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Extractive Spectrophotometric determination of Tramadol Hydrochloride in Pure and Pharmaceutical Dosage Forms

B. Rajitha, S. Prashanthi, K. Ramsubha Reddy, G. Tulja Rani*

Department of Pharmaceutical Analysis, Sarojini Naidu Vanitha Pharmacy Maha Vidyalaya, Exhibition grounds, Nampally, Hyderabad-50001, India

***Corres.author: tuljapharma@yahoo.com**

Abstract: Two simple, precise, and rapid extractive spectrophotometric methods were developed for the estimation of tramadol hydrochloride in both pure and pharmaceutical dosage forms. The methods were based on the formation of colored complex by the drug with reagents like erichorme black-T (method-I) and orange-G (method-II) in an acidic buffer. The linearity ranges of tramadol hydrochloride were found to be 2 to 18 µg/mL for method-I and 2.5 to 15 µg/mL for method-II. The ion-associated complex formed was quantitatively extracted under the experimental conditions with chloroform and the absorbances of the organic layers were measured at 506 nm and 486 nm for method-I and method-II, respectively. The correlation coefficient (r^2) for method-I and II were found to be 0.999 and 0.999, respectively. The methods were statistically evaluated and were found to be precise and accurate.
KeyWords: Tramadol hydrochloride, Extractive spectrophotometric, Erichorme black-T, Orange-G.

1.Introduction

Tramadol hydrochloride[1] (TH) [fig.1] is a monoamine uptake inhibitor and centrally acting analgesic, used for treating moderate to severe pain. Tramadol hydrochloride is chemical (+/-) cis-2-(Dimethylamino) methyl)-1-(3-methoxy phenyl) cyclohexanol hydrochloride.

Literature survey reveals that there are few spectrophotometric methods either individually[2, 3] or in combined dosage forms[4-10] and HPLC [11-14] methods were also reported.

There was no spectrophotometric method for the estimation of this drug using erichrome black-T and orange G. Therefore in the present study, two extractive spectrophotometric methods for the estimation of TH in pure and tablet dosage form are described. The methods-I and II are based on the formation of colored ion-pair complex of the drug with erichorme black-T and orange-G in acetate buffer, respectively.

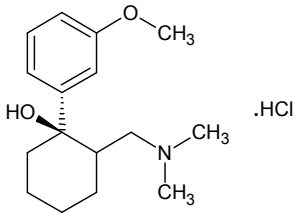

Fig. 2: Tramadol hydrochloride

2.Experimental

2.1 Instrument: Absorbance measurements were made on Shimadzu UV-1800 double beam UV-Visible spectrophotometer with 10 mm matched quartz cells.

2.2 Materials and reagents:

All the chemicals used were of analytical grade and solutions were prepared with distilled water.

Pharmaceutical grade tramadol hydrochloride was kindly gifted by M/S Hetero drugs, Balanagar, Hyderabad, India. and certified to contain 99.9% of

TH. Tramadol hydrochloride tablets [Tramadol PD, Meridol PD] were obtained from local market.

Tramadol hydrochloride stock solution: A standard stock solution of the drug was prepared by dissolving 0.1 gm of TH in 100 mL of distilled water.

Erichrome black-T [EBT] 0.1 w/v (S.D Fine Chem. Ltd., Mumbai): 100 mg of EBT was dissolved in 100 mL of distilled water and washed with chloroform to remove chloroform soluble impurities.

Orange-G 0.1 w/v (NR CHEM, Mumbai): 100 mg of orange-G was dissolved in 100 mL of distilled water and washed with chloroform to remove chloroform soluble impurities.

Acetate Buffer (pH 3.5): 4 gm of anhydrous sodium acetate is dissolved in about 840 mL of water and sufficient amount of glacial acetic acid was added to adjust pH to 3.5 and diluted to 1000 mL.

2.3 Calibration curve:

In to a series of 60 mL separating funnels, aliquots of standard solution (2 to 18 µg/mL for method-I and 2.5 to 15 µg/mL for method-II) were placed. To each of the separating funnel, 0.5 mL of buffer solution and 1.5 mL of EBT reagent for method-I and 1.0 mL of buffer solution 2.0 mL of orange-G reagent for method-II were added. The total volume of aqueous solutions was adjusted to 10 mL with distilled water. Then 10 mL of chloroform was added to each separating funnel and contents were shaken for 2 min. The organic layer was dried over anhydrous sodium sulphate and the absorbances of colored complexes were measured at 506 nm for method-I and 486 nm for method-II against reagent blank. All the colored species were stable for 2 hr. Respective calibration curves were prepared and a linear correlation was obtained between absorbance and concentration over the range mentioned above, there by obeying Beer's law. The regression equations were found to be Y= 0.06584x+0.1057 for method-I and 0.05204x -0.00501 for method-II where x is the concentration of TH and Y is the absorbance at their respective λ maxima [Table II]. The amount of TH in both the methods was calculated from Beer-Lambert's-plot.

2.4 Preparation of sample solution:

Twenty tablets were weighed and finely powdered in a glass mortar. Tablet powder equivalent to 100 mg of TH was weighed accurately and taken into 100 mL volumetric flask. The drug was dissolved in distilled water and the volume was made up to the mark. The solution was suitably diluted and assayed as under the respective assay procedure described for the preparation of calibration curves for both the methods.

3.0 Results and discussion

Experiments were carried out to optimize the reaction conditions for complete color formation. It was found that 1.5 mL of EBT for method-I and 2.0 mL of orange-G for method-II and 0.5ml of buffer solution for method-I and 1.0 mL of buffer solution for method-II were optimum for the achievement of maximum color intensity (Table No.1)

The optical characteristics such as Beer's law limits, Sandell's sensitivity, and Molar extinction co-efficient and % RSD (calculated from six measurements containing ¾ of the amount of upper Beer's law limit) were calculated for both the methods and the results were summarized in Table No.2. Regression characteristics like slope, intercept, correlation coefficient and % range of error (0.05 and 0.01 confident limits) were calculated for both the methods and were presented in the Table No.2.

Commercial formulations (Tramadol PD and Meridol PD tablets) containing 50 mg of TH were successfully analyzed by the proposed methods. The values obtained were compared with the reference methods. The t-test and F-test was statistically calculated and found to agree significantly. As an additional demonstration of accuracy, adding fixed amount of the drug to the pre-analyzed formulation recovery experiments was performed. These results were summarized in Table No.3. Commonly used excepients such as lactose, starch, and talc did not interfere in the methods.

Table No. 1: Optimum conditions and results of the proposed methods

Reagent	Method- I	Method-II
Drug solution taken (µg/ml)	2-18	2.5-15
Volume of buffer (ml)	0.5	1
pH of buffer solution	3.5	3.5
Volume of reagent employed (ml)	1.5	2
λ max (nm)	506	486

Table No.2: Optical and Regression characteristics and precision of the proposed methods for TH

Parameters	Method	
	1	II
λ max nm	510	486
Beer's law limits (mcg/ml)	2--20	2.5--20
Sandell's sensitivity (mcg/cm^2/0.001 A.U)	0.01930	0.01328
Molar Absorptivity (L mol^{-1}cm^{-1})	0.136441 * 10 ^{6}	0.19820* 10^6
Correlation coefficient (r^2)	0.99944	0.99977
Regression equation (y=mx+c)	0.06584x+0.10575	0.05204x -0.00501
Slope (m)	0.06584	0.05204
Intercept (c)	0.10575	-0.00501
Range of errors		
Confidence limit with 0.05 level	0.3037	0.2400
Confidence limit with 0.01 level	0.4494	0.3561
% Relative Standard Deviation*	0.3633	0.2400

*Average of six determinations

Table No. 3: Assay and recovery of TH in pharmaceutical formulations

Pharmaceutical formulations	Labeled amount found (mg)	Amount found in[a](mg) using proposed methods±S.D				Found by reference method ±S.D	%Recovery by proposed methods [b] ±S.D			
		A	B	C	D		A D	B	C	
Tablet-1	50	49.91 ±0.76 t= 0.824 F= 0.668	49.71 ±0.59 t= 0.783 F= 0.914	49.65 ±0.72 t = 0.703 F= 0.755	49.82 ±0.585 t= 0.879 F= 0.882	299.98 ±0.79	99.73 ± 0.74	99.06 ±0.33	99.83 ±0.24	99.43 ±0.80
Tablet-2	50	50.1 ±0.860 t=0 .532 F= 0.884	50.11 ±0.873 t =0.422 F= 0.849	50.09 ±0.89 t = 0.456 F = .816	50.16 ±0.92 t= 0.423 F= 0.767	299.83 ±0.72	100.2 ±0.57	100.1 ±0.50	100.08 ±0.57	100.3 ±0.61
Tablet-3	50	49.83 ±0.97 t= 0.944 F= 0.788	49.7 5±0.99 t =0.807 F= 0.757	49.91 ±0.77 t = 0.962 F= 0.826	49.75 ±0.77 t= 0.719 F= 0.829	299.87 ±0.56	99.86 ±0.64	99.87 ±0.57	99.8 ±0.37	99.63 ± 0.61

[a] Average ±standard deviation of eight determinations, the t and F-values refer to comparison of proposed method with reference method .Theoretical values at 95% confidence limits t=2.365 and F= 4.88 .

[b] Recovery of 10 mg added to the pre analyzed pharmaceutical formulations (average of three determinations).

[C] U.V method using distilled water as solvent and its λ max is 287.5 nm.

4.0 Conclusion

The low level of standard deviations indicates that the proposed extractive spectrophotometric methods for the estimation of tramadol hydrochloride are accurate and reliable. The proposed methods are simple, sensitive, accurate, precise, reproducible, and applicable for the routine estimation of tramadol hydrochloride in bulk and dosage forms.

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