Asian Journal of Chemistry Vol. 21, No. 8 (2009), 6111-6115

Spectrophotometric Estimation of Tramadol Hydrochloride in Pharmaceutical Dosage Forms

GARVENDRA SINGH RATHORE*, PAWAN K. BASNIWAL,
MANISH SUTHAR and ROOP. N. GUPTA†
Department of Pharmaceutrical Analysis, L.B.S. College of Pharmacy, Tilak Nagar, Jaipur-302 004, India
Tel: (91)(1425)254564; E-mail: garvendra@gmail.com; pawanbasniwal@gmail.com

Two rapid, simple, precise and economical methods *viz.*, linear regression equation and standard absorptivity were developed and validated for estimation of tramadol hydrochloride in pharmaceutical dosage forms. The estimation of tramadol hydrochloride was carried out at 271 nm. Beer-Lamberts law was obeyed in the concentration range of 50-250 µg/mL and standard absorptivity A (1 %, 1 cm) was found to be 58.95 dl g^{-1} cm^{-1}. The molar extinction coefficient (ε) for the drug was found to be 1767.61 mol^{-1} cm^{-1}. Both methods were validated for linearity, accuracy, precision and robustness. The numerical value for all validation parameters lies within the acceptable limits.

Key Words: Tramadol hydrochloride, Ultraviolet spectrophotometry, Linear regression equation, Standard absorptivity.

INTRODUCTION

Tramadol chemically, (1R,2R)-2-((dimethyl-amino)methyl)-1-(3-methoxyphenyl)cyclohexanol hydrochloride (Fig. 1), is a typical opioid which is a centrally acting analgesic used for treating moderate to severe pain[1].

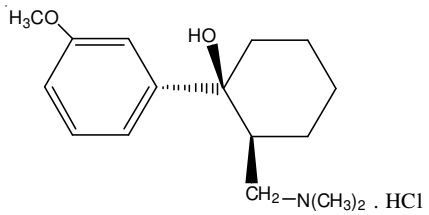

Fig. 1. Structure of tramadol hydrochloride

Literature described that tramadol content in the formulations can be determined by spectrophotometry[2], spectrofluorometry[3], HPLC[4,5], GC[6,7], GC-MS and LC-MS[8], capillary electrophoresis[9] and HPTLC[10,11]. Ahrens *et al.*[12] reported an advanced fibre

†Department of Pharmaceutical Sciences, B.I.T. Mesra, Ranchi-835 215, India.

optical scanning densitometry in HPTLC determination of tramadol in biological samples. The present paper describes a simple, rapid, accurate and reproducible method for the estimation of tramadol in various pharmaceutical formulations by spectrophotometry.

EXPERIMENTAL

UV 1601 series (Shimadzu), UV-VIS double beam spectrophotometer with 1 cm matched quartz cells was used for the measurement of absorbance. Shimadzu-AX-200 electronic balance was used for weighing the samples. Class 'A' volumetric glass-ware were used. Tramadol hydrochloride was gift sample from Cris Pharma (India) Ltd., Baddi, India. The commercial product was procured from the local market.

Standard solution and calibration curve: The standard solution (1000 µg/mL) of tramadol hydrochloride drug was prepared in distilled water. The standard solution (1000 µg/mL) was diluted with distilled water, to obtain various dilutions (50, 100, 150, 200 and 250 µg/mL). All the solutions of drug were scanned between 230 and 400 nm. The λ_{max} for tramadol hydrochloride was found at 271 nm (Fig. 2). The linear regression equation was y = 0.0059x + 0.004 having coefficient of variance 0.9998 (Fig. 3).

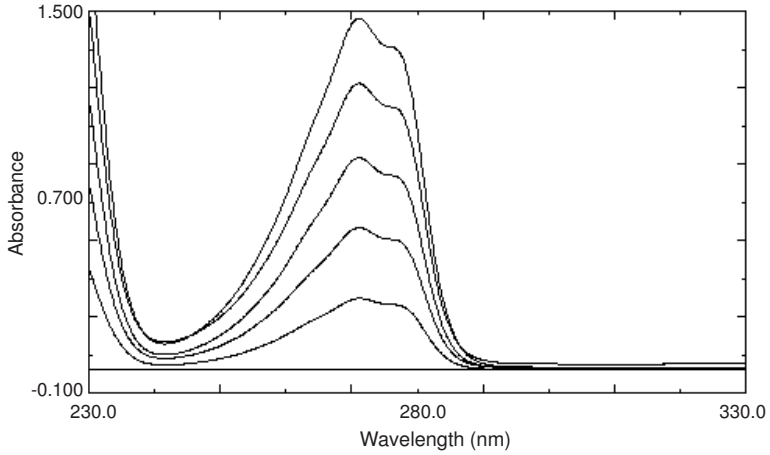

Fig. 2. Gaussian spectra of tramadol hydrochloride

Standard absorptivity method: Five dilutions were prepared in triplicate and the absorbances were observed at 271 nm. From above observations the standard absorptivity A (1 %, 1 cm) and molar extinction coefficient were calculated (Table-1).

Validation of method: As per ICH guidelines[13,14], six dilutions in three replicate were used to validate both methods for linearity, accuracy (by recovery studies-standard addition to pre-analyzed samples), repeatability (within day), intermediate precision (days, analyst and instrument variation) and robustness and statistical parameters were calculated for them (Table-2).

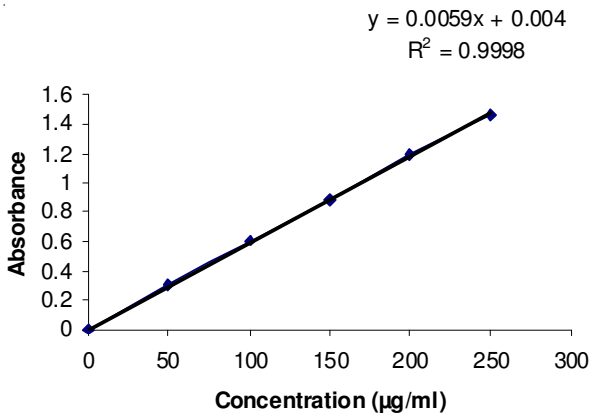

Fig. 3. Calibration curve for tramadol hydrochloride

TABLE-1
STANDARD ABSORPTIVITY A (1 %, 1 cm) AND
MOLAR EXTINCTION COEFFICIENT (ε)

Concentration (µg/mL)	Absorbance at 271 nm			Standard Absorptivity A (1 %, 1 cm) = A/bc		
	I	II	III	I	II	III
50	0.2961	0.2871	0.2988	59.22	57.42	59.76
100	0.5974	0.5876	0.5934	59.74	58.76	59.34
150	0.882	0.8953	0.8742	58.80	59.68	58.28
200	1.1891	1.1812	1.1863	59.45	59.06	59.31
250	1.4615	1.4656	1.4589	58.46	58.62	58.35
A (1 %, 1 cm)* in dl g^{-1} cm^{-1}				58.95		
ε** in mol^{-1} cm^{-1}				1767.61		

*Mean of 15 above standard absorptivities determination.
**Molar extinction coefficient ε = A (1%, 1cm) x Molecular weight/10.

Quantitative estimation: Powder equivalent to 100 mg was taken from powder of 20 tablets (strength 100 mg) and dissolved in 100 mL distilled water. Three different dilutions were prepared from stock solution, which were analyzed by linear regression equation and standard absorptivity methods. It was repeated six times (Table-3).

RESULTS AND DISCUSSION

Tramadol hydrochloride is highly water soluble, which give good shape of Gaussian spectra (Fig. 2) against water as a blank. Both methods, linear regression equation and standard absorptivity method for the estimation of tramadol hydrochloride in tablet and capsule dosage form were found to be simple, accurate, reproducible and economical. These methods were very much economical as solvent is water. Beer-Lambert's law was obeyed in the concentration range of 50-250 µg/mL.

TABLE-2
RESULTS OF VALIDATION PARAMETERS

Validation parameter	% Found* (mean)	SD	CV	SEx	SEσ
Linear regression equation method					
Accuracy	100.45	0.23	0.2289	0.0542	0.038
Precision					
I. Repeatability	100.74	0.45	0.4466	0.1060	0.075
II. Intermediate precision	100.98	0.26	0.2574	0.0612	0.043
a. Days	99.23	0.28	0.2821	0.0659	0.046
b. Analysts	99.48	0.29	0.2915	0.0683	0.048
c. Instruments	101.11	0.48	0.4747	0.1131	0.080
Robustness	100.72	0.25	0.2482	0.0589	0.041
Standard absortivity method					
Accuracy	100.78	0.46	0.4564	0.1084	0.076
Precision	99.76	0.24	0.2405	0.0565	0.040
I. Repeatability	100.65	0.56	0.5563	0.1319	0.093
II. Intermediate precision					
a. Days	101.05	0.65	0.6432	0.1532	0.108
b. Analysts	99.83	0.48	0.4808	0.1131	0.080
c. Instruments	99.72	0.36	0.3610	0.0848	0.060
Robustness	100.47	0.56	0.5573	0.1319	0.093

*Mean of six dilutions in three replicates, SD = Standard deviation, CV = Coefficient of variance, SEx = Standard error of mean and SEσ = Standard error of standard deviation.

TABLE-3
ESTIMATION OF PHARMACEUTICAL DOSAGE FORM

Concentration (μg/mL)	% Found					
→	Linear regression equation method			Standard absortivity method		
Batch	100	150	200	100	150	200
I	101.340	99.980	101.600	100.750	100.400	99.650
II	101.530	100.890	101.530	100.450	99.850	101.200
III	100.230	99.430	100.690	101.550	100.700	99.680
IV	102.690	101.570	102.260	101.250	100.900	101.430
V	101.620	101.050	99.950	99.670	100.150	99.560
VI	99.890	99.720	101.940	100.400	99.730	100.850
Mean	101.210	100.44	101.320	100.678	100.288	100.395
SD	1.017	0.848	0.856	0.669	0.464	0.859
CV	1.005	0.845	0.844	0.664	0.463	0.855
SEx	0.415	0.346	0.349	0.273	0.189	0.350
SEσ	0.293	0.245	0.247	0.193	0.134	0.247

Both methods were validated for validation parameters with the acceptable values of the coefficient of variation. The values of standard deviation, RSD and all other statistical data for the validated parameters were found to be satisfactory and therefore the methods may be used for routine analysis.

REFERENCES

1. P. Dayer, J. Desmeules and L. Collart, *Drugs*, **53S**, 18 (1997).
2. H.E. Abdellatef, *J. Pharm. Bioanal.*, **29**, 835 (2002).
3. H.E. Abdellatef, M.N. El-Henawee, H.M. El-Sayed and M.M. Ayad, *Spectrochim. Acta*, **65A**, 1087 (2006).
4. S. Negro, A. Salama, Y. Sánchez, M.L. Azuara and E. Barcia, *J. Clin. Pharmacol. Therapeut.*, **32**, 441 (2007).
5. Y. Aysel, A. Kucuk and Y. Kadioglu, *IL Farmaco*, **60**, 163 (2005).
6. Q. Tao, D.J.J. Stone, M.R. Borenstein, V. Jean-Bart, E.E. Codd, T.P. Coogan, D. Desai-Krieger, S. Liao and R.B. Raffa, *J. Chromatogr. B*., **763**, 165 (2001).
7. S.T. Ho, J.J. Wan, W.J. Liaw, C.M. Ho and J.H. Li, *J. Chromatogr. B.*, **736**, 89 (1999).
8. C. Moore, L. Marinetti, C. Coulter and K. Crompton, *Forensic Sci. Int.*, **176**, 47 (2008).
9. J. Li and H. Ju, *Electrophoresis*, **27**, 3467 (2006).
10. J. Krzek and M. Starek, *Biomed. Chromatogr.*, **18**, 589 (2004).
11. Y.N. Reddy, *Curr. Trends Biotech. Pharm.*, **2**, 421 (2008).
12. B. Ahrens, D. Blankenhorn and B. Spangenberg, *J. Chromatogr. B*, **772**, 11 (2002).
13. ICH, Text on Validation of Analytical Procedures, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceutical for Human Use, Geneva, July (2000).
14. ICH, Validation of Analytical Procedure: Methodology, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceutical for Human Use, Geneva, July (2000).

(*Received*: 22 October 2008; *Accepted*: 23 May 2009) AJC-7586

SEVENTH INTERNATIONAL CONFERENCE OF COMPUTATIONAL METHODS IN SCIENCES AND ENGINEERING"

29 SEPTEMBER — 4 OCTOBER 2009

CRETE, GREECE

Contact:
Secretary ICCMSE, Mrs Eleni Ralli-Simou, 10 Konitsis Street,
Amfithea Paleon Faliro, GR-175 64, Athens, Greece.
Fax:+30-2710-237-397, e-mail:tsimos.conf@gmail.com,
web site http://www.iccmse.org/