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Research Article

Development and Validation of High-Performance Liquid Chromatographic Method for Analysis of Polmacoxib and Paracetamol in an Uncoated Tablet Formulation

Shubham M. Ikade, Anil P. Dewani
Department of Chemistry, P. Wadhwani College of Pharmacy; Yavatmal.

Abstract: A simple, accurate, precise, and robust reverse phase high performance liquid chromatographic (RP-HPLC) method was developed and validated for the simultaneous estimation of Paracetamol and Polmacoxib in bulk drug and pharmaceutical tablet dosage form. Chromatographic separation was achieved using a C18 Hypersil Gold column (4.6 × 250 mm) with a mobile phase consisting of 0.1% orthophosphoric acid and acetonitrile in the ratio of 60:40 v/v at a flow rate of 1.0 mL/min. Detection was carried out at 240 nm with a run time of 15 minutes. The retention time of Paracetamol and Polmacoxib was found to be 5.2 min and 12.0 min respectively, indicating good resolution between the two drugs. The developed method was validated according to ICH guidelines for parameters such as accuracy, precision, linearity, robustness, specificity, and ruggedness. The method showed excellent linearity in the concentration range of 162.5–487.5 µg/mL for Paracetamol and 1–3 µg/mL for Polmacoxib with correlation coefficients greater than 0.99. The percentage recovery for both drugs was found within acceptable limits of 98–102%, confirming the accuracy of the method. The %RSD values for precision studies were less than 2%, demonstrating good repeatability and reproducibility. The proposed RP-HPLC method was successfully applied for the quantitative estimation of both drugs in marketed tablet formulation and was found to be suitable for routine quality control analysis.
Keywords: RP-HPLC, Paracetamol, Polmacoxib, ICH guidelines, Accuracy and precision.

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1. Introduction

Analytical chemistry plays a vital role in the identification, separation, and quantitative estimation of pharmaceutical compounds in bulk drugs and dosage forms. Among various analytical techniques, reverse phase high performance liquid chromatography (RP-HPLC) is widely employed due to its high sensitivity, precision, accuracy, and rapid analysis. RP-HPLC has become one of the most reliable methods for routine quality control analysis in pharmaceutical industries because it provides excellent resolution and reproducibility for multicomponent drug formulations. Paracetamol is a commonly used analgesic and antipyretic agent, while Polmacoxib is a non-steroidal anti-inflammatory drug (NSAID) used in the treatment of pain and inflammation. Combination therapy of these drugs offers improved therapeutic efficacy in the management of musculoskeletal and arthritic disorders.

A comprehensive literature survey revealed that limited analytical methods are available for the simultaneous estimation of Paracetamol and Polmacoxib in combined dosage form. Therefore, the present work was aimed at developing and validating a simple, precise, accurate, and robust RP-HPLC method for simultaneous estimation of these drugs in pharmaceutical formulation according to ICH guidelines. The developed method can be effectively utilized for routine quality control and assay analysis in pharmaceutical industries and research laboratories.

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2. Materials And Methods

Pure drug samples of Paracetamol and Polmacoxib were obtained as gift samples from Arrow Chem, Mumbai, with assay purity of 99.8% w/w and 99.02% w/w, respectively. The marketed formulation used for analysis was Palocap P® tablets manufactured by Ajanta Pharma containing 325 mg of Paracetamol and 2 mg of Polmacoxib. All chemicals and reagents used in the study were of analytical reagent (AR) grade and HPLC grade. Methanol, acetonitrile, triethylamine, orthophosphoric acid, distilled water, and disodium hydrogen phosphate were used throughout the experiment.

Instrumentation included a UV-Visible spectrophotometer (Thermo Electron Shimadzu UV-1601), Waters 600 HPLC system equipped with a 996 PDA detector, Hanna pH meter, Citizen CY-104 analytical balance, and an ultrasonic sonicator. Infrared spectral analysis of both drugs was carried out using potassium bromide pellet technique in diffuse attenuated reflectance mode for functional group identification and confirmation of drug purity.

For chromatographic analysis, RP-HPLC method development was performed using a C18 Hypersil Gold column (4.6× 250 mm). The optimized mobile phase consisted of 0.1% orthophosphoric acid and acetonitrile in the ratio of 60:40 v/v, delivered at a flow rate of 1.0 mL/min. Detection was carried out at 240 nm with an injection volume of 20 µL and total run time of 15 minutes under ambient temperature conditions. Methanol was selected as diluent based on solubility studies.

Standard and sample solutions were prepared in methanol, filtered through 0.45 µm membrane filters, and sonicated prior to injection. The developed method was validated according to ICH guidelines for parameters including accuracy, precision, linearity, robustness, ruggedness, specificity, and system suitability. Recovery studies were performed by standard addition method at different concentration levels, while robustness was evaluated by deliberate variation in flow rate, mobile phase composition, and wavelength.

3. Results

A simple, rapid, accurate, and reproducible RP-HPLC method was successfully developed and validated for the simultaneous estimation of Paracetamol (PAR) and Polmacoxib (POL) (Figure 1) in tablet dosage form. The developed analytical method provided satisfactory separation of both drugs with good peak symmetry and acceptable system suitability parameters.

Table No. 01: Details of API

Drug	Supplied by	Quantity	Purity (Assay)
Paracetamol	Arrow Chem Mumbai.	10 g	99.8 % w/w
Polmacoxib	Arrow Chem Mumbai	10 g	99.02% w/w

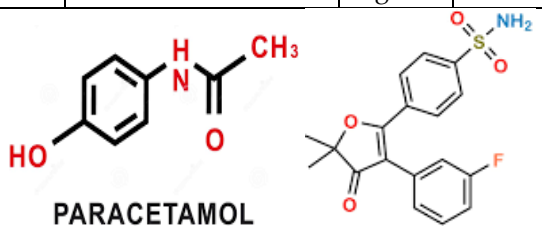

Figure 1: Chemical Structure of Paracetamol and Polmacoxib

Method Development and Optimization

Corresponding Author: shubham.ikade1994@gmail.com

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Different chromatographic conditions were evaluated to obtain optimum separation of PAR and POL. The final optimized chromatographic conditions included a C18 Hypersil Gold column (4.6 × 250 mm) with a mobile phase consisting of 0.1% orthophosphoric acid and acetonitrile in the ratio of 60:40 v/v under isocratic elution. The flow rate was maintained at 1.0 mL/min and detection was carried out at 240 nm using PDA detection. The total run time was 15 min. Under these optimized conditions, PAR and POL showed retention times of approximately 5.2 min and 11.9 min (Figure 2), respectively, with satisfactory peak resolution and tailing factor less than 2.

Table No. 02: Chromatographic Parameters:

Column	C18 (Hypersil gold) /4.6 x 250 mm
Flow Rate	1 ml/min
Wavelength	240 nm
Injection volume	20µl
Column oven Temperature	Ambient
Run Time	15 minutes
Mobile Phase	0.1% OPA and ACN (60:40)

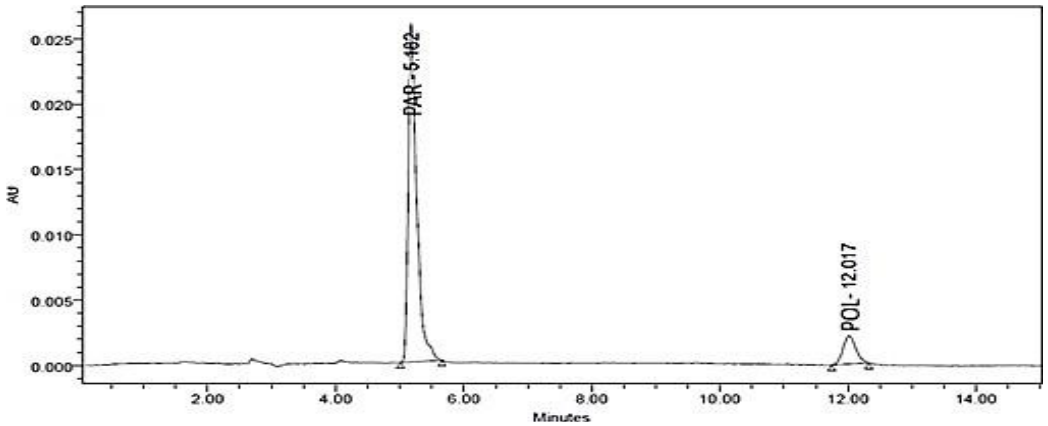

Figure 2: Chromatogram of Paracetamol and Polmacoxib

System Suitability Studies

System suitability studies were performed using five replicate injections of standard solutions. The % RSD values for peak area and retention time were found to be less than 2%, indicating good precision of the chromatographic system. Theoretical plate count was greater than 2000 for both drugs, confirming adequate column efficiency. Tailing factors were within acceptable limits, demonstrating symmetrical peak shape and suitability of the developed method for routine analysis.

Table No. 03: Summary of system suitability of Test results

Sr.No	Peak area		Retention Time		Symmetry		No .of theoretical Plates	
	PAR	POL	PAR	POL	PAR	POL	PAR	POL
1	508350	61060.2	5.21	12.1	0.722	0.956	8149.1	4138.7
2	508850	61629.2	5.16	11.9	0.723	0.954	8100.2	4042.8
3	509750	61111.0	5.20	11.9	0.722	0.971	8143.3	4190.0
4	506820	61012.4	5.25	12	0.726	0.956	8194.1	4167.3
5	508150	61120.2	5.19	11.8	0.727	0.978	8181.5	4100.2
Mean	508384	61386.6	5.202	11.94	0.722	0.960	8197.53	4157.53

Corresponding Author: shubham.ikade1994@gmail.com

S.D	2272.6	347.9	0.03	0.11	0.010	0.009	284.34	288.99
%R.S.D.	0.56	0.90	0.62	0.95	1.39	0.967	1.081	1.235

Assay of Marketed Formulation

The developed RP-HPLC method was successfully applied for the analysis of marketed tablet formulation (Palocap P®). The average assay values obtained were 324.9 mg (99.96%) for PAR and 1.99 mg (99.83%) for POL. Low %RSD values confirmed the accuracy and reproducibility of the method for pharmaceutical dosage form analysis.

Table No.04: Results and statistical data for estimation of PAR and POL in marketed formulation

Brand name: Palocap P® Tab Avg.wt = 439 mg

Sr.No.	PAR		POL	
	Assay (mg)	Assay % of LC	Assay (mg)	Assay % of LC
1	325	100	2.01	100.5
2	324.8	99.93	1.99	99.5
3	324.9	99.96	1.99	99.5
Average	324.9	99.96	1.99	99.83
SD	0.1	0.035	0.011	0.57
% RSD	0.03	0.035	0.57	0.57

Method Validation

Precision

System precision and method precision studies showed %RSD values below 2%, indicating excellent repeatability and precision of the proposed method. Intermediate precision (ruggedness) studies performed using different analysts and instruments also demonstrated consistent assay results, confirming reliability of the method under varied analytical conditions.

Table No. 05: Data showing system Precision

Sr. No.	Parameter	Observations		Limits
		PAR	POL	
1	The % RSD of peak area response for three replicate injections of standard	1.217	0.273	NMT 2.0
2	Theoretical plates	8197.53	4057.53	NLT 2000
3	Tailing factor	1.278	1.174	NMT 2.0

Linearity Range

The method exhibited excellent linearity over the concentration range of 50–150% for both drugs. Calibration plots of concentration versus peak area showed correlation coefficient (R^2) values of 0.999 for both PAR and POL, indicating strong linear relationship between concentration and detector response.

Accuracy

Accuracy of the developed method was evaluated by recovery studies using the standard addition method at 80%, 100%, and 120% concentration levels. Mean percentage recovery values ranged between 99% and 101% for both drugs with %RSD less than 2%, confirming the accuracy of the proposed RP-HPLC method.

Table No. 06: Result of Accuracy Studies

	PAR			POL		
	Levels			Levels		
	80%	100%	120%	80%	100%	120%
Amt added (µg/ml)	260	325	390	1.6	2	2.4
	260	325	390	1.6	2	2.4
	260	325	390	1.6	2	2.4
Amt taken (µg/ml)	260	325	390	1.6	2	2.4
	260	325	390	1.6	2	2.4
	260	325	390	1.6	2	2.4
Amt recovered (µg/ml)	259.9	324.40	388.55	1.602	2.00	2.39
	259.7	324.70	390.35	1.602	1.99	2.39
	259.4	325.65	389.25	1.597	2.00	2.39
% Recovery	99.96	99.80	99.63	100.16	100.02	99.90
	99.88	99.90	100.09	100.13	99.75	99.97
	99.77	100.20	99.81	99.85	100.06	99.94
Mean % recovery	99.87	99.96	99.84	100.04	99.94	99.93
% RSD	0.0955	0.208	0.232	0.170	0.168	0.035

Robustness

Robustness studies were carried out by deliberate variation in chromatographic conditions such as flow rate, organic phase composition, and detection wavelength. No significant changes in system suitability parameters were observed, indicating that the method is robust and reliable for routine quality control analysis.

Following Parameters were covered under robustness parameter.

1. Effect of variation in flow rate of mobile phase by ± 10%
2. Organic phase composition (± 10%)
3. Change in Wavelength by ± 5 units

Specificity

Specificity studies demonstrated that there was no interference from placebo or excipients at the retention times of PAR and POL. This confirmed the specificity and selectivity of the developed method for simultaneous estimation of both drugs in combined dosage form.

4. Discussion

The developed RP-HPLC method proved to be simple, sensitive, accurate, precise, and economical for simultaneous estimation of Paracetamol and Polmacoxib in tablet dosage form. The method showed excellent chromatographic separation with acceptable validation parameters as per ICH guidelines. The short retention time, good peak symmetry, high recovery, and low %RSD values indicate the suitability of the method for routine pharmaceutical quality control and stability studies. Therefore, the proposed RP-HPLC method can be effectively employed for simultaneous quantitative estimation of PAR and POL in combined pharmaceutical formulations.

5. Conclusion

From the studies it can be concluded that RP-HPLC technique can be successfully used for the estimation of the PAR and POL in their combined tablet formulations. The method shows good reproducibility to the RP-HPLC method is accurate, precise, specific,

reproducible and sensitive. The analysis of combined dose formulation of PAR and POL can also be successfully performed by the RP-HPLC method.The RP-HPLC method is also simple, accurate, precise, reproducible, economical and rapid too. It may be adopted for routine control analysis of these two drugs in combined dosage form.No interference of additives, matrix etc. is encountered in these methods. Further studies on other pharmaceutical formulations would throw more light on these studies. Suitability of these methods on biological samples also needs study.

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