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DEVELOPMENT AND VALIDATION OF ANLYTICAL METHODS FOR THE SIMULTANEOUS ESTIMATION OF LORNOXICAM AND PARACETAMOL FROM THEIR PHARMACEUTICAL DOSAGE FORM

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ABSTRACT
A simple Reverse phase liquid chromatographic method has been also developed and subsequently validated for simultaneous determination of Paracetamol and Lornoxicam in combination. The separation was carried out using a mobile phase consisting of Potassium dihydrogen phosphate, pH adjusted to 7.3 with triethyl amine and acetonitrile 70:30(%v/v).The column was used Phenomex C_{18}, 5 µm, (250x 4.6 mm) with flow rate 1.5ml/min using UV detection at 257nm. The described method was linear over concentration range 20 to 60 µg/ml & 0.2 to1.8µg/ml for assay of Paracetamol & Lornoxicam respectively. The retention time of Paracetamol & Lornoxicam were found to be 2.33 & 7.61 respectively. Result of analysis was validated statistically. The method show good reproducibility & recovery with % less than 1, all the tests of above mentioned studies were found to be in acceptance criteria.The method was found to be rapid, specific, precise & accurate and can be successfully applied for routine analysis of Paracetamol & Lornoxicam in bulk & combined dosage forms.

***Keywords*:** Paracetamol, Lornoxicam, HPLC

INTRODUCTION
Paracetamol (PARA), chemically 4-hydroxy acetanilide, is a centrally and peripherally acting non-opioid analgesic and antipyretic[1-3]. Literature survey reveals, there are UV and HPLC methods reported for the estimation of PARA in Pharmaceutical formulations.

Lornoxicam (LOX) is 6-chloro-4-hydroxy-2-methyl-N-2-pyridinyl-2H-thieno-[2,3-e]-1,2-thiazine-3-carboxamide 1,1-dioxide; is a novel non-steroidal anti-inflammatory drug (NSAID) with marked analgesic properties. LOX belongs to the chemical class oxicams, which includes piroxicam,tenoxicam and meloxicam. LOX, which is commercially available as an 8-mg tablet, is used to treat inflammatory diseases of the joints, osteoarthritis, and pain after surgery. It works by blocking the action of cyclooxygenase, an enzyme involved in the production of chemicals, including some prostaglandins in the body [1-5].

Extensive literature survey reveals, none of the method is available that is based on estimation of Paracetamol and Lornoxicam by HPLC. Aim of present work was to develop simple, precise, accurate and economical HPLC methods for simultaneous determination of binary drug formulation.

The proposed method was optimized and validated in accordance with International Conference on Harmonization (ICH) guidelines [6-9]

MATERIALS & METHOD
Apparatus: Sonicator, Shimadzu 2010(Auto injector), pH Meter, Beaker, Volumetric Flask.

Reagent: Water (HPLC Grade), Potassium Dihydrogen Phosphate, Triethylamine, Acetonitrile(HPLC Grade), API Lornoxicam & Paracetamol.

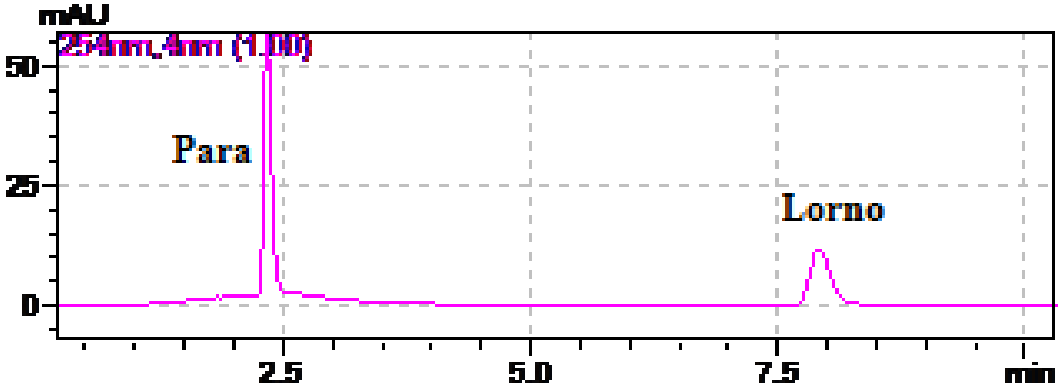
Experimental Chromatographic Conditions

Stationary phase	:	Phenomex, 5 µm, C_{18} (250x4.6 mm) column
Mobile phase	:	21mM potassium dihyrogen phosphate (pH adjusted to 7.3 with Triethyl amine): acetonitrile
Solvent ratio	:	70: 30%v/v
pH	:	7.3
Detection wavelength	:	257 nm

Flow rate : 1.5 ml/ minute
Operating pressure : 158 kgf
Temperature : Room temperature

Validation Parameters of RP-HPLC

Parameters	Paracetamol	Lornoxicam
LOD (Detection limit) (ng/ ml)	0.5µg	10µg
LOQ (Quantitation limit) (ng/ ml)	10µg	20µg
Accuracy (%)	50% - 99.24% 100% - 98.92%	50% -101.01 100% -100.84%
Tailing Factor (NMT 2)	1.312	1.283
Precision (%RSD) (NMT 2)	-	-
Intra-day (n=3)	0.2045	1.3560
Inter-day (n=3)	0.1944	1.3662
Repeatability of injection (%RSD)	0.0919	0.7860
Robustness	Meets (RSD of 6 replicates: ≤ 2%)	Meets (RSD of 6 replicates: ≤ 2%)



ANALYSIS OF FORMULATION:

Preparation of standard solution:

100 mg of Paracetamol and 1.6 mg of Lornoxicam diluted with the Mobile phase up to 100 ml (Stock Solution).

Make 100 µg/ml of Paracetamol and 1.6 µg/ml of Lornoxicam diluted with the Mobile phase.

↓

Aliquots of standard solutions containing 25 µg/ml of Paracetamol and 0.4 µg/ml of Lornoxicam.

Preparation of sample solution

20 tablets → Average weight → Powdered & weighed a quantity equivalent to 100 mg of Paracetamol and 1.6 mg of Lornoxicam were transferred to 100 ml standard flask and make up with the with mobile phase.

↓

Aliquots of solutions containing 25 µg/ml of Paracetamol and 0.4 µg/ml of Lornoxicam diluted with mobile phase.

Analysis of formulation

Drug	Amount (µg/tablet)		% label claim	% RSD*
	Labeled	Estimated		
Para	25	24.85	99.40	0.2581
Lorno	0.4	0.39	97.50	0.3214

*RSD of six observations

Para - paracetamol, Lorno – Lornoxicam

CONCLUSION

The developed assay method was found to be simple, accurate, sensitive, précised, and rapid. This method can be applied for routine quantitative analysis of Paracetamol and Lornoxicam in pharmaceutical formulations like Tablet dosage form.

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