Research Article

Spectrophotometric Determination of Tramadol Hydrochloride in Pharmaceutical Formulations

Nagaraja Setty K[1], Prabhavathi K[*2], Chakravarthi I.E[3], Manjula gayathri M[4]

[1]Department of chemistry, Government Degree College for Men, Kurnool(Dt), A.P, India
[2*]Department of Chemistry, S.B.S.Y.M. Degree College, Kurnool(Dt), A.P, India
[3]Department of Chemistry, Rayalaseema University, Kurnool(Dt), A.P, India
[4]Department of chemistry, Bhanvan's New Science College Narayanaguda, Hyderabad, A.P, India

Abstract

A simple, accurate, rapid and sensitive spectrophotometric method has been developed for the determination of tramadol hydrochloride in pharmaceutical dosage forms. In this method 2,3-dichloro-5,6-dicyano-p-benzoquinone (DDQ) was utilized for determination of tramadol hydrochloride forming charge transfer complex with maximum absorbance at λmax 455 nm. Optimization of the reaction conditions has been investigated. Obedience to Beer's law permitted the assay of tramadol hydrochloride in their dosage form. Statistical analysis of the obtained results showed no significant difference between the proposed method and other official and reported methods as evident from the t-test. The proposed method is simple, rapid accurate, precise, reproducible, and economic and can be used for routine quantitative analysis of tramadol hydrochloride in pure and tablet dosage form.

***Correspondence**
Prabhavathi K
katamprabhavathi@gmail.com

Keywords: Ultraviolet-Visible Spectrophotometry, tramadol hydrochloride, 2,3-dichloro-5,6-dicyano-*p*-benzoquinone, (DDQ), Formulations

Introduction

Tramadol hydrochloride is a centrally acting analgesic, used for treating moderate to severe pain. Tramadol hydrochloride possesses agonist actions at the μ-opioid receptor and effects reuptake at the noradrenergic and serotonergic systems. Tramadol is a compound with μ-agonist activity. Chemically it is [2-(dimethylaminomethyl)-1-(3-methoxyphenyl) cyclohexanol]. It is used to treat moderate to moderately severe pain and most types of neuralgia, including trigeminal neuralgia. Literature survey reveals that, several spectrophotometric method[1-3], TLC-densitometry[4], UV spectrophotometric and HPLC-DAD methods[5]**,** HPLC method[6-8] High Performance Thin Layer Chromatography –Densitometry[9], have been reported for the estimation of tramadol in pharmaceutical formulations. Few analytical methods were reported in literature for the determination of tramadol and other combination drugs which includes spectrophotometric method [10-16], Spectrophotometric and spectrofluorimetric method[17]**.**

Experimental

Apparatus

All absorbance measurements were made on a Spectronic 1001 plus spectrophotometer (Milton Roy Company, USA) with 1 cm matched quartz cells**.**

Chemicals and Reagents

Glass wares used in each procedure were soaked overnight in a mixture of chromic acid and sulphuric acid rinsed thoroughly with double distilled water and dried in hot air oven. All the solutions were freshly prepared. All solvents and other chemicals used through this study were of analytical grade. 2,3-dichloro 5,6-dicyano-p-benzoquinone(DDQ; Merck, Schuchardt, Munich, Germany) solution(0.1%) solution was freshly prepared in methanol and it was prepared a fresh daily.

Preparation of standard stock solution

A standard stock solution containing 1 mg/mL was prepared by dissolving 100 mg of tramadol hydrochloride in 100 mL of distilled water. From this, a

working standard solution containing 100 µg/mL was prepared for the proposed method.

Assay procedure

Aliquots of standard drug solution of tramadol hydrochloride 0.2-1.0 mL were transferred into a series of 10 mL calibration flasks. To each flask 1.0 ml of the DDQ solution was added, and the reaction was allowed to proceed at room temperature (25±5oC). The reaction was achieved instantaneously. The solutions were diluted up to the mark of the calibration flask with methanol. The absorbance of the resulting solutions was measured at the wavelengths of maximum absorption 455 nm against reagent blanks treated similarly. Beer's law is obeyed in the concentration of 20-100 µg/ml of tramadol hydrochloride. Calibration curve was plotted from absorbance values against concentration of drug (**Figure 1**).

Preparation of sample solution

Twenty tablets of tramadol hydrochloride were accurately weighed and powdered. Tablet powder equivalent to 100 mg of tramadol hydrochloride was dissolved in 50 mL of methanol, sonicated for 15 minutes, filtered and washed with methanol. The filtrate and washings were combined and the final volume was made to 100 mL with methanol. The solution was suitably diluted and analyzed as given under the assay procedure for bulk samples. The results are represented in **Table 2**.

Results and Discussion

The method was based on the charge transfer reactions of tramadol hydrochloride as *n*-electron donor with acceptor, 2,5-dichloro-3,6-dihydroxy-1,4-benzoquinone. The absorbance of the highly intensive coloured solution was measured at 455 nm against reagent blank treated similarly. The conditions required for the formation of colored complexes were optimized. Statistical analysis was carried out and the results were found to be satisfactory. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sand ell's sensitivity are presented in **Table 1**. The regression analysis using the method of least squares was made for slope (b), intercept (a) and correlation obtained from different concentrations and the results are summarized in **Table 1**. The high molar absorptivities of the resulting colored complexes indicate the high sensitivity of the methods. The percent relative standard deviation, standard deviation and student's 't' test values calculated from the five measurements of tramadol hydrochloride are presented in Table 2. Relative standard deviation values and standard deviation were low that indicates the reproducibility of the proposed methods. In the student's 't' tests, no significant differences were found between the calculated and theoretical values of both the proposed methods at 95% confidence level. This indicated similar precision and accuracy in the analysis of tramadol hydrochloride in its tablets.

Table 1 Optical characteristics of proposed method.

Statistical Parameters	Proposed Method
λ_{max}, nm	455
Beer's law limit, µg/mL	20-100
Molar absorptivity, l mole^{-1} cm^{-1}	3.81×10^3
Sandell's sensitivity (µg cm^{-2} / 0.001 absorbance unit)	0.0241
Regression equation (Y = a + bC)	Y=0.004x+0.002
Slope (b)	0.004
Intercept (a)	0.002
Correlation coefficient (r)	0.999

*Y = a+bC,

Where, Y is the absorbance and C concentration in µg / mL

Table 2 Assay of tramadol hydrochloride in tablet formulations

Tablets	Labeled amount (mg)	*Amount found (mg)±S.D*	%RSD*	*t value
Tablet 1	100	100.01±0.23	0.1283	0.1742
Tablet 2	100	100.14±0.24	0.2494	1.2533
Tablet 3	100	100.09±0.39	0.3974	0.5059

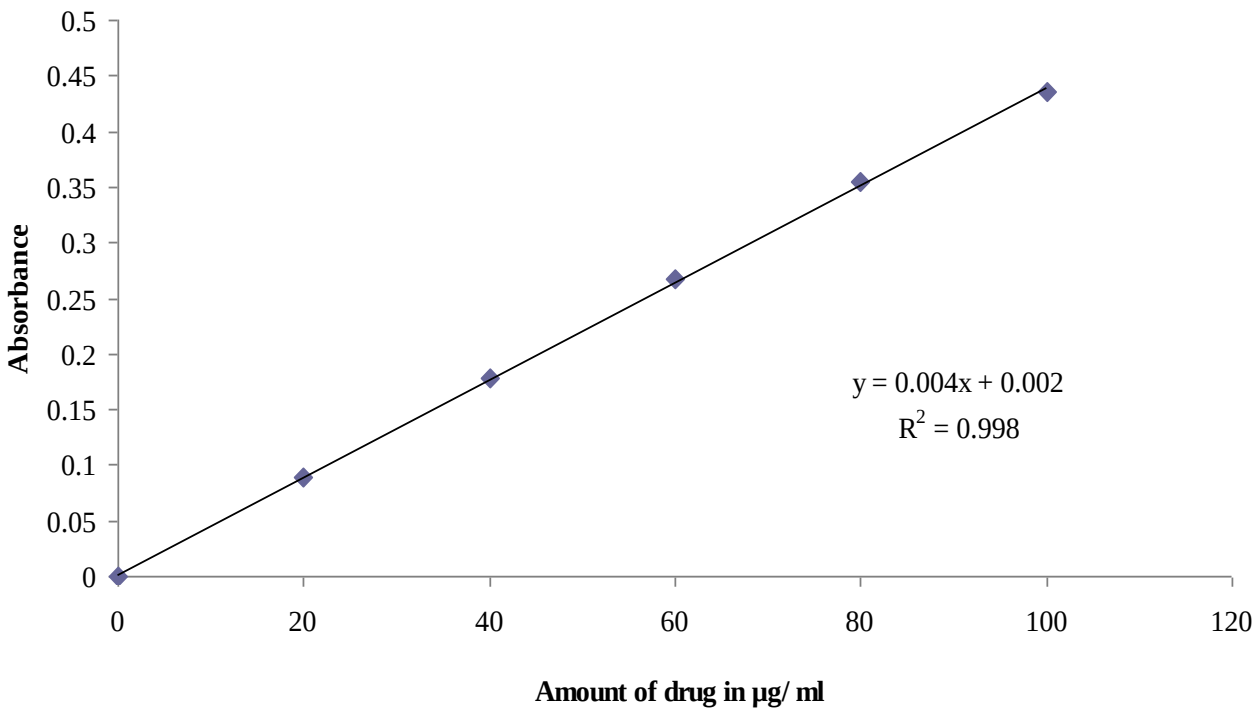

Figure 1 Calibration curve of tramadol hydrochloride

Conclusion

The proposed methods are simple, sensitive, accurate and economical for the routine estimation of tramadol hydrochloride in bulk and in its tablet dosage form.

References

[1] H. E. Abdellatef, J Pharm Biomed Anal., 2002, 29(5), 835.
[2] K. K. RajaSekhar, V. Shankarananth, A. Sreenivasa Charan, L. NagaMallika, D. Narmada, M. Padmavathamma, Journal of Pharmacy Research. 2011, 4(10), 4842–4844.
[3] B. Rajitha, S. Prashanthi, K. Ramsubha Reddy, G. Tulja Rani, International Journal of Pharm Tech Research,. 2011, 3(1), 114–117.
[4] W. D. Sam Solomon, P. R. Vijai Anand, R. Shukla, R. Sivakumar, R. Venkatnarayanan,. International Journal of Chem Tech Research, 2010, 2(2), 1188–1193.
[5] A. Kucuk, Y. Kadıoglu, I. Farmaco, 2005, 60(2), 163–169.
[6] K. Kalra, S. Naik, G. Jarmal, N. Mishra, International Journal of Applied Chemistry, 2009, 5(2), 73–76.
[7] H. A. Yalda, S. H. Faezeh, A-E. Alireza, J.Chromatogr. *B*, 2006, 830(2), 207–211.
[8] F. K. Wiwin, P. Tini, I. Gunawan. J. Liq. Chromatogr. Related Tech., 2005, 27, (4), 737–744.
[9] K. Venkateshwarlu, Y. N. Reddy, K. Srisailam, V. Rajkumar, M. G. Pai, CurrentTrends in Biotech. Pharm., 2008, 2(3), 421–425.
[10] D. Gharge, P. Dhabale, International Journal of Pharm Tech Research. 2010, 2(2), 1119–1123.
[11] K. Amit, N. Sanju, C. Rajiv. Indian Pharmacist. 2010, 8(11), 85–87.
[12] V. Jain, R. Sharma. Stamford Journal of Pharmaceutical Sciences, 2010, 3(1), 28–33.
[13] D. Gharge, P. Dhabale, International Journal of Chemical and Analytical Science. 2010, 1(3), 2075.
[14] A. B. Thomas,, N. G. Dumbre, R. K. Nanda, L. P. Kothapalli, A. A. Chaudhari, A. D. Deshpande, Chromatographia, 2008, 68(9-10), 843-847.

[15] M. Puranik, A. Hirudkar, S. J. Wadher, P. G. Yeole, Indian J Pharm Sci., 2006, 68, 737-739.
[16] K. K Srinivasan, J. Alex, A. A. Shirwaikar, S. Jacob, M. R. Sunil Kumar, S.L. Prabu**,** Indian Journal of Pharmaceutical Sciences**,** 2007, 69(4), 540–545.
[17] A. Manisha Puranik, S. J. Hirudkar, Wadher**,** P. G. Yeole, Indian Journal Pharmaceutical Sciences, 2006, 68(6), 737–739.

Received : 25th, November, 2012
Revised : 10th, December, 2012
Accepted : 3rd, January, 2013
Online : 19th, January, 2013