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Spectrophotometric Methods for Determination of Tapentadol Hydrochloride

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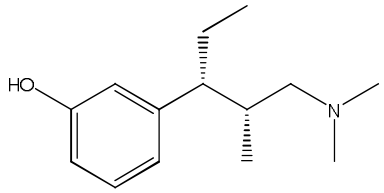
ABSTRACT

Two simple, fast, environmental friendly and reliable spectrophotometric methods were developed for determination of tapentadol hydrochloride in bulk and synthetic mixture containing the possible excipients. The first method is based on measuring the first derivative values of aqueous solution of the drug at 228 nm (method I) and the second method based on measuring the second derivative values at 235 nm (method II). Calibration graphs constructed at their wavelengths of determination were linear in the concentration range of tapentadol 5-60 $\mu g.ml^{-1}$ for both methods. The proposed methods have been extensively validated as per ICH guidelines. The developed spectrophotometric methods in this study are simple, accurate, precise, specific and reproducible and can be directly applied to pharmaceutical dosage form.

INTRODUCTION

Tapentadol 3-[(1R, 2R)-3-(3-dimethylamino) -1- ethyl -2- methyl propyl] phenol (I) is a recently FDA approved centrally-acting analgesic drug. Tapentadol is mainly used for the relief of moderate to severe pain (FDA, 2008). Tapentadol is classified as a schedule II drug under the controlled substance act (Drug Enforcement Administration, 2009).



Tapentadol chemical structure

Literature review revealed that few analytical methods have been reported for determination of Tapentadol Hydrochloride.

The reported methods include UPLC (Bourland *et al*., 2010) HPLC (Giorgim *et al*., 2012) and LC/MS/MS (Coulter *et al*., 2010) for the determination of the drug in various biological fluids and RP- HPLC (Gandhi *et al*., 2012, Ramanaiah *et al*., 2012 and El-Fatatry *et al*., 2013) methods for determination of the drug in its pharmaceutical dosage form. Recently a spectrophotometric method was developed for determination of tapentadol in bulk and pharmaceutical formulation (Pavan *et al.*, 2012). The application of derivative spectrophotometry in pharmaceutical analysis is very important. In pharmaceutical application, derivative spectrophotometry has led to significant developments in the analysis of drugs in the presence of their degradation products or in multi-component mixtures.

There is no derivative spectrophotometric method reported for the analysis of tapentadol in pharmaceutical formulation. Derivative spectrophotometry is an analytical technique of great utility for extracting both qualitative and quantitative information from spectra composed of unresolved bands. The aim of the present research work was to develop simple, specific and accurate derivative spectrophotometric methods for the determination of tapentadol hydrochloride in bulk and synthetic mixture containing the possible excipients.

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EXPERIMENTAL

Materials

Tapentadol hydrochloride was purchased from Beijing Huikang Boyuan Chemical Co., Ltd, China. Povidone was purchased from sigma. Other tablet excipients (magnesium stearate and avicel) were purchased from Inter. Trade. Co. Egypt.

Instrumentation

UV and derivative spectra of the solutions were recorded on double beam UV–Vis spectrophotometer Jasco V-530 using 10mm path length quartz cells with fixed slit width of 2 nm at a scanning speed of 1000 nm/min scan range of 200–350 nm, datapitch 1 nm. Spectrophotometer connected to a personal computer loaded with [Jasco]-[spectra manager] software.

Preparation of standard solutions & Construction of calibration curve

Stock standard solution of tapentadol hydrochloride was prepared in distilled water to give a final concentration of 500 $\mu g.mL^{-1}$. Different aliquots from tapentadol stock solution were taken and diluted with water to obtain solutions of tapentadol hydrochloride in the concentration range (5-60 $\mu g.mL^{-1}$). The first and second order derivative spectra were recorded using the prepared solutions against water as blank.

Calibration curves were constructed by plotting the values of the first derivative absorbance (^1D) at 228 nm and of the second derivative absorbance (^2D) at 235 against corresponding concentrations of standard solutions for method I and II respectively.

Preparation of assay solution

Synthetic mixture was prepared by mixing 50 mg of tapentadol hydrochloride, 2 mg povidone, 2 mg magnesium stearate and 46 mg avicel. 100 mg of this mixture was transferred to 50-ml volumetric flask and the solution was made up to required volume using distilled water. The solution was filtered and the first 10 mL of the filtrate is discarded. 1 ml of this filtrate was transferred to a 25-ml volumetric flask and made up to final volume using distilled water to obtain a concentration of 40 $\mu g.mL^{-1}$. The drug concentration was calculated from the calibration curves.

RESULTS AND DISCUSSION

Method optimization

At the beginning, the absorption UV spectra of tapentadol over the range 200 – 350 nm in water, methanol, ethanol and 0.1N HCl were recorded. There was no significant difference between different solvents so water was chosen.

For spectrophotometric methods, order of derivative and "N" value were optimized. The first derivative (N=9) and second derivative (N=9) were chosen as optimum conditions.

Method validation

The validity of the method was tested regarding linearity, specificity, accuracy, and precision according to ICH guide lines (ICH-Q2B, 1996) and was compared to the reported spectrophotometric method (Pavan *et al*., 2012).

Linearity and range

Under the experimental conditions described, the graph obtained for first and second derivative spectra showed linear relationship. Regression analysis was made for the slope, intercept and correlation coefficient values.

The statistical parameters are calculated from the calibration graphs as shown in Table 1.

Precision

To establish the intra-day and inter-day precision of the method, three replicate standard solutions at three different concentrations (15, 25 and 35 $\mu g.mL^{-1}$) were assayed on single day and three separate days.

The precision was determined as RSD of the recovered drug concentration. The intra-day and inter-day variability showed RSD values less than 2% in all three selected concentrations indicating good repeatability over the entire concentration range, which revealed that the proposed method was precise as shown in Table 2.

Accuracy

The accuracy of the method was checked by recovery study using standard solution at three different concentration levels, *i.e*., multilevel recovery study.

Mean % Recovery ± S.D of standard drugs analyzed by method I and II were found to be 99.67 ± 1.36% and 98.9 ± 0.27% respectively indicating that the proposed method was accurate. Results of recovery study are shown in Table 3.

Specificity

For testing specificity of the method the percentage recovery of tapentadol was determined in mixture containing the possible excipients such as povidone, avicel, magnesium stearate. The results obtained exhibited no interference as illustrated in Table 4.

The ratio of derivative optima of UV absorption spectra is used to test for the presence of nonspecific matrix interference and to predict the validity of application of derivative spectrophotometry during analysis of pharmaceutical formulations. The ^1D and ^2D order spectra of different concentrations of standard tapentadol solutions were recorded and the ratio of $^1D_{228}/^1D_{282}$ and $^2D_{235}/^2D_{288}$ were calculated for both standard and assay solutions of tapentadol.

The ratios of ^1D and ^2D maxima of tapentadol standard and assay solution were found to be too close to each other as illustrated in Table 5.

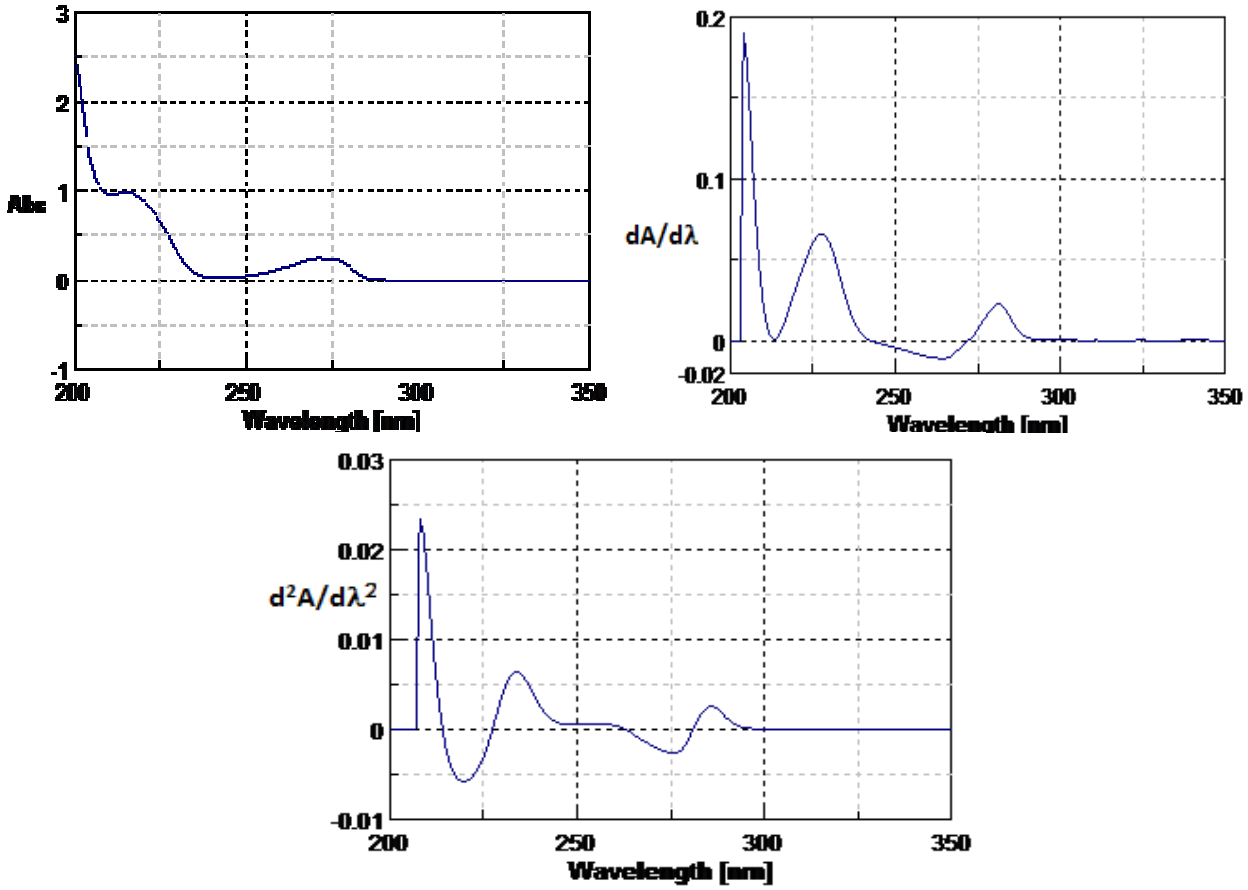

Fig. 1: Absorption spectrum of standard solution of tapentadol (40 µg.mL^{-1}) in distilled water (a), its first derivative (b), its second derivative(c).

Table. 1: Statistical data of calibration curves of tapentadol hydrochloride.

	Method I	Method II	^{0}D Spectroscopic Method*
Linearity Range, µg.mL^{-1}	5-60	5-60	25-150
Regression equation (y=mx+c)	0.0017x + 8E-06	0.0002x + 9E-05	0.0078x- 0.0261
Correlation coefficient (R^2)	0.9996	0.9998	0.9999
LOD, µg.mL^{-1}	1.06	1.5	1.4
LOQ, µg.mL^{-1}	3.2	4.6	4.2

* (Pavan *et al*., 2012)

Table. 2: Precision of method for determination of tapentadol hydrochloride.

Method	Concentration Taken, µg.mL^{-1}	Intra-day *		Inter-day *	
		Concentration found mean ± S.D, µg.mL^{-1}	R.S.D, %	Concentration found mean ± S.D, µg.mL^{-1}	R.S.D, %
^{0}D	30	29.97 ± 0.17	0.56	30.15 ± 0.2	0.65
	50	49.57 ± 0.26	0.52	49.47 ± 0.15	0.31
	70	69.34 ± 0.26	0.37	69.32 ± 0.15	0.22
I	15	15.31 ± 0.07	0.46	15.26 ± 0.1	0.66
	25	25.17 ± 0.18	0.73	25.14 ± 0.56	1.8
	35	35.9 ± 0.42	1.18	35.67 ± 0.64	1.79
II	15	14.80 ± 0.06	0.38	14.91 ± 0.21	1.41
	25	24.80 ± 0.23	0.92	25.02 ± 0.19	0.75
	35	34.59 ± 0.17	0.49	34.84 ± 0.37	1.06

* The mean found concentration is calculated from three determinations of each concentration.

Table. 3: Recovery data for the proposed spectrophotometric methods.

Method	I	II	^{0}D
Concentration taken, µg.ml^{-1}	15	15	30
	25	25	50
	35	35	70
Concentration found, µg.ml^{-1}	15.14	14.8	29.97
	24.56	24.8	49.57
	34.93	34.59	69.34
Recovery* %	100.96	98.68	99.89
	98.25	99.21	99.14
	99.81	98.83	99.06
Mean recovery % ± SD	99.67 ± 1.36	98.9 ± 0.27	99.36 ± 0.46

* The mean recovery % is calculated from three determinations of each concentration

Table. 4: Recovery data of tapentadol from synthetic mixture.

Method	I	Ii	^{0}D
Mean recovery* % ± S.D	100.68 ± 0.89	101.71 ± 0.13	97.9 ± 0.48
RSD %	0.88	0.13	0.97

* The mean recovery % is calculated from three determinations

Table. 5: The ratio of two maxima of ^{1}D and ^{2}D order spectra of standard tapentadol and assay solution.

	Standard tapentadol	Assay solution, (50µg.mL^{-1})
$^{1}D_{228}/^{1}D_{282}$	4.35 ± 0.74	4.29
$^{2}D_{235}/^{2}D_{288}$	3.17 ± 0.08	3.11

CONCLUSION

No derivative spectrophotometric methods have been described for the determination of tapentadol hydrochloride. Rapid, simple, accurate, sensitive and reproducible derivative spectrophotometric quantitative and qualitative methods for routine analysis of tapentadol hydrochloride in bulk and pharmaceutical formulations were developed and validated. The major advantage of these methods is the quick sample analysis without prior separation or purification. Sample preparation procedure was simple making the method suitable for processing multiple samples in a limited period of time.

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