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A New Facile and Sensitive Method for the Estimation of Tapentadol

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ABSTRACT

A simple, economical, precise, reliable and reproducible visible Spectrophotometric method has been developed for the estimation of Tapentadol in bulk as well as in tablet formulations. This method is based on the formation of Blood red colored chromogen with2, 2 -bipyridyl which shows maximum absorption at λ_{max} 520 nm. The absorbance-concentration plot is linear over the range 50-250µg/mL. Results of analysis were validated statistically. Recovery studies were also performed. The proposed method is economical, accurate precise and sensitive for the estimation of Tapentadol in bulk drug and its formulation.

Keywords: Tapentadol, 2, 2- bipyridyl, Blood red colored, Visible Spectrophotometric.

INTRODUCTION

Tapentadol, (Fig. 1) chemically known as (–)-(1*R*,2*R*)-3-(3-dimethylamino-1-ethyl-2-methyl-propyl) - phenol hydrochloride (tapentadol HCl), with respect to its *in vitro* characteristics and its analgesic, antihyperalgesic, and antiallodynic properties in rat and mouse models of acute and chronic pain. Tapentadol, a centrally acting synthetic analgesic, received initial U.S. approval in 2008 [1] and was then placed into the schedule II category of the Controlled Substances Act in May of 2009. [2] The drug is a novel, centrally acting oral analgesic with a dual mode of action that has demonstrated efficacy in clinical application. It is suggested that the broad analgesic profile of tapentadol and its relative resistance to tolerance development may be due to a dual mode of action consisting of both MOR activation and NE reuptake inhibition. [3] Literature survey reveals many chromatographic methods in biological fluids for the determination of Tapentadol. [4-5] Few spectrophotometric and RP-HPLC methods are also reported. [6-11] Therefore the need for fast, low cost and selective method is obvious especially for routine Quality Control analysis of pharmaceutical formulation.

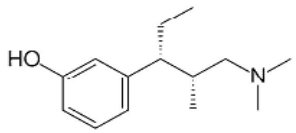

Fig. 1: Structure of tapentadol

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MATERIALS AND METHODS

Instrument

Elico double beam Ultraviolet-Visible double beam spectrophotometer SL-164 with 1 cm matched quartz cells was used for all spectral measurements.

Preparation of Reagents

All chemicals used were of analytical reagent grade.

Preparation of 0.01 M 2, 2-bipyridyl (156.18 g mol^{-1}) for 100 mL: Weigh 0.156 gms of 2, 2-bipyridyl in 100 mL of 0.1N HCL and make up to 100 mL.

Preparation of 0.003 M Ferric chloride (MWT 162.2 g) solution: Weigh 0.162 gms of ferric chloride, dissolved in distilled water and make up to 100 mL and take 33.3 mL of above stock solution was further diluted to 100 mL with distilled water

Preparation of 0.2 M Ortho phosphoric acid (MWT- 98 gms) solution: Weigh 1.3 mL of Orthophosphoric acid, dissolved in distilled water and make up to 100 mL.

Preparation of standard solution of 100 mg in 100 mL stock solution: Weigh 100 mg of bulk drug (Tapentadol) and dissolve in distilled water and make up to 100 mL to give a stock solution of 1000 mcg/mL.

Assay Procedure

Aliquots of standard drug solution containing Tapentadol (0.5-2.5 mL) (100 µg/mL) were transferred into series of 10 mL graduated test tubes, 1 mL of ferric chloride (0.003 M) and add 2 mL of 2, 2-Bipyridyl reagent, 1 mL of ferric chloride were added to each test tube. The test tubes were then heated on water bath at 70 ^{0}C for 20 min and then cooled to room temperature and then 2 mL of orthophosphoric acid (0.2 M) was added and the total volume was made up to 10 mL with distilled water. The absorbance of blood red colored chromogen was measured at maximum

wavelength is determined and measured at 510 nm against reagent blank which shown by Fig. 2 and a calibration curve was constructed shown by Fig. 3. The absorbance of the solution was measured and the amount of Tapentadol was determined by referring to the calibration curve.

Preparation of sample solution

10 tablets of Tapentadol (TYDAL-100mg) were accurately weighed and powered. Tablet powder equivalent to 270mg of Tapentadol was dissolved in 100ml of distilled water, sonicated for 15min and filtered. The solution was suitably diluted and analyzed as given under the assay procedure for bulk sample. The analysis procedure was repeated three times with Tablet formulations and the results of analysis for the method are shown in Table 2.

Recovery Studies

To ensure the accuracy and reproducibility of the results obtained, known concentration of the pure drug solution was added to the previously analyzed formulated solution samples and these samples were reanalyzed by the proposed method and also preformed recovery studies. The percentage recoveries, thus obtained for method is given in Table 2.

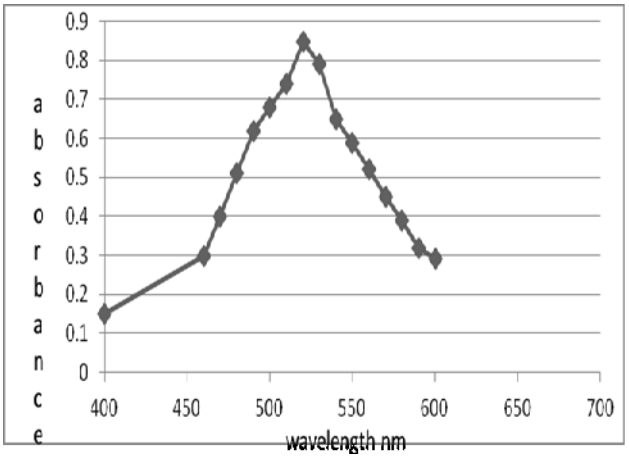

Fig. 2: Absorption spectrum of Tapentadol with 2, 2-Bipyridyl

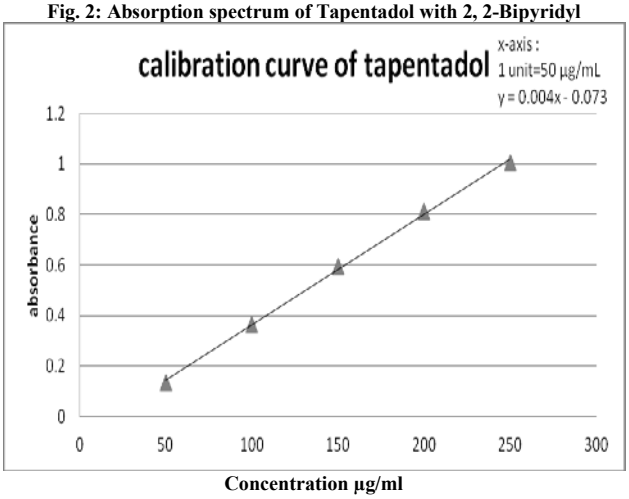

Fig. 3: Linearity calibration curve of Tapentadol with 2, 2'-Bipyridyl

RESULTS AND DISCUSSION

The optimum conditions were established by varying one parameter at a time and keeping the others fixed and observing the effect on absorbance of chromogen. The Method is based on the reduction of Ferric chloride to ferrous form by the drug, which forms complex with 2, 2'-bipyridyl to yield blood red colored chromogen, having absorbance maximum at 520 nm. The linearity was found to be in the concentration of 50-250 mcg/ml. The colored chromogen was stable for 2 hrs.

Statistical analysis was carried out and the results were found to be satisfactory. Relative standard deviation values were low indicating the reproducibility of the proposed methods. Recovery studies were close to 100% that indicates the accuracy and precision of the proposed methods. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity, Sandell's sensitivity and other parameters are presented in Table 1.

Table 1: Optical characteristics and precision data

Parameter	Values
λ_{max} (nm)	520
Beers law limit µg/Ml	50-250
Molar absorptivity (µgms/cm^2/0.001Absorbance unit)	0.224x10^4
Sandell's sensitivity (µgms/cm^2/0.001Absorbance unit)	0.98418
Regression Equation (y)	
Slope(m)	0.004
Intercept(c)	0.0735
Correlation Coefficient (r)	0.9989
Precision(% Relative standard deviation)	0.527
Standard error of estimate	0.0166

Table 2: Assay of Tapentadol in Tablet Formulations

Tablet Formulation	Labelled Amount (mg)	*Amount Obtained (mg) by proposed method	% **Recovery by the proposed method
1.	100mg	97.8 ±0.5	98.73 ±0.5
2.	100mg	98.3 ±0.3	99.01 ±0.3
3.	100mg	99.5 ±0.4	99.6 ±0.4

*Average of three determination, **After spiking the sample.

This new procedure for the spectrophotometric determination of Tapentadol described in this work is simple, rapid and cost-effective with high accuracy and precision, when compared with previously reported procedures. It could find application as a convenient technique for the in-process control analysis of Tapentadol in bulk and its pharmaceutical formulations.

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