Research Article

Determination of Tapentadol Hydrochloride in Bulk and Its Solid Dosage Form by UV – Spectrophotometry

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ABSTRACT

A simple and reproducible UV spectrophotometric method for the quantitative estimation of Tapentadol hydrochloride in bulk and its formulation was developed and validated in the present work. Tapentadol hydrochloride has the maximum wavelength at 271nm. Beer's law was obeyed in the concentration range of 42.85 – 61.15µg/mL with correlation coefficient r = 0.9996. Recovery studies for Tapentadol hydrochloride were performed and the percentage recovery was obtained in the range of 99.95% confirming the accuracy of the proposed method. The developed method showed good reproducibility and recovery with %RSD less than 2. Statistical validation of the data shows that the proposed method can be successfully applied for the routine analysis of Tapentadol hydrochloride in pure and its Pharmaceutical tablet formulations.

Keywords: Absorbance, Pharmaceutical dosage form, Tapentadol hydrochloride, UV- Visible Spectrophotometer.

INTRODUCTION

Tapentadol hydrochloride is a novel next generation centrally acting analgesic with two mechanism of action. It has opioid and non opioid activity in a single compound. It has dual mode of action as an agonist effective against moderate to severe pain, whereas norepinephrine reuptake effective against chronic pain. The combined both mechanisms effective broad spectrum for many pain conditions like cancer pain, osteoarthritis, neuropathic pain and low back pain.[1-5]

The chemical name of Tapentadol hydrochloride is 3-[(1*R*, 2*R*)-3-(dimethylamino)-1-ethyl-2-methylpropyl] phenol monohydrochloride (Figure 1) and its molecular weight is 221.0. It is not official in any pharmacopoeia. Literature survey revealed few HPLC, Spectrophotometric and pharmacological methods have been reported for the estimation of Tapentadol hydrochloride.[5-10]

The objective of the study is to develop a new, simple and rapid UV Spectrophotometric method for the estimation of tapentadol hydrochloride in bulk and its tablet dosage form. The developed method has been validated as per ICH guidelines.

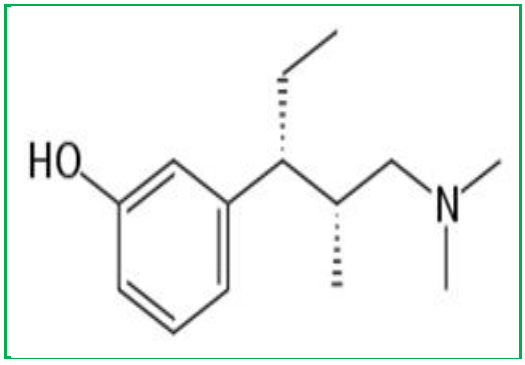


Figure 1: Chemical Structure of Tapentadol hydrochloride

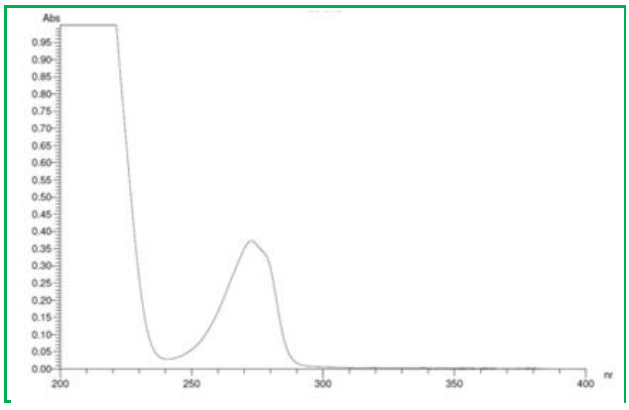
MATERIALS AND METHODS

Apparatus and chemicals

UV-Visible spectrophotometer Techcomp 2301 with 1cm matched quartz cells was used for all spectral measurements. All the chemicals used were of analytical reagent grade. Tablets were purchased from local market.

Preparation of standard solution

About 62.5 mg of tapentadol hydrochloride was weighed accurately and transferred into 50mL volumetric flask and dissolved in 20mL of water by sonication for 15 minutes with intermittent shaking and made up to the volume with water. Transfer the 1 mL of the above solution into 25mL of volumetric flask and diluted with water: methanol (50:50) mixture and made up to the mark with the same mixture to get concentration of 50µg/mL. This solution was scanned against blank for 200-400 nm. Based on the spectrum, λ_{max} of 271nm was fixed for the further analysis. The spectrum was shown in figure 2.



X-axis: Wavelength (nm); Y-axis: Absorbance

Figure 2: UV spectrum of the standard Tapentadol hydrochloride

Preparation of standards for linearity

To perform linearity 42.85µg/mL, 46.45 µg /mL, 50 µg/mL, 55.65 µg/mL, 61.15 µg /mL of standard drugs were prepared using diluent as water: methanol (50:50) mixture. Absorbances of these standards were measured at a λ_{max} of 271 nm. The absorbance values for respective concentrations were given in table 1.

Table 1: Beer's law plot readings for Tapentadol hydrochloride at 271nm

Concentration in µg/mL	Absorbance
42.8	0.316
46.45	0.344
50	0.370
55.65	0.417
61.15	0.461

Preparation of sample solution

Weighed and powder 20 tablets. Accurately weighed about powder equivalent to 62.5mg and transferred to a 50mL volumetric flask. Dissolved the drug using water and sonicate for 15 minutes with intermittent shaking and made up to volume with water. Filter the solution through 0.45µ membrane. Transferred 1mL of the filtered solution into a 25mL volumetric flask and dilute to volume with water: methanol (50:50) mixture. The absorbance of the resulting solution was measured at 271nm. The results were shown in table 2.

Table 2: Analysis data of tablet formulations of Tapentadol HCl

Formulation	Label claim (mg/tab)	*Amount obtained (mg)	% Drug present	% RSD
A	50	50.03	100.05	0.134

Recovery studies

The accuracy of proposed method was checked by recovery study by addition of standard drug solution to pre-analyzed solution at three different concentration levels (110%, 120%, and 130%). Each level was repeated six times. The recovery experiments were performed for two different brands of tablets. The result of recovery study is reported in table 3.

Table 3: Results of recovery studies

% Levels	Amount taken from formulation (in µg/mL)	Amount of pure drug added (in µg/mL)	Amount of drug recovered (in mg)	% recovery
100	50	0	49.93	99.86
110	50	5	54.92	99.85
120	50	10	60.09	100.15

RESULTS AND DISCUSSION

The wavelength of 271nm (λ_{max} for Tapentadol hydrochloride) was fixed for analysis of the drug and Beer's law was obeyed in the concentration range of 40-60µg/mL with correlation coefficient (r) is 0.9998.The low relative standard deviation values indicates good precision and high recovery values indicates accuracy of the proposed method. The optical characteristics and validation parameters were calculated for the proposed method and the results were shown in table 4.

Table 4: Optical characteristics and validation parameters of the proposed UV method

Parameters	Results
λmax(nm)	271
Linearity range(µg/mL)	40-60
Regression equation Y* = a + bc	
Intercept (a)	0.0252
Slop (b)	0.0040
Correlation coefficient	0.9996

Y* = a + bc; where y = absorbance, c = concentration of Tapentadol hydrochloride in µg/mL

CONCLUSION

The proposed UV-method was found to accurate and can be applied for routine analysis of tapentadol hydrochloride in pure form and its tablet formulations.

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