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Analytical Method Development of Lornoxicam in Bulk and Tablet Dosage Form by UV Visible Spectrophotometry

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ABSTRACT

Three simple, precise and economical UV spectrophotometric methods have been developed for the estimation of lornoxicam in bulk and pharmaceutical formulations. Lornoxicam is a non steroidal anti-inflammatory agent belonging to a chemical class, oxicam derivative. Lornoxicam has absorbance maxima at 288.5 nm in zero order spectrum method (Method A), in the first order derivative spectra, showed sharp peak at 250 nm when n = 1 (Method B). The drug followed the Beer- Lambert's law in the concentration range of 5-50 µg/ml in all three methods. Results of the analysis, validated statistically and by recovery studies were found to be satisfactory.

INTRODUCTION

Lornoxicam is aoxicam derivative. Chemically, Lornoxicam is (3E)-6-chloro-3-[hydroxy(pyridin-2-ylamino)methylene]-2-methyl-2,3-dihydro-4H-thieno[2,3-e][1,2]thiazin-4-one 1,1-dioxide. Lornoxicam is a non steroidal anti-inflammatory drug which inhibits prostaglandins biosynthesis by blocking the cyclooxygenase. Lornoxicam inhibits both isoforms in the same concentration range, that is, the ratio of COX-1 inhibition to COX-2 inhibition is 1:1. It readily penetrates into the synovial fluid. Lornoxicam is not official in any of the pharmacopoeias and only listed in the Merck Index & Martindale, The Complete Drug Reference. Literature survey has indicated that there are reported few analytical methods for determination of Lornoxicam in plasma by UV spectroscopy, HPLC, HPTLC and other few methods like RP-HPLC has been reported for analysis of combination formulation of Lornoxicam. Hence the objective of the work is to develop simple, precise, accurate, sensitive, rapid and economical UV Visible Spectrophotometric methods for the estimation of Lornoxicam in bulk and pharmaceutical formulations.

MATERIALS AND METHODS

Instrument

A Shimadzu UV/VIS double beam spectrophotometer model 1700, with matched quartz cells corresponding to 1 cm path length and spectral bandwidth of 2 nm.

Materials

Standard gift sample of lornoxicam was procured from Emcure Pharmaceuticals Ltd. Tablets of 8 mg strength were procured from local pharmacy of commercial brand i.e. Lorgem (Helios pharmaceutical).

Solvent used

Methanol AR grade was used as a solvent in the study.

Stock solution

Accurately about 10 mg of the pure drug was weighed and dissolved in 25 ml methanol and the volume was made up to 100 ml with methanol to give standard stock solution (100 µg/ml).

Method A

Aliquots of standard stock solution were pipetted out and suitably diluted with methanol to get the final concentration of 5, 10, 15, 20, upto 50 µg/ml of standard solutions. The solutions were scanned in the spectrum mode from 400 nm to 200 nm wavelength range and the zero order derivative spectra was obtained (Fig.1). The maximum absorbance of lornoxicam was observed at 288.5 nm. The drug followed the Beer-Lambert's law in the concentration range of 5-50 µg/ml. The calibration curve was plotted as absorbance against concentration of lornoxicam [6,7]. The coefficient of correlation (r), slope and intercept values of this method are given in Table I. The concentrations of sample solutions were determined from calibration curve.

Method B

The first order derivative spectra at n=1 showed a sharp peak at 250.0 nm (Fig. 2). The absorbance difference at n=1 (dA/dl) was calculated by the inbuilt software of the instrument which was directly proportional to the concentration of the standard solution. The standard drug solutions were scanned in the first order derivative spectra. A calibration curve was plotted taking the absorbance difference (dA/dl) against the concentration of lornoxicam [8]. The coefficient of correlation (r), slope and intercept values of this method are given in Table I. The method was applied for determination of concentration of sample solution.

Analysis of tablet formulation

For estimation of lornoxicam in tablet formulation by all the methods, twenty tablets were weighed and triturated to the fine powder. Tablet powder equivalent to 5 mg of lornoxicam was weighed and transferred to 50 ml volumetric flask and dissolved in 15 ml methanol and further diluted with methanol. It was kept for ultrasonication for 45 min. Finally, the volume was made up to the mark with methanol; it was filtered through Whatman filter paper no. 41 to get tablet stock solution of concentration 100 µg/ml. Various dilutions of tablet stock solution were prepared and analyzed for six times by all three methods and concentrations of lornoxicam in tablet formulation T1 were calculated by all three methods (Table II). All these methods were validated according to ICH guidelines 6. Recovery studies were carried out at three different levels i.e. 80%, 100% and 120% by adding the pure drug (8 mg,10 mg and 12 mg respectively) to previously analyzed tablet powder sample (10 mg) as per ICH guidelines 6,7. Percentage

recovery was calculated as shown in Table III. All the methods A and B were validated for linearity, accuracy and specificity.

RESULTS AND DISCUSSION

All methods A and B for the estimation of Lornoxicam in tablet dosage form were found to be simple, accurate, specific and reproducible. Beer-Lambert's law was obeyed in the concentration range of 5-50 µg/ml in all the methods. The values of standard deviation were satisfactory low and the recovery studies were close to 100%. Lornoxicam showed a broad spectrum the derivative spectroscopy method applied has the advantage that it locates the hidden peaks in the normal spectrum when the spectrum is not sharp and it also eliminates the interference caused by the excipients present in the formulation. Hence these methods can be useful in the routine analysis of Lornoxicam in bulk drug and formulations.

CONCLUSION

Derivatization method was developed and validated as per ICH guidelines for estimation of lornoxicam. This method was applied for estimation of the compounds in the marketed formulations. The method has been evaluated for the linearity, accuracy, precision and robustness in order to ascertain the suitability of the method was linear. It has been proved that the developed method was linear in the concentration range of 5-50 µg/ml. High percentage recovery showed that method was free from interference of excipients used in the formulations. The results of the study indicates that the proposed absorbance ratio UV- spectrophotometric method of analysis can be used in quality control departments with respect to routine analysis for the assay of the tablets containing lornoxicam

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TABLES & FIGURES

Table I: Standard calibration table for Lornoxicam Zero Order Derivative Spectrum

Sr.No.	Conc. (µg/ml)	Absorbance
1	5	0.125
2	10	0.248
3	15	0.375
4	20	0.512
5	25	0.623
6	30	0.746
7	35	0.858
8	40	0.972
9	50	1.247

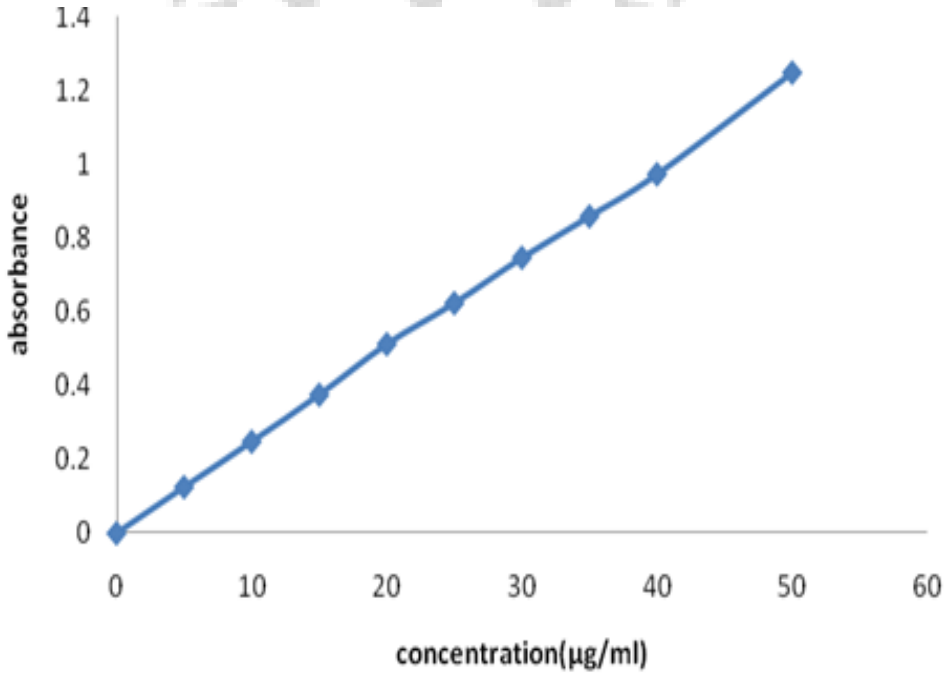

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Fig. 1: Calibration curve of Lornoxicam in zero order derivative spectrum

Table II: Standard calibration table for Lornoxicam First order derivative spectrum

Sr.No.	Conc (µg/ml)	Absorbance
1	05	0.003
2	10	0.006
3	15	0.009
4	20	0.012
5	25	0.015
6	30	0.018
7	35	0.021
8	40	0.024
9	45	0.026
10	50	0.029

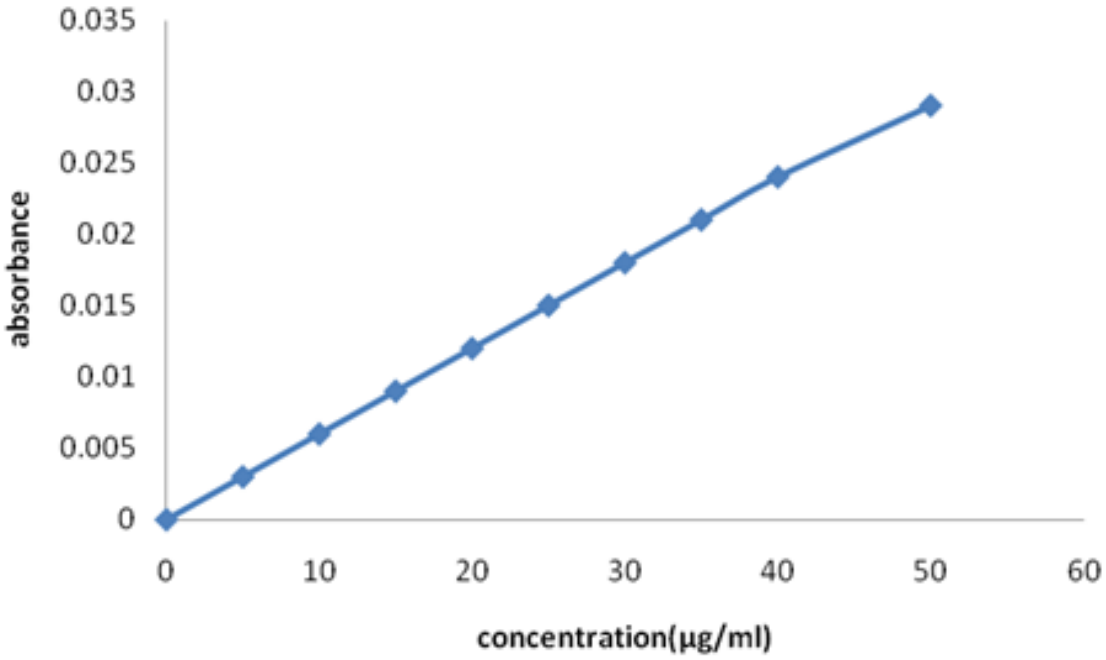

Fig. 2: Calibration curve of Lornoxicam in first order derivative spectrum

Table III: Optical characteristic and other parameter of Lornoxicam

Parameter	Method A	Method B
λ_{Max} (nm) / wavelength range (nm)	288.5	250
Beer's-lambert's range (µg/ml)	5-50	5-50
Coefficient of correlation (r^2)	0.9991	0.9981
Regression equation Y = mx + c a. Slope (m) b. Intercept (c)	 0.0247 -	 0.0006 -
LOD (µg/ml)	0.040	0.836
LOQ (µg/ml)	0.121	2.533

Where, x is concentration in µg/ml and Y is absorbance unit. A is Zero order derivative spectrum method with n = 0. B is First order Derivative spectrum method with n = 1.

Table IV: Estimation of Lornoxicam in tablet formulation

Method	Tablet formulation	Label claim (mg)	Amount found (mg)	% mean	S.D.	C.O.V.	S.E.
A	T_1	8	7.98	99.76	0.5296	0.5308	0.2162
B	T_1	8	7.99	99.89	0.5829	0.5835	0.2380

Where, T1 (Lorgem) is brand of tablet formulation.

* Mean of six estimations (n=6).

Table V: Recovery study data

Method	Tablet	Level of recovery (%)	Amount present (mg/tab)	Amount of drug added (mg)	Amount recovered (mg)	% recovery	S.D.	C.O.V.	S.E.
A	T_1	80	10	8	17.88	99.35	0.1955	0.1967	0.1129
		100	10	10	19.89	99.47	0.2255	0.2267	0.1302
		120	10	12	21.89	99.50	0.2084	0.2094	0.1203
B	T_1	80	10	8	17.95	99.74	0.2829	0.2836	0.1633
		100	10	10	19.98	99.91	0.1607	0.1608	0.0928
		120	10	12	22.06	100.25	0.4732	0.4720	0.2731

* Mean of six estimations (n=6).

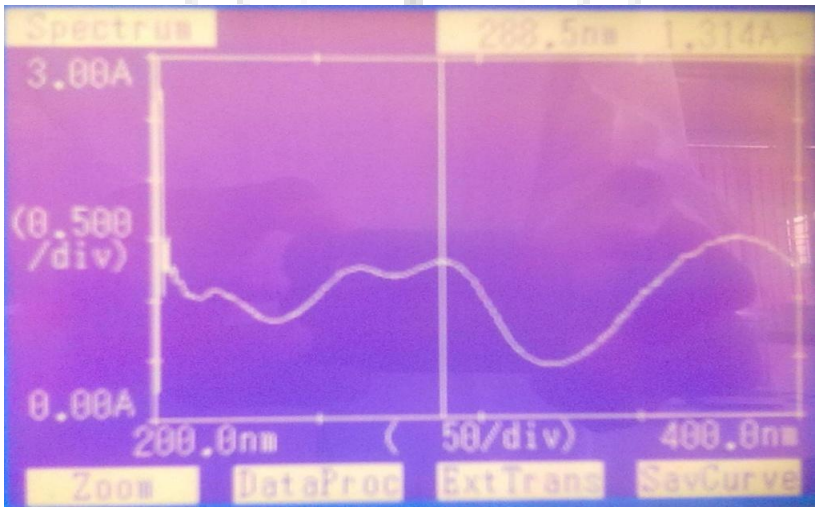

Fig. 3: Zero order spectrum of Lornoxicam

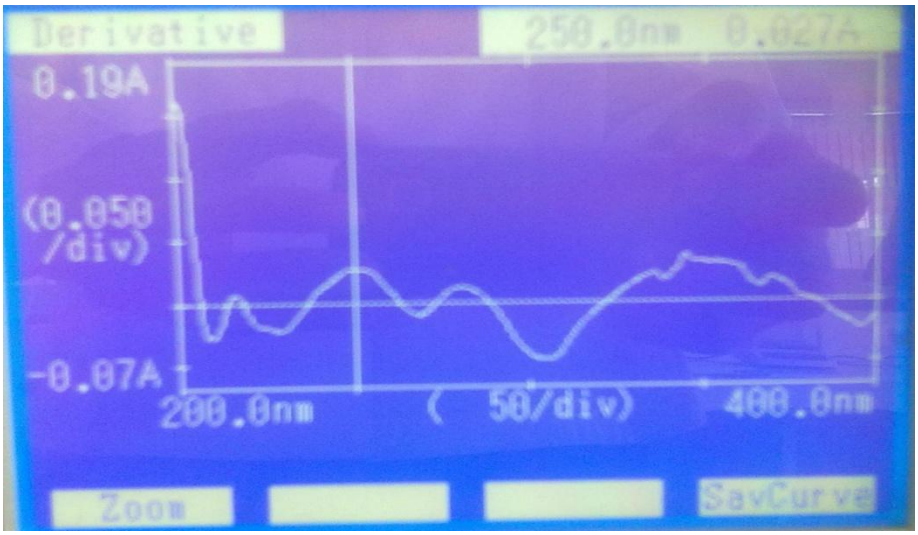

Fig. 4: First order derivative spectrum of Lornoxicam