ISSN: 2347-4742

Research Article
Journal of Pharmaceutical and Biomedical Analysis Letters
www.pharmaresearchlibrary.com/jpbmal

A Simple Validated UV Spectroscopic Method for the Determination of Tapentadol in Bulk and Its Tablet Dosage Forms

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Received: 10 April 2014, Accepted: 18 May 2014, Published Online: 18 June 2014

Abstract

Tapentadol (TAP) is a novel opioid pain reliever drug that is unusual in its possession of dual mechanism of action (mu opioid-receptor agonist and noradrenaline reuptake inhibitor), this feature makes the active ingredient an attractive potential progenitor of a new pharmacological class. The present research work discusses the development and validation of a UV spectrophotometric method for TAP. Simple, accurate, precise and cost efficient spectrophotometric method has been developed for the estimation of TAP in bulk and its tablet dosage form. The optimum conditions for the analysis of the drug were established. The maximum wavelength (λ max) was found to be 272 nm in water. The mean percentage recovery of TAP was found to be in range 99.860 %. Beers law was obeyed in the concentration range of 15-120 µg/ml. Calibration curves shows a linear relationship between the absorbance and concentration. The line equation y = 0.0064x + 0.0224 with R^2 = 0.9978 was obtained. Validation was performed as ICH guidelines for Linearity, accuracy, precision, LOD and LOQ. The proposed method may be suitable for the analysis of TAP in bulk and tablet formulation for routine quality control purposes.

Keywords: Tapentadol, mu opioid, UV spectrophotometric.

Contents

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Manuscript ID: JPBMAL2073

PAPER-QR CODE

1. Introduction

Tapentadol, 3 - [(1 R, 2 R) - 3 - (dimethylamino) - 1- ethyl - 2 - methyl - propyl] phenol hydrochloride (TAP), differs distinctly from previously characterized centrally acting analgesics in that it has a peculiar dual mechanism of action. For this reason, a new pharmacological class has been proposed, namely mu opioid receptor agonist and

noradrenaline reuptake inhibitor (MOR-NRI) [1]. Tapentadol Hydrochloride is not official in any Pharmacopoeia[2]. The chemical structure of TAP was shown in Figure 1.

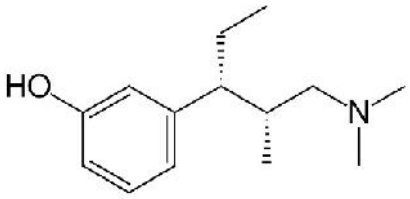

Figure 1. Chemical structure of Tapentadol

To date, only two LC–MS methods to detect TAP in biological matrices (urine [3] and urine and oral fluid [4]) and few HPLC [1, 5, and 6] methods have been reported in the literature, however there have been no studies on UV method for detection of TAP in pharmaceutical formulations. To address this shortfall, the aim of the present paper was to develop and validate a new simpler methodology to quantify TAP in tablet formulation using UV Spectrophotometer and validated as per the guidelines of ICH [7, 8].

2. Materials and Methods

Instruments

Electronic Weighing balance - single (pan balance, Model Axis LC/GC), Digital pH meter (Model- Systronics), Sonicator- Ultra Sonicator (Model- Bandelin sonorex), Double Beam UV-Visible spectrophotometer - Schimadzu 1800. UV spectra of standard and sample solutions were recorded in 1cm quartz cells at the wavelength ranges of 200-400 nm.

Chemicals and Reagents

TAP was obtained as a gift sample from MSN Laboratories, Ltd, Hyderabad. Methanol A.R, potassium dihydrogen phosphate A.R were purchased from Merck. Distilled water was prepared in-house by Milli Q water system.

Preparation of Stock solution

Accurately weighed 100 mg of Tapentadol was transferred into 100 ml volumetric flask, dissolved in distilled water and volume was made up to the mark with distilled water to give 1000µg/ml solution. Working standard solution of 60µg/ml was prepared by diluting 1.5 ml of the stock solution to 25ml with distilled water. The working standard solution were daily prepared by diluting stock solution in water.

Preparation of test sample

Twenty tablets of Tapentadol were weighed and powdered. The quantity of the powder equivalent to 100 mg (293.33 mg) of Tapentadol was transferred in to 100 ml volumetric flask. 50 ml distilled water was added and mixed for 5-10 min, filtered the solution and first few ml was discarded (1000µg/ml). 1.5 ml of above solution was transferred into 25 ml volumetric flask and volume was made up to the mark with distilled water to give 60µg/ml.

3. Results and Discussion

Analytical method development

To develop accurate, precise and sensitive UV spectrophotometric method for TAP various solvent systems such as water, methanol, ethanol and 0.1 N HCl etc., were tried alone and in combinations. Selection of Distilled water was based on sensitivity, minimal interference, ease of preparation, suitability for drug content estimation, stability, analysis time and cost. The λ_{max} for TAP in water was found to be 272 nm. The λ_{max} curve was shown in Figure 2.

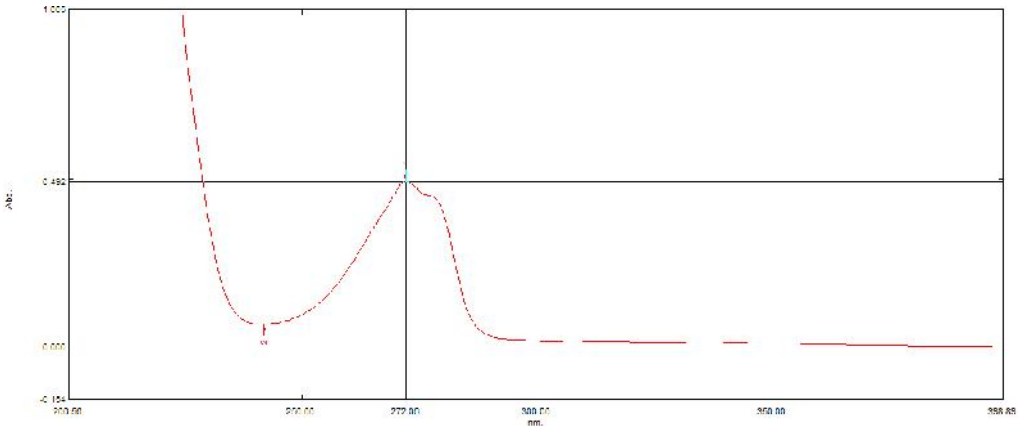

Figure 2. λ_{max} of Tapentadol

Analytical method validation:

Linearity and Range:

Various concentrations were prepared from the secondary stock solution ranging from 15-120 µg/ml. The samples were scanned in UV-VIS Spectrophotometer against distilled water as blank. The calibration curve of TAP (Figure 3) was plotted between concentration of TAP and respective measured absorbance values at 272 nm. It was found to be linear in the specified range and the regression coefficient was found to be 0.9978.

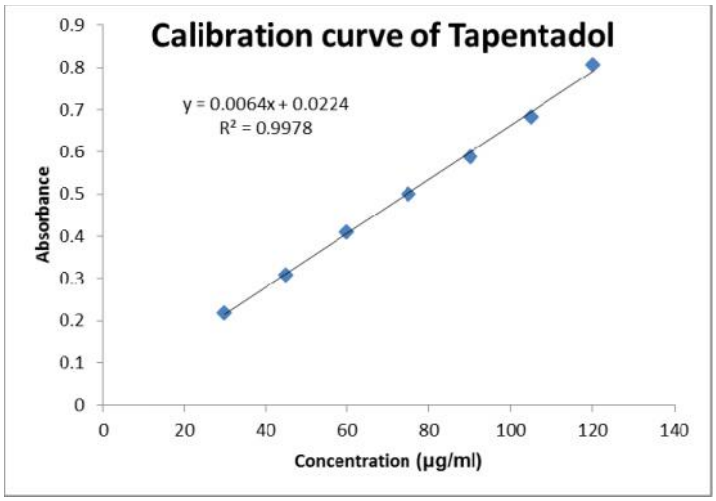

Figure 3. Calibration (Linearity) of Tapentadol

Precision:

The precision of the method was confirmed by intra-day and inter-day analysis. The analysis of formulation was carried out for three times in the same day and ones in the three consecutive days. The results were shown in Table 1 and 2.

Table 1. Intraday Precision

S.No	Concentration (µg/ml)	Absorbance & % purity					
		9:00 AM		1:00 PM		5:00PM	
		Absorbance	% purity	Absorbance	% purity	Absorbance	% purity
1	60	0.465	101.948	0.459	100.650	0.454	99.552
2	60	0.462	101.349	0.462	101.349	0.462	101.349
3	60	0.458	100.451	0.459	100.650	0.460	100.850
4	60	0.460	100.850	0.453	99.352	0.454	99.552
5	60	0.450	98.753	0.449	98.454	0.458	100.451
6	60	0.452	99.153	0.455	99.852	0.452	99.153
Average		0.458	100.417	0.456	100.051	0.456	100.151
Standard deviation		0.0058	1.246	0.0047	1.046	0.0039	0.863
% RSD		1.269	1.241	1.041	1.046	0.861	0.862

Table 2. Inter-day precision

S.No	Concentration (µg/ml)	Absorbance & % purity					
		Day-1		Day-2		Day-3	
		Absorbance	% purity	Absorbance	% purity	Absorbance	% purity
1	60	0.444	97.344	0.452	99.153	0.448	98.254
2	60	0.453	99.352	0.454	99.552	0.447	98.054
3	60	0.469	102.847	0.450	98.753	0.450	98.753
4	60	0.456	100.061	0.452	99.153	0.449	98.454
5	60	0.448	98.254	0.458	100.451	0.462	101.348
6	60	0.460	100.850	0.456	100.061	0.444	97.355
Average		0.455	99.784	0.453	99.520	0.450	98.703
Standard deviation		0.008	1.953	0.003	0.635	0.006	1.378
% RSD		1.955	1.957	0.648	0.638	1.384	1.396

Accuracy (recovery)

The accuracy of the method was evaluated by recovery studies. A known quantity of TAP was added at different levels (50, 100 and 150%). The absorbance of the solutions were measured and the percentage recovery was calculated. The mean percentage recovery was found to be in the range of 99.86 % for TAP in water. The recovery data was shown in Table 3.

Table 3. Accuracy results

S.No	Samples concentration	Sample Weight (mg)	Sample Absorbance	µg/ml added	µg/ml found	Percentage Recovery	Average	Mean Recovery
1	50%	148.665	0.225	30.189	29.670	98.280	99.467%	99.860%
2	50%	148.665	0.230	30.189	30.329	100.463		
3	50%	148.665	0.228	30.189	30.065	99.591		
4	50%	148.665	0.231	30.189	30.461	100.16		
5	50%	148.665	0.226	30.189	29.802	98.718		
6	50%	148.665	0.228	30.189	30.065	99.591		
7	100%	297.33	0.458	60.382	60.395	100.021	99.439%	
8	100%	297.33	0.452	60.382	59.604	98.711		
9	100%	297.33	0.456	60.382	60.382	99.584		
10	150%	445.99	0.705	90.572	92.94	102.643	100.677%	
11	150%	445.99	0.695	90.572	91.648	101.186		
12	150%	445.99	0.690	90.572	90.989	100.459		
13	150%	445.99	0.685	90.572	90.329	99.732		
14	150%	445.99	0.691	90.572	91.120	100.605		
15	150%	445.99	0.683	90.572	90.065	99.440		

Detection and Quantification limit:

The limit of quantification (LOQ) is the lowest concentration of TAP on the calibration curve that can be quantified with acceptable precision and accuracy. The LOQ was found as 2153.236 µg/ml for proposed method. And the limit of detection was found to be 645.978 µg/ml.

Assay of marketed formulation:

The proposed method was applied to analyze commercially available TAP tablets having content equivalent to 100mg. Ten tablets were weighed and powder equivalent to 100 mg transferred in 100 ml volumetric flask and dissolved in distilled finally volume was made up to mark with the same. The solution was then filtered through Whattman filter paper #41. This filtrate was diluted suitably with solvent to get the solution of 60 µg/ml. The absorbance was measured against distilled water as blank. The readings were taken in triplicate by performing the same experimentation in three times. The % Purity and content of the drug in tablet dosage form was calculated. The mean assays of six replicate samples were found to be 100%. The results of Assay (% purity) was shown in table 2.

$$\%\text{purity} = \frac{\text{Test absorbance x std dilution x avg wt x 100}}{\text{Std absorbance x test dilution x labeled claim}}$$

4. Conclusion

The developed UV spectrophotometric method for the estimation of tapentadol was found to be simple and useful with high accuracy, precision, and reproducible. Sample recoveries in all formulations using the above method were in good agreement with their respective label claim or theoretical drug content, this suggesting the validity of the method and non-interference of formulation excipients in the estimation. The developed method was applied for routine quality control analysis of tapentadol tablets.

5. Acknowledgement

The authors thank to MSN Laboratories, Hyderabad, India for providing standard tapentadol.

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