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UV VISIBLE SPECTROPHOTOMETRIC ESTIMATION OF NON STEROIDAL DRUG LORNOXICAM

Dr. C. M. Bhaskar Reddy*[1], Dr. L. Sreekanth Reddy[2], Dr. L. Maheswara Reddy[3], Dr. B. Moksharagni[4], B. Eswar Naik[5] and B. Emmanuel[6]

[1,4]Asst. Prof. of Chemistry, APIIIT-Ongole, Rajiv Gandhi University of Knowledge Technologies, R.K. Valley, Vaimpalli, Kadapa(dt), AP, India.

[2,5,6]Faculty of Chemistry, APIIIT-R.K. Valley, Rajiv Gandhi University of Knowledge Technologies, R.K. Valley, Vaimpalli, Kadapa(dt), AP, India.

[3]Asst. Prof. of Chemistry, YSR Engineering College of Yogi Vemana University, Proddatur, Kadapa(dt), AP, India.

***Corresponding Author: Dr. C. M. Bhaskar Reddy**

Asst. Prof. of Chemistry, APIIIT-Ongole, Rajiv Gandhi University of Knowledge Technologies, R.K. Valley, Vaimpalli, Kadapa(dt), AP, India.

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ABSTRACT

The new more accurate and precise spectrophotometric method has been developed for the estimation of Lornoxicam in bulk and tablet dosage form. Lornoxicam shows maximum absorbance at 480nm in presence of solvent chloroform, double distilled water and phosphate buffer of pH 7.4. The Beer's law is obeyed in the concentration range of 4-20 µg/ mL and the graph shows a straight line with correlation coefficient of 0.9921. The assay method of the drug was validated by accuracy and precision of the proposed method. The results are validated as per the directions of International conference on Harmonization.

KEYWORDS: Lornoxicam, U v spectrophotometry, Beer's law, validation.

INTRODUCTION

Lornoxicam[1] is famous nonsteroidal anti-inflammatory drug also called as chlortenoxicam, and used to prevent severe pain in human beings. IUPAC name of this drug is 6-chloro-4-hydroxy-2-methyl-1,1-dioxo-N-pyridin-2-ylthieno[2,3-e] thiazine-3-carboxamide. It is poorly soluble in water and freely soluble in chloroform with a molecular formula of $C_{13}H_{10}ClN_3o_4S_2$ and a molecular mass of 371.81 g/mol.

The molecular structure of the drug is shown in the fig:1.

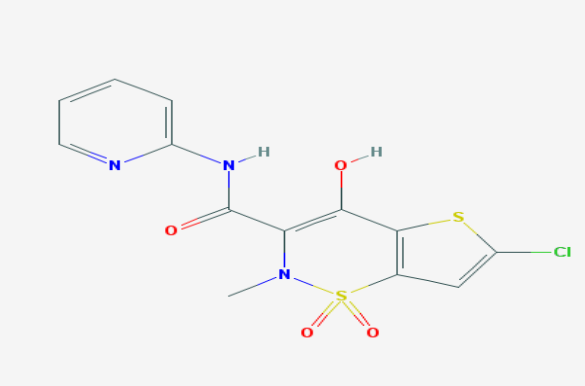

Fig. 1: Molecular Structure of Lornoxicam.

Literature survey of Lornoxicam reveals that Different spectrophotometric methods have been reported which includes reagents NaOH by Sunit Kumar Sahoo et al[2], Phosphate buffer by J.J. Waghmare et al[3], Methanol and Phosphate buffer by Singh et al[4], NaOH by E. Nemutlu et al[5], Sivasubramanian et al[6], and Santosh R. Karajgi et al[7], Hcl and Phosphate buffer by Dasharath m. patel et al[8], Methanol and Phosphate buffer by Bhupendra Singh et al[9], Methanol by Ayya rajendra rasad et al[10], Brilliant blue G (BBG), Bromocresol green (BCG), Bromocresol purple (BCP) Britton-Robinson (B-R) buffer by Ayya rajendra rasad et al[11], Phosphate buffer by M.S. Kondavar et al[12], NaOH and Methanol by Sachin Gholve et al[13], Methanol by Roy Madhumita et al.[14] The comparisons of the proposed method with other existing methods for the assay of Lornoxicam in pharmaceutical formulations have shown in table: 1. Therefore, an attempt was made to develop a low cost precise, accurate spectrophotometric method for the estimation of Lornoxicam in bulk and tablet dosage form.

Table 1: Comparisons of the proposed method with other existing methods for the assay of Lornoxicam in pharmaceutical formulations.

S.No	Reagent	λ Max	Beer's law limits µg mL^{-1}	Correlation Coeffcient (R^2)	Reference
1.	NaOH	377nm	2 - 20 µg/ml	0. 9999	2
2.	Phosphate Buffer	376nm	2 - 14 µg/ml	0.9998	**3**
3.	Methanol- Phosphate Buffer	380nm	1 - 20 µg/ml	0.9997	4
4.	NaOH	376nm	5 - 35 µg/ml	0.9992	**5**
5.	NaOH	257nm	2- 10 µg/ml	0.9994	**6**
6.	NaOH	377nm	10-50 µg/ml	0.9999	**7**
7.	HCl and Phosphate buffer	374nm	4-16µg/ml	0.9998	**8**
8.	Methanol and Phosphate Buffer	380nm	1-20µg/ml	0.9970	**9**
9.	Methanol	353nm	3-15µg/ml	0.9995	**10**
10.	Brilliant blue G (BBG), Bromocresol green (BCG), Bromocresol purple (BCP) Britton-Robinson (B-R) buffer	537nm 650nm 616nm	1-12µg/ml 1.0 - 18 µg/ml 1.0 - 18 µg/ml	0.9990 0.9990 0.9991	**11**
11.	Phosphate Buffer	376nm	1 2 – 14 µg/ml	0.9994	**12**
12.	NaoH-Methanol	377nm	5-30 µg/ml	0.9990	**13**
13.	Methanol	288.5nm 250nm	5-50 µg/ml 5-50 µg/ml	0.9991 0.9981	**14**
14.	Chloroform, Double Distilled water phosphate buffer 7.4	480nm	4-20 µg/ml	0.9921	Proposed method

Note: Table: 1 shows related to literature may be included in the introduction part as text by literature citation.

MATERIALS AND METHOD

Instruments and Apparatus: The absorbance of the drug Lornoxicam were carried out by using shimadzu company model 1800 UV-visible double beam spectrophotometer with 1 cm matched quartz cell, spectral band width is 1 nm, supported by UV win 5.0 software.

Reagents and Chemicals: All chemicals are AR grade. Chloroform, double distilled water and phosphate buffer of pH 7.4 is used throughout the analysis. Pharmaceutical formulation of Lornoxicam was supplied by Glenmark pharmaceuticals, Bangalore. Chloroform, double distilled water and phosphate buffer 7.4 was purchased from Qualigens India Ltd, Mumbai. Commercially available tablets namely Lornoxi(8mg), Lornstar (8mg), procured from Reddy's pharmacy, Vijayawada, Ap, India.

Selection of Solvent

Chloroform, double distilled water and phosphate buffer of pH 7.4 are used throughout the analysis.

Selection of Method and Wave Length

UV scan range of 400 nm to 800 nm was selected for the proposed method of Lornoxicam. The wavelength corresponding to maximum absorbance was found at 480 nm and calibration curve was taken at 480 nm. The intercept of calibration line of the drug was determined by linear regression Analysis.

Preparation of Standard Solutions of Lornoxicam

The 100 mg of standard (pure) drug of Lornoxicam is weighed accurately and dissolved in 100 ml chloroform solvent then transferred into 100 ml volumetric flasks to prepare 1000 µg/ mL stock solution of the drug. Then different aliquots of 4,6,8,10,12,14,16,18 and 20 µg/mL were taken in nine 10 ml volumetric flasks and make up volume with double distilled water. To each flask 2mL of phosphate buffer[16] of pH 7.4 solution is added, then all stock solutions of the drug were scanned in the UV scan range of lambda max (λmax) 400 nm to 800 nm to determine maximum absorbance for this method. The calibration curve was plotted in the concentration range of 4-20 µg/ mL. The wavelength corresponding to maximum absorbance of Lornoxicam measured at 480nm against chloroform as blank.

Preparation of Sample Solutions of Lornoxicam

For the analysis of Lornoxicam, two commercial brands of Twenty tablets of the drug namely Lornoxi (8mg) and Lornstar (8mg) was weighed accurately and powdered, then 100 mg of the drug in powdered form dissolved in 40 ml of chloroform and sonicated for few minutes and filtered by using whatmann filter paper No.42. The filtrate formed is again diluted with double distilled water to get 10µg/mL concentration, taken in a ten 10 ml volumetric flasks. To each 10 ml flask 2mL of phosphate buffer of pH 7.4 solution is added. Then absorbance of Lornoxicam measured at 480nm against chloroform as blank.

Determination of λ Max

UV scan range of 400 nm to 800 nm was selected to determine maximum absorbance by using 10 µg/ml solution of the drug namely Lornoxicam the wave length corresponding to maximum absorbance was found at 480

nm for this drug. The spectrophotometric spectrum of Lornoxicam is shown in fig.2.

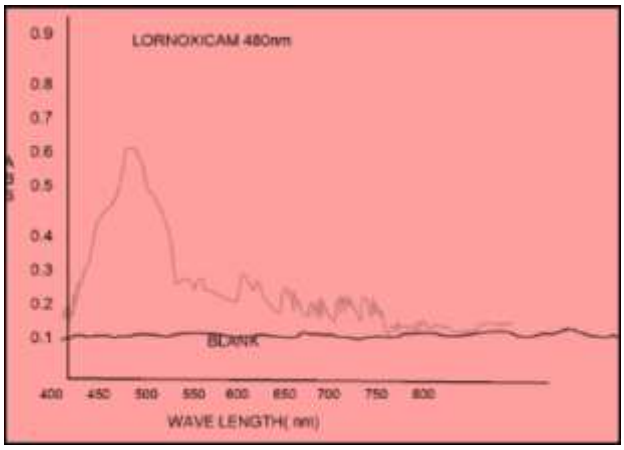

Fig. 2: U V Visible Spectrum of Lornoxicam.

Table 2: Optical Parameters of Lornoxicam.

S.NO	PARAMETER	LORNOXICAM
1	λMax (nm)	480 nm
2	Beer's Law Limit (µg/ mL)	4-20
3	Correlation Coeffcient(r^2)	0.9921
4	Regression Equation (Y= a+bc)	0.0595X+0.1548
5	Intercept (a)	0.1548
6	Slope (c)	0.0595
7	SD	5.4772
8	Mean	12
9	Variance	30
10	LOD (%)	0.210
11	LOQ (%)	0.101

Preparation of Calibration Curve

On the basis of experimental results, calibration curve is plotted and shown in fig: 3 in the concentration range of 4-20 µg/ mL of nine standard solutions of Lornoxicam in chloroform as blank. UV scan range of 400 nm to 800 nm was selected to determine maximum absorbance of the drug. In this method the wavelength corresponding to maximum absorbance was found at 480 nm.

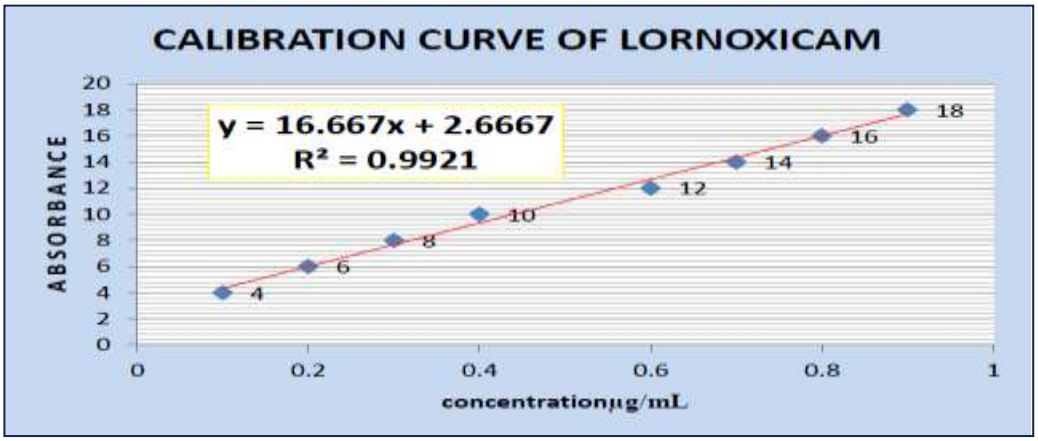

Fig. 3: Calibration Curve of Lornoxicam.

Validation of Method[15]

The spectrophotometric estimation of Lornoxicam is validated as per the directions of International conference on Harmonization to determine statistical parameters like linearity, precision, accuracy, LOD and LOQ of the proposed method.

Linearity and Range

Standard stock solution of Lornoxicam in appropriate dilution were assayed as per the proposed method According to Beer's –Lambert's law the concentration range of Lornoxicam was found to be 4-20 µg/ mL, So that the calibration curve in the figure : 3 is linear in the given concentration range.

Precision

The precision of the proposed method of Lornoxicam was estimated by using concentrations of the drug were analyzed eight times in a day (intra-day precision) and eight continuous days (inter-day precision). Data is given in the table-3.

Accuracy

The Accuracy of the proposed method of Lornoxicam was estimated by using standard addition method. This process is carried out by adding different amounts of the drug Lornoxicam namely 80%, 100% and 120% of the pure sample of the drug to the pre-analysed formulation. Accuracy data of the drug is shown in the table-3.

Table 3: Determination of Accuracy and Precision of Lornoxicam.

S.NO	NAME OF THE SAMPLE	LABELED AMOUNT (mg/capsule)	AMOUNT FOUND* (mg)	PRECISION	
				INTER DAY	INTRADAY
1	LORNOXI	8	99.94	0.0091	0.0087
2	LORNSTAR	8	99.92	0.0090	0.0089
(*average of 6 determinations)					

LOD and LOQ

LOD is Limit of Detection and LOQ is Limit of Quantitation. The LOD and LOQ of Lornoxicam were determined (Table : 1) by using standard deviation of the response and slope approach method as per the directions of International Conference on Harmonization (ICH) guidelines. The limits of detection (LOD) is calculated by using the equation $\text{LOD} = \frac{3s}{k}$ Where, S = intercept of the standard deviation K = The slope of the calibration curve (mean) The limits of quantitation (LOQ), is calculated by using the equation $\text{LOQ} = \frac{10\ S}{K}$ Where, S = intercept of the standard deviation K = The slope of the calibration curve (mean).

Recovery Studies of Lornoxicam

Recovery analysis of Lornoxicam was performed to know the accuracy of the proposed method. This process is done by adding a known quantity of pure Lornoxicam to a pre-analysed sample of the drug. The result of analysis of the drug Lornoxicam is notified in the table: 4.

Table 4: Recovery studies of Marketed Formulations of Lornoxicam.

S.NO	NAME OF THE SAMPLE	LABELED AMOUNT (mg/capsule)	%LEVEL	AMOUNT FOUND* (mg)	% RECOVERY
1	LORNOXI	8	80	99.94	99.96
2	LORNSTAR	8	100	99.92	99.64

RESULTS AND DISCUSSION

The U.V Spectrum of standard stock solutions of Lornoxicam shows absorption maximum at 480nm, then the calibration curve is obtained by plotting a graph of absorbance verses concentration, the Beer –lamberts' law was verified from the data of calibration curve of the drug under investigation. The calibration curve of the drug Lornoxicam is shown in the figures 3. The linearity was observed between 4-20 µg/ mL for Lornoxicam. The graph of this drug shows a straight line with correlation coefficient of 0.9921. The assay method of the drug Lornoxicam was validated by the accuracy and precision of the proposed method is shown in table: 3. The % recovery of 99.96-99.64 shows accuracy of the proposed method of the drug Lornoxicam. The validated optical, statistical parameters, LOD and LOQ data of Lornoxicam were shown in table: 2.

CONCLUSION

In this paper a low cost simple, precise and more economical UV visible spectrophotometric method for the determination of Lornoxicam in bulk and pharmaceutical formulation has been developed and

validated as per the directions of International conference on Harmonisation.

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