International Journal of Pharmaceutical Sciences and Drug Analysis

E-ISSN: 2788-9254
P-ISSN: 2788-9246
Impact Factor (RJIF): 6.03
IJPSDA 2025; 5(2): 120-127
www.pharmacyjournal.info
Received: 07-08-2025
Accepted: 11-09-2025

Indhumathi K
M. Pharm Student
Department of Pharmaceutical Analysis Adhiparasakthi College of Pharmacy, Melmaruvathur, Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai, Tamil Nadu, India.

Murugan
Associate Professor
Department of Pharmaceutical Analysis Adhiparasakthi College of Pharmacy, Melmaruvathur, Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai, Tamil Nadu, India.

Vetrichelvan T
HOD-cum-Dean (Research), Department of Pharmaceutical Analysis, Adhiparasakthi College of Pharmacy, Melmaruvathur, Affiliated to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, Tamil Nadu, India

Correspondence
Indhumathi K
M. Pharm Student
Department of Pharmaceutical Analysis Adhiparasakthi College of Pharmacy, Melmaruvathur, Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai, Tamil Nadu, India.

Stability indicating method development and validation of polmacoxib in bulk and capsule dosage form by UV spectrophotometric method

Indhumathi K, Murugan S and Vetrichelvan T

Abstract
Three simple UV techniques have been developed to determine the dosage of Polmacoxib in both bulk and capsule form. Using a forced degradation study, the techniques include the zero, first order derivative, and area under the curve. The zero-order λmax of Polmacoxib is 316 nm. 256 nm was chosen as the wavelength for first order. The area under the curve was integrated between the wavelength ranges of 325 nm and 305 nm in this study. The area under the curve and zero order method for Polmacoxib in methanol were found to be linear between 5 and 25 µg/ml, while the first order method was found to be linear between 20 and 100 µg/ml. The correlation coefficients for the zero-order, first-order derivative, and area under the curve methods are 0.9999, 0.9998, and 0.9998, respectively, and they demonstrate strong linearity in the concentration range mentioned above.

Keywords: Polmacoxib, uv visible spectrophotometry, zero order method, first order derivative spectroscopy, area under the curve method.

Introduction
Polmacoxib (Fig.1) is 4-[3-(3-fluorophenyl)-4, 5-dihydro-5,5-dimethyl-4-oxo-2-furanyl]-benzenesulfonamide. Its molecular formula is $C_{18}H_{16}FNO_4S$ and its molecular weight is 361.39 gm/mol. [1].

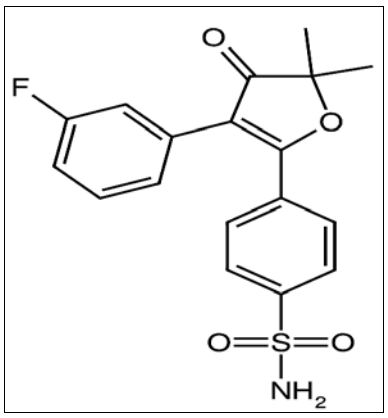

Fig 1: Chemical structure of Polmacoxib

Polmacoxib, a type of nonsteroidal anti-inflammatory drug (NSAID), is used primarily in the management of osteoarthritis and has received regulatory approval in South Korea. Its mechanism involves dual inhibition of COX-2 and carbonic anhydrase enzymes. Comparative studies involving healthy participants have indicated that both Polmacoxib and celecoxib exhibit similar impacts on urinary prostaglandin metabolites, implying a comparable cardiovascular safety profile [2].
The chronic condition known as osteoarthritis (OA) is characterized by cartilage degradation and injury. It is very common in society and contributes to disability. Because of aging and obesity, adults are more prone to this condition. Osteoarthritis has no known cure, and the available therapies mostly aim to reduce pain and increase functional abilities. When treating osteoarthritis, a multidisciplinary approach tailored to each patient's unique needs is essential. The main purposes of nonsteroidal anti-inflammatory medicines (NSAIDs) are to

reduce excruciating inflammation and prevent joints from damages. However, because they inhibit cyclooxygenase (COX), classic NSAIDs have a significant risk of side effects, including cardiovascular, renal, and gastrointestinal. Uncertainty surrounding the use of COX-2 inhibitors in supporting the development of selective COX-2 drugs has resulted from health concerns about both COX-2 inhibitors and standard NSAIDs. Polmacoxib (CG100649) is a recently developed COX-2 inhibitor. [3].

No methodology for estimating Polmacoxib was mentioned in the literature review. Therefore, in accordance with ICH recommendations, an innovative, simple, quick, accurate, precise, cost-effective, and highly sensitive stability indicating UV spectrophotometric approach was established for the evaluation of Polmacoxib in bulk and capsule dosage form. According to ICH guidelines, the developed method was validated. [4].

Materials and Methods

Instrumentation

The Shimadzu double beam UV/visible spectrophotometer (Model UV-1700) with a 1 nm spectral band width and the Lab India 3000 double beam UV-visible spectrophotometer were the instruments used for this study. The Shimadzu AUX-220 electronic balance was used for all weighing, and the sample solution was sonicated using a Sonicator and a hot air oven (InfraDIGI-250ºC).

Reagents and Chemicals

Qualigens India Pvt Ltd, located in Mumbai, India, supplied all of the chemicals and reagents used in the HPLC grading process. The study's pharmaceutical dose form was Poliexar capsules, which were purchased from an adjacent drugstore and contained 2 mg of Polmacoxib each.

Method Optimization

Selection of solvent

One of the most important aspects of developing a UV analysis method involves selecting an appropriate solvent. Methanol was the solvent used in the proposed method's Polmacoxib estimation.

Preparation of stock standard solution

20 mg of accurately weighed Polmacoxib were added to a 10 ml volumetric flask, dissolved, and diluted with methanol to the appropriate volume. A stock solution (stock I) with a concentration of 2000 µg/ml was given to this.

In order to produce 200 µg/ml of Polmacoxib standard stock solution (stock II), 1 ml of standard stock solution was diluted with methanol in a 10 ml volumetric flask until the desired concentration was obtained.

Preparation of working standard solution of Polmacoxib

For the zero order and area under the curve methods, 0.5 ml of this standard stock solution (stock II) has been taken out and diluted with 10 ml of methanol to obtain a working concentration of 10 μg/ml, and for the first order method, 2 ml was taken out and diluted with 10 ml of methanol to obtain a working concentration of 40 μg/ml.

Selection of wavelengths

Zero order method

To achieve a final concentration of 10 µg/ml, 0.5 ml of the standard stock solution (stock-II) was taken out and diluted with 10 ml of methanol. Using methanol as a blank, the solution was scanned in the 200-400 nm range. The wavelength selected for the zero-order method was 316 nm based on the drug's overlain spectra.

First order derivative method

A final concentration of 40 µg/ml was obtained by diluting the 2 ml of the standard stock solution (stock-II) with 10 ml of methanol. Using methanol as a blank, the solution was scanned in the 200-400 nm range. The wavelength selected for the first order method was 256 nm based on the drug's overlain spectra.

Area under curve method

By appropriately diluting the standard stock solution (stock II) with methanol and measuring the integrated absorbance across a specific wavelength range between 325 nm and 305 nm, a solution of Polmacoxib (10 µg/ml) was developed.

Preparation of Calibration Curve

Using methanol as a solvent, Polmacoxib solutions with concentrations of 5, 10, 15, 20, and 25 µg/ml were prepared from a standard stock solution of 200 µg/ml for zero order and area under the curve. Using methanol as a solvent for the first order derivative method, solutions of Polmacoxib with concentrations of 20, 40, 60, 80, and 100 µg/ml were prepared from a standard stock solution of 200 µg/ml.

Analysis of Marketed Capsule Formulation

Twenty capsules containing 2 mg of Polmacoxib were weighed, and the average weight was determined in order to estimate the drugs used in commercial formulations. A 10 ml clean dry volumetric flask with 5 ml of methanol was filled with a precisely weighed quantity of powder sample equivalent to 2 mg. To obtain a stock concentration of Polmacoxib, the contents of the flask were sonicated for 15 minutes, and then the volume was adjusted by adding additional methanol.

To find the concentration of Polmacoxib, 0.5 ml of the above stock solution was pipetted out into a 10 ml volumetric flask. The volume was then adjusted with methanol diluted to 10 ml to obtain 10 μg/ml of Polmacoxib. The absorbance of the sample solution was measured in zero order, and the area under the curve was measured using 316 nm and 325 to 305 nm, respectively.

To determine the concentration of Polmacoxib, the absorbance of the sample solution in first order was measured using 256 nm. The concentration of Polmacoxib in the diluted solution was obtained from calibration curves. For the first order derivative, pipette 2 ml from 200 µg/ml of stock solution into a 10 ml volumetric flask. The volume was adjusted to the mark with the methanol diluted to 10 ml using methanol to get 40 μg/ml of Polmacoxib. The concentration was then multiplied by the dilution factor to determine the amount of Polmacoxib in mg/cap.

Method Validation

In accordance with ICH criteria, the suggested methods were validated.

Linearity

A series of 10 ml volumetric flasks were filled with various aliquots of 0.25-1.25 ml of Polmacoxib, and the volume was adjusted with methanol to obtain concentrations of 5, 10, 15,

20, and 25 µg/ml, respectively. The zero-order derivative of the absorption spectra was observed at 316 nm. The area under the curve against concentration was plotted using the AUC calibration plot, and the regression equation was obtained. The area under the curve has been integrated into the 305.00-325.00 nm range. For first order method, Different aliquots of 1 -5 ml of Polmacoxib were transferred into series of 10 ml volumetric flasks, separately and the volume was made up to the mark with Methanol to get concentrations 20, 40, 60, 80 and 100 µg/ml, respectively. The absorption spectrum was recorded at 256 nm in first order derivative.

Accuracy
To the pre-analyzed sample solutions, a known amount of standard stock solution was added at different levels i.e. 50, 100 and 150 %. The solutions were reanalyzed by proposed method.

Precision
By examining capsules at various times on the same day in sextuplicate (Intra-day assay precision) and on six separate days (Inter-day assay precision), the repeatability of this approach was determined.

Ruggedness
Two analysts using various operational and environmental conditions analyze the aliquots from a homogeneous slot to determine the robustness of the suggested method.

Limit of Detection and Limit of Quantitation
They were measured using standard deviation of Y-intercept and slope of calibration curve as per ICH guideline. The LOD and LOQ were calculated using following formula
$LOD = 3.3 \times \sigma / s$
$LOQ = 10 \times \sigma / s$
Where,
σ = the standard deviation of response
s = the slope of the calibration curve

Degradation Studies
Forced Degradation for Zero Order method
Acid Degradation
In order to perform acid degradation studies, 0.5 ml of standard stock solution (stock II) was transferred into a 10-ml volumetric flask. After adding and thoroughly mixing 0.5 ml of 0.1 N H_2SO_4 solutions, the mixture had been kept at 60°C for 24 hours. After the duration time period, 0.5 ml of 0.1 N KOH added to neutralize the solution with methanol to made up the volume [6,8].

Base degradation
In order to perform base degradation studies, 0.5 ml of standard stock solution (stock II) was transferred into a 10-ml volumetric flask. After adding and thoroughly mixing 0.5 ml of 0.1 N KOH solutions, the mixture had been kept at 60°C for 24 hours. After the duration time period, 0.5 ml of 0.1 N H_2SO_4 added to neutralize the solution with methanol to made up the volume
[6,8].

Oxidation degradation
In order to perform oxidation degradation studies, 0.5 ml of standard stock solution (stock II) was transferred into a 10-ml volumetric flask. After thoroughly mixing and adding 0.5 ml of 1% H_2O_2 solutions, the mixture was allowed stand at 60°C for 24 hours. After a while, methanol was added to made up the volume [6].

Reduction degradation
In order to perform reduction degradation studies, 0.5 ml of standard stock solution (stock II) was transferred into a 10-ml volumetric flask. After thoroughly mixing and adding 0.5 ml of 10 % sodium bisulfate solutions, the mixture was allowed stand at 60°C for 24 hours. After a while, methanol was added to made up the volume [7].

UV light degradation
To perform UV light degradation testing, 20 mg of accurately weighed Polmacoxib raw material that had been exposed to UV light for 24 hours was transferred into a 10 ml volumetric flask which was filled with methanol. In a 10-ml volumetric flask, 1 ml of stock solution was diluted, and methanol was added to made up the remaining volume. A 10 ml volumetric flask was filled with 0.5 ml of the above standard stock solution that had been diluted at 316 nm [8].

Results and Discussion
Method development and optimization
Method 1: Zero order methods
This method involved preparing a solution of Polmacoxib (10 µg/ml) by appropriately diluting a standard stock solution with methanol. The solution was then scanned in the spectrum mode between 400 to 200 nm. 316 nm was selected as the wavelength for quantification based on the drug's spectrum. Figure No. 2 shows the Polmacoxib zero order derivative spectrum.

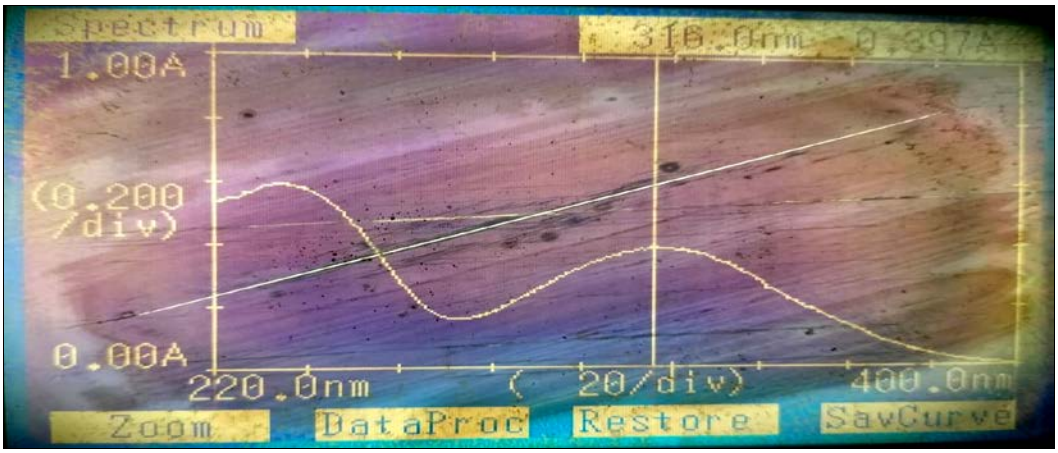

Fig 2: Zero order spectrum of Polmacoxib

Method 2: First order derivative method

This method involved preparing a solution of Polmacoxib (40 µg/ml) by appropriately diluted a standard stock solution with methanol. The solution was then scanned in the spectrum mode between 400 to 200 nm. The resulting absorption spectra were then derivatized for first order. 256 nm was selected as the wavelength for Polmacoxib quantification based on the drug's initial spectra. Figure No. 3 shows the Polmacoxib first order derivative spectra.

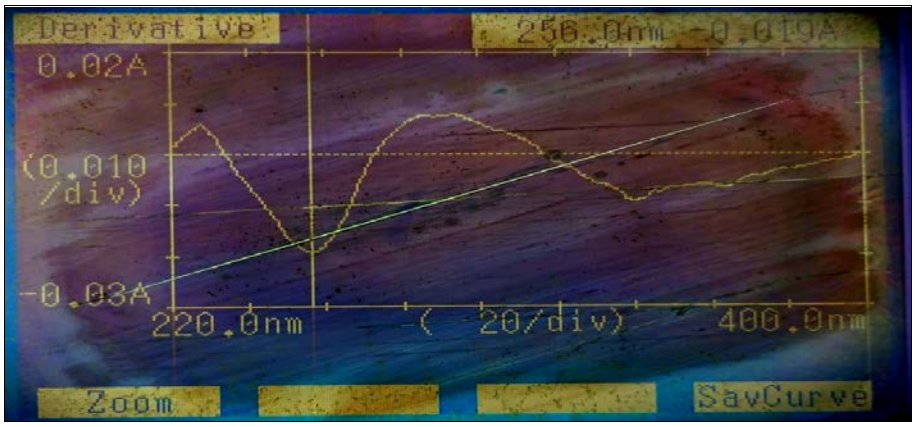

Fig 3: First order spectra of Polmacoxib

Method 3: Area Under Curve: This method involves the calculation of the integrated value of absorbance concerning the wavelength in the indicated range. Area calculation processing calculates the area bounded by the curve and horizontal axis. Here horizontal axis represents baseline. Whereas α is the area of portion bounded by curved at a and a straight line connecting the start and end point, β is an area of portion bounded by a straight line connecting the start and end point on curve data and horizontal axis, λ_1 and λ_2 are wavelengths representing the start and end point of curve region. In this study area was integrated between wavelength ranges from 325 nm-305 nm.

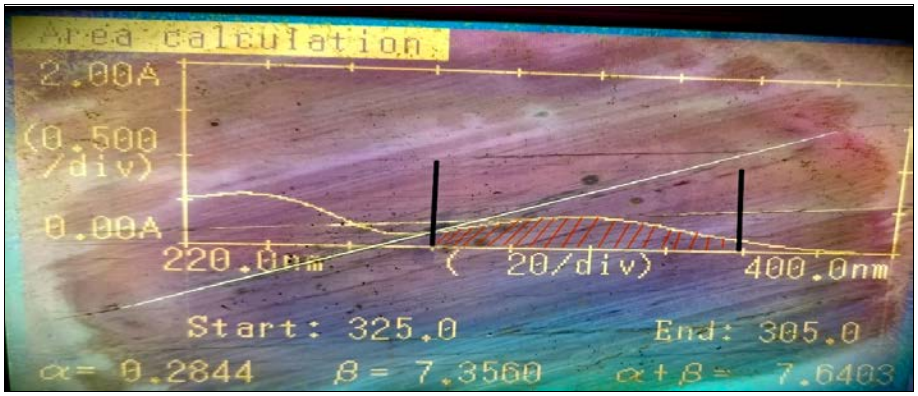

Fig 4: AUC spectra of Polmacoxib

Preparation of Calibration Curve: Using methanol as a solvent, Polmacoxib solutions with concentrations of 5, 10, 15, 20, and 25 µg/ml were made from a standard stock solution of 200 µg/ml for zero order and area under the curve. Using methanol as a solvent for the first order derivative approach, solutions of Polmacoxib with concentrations of 20, 40, 60, 80, and 100 µg/ml were made from a standard stock solution of 200 µg/ml. Figures No. 5, 6, and 7 show the Polmacoxib zero, first, and AUC calibration curves.

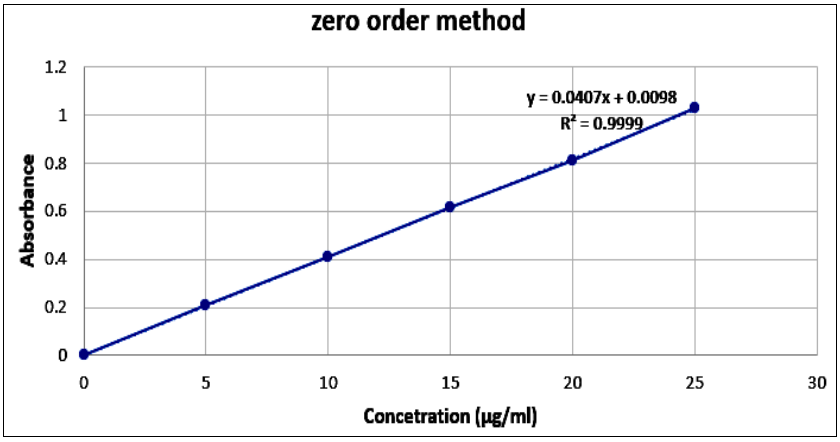

Fig 5: Calibration graph of Polmacoxib for zero order

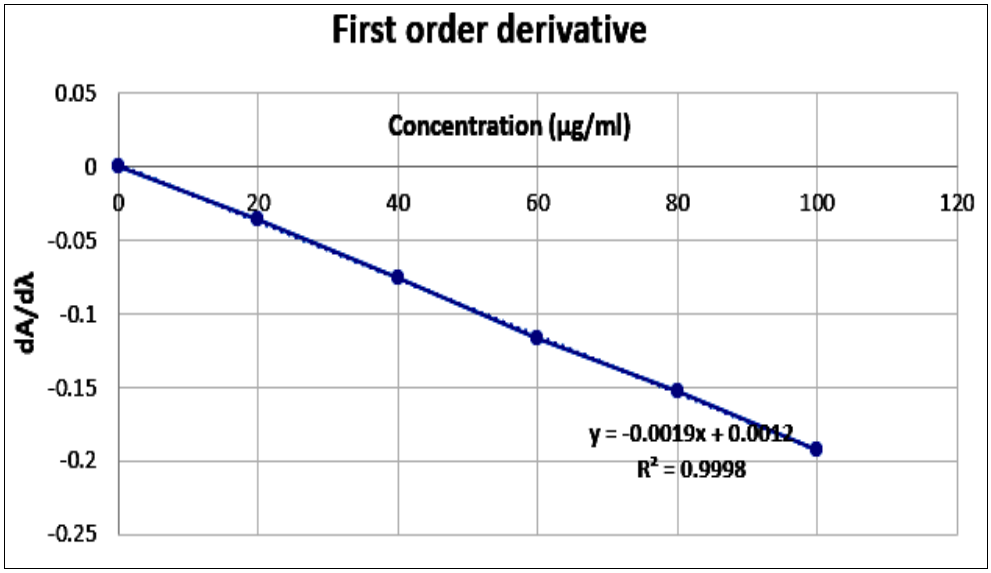

Fig 6: Calibration graph of Polmacoxib for first order

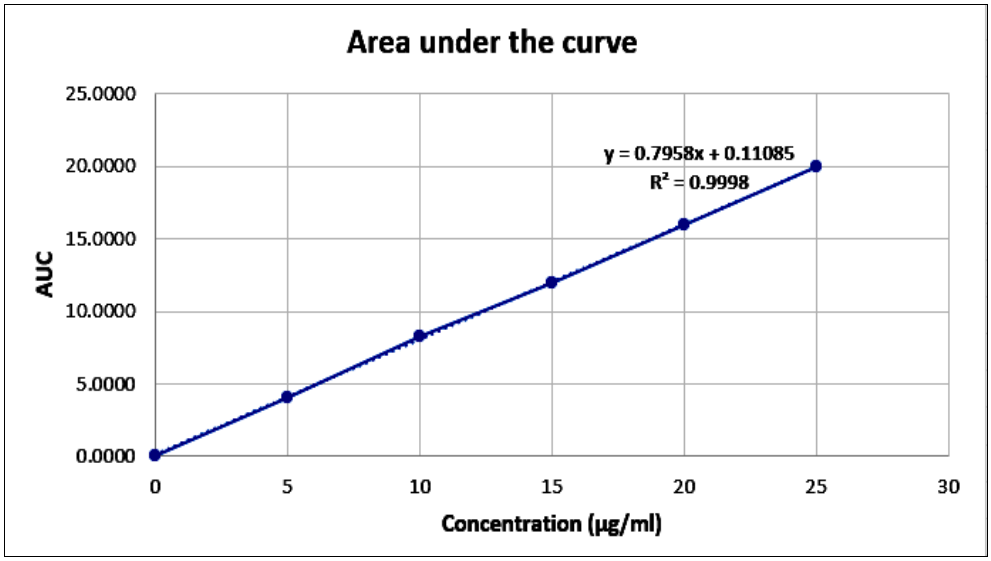

Fig 7: Calibration graph of Polmacoxib for AUC

Method Validation for Zero Order Method

Table 1: Polmacoxib Linearity for zero order

S.no	Concentration (µg/ml)	Absorbance
1	5	0.210
2	10	0.411
3	15	0.614
4	20	0.811
5	25	1.028

Table 2: Optical characterization for zero order

Parameters	Zero order method - Polmacoxib (316nm)
Beer's law range * (µg/ml)	5 - 25
Regression equation (y=mx + c)	Y=0.0407+0.0098
Slope	0.0407
Intercept	0.0098
Correlation coefficient (r^2)	0.9999
Standard error	0.0037
Limit of detection (µg/ml)	0.7358
Limit of quantification **(**µg/ml)	2.2297

Table 3: Polmacoxib precision for zero order

Sample	Sample number	Label claim (mg/cap)	Amount present (mg/cap)	% purity	Mean % purity	SD	% RSD
POLM	1	2	2.0109	100.54	100.24	0.4575	0.4565
	2	2	2.0109	100.54			
	3	2	2.0004	100.02			
	4	2	2.0151	100.75			
	5	2	1.9939	99.52			
	6	2	2.0008	100.04			

Table 4: Interday and intraday of Polmacoxib formulation

Sample	Sample number	Label claim (mg/cap)	% purity		SD		%RSD	
			Intraday	Interday	Intraday	Interday	Intraday	Interday
POLM	1	2	100.01	100.49	0.6449	0.8168	0.6432	0.8135
	2	2	100.63	100.99				
	3	2	99.07	100.30				
	4	2	100.29	99.74				
	5	2	101.17	101.56				
	6	2	100.49	99.31				

Table 5: Recovery study of Polmacoxib formulation

Sample	% Concentration	Sample amount (µg/ml)	Amount spiked (µg/ml)	Estimated Amount (µg/ml)	Recovered Amount (µg/ml)	Average % Recovery	SD	%RSD
POLM	50	10	5	15.05	5.05	101.00	0.7429	0.7454
	100	10	10	20.00	10.00	100.00	0.4272	0.4279
	150	10	15	25.15	15.15	101.00	0.6813	0.6746

Mean of 3 observations (n=3), POLM= Polmacoxib

Table 6: Ruggedness of Polmacoxib formulation

Sample	Type of ruggedness	Average % obtained	SD	% RSD
POLM	Analyst-1	100.33	0.6912	0.6889
	Analyst-2	100.69	0.9025	0.8963
	Instrument-1	100.18	0.5475	0.5465
	Instrument-2	100.40	0.5839	0.5816

For First Order Derivative Method

Table 7: Linearity of Polmacoxib

S.no	Concentration (µg/ml)	Absorbance
1	20	-0.036
2	40	-0.076
3	60	-0.116
4	80	-0.153
5	100	-0.193

Table 8: Optical characterization of Polmacoxib

Parameters	First order derivative method - Polmacoxib (256 nm)
Beer's law range* (µg/ml)	20 - 100
Regression equation (y=mx + c)	Y=0.0019+0.0012
Slope	0.0019
Intercept	0.0012
Correlation coefficient (r^2)	0.9998
Standard error	0.00086
Limit of detection (µg/ml)	-5.8075
Limit of quantification (µg/ml)	-17.5986

Table 9: Precision of Polmacoxib formulation

Sample	Sample number	Label claim (mg/cap)	Amount present (mg/cap)	% purity	Mean % purity	SD	% RSD
POLM	1	2	2.0139	100.69	100.25	0.6528	0.6511
	2	2	2.0139	100.69			
	3	2	2.0071 2.0003	100.35			
	4	2	2.0142	100.01			
	5	2	1.9808	100.71			
	6	2		99.04			

Table 10: Interday and intraday of Polmacoxib formulation

Sample	Sample number	Label claim (mg/cap)	% purity		SD		%RSD	
			Intraday	Interday	Intraday	Interday	Intraday	Interday
POLM	1	3	100.39	100.66	0.5974	0.6014	0.8824	0.8846
	2	3	100.30	100.35				
	3	3	99.74	100.02				
	4	3	99.01	100.91				
	5	3	100.39	100.35				
	6	3	101.69	101.73				

Table 11: Recovery study of Polmacoxib formulation

Sample	% Concentration	Sample amount (µg/ml)	Amount spiked (µg/ml)	Estimated Amount (µg/ml)	Recovered Amount (µg/ml)	Average % Recovery	SD	%RSD
POLM	50	40	20	60.07	20.07	100.35	1.5242	1.5180
	100	40	40	80.07	40.07	100.17	0.7563	0.7550
	150	40	60	100.21	60.21	100.35	0.4668	0.4652

Mean of 3 observations (n=3)

Table 12: Ruggedness of Polmacoxib formulation

Sample	Type of ruggedness	Average % obtained	SD	% RSD
POLM	Analyst-1	100.48	0.3667	0.3650
	Analyst-2	100.56	0.3155	0.3138
	Instrument-1	100.36	0.4593	0.4576
	Instrument-2	100.18	0.4076	0.4069

Mean of 6 observations (n=6)

For Area under the Curve Method

Table 13: Linearity of Polmacoxib

S.no	Concentration (µg/ml)	Absorbance
1	5	4.0781
2	10	8.3378
3	15	12.004
4	20	15.986
5	25	19.956

Table 14: Optical characterization of Polmacoxib

Parameters	AUC - Polmacoxib (325 -305 nm)
Beer's law range* (µg/ml)	5 - 25
Regression equation (y=mx + c)	Y=0.7958x+0.11085
Slope	0.7958
Intercept	0.11085
Correlation coefficient (r^2)	0.9998
Standard error	0.0951
Limit of detection (µg/ml)	0.9665
Limit of quantification (µg/ml)	2.9290

Table 15: Precision of Polmacoxib formulation

Sample	Sample number	Label claim (mg/cap)	Amount present (mg/cap)	% purity	Mean % purity	SD	% RSD
POLM	1	2	2.0102	100.51	100.41	0.4835	0.4185
	2	2	2.0186	100.93			
	3	2	2.0074	100.37			
	4	2	1.9928	99.64			
	5	2	2.0028	100.14			
	6	2	2.0176	100.88			

Table 16: Interday and intraday of Polmacoxib formulation

	Sample number	Label claim (mg/cap)	% purity		SD		%RSD	
			Intraday	Interday	Intraday	Interday	Intraday	Interday
POLM	1	2	100.45	100.57	0.6157	0.4407	0.6104	0.4387
	2	2	100.67	100.19				
	3	2	100.89	100.11				
	4	2	100.08	100.04				
	5	2	100.11	100.90				
	6	2	101.00	101.09				

Table 17: Recovery study of Polmacoxib formulation

Sample	% Concentration	Sample amount (µg/ml)	Amount spiked (µg/ml)	Estimated Amount (µg/ml)	Recovered Amount (µg/ml)	Average % Recovery	SD	%RSD
POLM	50	10	5	15.01	5.01	100.20	0.1779	0.1175
	100	10	10	19.96	9.96	99.60	0.0896	0.0900
	150	10	15	25.09	15.09	100.60	0.8156	0.8107

Mean of 3 observations (n=3)

Table 18: Ruggedness of Polmacoxib formulation

Sample	Type of ruggedness	Average % obtained	SD	% RSD
POLM	Analyst-1	100.74	0.4120	0.4090
	Analyst-2	100.37	0.8027	0.7997
	Instrument-1	100.30	0.7843	0.7819
	Instrument-2	100.46	0.5791	0.5765

Mean of 6 observations (n=6)

Table 19: Forced degradation studies of Polmacoxib

Stress condition	Time (h)	% Degradation
0.1 N H_2SO_4	24	Not degraded
0.1 N KOH	24	Not degraded
1 % H_2O_2	24	Not degraded
10 % $NaHSO_4$	24	Not degraded
UV light	24	Not degraded

Conclusion

The proposed UV spectrophotometric methods for stability indication, such as zero order, first order derivative, and area under the curve (AUC) approaches, were effectively developed and validated in accordance with ICH guidelines, demonstrating acceptable results for linearity, accuracy, precision, ruggedness, LOD, and LOQ. Studies on stress degradation under acidic, basic, oxidative, reductive, and UV light degradation confirmed the method's stability-indicating properties. The drug's stability was confirmed by the result, which showed no significant degradation under the measured conditions. Moreover, the method's specificity and potential for regular quality control were established by the absence of influence from formulation excipients. For the estimate of an analyte, all three methods demonstrated good linearity, accuracy, precision, specificity, and reproducibility. Improved sensitivity and selectivity have been provided by the derivative and AUC approaches among them. The outcomes demonstrate that these proven techniques are accurate, simple to use, economical, and appropriate for regular Polmacoxib quality control study.

Acknowledgement

The management of ACMEC trust is hereby thanked by one of the author Miss. K. Indhumathi for their support in doing this research.

Authors Contributions

All the authors have contributed equally.

Conflict of Intrests

Declared none

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