor agonist and norepinephrine reuptake inhibitor with broad spectrum analgesic properties[6]. There are stereoisomers of the novel µ-opioid receptor agonist tapentadol hydrochloride because of two chiral centers four[7]. Bourland *et, al.* were reported estimation of tapentadol (Nucynta®) and *N*-desmethyltapentadol in authentic urine specimens using Ultra-Performance Liquid Chromatography-Tandem Mass Spectrometry[8]. The aim of present investigation is to develop spectrophotometric methods for the analysis of tapentadol hydrochloride in bulk and pharmaceutical preparations as per ICH guidelines[9]. Chemical structure of tapentadol was shown in Figure 1.

EXPERIMENTAL

Instrument

A Shimadzu UV-1700 recording double-beam UV-

Visible Spectrophotometer with a data processing system was used. UV spectra of reference and sample solutions were recorded in 1 cm quartz cells.

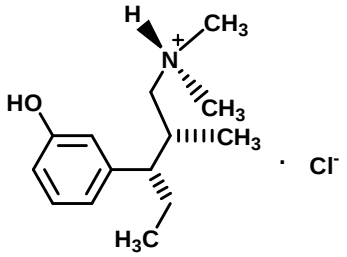

Figure 1 : Chemical structure of tapentadol hydrochloride

Materials

Pure drug of Tapentadol hydrochloride was obtained as a gift sample from zydus cadila, Ahemdabad, India, duovolt ® tablet IPCA. Distilled water, 0.1 N HCl. Tablet formulation was purchased from Indian market, containing tapentadol hydrochloride 50 mg.

Selection of solvent

Distilled water and 0.1 N HCl were selected as solvent for developing spectral characteristics of drug.

Preparation of standard stock solution of tapentadol

Stock solutions of tapentadol hydrochloride were prepared at a concentration of 100 µg/ml in water and 0.1 N HCl. Working standard solutions were prepared by diluting stock solutions at the concentrations of 30µg /ml in water and 0.1 N HCl same was used as a reference. Working standard solution of tapentadol hydrochloride was scanned between 200-400 nm on Shimadzu double beam UV visible spectrophotometer. A wavelength maximum exhibited for tapentadol hydrochloride was at 214 nm in water and 214.6 nm in 0.1 N HCl.

Construction of calibration curve

Aliquot of the standard stock solution (0.5, 1, 1.5, 2, 2.5, 3 ml) was transferred into a series of volumetric flask (10 ml) and volume was adjusted up to the mark with water to get desired concentration (5–30µg/ml). The absorbance's of the prepared solutions were measured at 214 nm and 214.6.

Assay

Assay of the proposed method was ascertained by performing assay of the standard drug with reference to the sample drug and finding out the absorbance. From the absorbance percentage purity was calculated (TABLE 1).

TABLE 1 : Assay results of tapentadol hydrochloride

Brand Name	Label Claim (mg/tablet)	% Label Claim (n = 3)	% RSD
Duovolt® 50mg (in water)	50	99.7966	0.9036
Duovolt® 50mg (in 0.1 N HCl)	50	99.73	0.6728

Validation

Linearity

To establish linearity of the proposed methods, five separate series of solutions of tapentadol (5-30 µg/ml) in water were prepared from the stock solutions and analyzed. Least square regression analysis was performed on the obtained data.

Precision

Repeatability

Repeatability expresses the precision under the same operating conditions over a short interval of time. Repeatability is also termed intra-assay precision. Six number of determination of same concentration were performed.

Intra-day and inter-day precision

Intra-day and inter-day precision were determined by analyzing three different solutions of tapentadol within the same day and three different days over period of week. Intra-day precision was estimated by analyzing 10 µg/ml, 15 µg/ml, 20 µg/ml for three times within same day. Inter-day precision was estimated by analyzing above mentioned concentration of tapentadol for three different days over a period of week.

Accuracy

It is defined as closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and value found. It is measure of exactness of analytical method. Accuracy should be expressed as % recovery by the assay of known added amount of analyte in the sample or as the difference between mean and accepted true value together with the confidence intervals. Accuracy should

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be established across the specified range of the analytical procedure.

Limit of detection

LOD was found to be 0.541 in water and 0.507 in 0.1 N HCl.

Limit of quantification

LOQ was found to be1.641 in water and 1.538 in 0.1 N HCl.

RESULTS AND DISCUSSION

Tapentadol hydrochloride was freely soluble in water and in 0.1N hydrochloric acid and has λmax of 214 nm and 214.6 nm respectively, shown in Figure 2 and Figure 3.

The linearity of tapentadol hydrochloride was found in the range of 5-30µg/ml in water and 0.1N hydrochloric acid with correlation coefficient 0.9981 and 0.9996 respectively. Results are shown in Figure 4, 5 and TABLE 2.

The percentage RSD was found to 1.0666 and 0.9522 for water and O.1 HCl respectively in precision study of tapentadol hydrochloride, shown in TABLE 3.

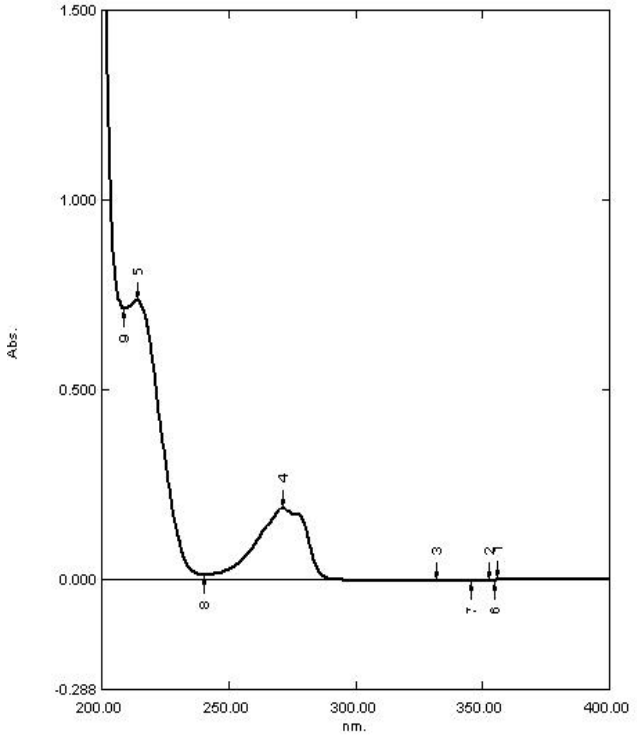

Figure 2 : Spectrum of tapentadol hydrochloride in distilled water

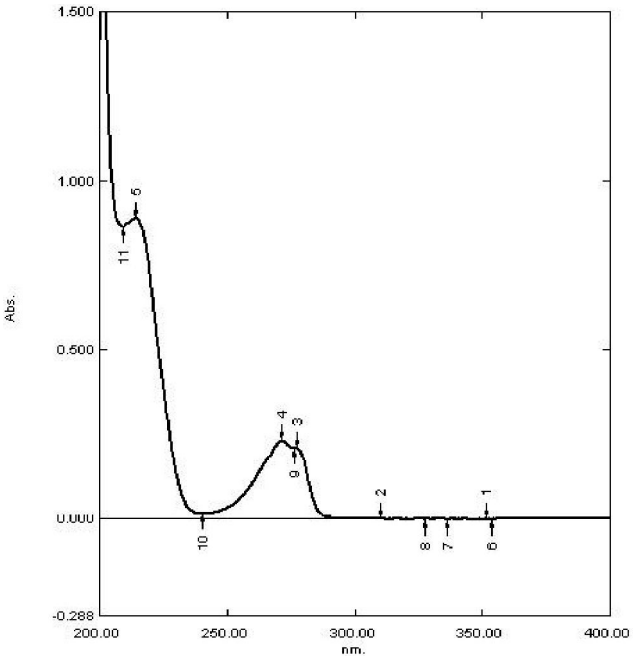

Figure 3 : Spectrum of tapentadol hydrochloride in 0.1N HCl

TABLE 2 : Results of linearity study

Features	water	0.1N HCl
Regression equation	y = 0.0251x + 0.0155	y = 0.0286x + 0.0268
Correlation coefficient	R^2 = 0.9981	R^2 = 0.9996
Slope (m)	0.0251	0.0286
Y-Intercept(c)	0.00155	0.0268
Beer's law range(µg/ml)	5-30 µg/ml	5-30 µg/ml

TABLE 3 : Results of precision study

Concentration (µg/ml)	Solvent	Mean of absorbance (n= 6)	S.D	% R.S.D
15	Water	0.3861	0.004119	1.066654
15	0.1 N HCl	0.4621	0.004401	0.9522

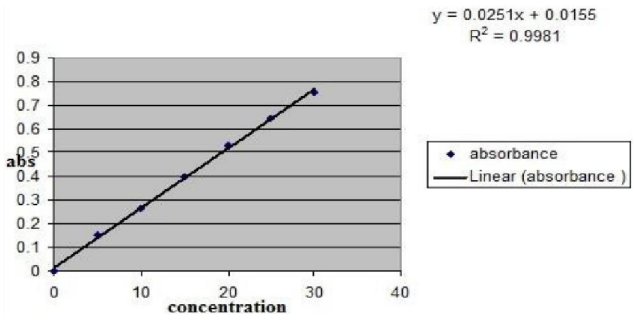

Figure 4: Linearity of tapentadol hydrochloride in distilled water

Precision was calculated as inter and intraday variations (%RSD is less than 2) for tapentadol hydrochloride (% RSD is less than 2), shown in TABLE 4.

TABLE 4 : Results of intra-day and inter-day precision study

Drug	Concentration [µg/ml]	Intra-day [n=3]		Inter-day [n=3]	
		Amount found [µg/ml]	% RSD	Amount Found [µg/ml]	% RSD
Tapentadol (water)	10	9.93	0.8074	10.07	1.088
	15	15.066	0.4284	15.04	0.436
	20	20.02	0.6531	19.91	0.635
0.1N HCl	10	9.97	0.7757	9.923	0.763
	15	14.92	0.6710	14.92	0.697
	20	19.88	0.6119	19.92	0.925

The mean percentage recovery was 99.323±0.396% from water and 99.99443±1.357 from 0.1N hydrochloric acid, shown in TABLE 5.

There were no interferences observed from the common excipients present in the formulations. Above parameters demonstrates that the developed UV spectrophotometric method was specific, fast, accurate, simple, linear, precise, sensitive, robust and rugged. Thus the developed method can be easily used for the routine quality control of bulk and tablet dosage form of tapentadol hydrochloride.

TABLE 5 : Results of accuracy study

Percentage	% recovery in water	% recovery in 0.1N HCl	Mean of % recovery in water	Mean of % recovery in 0.1 N HCl	Mean±SD in water	Mean±SD in 0.1 N HCl
80	98.38	102.4				
	101.7	101.43	99.78 ± 1.72	101.56 ± 0.783		
	99.26	100.85				
100	98.1	98.63				
	99.1	99.33	99.06 ± 0.95	99.27 ± 0.616	99.323±0.396	99.99443±1.357
	100	99.86				
120	98.06	98.25				
	99.14	99.36	99.12± 1.05	99.15 ± 0.815		
	100.17	99.84				

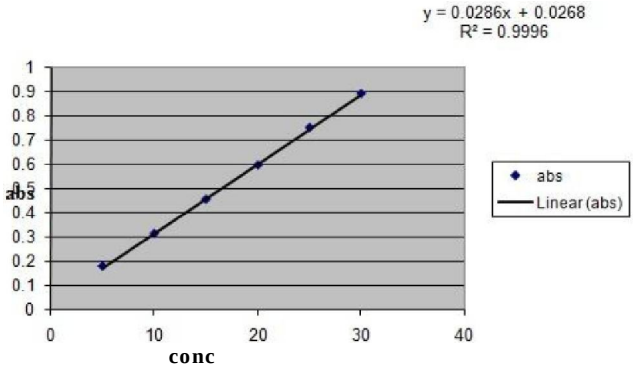

Figure 5: Linearity of tapentadol hydrochloride in 0.1N HCl

CONCLUSION

The proposed method was simple and reliable with good precision, accuracy, linearity, LOD, LOQ. The proposed method is specific while estimating the commercial formulations without interference of the excipients and other additives. Developed spectrophotometric methods are accurate, sensitive, precise, and reproducible and can be easily and directly applied to the tablet containing tapentadol hydrochloride. Additionally, the short analysis time and low costs are the other advantages of these methods for routine analysis.

ACKNOWLEDGEMENTS

The authors are thankful to Dr. S. B. Bari, Principal, H.R. Patel Institute of Pharmaceutical Education and Research, Shirpur (M.S.), India for providing the required facilities to carry out this research work. Authors gratefully acknowledge Zydus cadila, Ahemdabad, India to providing gift sample of tapentadol hydrochloride and department of analysis, H.R.P.I.P.E.R,Shirpur, Dhule.

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