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Original Article

Simultaneous Derivative Spectrophotometric Determination of Lornoxicam and Paracetamol in Tablet Dosage Forms

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ABSTRACT

A simple, rapid, precise and accurate derivative spectrophotometric method has been developed for the determination of Lornoxicam and Paracetamol in combined dosage forms (Tablets). The zero crossing point of Paracetamol (247.42 nm) has been selected for the quantification of Lornoxicam whereas the zero crossing point of Lornoxicam (233.28 nm) has been selected for the quantification of Paracetamol from the first order derivative spectrum observed in borate buffer. The method obeys Beer-Lambert's law over the concentration range 5-50 µg/ml for Lornoxicam and 5-60 µg/ml for Paracetamol. The proposed method was validated and can be used for the analysis of tablet dosage forms containing Lornoxicam and Paracetamol.

Key words: Lornoxicam, Paracetamol, Spectrophotometry, Derivative Spectroscopy, Validation.

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INTRODUCTION

Lornoxicam (LCM) is a non-steroidal anti-inflammatory drug belongs to the oxicam class with analgesic, anti-inflammatory and antipyretic properties,chemicallyitis(3E)-6-chloro-3-[hydroxyl(pyridin-2-ylamino) methylene]-2-methyl-2, 3-dihydro-4H-thieno [2,3-e][1,2]thiazin-4-one 1,1-dioxide.[1] Lornoxicam inhibits prostaglandin biosynthesis by blocking the enzyme cyclooxygenase.[2] and it is absorbed rapidly and almost completely from the gastro-intestinal tract.Paracetamol (PCM) is a widely used over-the-counter analgesic and antipyretic, chemically it isN-(4-hydroxyphenyl) acetamide.[3] Lornoxicam and Paracetamol was also as effective as other non-steroidal anti-inflammatory drugs in relieving symptoms of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis etc.

Literature survey reveals UV spectroscopic,[4-13] HPLC,[14-24] LCMS,[25] HPTLC[26-7] and UPLC[28] methods have been developed for the simultaneous estimation of LCM and PCM. The authors have developed a new derivative spectrophotometric method for the simultaneous determination of LCM and PCM and validated.[29]

MATERIALS AND METHODS

Instrumentation

A double beam UV-VIS spectrophotometer (UV-1800, Shimadzu, Japan) connected to computer loaded with software UV Probe was employed with spectral bandwidth of 1 nm and wavelength accuracy of ± 0.3 nm with a pair of 10 mm path length matched quartz cells. For scanning, the wave length range selected was 400 nm to 200 nm with medium scanning speed. All weights were taken using electronic balance (Shimadzu, Japan). All experiments were performed at room temperature (25 ± 1)°C.

Chemicals and reagents

LCM and PCM were obtained as gift samples from Dr. Reddy's Labs (India). Methanol, boric acid and Sodium hydroxide were purchased from Merck (India). All chemicals were of analytical grade and used as received. Both LCM and PCM are available as a combined dosage form in the local pharmacy store as tablets with trade names LORNAC-P (Active Healthcare, India) and LORNA-P (Adcock Ingram Healthcare Pvt. Ltd., India) (Label claim: LCM 8 mg and PCM 500 mg).

Preparation of borate buffer (pH-9.0)

6.20 gm of Boric acid was dissolved in 500 ml of distilled water, adjusted to pH 9.0 with 0.1 M sodium hydroxide (about 41.5 ml) and diluted to 1000 ml with distilled water.

Preparation of Stock Solution

The stock solutions of Lornoxicam and Paracetamol were prepared by dissolving each of 10 mg of Lornoxicam and Paracetamol in 10 ml volumetric flasks separately with methanol and the working standard solutions were prepared on dilution with borate buffer.

Assay of commercial formulations (Tablets)

Twenty tablets were weighed and crushed to a fine powder. An accurately weighed powder sample equivalent to 25 mg of Paracetamol was transferred to a 25 ml volumetric flask and dissolved in 10 ml methanol, sonicated for 30 mins and then filtered through Whatman filterpaper No.41. The filtrate was diluted with borate buffer as per the requirement.

Linearity

A series of drug solutions were prepared for this method and scanned (200-400 nm) against the irreagent blank. The absorption spectra was recorded and transformed into first order derivative spectra (D_1) by the inbuilt software. A standard graph was drawn by taking the concentration n of the drug solution on the x-axis and the corresponding derivative absorbance on the y-axis.

Precision and Accuracy

The intra-day precision studies were carried out at three different concentration levels (5, 10 and 20 µg/ml) on the same day and the % RSD

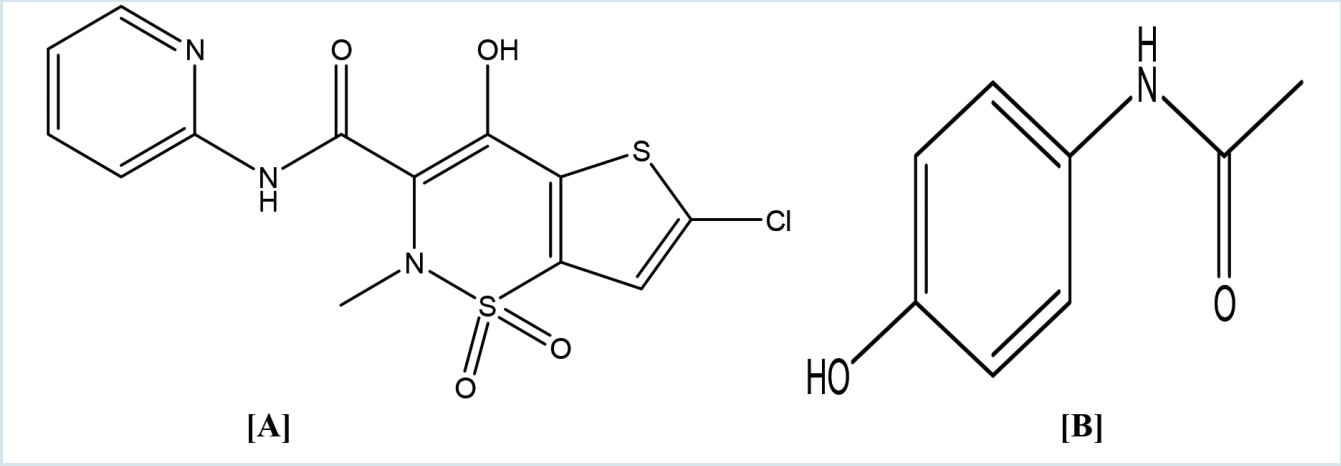

Figure 1: Chemical Structures of Lornoxicam [A] and Paracetamol [B]

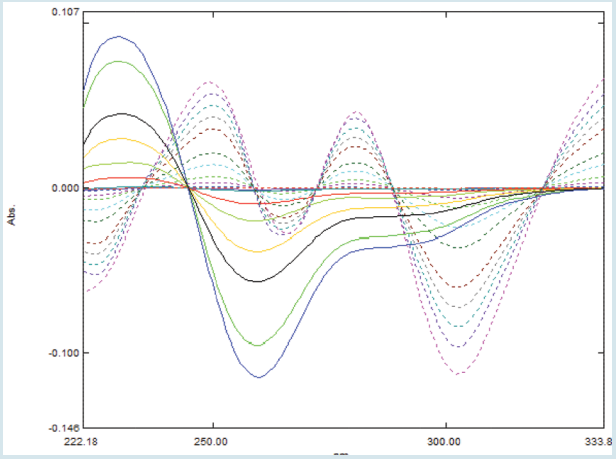

Figure 2: Overlay first derivative spectrum of Lornoxicam (—) over Paracetamol (—)

Table1: Optical characteristics of Lornoxicam and Paracetamol

Parameters	LCM	PCM
Wavelength (Maxima)(nm)	247.42	233.28
Linearityrange (µg/ml)	5-60	5-50
Regression equation	y = 0.0006x-0.0004	y = 0.0018x-0.0017
Slope	0.0006	0.0018
Intercept	0.0004	0.0017
Correlationcoefficient	0.9992	0.9992
Precision(% RSD)	-	-
Intra-day(n=3)	0.25-0.63	0.12-0.44
Inter-day(n=3)	0.41-0.84	0.37-0.53
Accuracy(%Recovery)	99.45-99.77	99.21-99.53
(% RSD)	(0.21)	(0.34)

was calculated. The inter-day precision study was also performed at three different concentration levels on three different days i.e. day 1, day 2 and day 3 and the % RSD was calculated. The accuracy of the method was performed by standard addition method i.e. by spiking the formulation solution with pure drug solutions (80, 100 and 120%) followed by recovery studies and the percentage RSD was calculated.

RESULTS AND DISCUSSION

The authors have proposed a new first order derivative spectrophotometric method for the simultaneous determination of Lornoxicam and Paracetamol. The overlay first order derivative spectrum of Lornoxicam and Paracetamol was shown in Figure 2. The derivative spectrum of Paracetamol shows zero crossing points at 220.13, 247.42 and 328.71 nm and that of Lornoxicamat 233.28, 255.45, 273, 291.42, 314.85, and 358.42 nm. The maxima values were taken for the quantification of LCM at 247.42 nm which is one of the zero crossing points of PCM and similarly at 233.28 nm which is one of the zero crossing points of LCM for the quantification of PCM.

A graph was drawn bytaking the drug concentration on the x-axis and the corresponding derivative absorbance on the y-axis. A straight line graph was obtained proving that Beer-Lambert's law was obeyed over the concentration range 5-60 µg/ml and 5-50 µg/ml for Lornoxicam and Paracetamol respectively (Figure3A and 3B) with linear regression equations,

$y = 0.0006\times-0.0004$ ($R^2 = 0.9992$) and $y = 0.0018\times-0.0017$ ($R^2 = 0.9992$) for Lornoxicam and Paracetamol respectively.

In the accuracy study it was found that the % recovery was 99.45-99.77 (% RSD 0.21) for LCM and 99.21-99.53(%RSD 0.34) for PCM. In precision study the % RSD was found to be 0.25-0.63 (Intra-day) and 0.41-0.84 (Inter-day) for LCM and that of PCM 0.12-0.44 (Intra-day) and 0.37-0.53 (Inter-day). The percentage RSD in accuracy as well as in precision studies were found to be less than 2.0 indicating that the method is precise and accurate. The optical characteristics of Lornoxicam and Paracetamol were shown in Table 1. The method was applied to the tablet formulations of two different brands available from the local pharmacy store and the % recovery was found to be 99.25-99.5 and 99.52-99.68 for LCM and PCM.

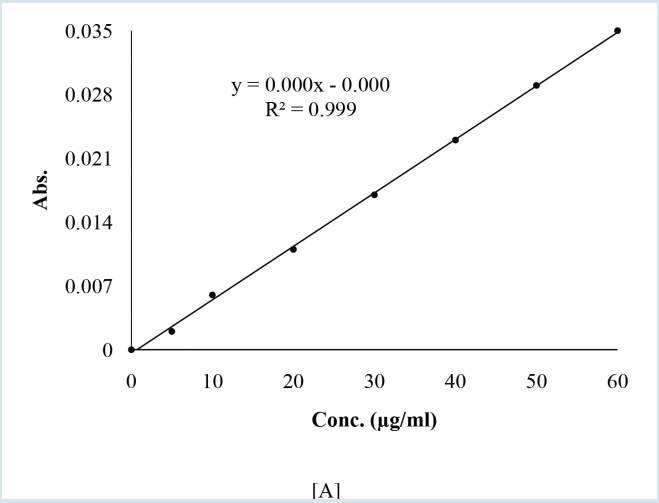

Figure 3: Calibration curves of Lornoxicam and Paracetamol

Table2: Assay of commercial formulation

Brand	Labeled Amount (mg)		Amount obtained (mg)*		% Recovery*		% RSD*	
	LCM	PCM	LCM	PCM	LCM	PCM	LCM	PCM
I	0.8	50	0.794	49.76	99.25	99.52	0.65	0.37
II	0.8	50	0.796	49.84	99.50	99.68	0.79	0.22

*Mean of three replicates.

CONCLUSION

The proposed method is simple, precise and accurate and can be applied for the simultaneous determination of Lornoxicam and Paracetamol in tablets successfully.

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CONFLICTS OF INTEREST

The authors have no conflict of interest.

ABBREVIATION USED

UV: Ultra Violet; **LCM:** Lornoxicam; **PCM:** Paracetamol; **RP-HPLC:** Reverse phase high performance Liquid chromatography; **UPLC:** Ultra performance liquid chromatography; **HPTLC:** High performance thin layer chromatography; **LC-MS:** Liquid chromatography–Mass spectrometry; **ICH:** International conference on harmonization.

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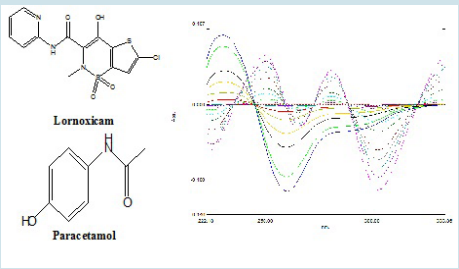
PICTORIAL ABSTRACT



SUMMARY

- A simple first order derivative spectrophotometric method was developed for the simultaneous determination of Lornoxicam and Paracetamol in tablets and validated.
- In this method each drug is determined at the zero crossing point of the other drug from the overlay derivative spectrum of Lornoxicam and Paracetamol.

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