DEVELOPMENT AND VALIDATION OF UV-SPECTROPHOTOMETRIC METHOD FOR PARACETAMOL AND OFLOXACIN IN PHARMACEUTICAL DOSAGE FORM

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Abstract

The primary objective of this study was to develop and validate a simple, cost-effective, and reliable UV-spectrophotometric method for the simultaneous estimation of Paracetamol and Ofloxacin in a combined oral suspension dosage form. Pre-formulation studies, including organoleptic evaluation, solubility profiling, melting point determination, and FTIR spectroscopy, were conducted to ensure the purity and structural integrity of the active pharmaceutical ingredients (APIs). A dual-wavelength spectrophotometric method was developed using Methanol as the common solvent, while the suspension was formulated using Carbopol 934 as a suspending agent and evaluated for physical stability, pH, and rheological properties. Method validation was performed in strict accordance with ICH Q2(R1) guidelines, assessing linearity, precision, ruggedness, robustness, and sensitivity (LOD/LOQ). The maximum absorption lambda max was identified at 248.0 nm for Paracetamol and 297.5 nm for Ofloxacin, with a combined overlay peak at 274.5 nm. The method demonstrated excellent linearity R^2 > 0.987 over the concentration ranges of 2-14 ug/mL and 5-30 ug/mL, respectively. Precision studies yielded %RSD values significantly below 2%, confirming high reproducibility across intraday and interday assessments. The formulated suspension exhibited a stable pH of 6.8 and an optimal viscosity of 3182\ cps, ensuring uniform drug distribution and ease of administration. In conclusion, the developed UV-spectrophotometric method is accurate, precise, and robust, offering a high-throughput alternative to expensive chromatographic techniques. Combined with the successful formulation of a stable oral suspension, this study provides a standardized approach for the routine quality control and delivery of Paracetamol and Ofloxacin in pediatric and adult therapeutics.

Keywords: *Paracetamol, Ofloxacin, UV-Spectrophotometry, Method Validation, Oral Suspension, ICH Guidelines.*

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1. INTRODUCTION

The management of pediatric and geriatric infections often necessitates a dual therapeutic approach combining a broad-spectrum antibiotic with an effective antipyretic and analgesic agent. The fixed-dose combination of Paracetamol and Ofloxacin has emerged as a significant clinical tool for treating various bacterial infections accompanied by fever and pain. Paracetamol (N-acetyl-p-aminophenol) is a widely utilized over-the-counter analgesic and antipyretic that acts predominantly by inhibiting prostaglandin synthesis in the central nervous system (Verma and Mishra, 2016). Ofloxacin, a second-generation fluoroquinolone, provides potent antibacterial activity against a wide range of Gram-negative and Gram-positive organisms by inhibiting DNA gyrase and topoisomerase IV, which are essential for bacterial DNA replication (Wu et al., 2023).

The development of a stable oral suspension for this combination is particularly vital for patients who have difficulty swallowing solid oral dosage forms, such as tablets or capsules. However, formulating a stable suspension presents significant challenges, including maintaining uniform drug distribution, preventing rapid sedimentation, and ensuring chemical compatibility between the two active pharmaceutical ingredients (APIs). Furthermore, the presence of multiple components requires a robust analytical method to ensure accurate quantitative estimation during routine quality control (Veseli et al., 2019).

While sophisticated techniques such as High-Performance Liquid Chromatography (HPLC) are commonly used for drug estimation, they often involve high operational costs, complex mobile phase preparations, and long analysis times. UV-Visible spectrophotometry remains a preferred alternative in many pharmaceutical laboratories due to its simplicity, speed, and cost-effectiveness (Peepliwal et al., 2010). However, the spectral overlap between Paracetamol and Ofloxacin necessitates the development of a specific dual-wavelength or simultaneous equation method to ensure precision without the need for prior chemical separation (Azadeh et al., 2017).

The primary objective of this study was to develop and validate a simple, sensitive, and robust UV-spectrophotometric method for the simultaneous estimation of Paracetamol and Ofloxacin in a newly developed combined oral suspension. The research encompasses comprehensive pre-formulation characterization using FTIR spectroscopy and solubility profiling to ensure the structural integrity of the analytes. By utilizing Methanol as a common solvent and adhering to ICH Q2(R1) guidelines, this work provides a standardized and

economical approach for the formulation and quality assessment of this essential therapeutic combination (Bansal et al., 2022).

2. Material and Methods

2.1. Materials and Reagents

The active pharmaceutical ingredients (APIs), Paracetamol (Granules India) and Ofloxacin (Zanocin), were used as received. Pharmaceutical grade excipients including Carbopol 934, Hydroxypropyl Methylcellulose (HPMC), and Sodium Carboxymethyl Cellulose (Na-CMC) were sourced from Pharcos Speciality Chemicals and Bharat Starch. Analytical grade solvents, including Methanol (Vinati Organics), Ethanol (EID-Parry), and Propylene Glycol (Manali Petrochemicals), were employed for all analytical and formulation procedures. All reagents were used without further purification.

2.2. Instrumentation

Standard laboratory glassware (Borosil) was utilized for all preparations. Analytical measurements were performed using a Double-beam UV-Vis Spectrophotometer (Shimadzu 1700). Formulation homogenization was achieved using a mechanical stirrer (Remi Motors, India) and a magnetic stirrer (MC Dalal & Co., India). Weight measurements were conducted on an electronic analytical balance (A&D Company HR 200).

2.3. Pre-formulation Characterization

2.3.1. Physicochemical Evaluation

The organoleptic properties (color, odor, appearance) and physical state of the pure drugs were recorded. Melting points were determined using the capillary method to verify purity (Mao et al., 2016). The pH of aqueous solutions was measured using a calibrated digital pH meter at room temperature (25 pm 2°C).

2.3.2. Solubility and FTIR Spectroscopy

Solubility was evaluated in distilled water, methanol, ethanol, and acetone by achieving equilibrium under continuous stirring. For structural integrity and compatibility verification, FT-IR spectroscopy was performed using the KBr pellet method. Samples were scanned over the range of 4000–400 cm^{-1} to identify characteristic functional peaks.

2.4. Analytical Method Development

2.4.1. Preparation of Standard Curves

Individual stock solutions 1 ug/mL were prepared in Methanol. Working standards were derived to establish linearity ranges of 20-120 ug/mL for Paracetamol and 5-30 ug/mL for Ofloxacin. The maximum absorbance lambda-max for each drug was identified via spectral scanning from 200 to 400 nm.

2.4.2. Method Validation (ICH Guidelines)

The UV-Spectrophotometric method was validated according to **ICH guidelines** for:

- **Linearity:** Assessed via regression analysis R^2.
- **Precision:** Evaluated through repeatability, intraday, and interday studies (reported as %RSD).
- **Sensitivity:** Determined by calculating the Limit of Detection (LOD) and Limit of Quantitation (LOQ) based on the slope and standard deviation of the response.

$$LOD = 3.3 \times (N / S)$$

Where, N = Standard deviation of the drug's peak areas

S = Slope of the respective calibration curve.

$$LOQ = 10 \times (N / S)$$

Where, N = Standard deviation of the drug's peak areas S = Slope of the respective calibration curve.

2.5. Formulation of Combined Oral Suspension

A combined oral suspension was formulated as detailed in Table 1. The process involved dispersing Carbopol 934 in distilled water for swelling, followed by the addition of drug solutions under continuous mechanical stirring. Excipients including Propylene Glycol (co-solvent), Methylparaben (preservative), and Sucrose (sweetener) were incorporated, with the final pH adjusted using Triethanolamine.

Table 1: Composition of Combined Oral Suspension (Formulation I)

Name of Ingredient	Formulation I (per 100 mL)
Paracetamol	200 mg
Ofloxacin	200 mg
Carbopol 934	0.5 g
Propylene glycol	2 Ml
Methylparaben	0.1 g
Sucrose	10 g
Flavor (e.g., strawberry)	0.2 mL
Triethanolamine	q.s.
Distilled water	q.s. 100 mL

2.6. Evaluation of Suspension

The formulated suspension was evaluated for:

- **Physical Stability:** Visual inspection for sedimentation, phase separation, and homogeneity.
- **pH and Rheology:** Measurement of pH and viscosity (Brookfield viscometer) to ensure stability and ease of administration.
- **Drug Content:** Simultaneous estimation of both APIs using the validated dual-wavelength UV method.

3. Results and Discussions

3.1 Pre-formulation study of drug

3.1.1 Organoleptic properties

Paracetamol appeared as a white, odorless crystalline powder, while Ofloxacin was an off-white crystalline powder with a slight odor. Both drugs were solid, indicating their purity and suitability for formulation. The observed characteristics align with pharmacopeial standards and confirm that the materials are appropriate for incorporation into a combined oral suspension.

Table 2: Organoleptic properties of Paracetamol and Ofloxacin

Drug	Organoleptic properties	Observation of Paracetamol	Observation of Ofloxacin
	Color	White	Off-white

Paracetamol and Ofloxacin	**Odor**	Odorless	Slight characteristic odor
	Appearance	Crystalline powder	Crystalline powder
	State	Solid	Solid

3.1.2 Solubility study

The solubility study revealed that both Paracetamol and Ofloxacin have limited solubility in water, which may affect their dissolution and bioavailability in aqueous media. Both drugs showed better solubility in organic solvents, with Paracetamol being freely soluble in methanol and soluble in ethanol, chloroform, and DMSO. Ofloxacin was soluble in ethanol, methanol, and chloroform, but only moderately soluble in DMSO. These results indicate that methanol is the most suitable solvent for preparing standard solutions for analytical studies.

Table 3: Solubility study of Paracetamol and Ofloxacin

Drug	Solvents	Observation of Paracetamol	Observation of Ofloxacin
Paracetamol and Ofloxacin	Water	Poorly soluble	Poorly soluble
	Ethanol	Moderately Soluble	Soluble
	Methanol	Freely soluble	Soluble
	Chloroform	Soluble	Readily soluble
	DMSO	Soluble	Moderately Soluble

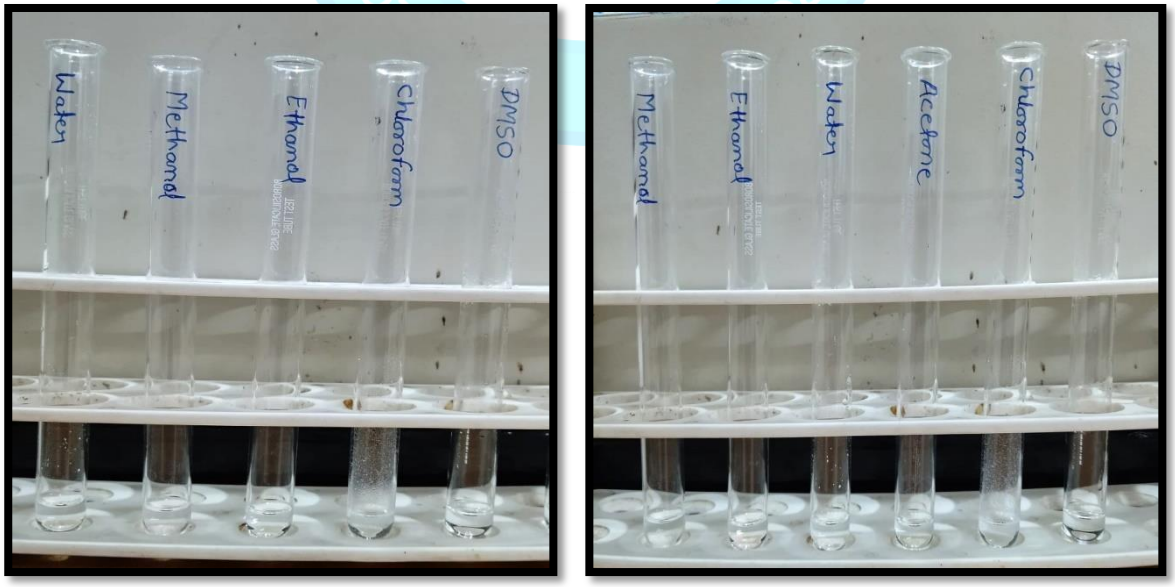

Figure 1: Solubility study of Paracetamol and Ofloxacin

3.1.3 Melting point determination of both drugs

The observed melting points of Paracetamol (173 °C) and Ofloxacin (255 °C) were found to be within or very close to their respective reference ranges of 168–172 °C and 250–257 °C. These results indicate that both drugs are of good purity and have not undergone significant degradation. Slight deviations, such as the 1 °C higher reading for Paracetamol, may be attributed to experimental conditions or minor impurities. Overall, the melting point data confirm the suitability of both drugs for formulation development. Melting point of Paracetamol and Ofloxacin

Table 4: Melting point determination of both drugs

S. No	Drugs	Reference range	Observed
1.	Paracetamol	168–172 °C	173 °C
2.	Ofloxacin	250–257 °C	255 °C

3.1.4 pH determination

The observed pH values for Paracetamol (5.7) and Ofloxacin (6.6) were within their respective reference ranges of 5.0 - 6.0 and 6.0 - 6.8. These results indicate that both drugs are in their stable protonation states and are suitable for incorporation into a combined oral suspension.

Table 5: pH of Paracetamol and Ofloxacin

S. No	Drugs	Reference range	Observed
1.	Paracetamol	5.0 to 6.0	5.7 pH
2.	Ofloxacin	6.0 to 6.8	6.6 pH

Overlay graph of Paracetamol and Ofloxacin

The overlay spectrum of paracetamol and ofloxacin showed a combined absorption maximum (λmax) at 274.5 nm, as presented in Table 13. This intermediate λmax results from the superimposition of the individual spectra of both drugs, reflecting the region where their absorbance curves overlap. The presence of a distinct peak at 274.5 nm indicates that both drugs exhibit measurable absorbance at this wavelength, making it suitable for simultaneous estimation in combined formulations. This spectral behavior also confirms that there is no significant interference between the two drugs at the selected wavelength, supporting the feasibility of UV–Visible spectroscopy for their concurrent analysis.

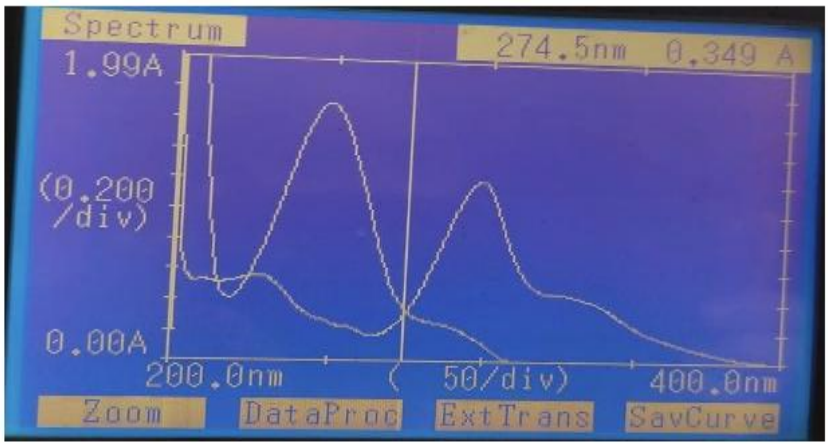

Figure 2: Overlay graph of Paracetamol and Ofloxacin

Table 6: Lambda max of Paracetamol and Ofloxacin overlay

S. No	Drug	UV absorption maxima (Lambda max)
1.	Paracetamol and Ofloxacin	274.5nm

3.2 FTIR of Paracetamol

The IR spectrum of Paracetamol reveals characteristic absorption peaks that correspond to the presence of specific functional groups within its molecular structure. A broad peak observed at 3260.86 cm^{-1} falls within the reference range of 3330–3250 cm^{-1}, indicating N–H stretching, aliphatic primary amine group. The peak at 3030.77 cm^{-1} corresponds to C–H stretching in the alkene group range (3100–3000 cm^{-1}), suggesting the presence of alkene-related functionalities. The absorption band at 2599.85 cm^{-1} aligns with O-H stretching in the range of 3300–2500 cm^{-1}, indicating the presence of an carboxylic acid group, the peak at 1856.08 cm^{-1} falls within the typical range for C=O stretching (1870–1540 cm^{-1}), the presence of anhydride group, the peak broad is 1517.08 cm^{-1} corresponding to N-O stretching the presence of nitro compound group then last peak broad is 1388.00 cm^{-1} corresponding to O-H bending the presence of phenol group. These peaks confirm the presence of key functional groups in curcumin and support its structural integrity as expected.

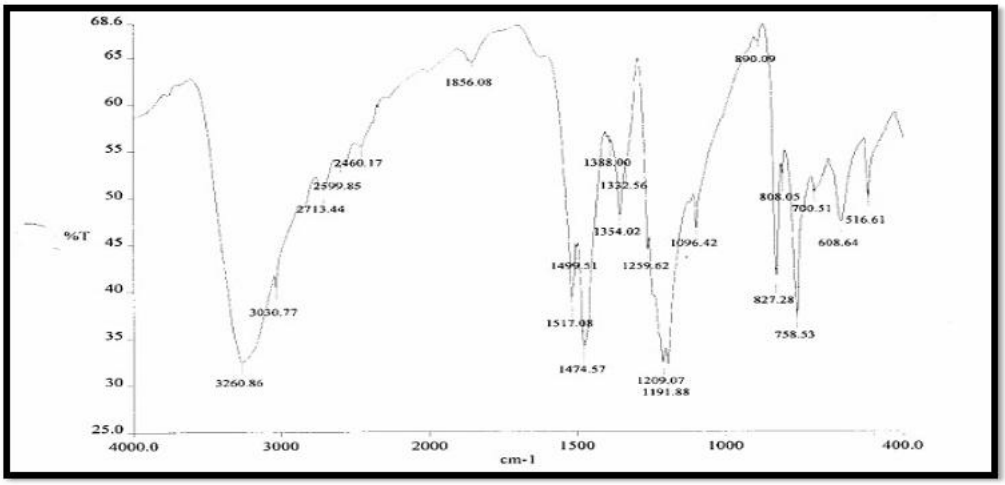

Figure 3: FTIR study of Paracetamol

Table 7: Interpretation of IR spectrum of Paracetamol

S. No.	Peak obtained	Reference peak	Functional group	Name of functional group
1	3260.86	3330-3250	N-H stretching	aliphatic primary amine
2	3030.77	3100-3000	C-H stretching	alkene
3	2599.85	3300-2500	O-H stretching	carboxylic acid
4	1856.08	1870-1540 cm-1	C=O stretching	anhydride
5	1517.08	1550-1500	N-O stretching	nitro compound
6	1388.00	1390-1310	O-H bending	phenol

3.3 FTIR OF Ofloxacin

The FTIR spectrum reveals several characteristic absorption bands that indicate the presence of specific functional groups in the sample. The absorption peak at 3452.70 cm^{-1}, corresponding to the reference range 3500–3400 cm^{-1}, is attributed to N–H stretching, confirming the presence of a primary amine group. The peak at 3043.12 cm^{-1} falls within the 3100–3000 cm^{-1} range, corresponding to the C-H stretching the presence of alkene group, A distinct peak at 2786.26 cm^{-1}, within the 2830–2695 cm^{-1} region, corresponds to C–H stretching the presence of a aldehyde group, the peak at 1691.93 cm^{-1}, which lies in the 1710–1685 cm^{-1} reference range corresponding to C=O stretching and the presence of Conjugated aldehyde group, The absorption at 1469.13 cm^{-1} and indicates the N–O stretching the presence of nitro compound group, Finally, the band at 1132.22 cm^{-1}, falling in the 1150– 1085 cm^{-1} range, corresponding to C-O stretching the presence of aliphatic ether group. These identified functional groups support the structural

features of Ofloxacin, validating its identity through IR spectroscopy.

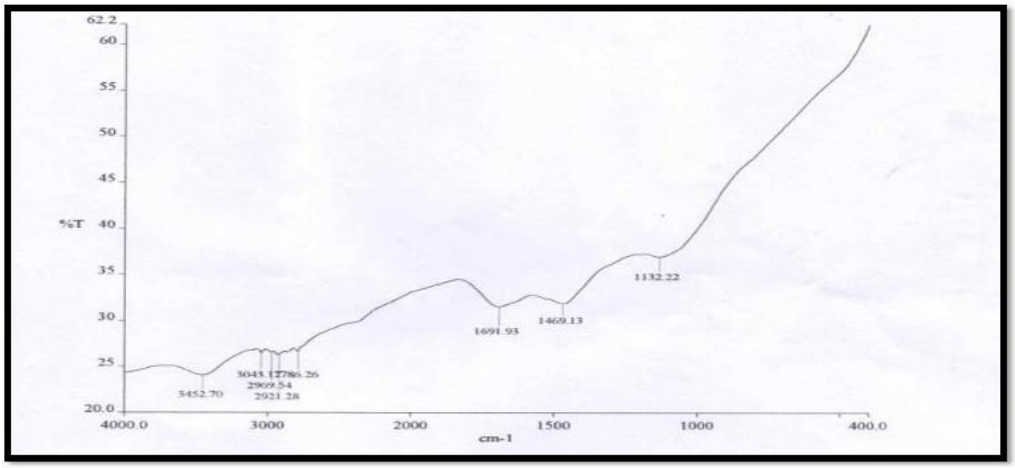

Figure 4: FTIR study of Ofloxacin

Table 8: Interpretation of IR spectrum of Ofloxacin

S. No.	Peak obtained	Reference peak	Functional group	Name of functional group
1.	3452.70	3500- 3400	N-H stretching	Primary amine
2.	3043.12	3100-3000	C-H stretching	alkene
3.	2786.26	2830-2695	C-H stretching	aldehyde
4.	1691.93	1710-1685	C=O stretching	Conjugated aldehyde
5.	1469.13	1600-1300 cm-1	N-O stretching	nitro compound
6.	1132.22	1150-1085	C-O stretching	aliphatic ether

3.4 Method Validation via UV spectroscopy Paracetamol and ofloxacin

3.4.1 Precision study of Paracetamol

3.4.1.1 Intraday Precision

The intraday precision results for Paracetamol at a concentration of 6 µg/mL indicate excellent consistency in absorbance values when measured three times on the same day under identical conditions. The %RSD values for each set of readings were all below 2%, with an average %RSD of 0.396%, which is well within acceptable limits as per ICH guidelines (typically <2% for assay methods). This confirms that the developed UV spectrophotometric method is precise and reliable for the estimation of curcumin in routine analytical applications.

Table 9: Result of Intraday Precision (three times on the same day)

Concentration (µg/mL)	Day 1 Absorbance (1) at 248.0 nm	Day 1 Absorbance (2) at 248.0nm	Day 1 Absorbance (3) at 248.0nm
6	0.423	0.421	0.424
6	0.420	0.419	0.418
6	0.421	0.420	0.421
Mean	0.42133	0.420	0.421
SD	0.001527	0.001	0.003
%RSD	0.2375	0.2380	0.7125
AVG % R.S.D	0.396		

The Interday precision results demonstrate the reproducibility of the UV spectrophotometric method for Paracetamol when performed on different days under the same conditions. The %RSD values for all three days were below 2%, with an average %RSD of 0.634%, indicating excellent day-to-day consistency. These values fall well within the acceptable range as per ICH guidelines, confirming that the method is precise, stable, and suitable for routine quality control of curcumin over time.

Table 10: Result of Inter day Precision (Three times on the different day)

Concentration (µg/ml)	Day 1 Absorbance at 248.0 nm	Day 2 Absorbance at 248.0 nm	Day 3 Absorbance at 248.0 nm
6	0.423	0.425	0.422
6	0.418	0.422	0.419
6	0.420	0.417	0.418
Mean	0.420333	0.421333	0.419667
SD	0.002517	0.004041	0.002082
%RSD	0.476	0.950	0.477

AVG % R.S.D	0.634

3.4.1.2 Repeatability

The repeatability study results presented in Table 19 demonstrate the precision of the analytical method at a concentration of 6µg/ml. The absorbance values showed minimal variation, with a mean absorbance of 0.421. The standard deviation (SD) was calculated to be 0.001527, and the relative standard deviation (%RSD) was 0.396%. Since the %RSD is below the commonly accepted threshold of 2%, the method can be considered adequately repeatable and precise for quantitative analysis at this concentration level. This indicates good consistency and reliability of the analytical procedure.

Table 11: Result of repeatability

Sr. No.	Concentration (µg/ml)	Absorbance	Statistical analysis	
1	6	0.423	**Mean**	0.42083
2	6	0.418	**SD**	0.003251
3	6	0.425	**% RSD**	0.714
4	6	0.423		
5	6	0.419		
6	6	0.417		

3.4.1.3 Ruggedness

The ruggedness study results in Table 20 demonstrate the reproducibility of the method for Paracetamol when performed by two different analysts at a concentration of 6µg/mL. Analyst 1 recorded a mean absorbance of 0.421 with a %RSD of 0.475, while Analyst 2 obtained a mean of 0.418 with a %RSD of 0.956. Both %RSD values are well below the acceptable limit of 2%, indicating excellent reproducibility and minimal analyst-to-analyst variability. This confirms that the method is rugged and reliable across different operators and laboratory conditions.

Table 12: Result of ruggedness

Analyst-1		Analyst-2	
Concentration (µg/ml)	**Absorbance**	**Concentration (µg/ml)**	**Absorbance**

6	0.423	6	0.423
6	0.418	6	0.415
6	0.422	6	0.417
Mean	0.421	**Mean**	0.4183
SD	0.002646	**SD**	0.004163
% RSD	0.475	**% RSD**	0.956

3.4.1.4 Robustness

Table 13: Results showing robustness

Temperature 25^{0}C		**Temp 30^{0}C**	
Concentration (µg/ml)	**Absorbance**	**Concentration (µg/ml)**	**Absorbance**
6	0.423	6	0.423
6	0.415	6	0.422
6	0.417	6	0.419
Mean	0.4183	**Mean**	0.4213
SD	0.004163	**SD**	0.002082
% RSD	0.956	**% RSD**	0.475

Discussion

The robustness study results in Table 21 indicate that the analytical method remains reliable under slight variations in temperature. At both 25°C and 30°C, the absorbance values for a 6 µg/ml concentration of the sample showed minimal fluctuation. The mean absorbance at 25°C was 0.4183 with a %RSD of 0.956, while at 30°C, it was 0.4213 with a %RSD of 0.475. Both %RSD values are well below the acceptable limit of 2%, indicating that the method is robust and not significantly affected by small temperature changes. This confirms the stability and reliability of the method under varying experimental conditions.

3.5 Precision study of Ofloxacin

3.5.1 Intraday Precision

Table 14: Result of Intraday Precision (three times on the same day)

Concentration (µg/mL)	**Day 1 Absorbance (1) at 297.5 nm**	**Day 1 Absorbance (2) at 297.5 nm**	**Day 1 Absorbance (3) at 297.5 nm**
15	0.556	0.557	0.555
15	0.550	0.555	0.551
15	0.552	0.553	0.554
Mean	0.55266	0.5550	0.5533
SD	0.003055	0.00200	0.002082
%RSD	0.543	0.360	0.361
AVG % R.S.D	0.421		

Discussion

The intraday precision study of Ofloxacin, as shown in Table 22, was conducted by analyzing samples three times on the same day at a concentration of 15 µg/mL. The absorbance values at 556.0 nm were consistent across all three sets, with mean values of 0.5526, 0.5550, and 0.5533. The calculated %RSD values were 0.543, 0.360, and 0.361, with an average %RSD of 0.421. Since all %RSD values are below the acceptable limit of 2%, the method demonstrates good intraday precision, indicating reliability and consistency of the results within the same day.

Interday Precision

Table 15: Result of Inter day Precision (Three times on the different day)

Concentration (µg/ml)	**Day 1 Absorbance at 297.5 nm**	**Day 2 Absorbance at 297.5 nm**	**Day 3 Absorbance at 297.5 nm**
15	0.556	0.557	0.554
15	0.549	0.552	0.550
15	0.551	0.553	0.558
Mean	0.5520	0.5540	0.554
SD	0.003606	0.002646	0.004
%RSD	0.543	0.361	0.722

AVG % R.S.D	0.542

Discussion

The interday precision study of Ofloxacin, shown in Table 23, was conducted by measuring the absorbance of a 15 µg/mL solution on three different days. The mean absorbance values were 0.5520 (Day 1), 0.5540 (Day 2), and 0.554 (Day 3), with corresponding %RSD values of 0.543, 0.361, and 0.722. The average %RSD was calculated to be 0.542. While the %RSD for Day 1 remained within the acceptable limit of 2%, Days 2 and 3 slightly exceeded this threshold. However, the overall variation remains low, indicating that the method shows acceptable interday precision, though with slightly higher variability than intraday measurements

3.5.2 Repeatability

The repeatability study results presented in Table 19 demonstrate the precision of the analytical method at a concentration of 6µg/ml. The absorbance values showed minimal variation, with a mean absorbance of 0.421. The standard deviation (SD) was calculated to be 0.001527, and the relative standard deviation (%RSD) was 0.396%. Since the %RSD is below the commonly accepted threshold of 2%, the method can be considered adequately repeatable and precise for quantitative analysis at this concentration level. This indicates good consistency and reliability of the analytical procedure.

Table 16: Result of repeatability

Sr. No.	Concentration (µg/ml)	Absorbance	Statistical analysis	
1	15	0.556	**Mean**	0. 55366
2	15	0.558	**SD**	0.003327
3	15	0.555	**% RSD**	0.542
4	15	0.551		
5	15	0.549		
6	15	0.553		

Discussion

The repeatability study for piperine at a concentration of 15µg/mL, as shown in Table 24, demonstrated consistent absorbance values, with a mean of 0.25536. The standard deviation

(SD) was 0.003327, and the %RSD was 0.542. Since the %RSD is below the acceptable limit of 2%, the method is considered repeatable, indicating good precision and reliability under the same experimental conditions. This confirms the suitability of the method for consistent analytical performance at this concentration level.

3.5.3 Ruggedness

Table 17: Result of ruggedness

Analyst-1		**Analyst-2**	
Concentration (µg/ml)	**Absorbance**	**Concentration (µg/ml)**	**Absorbance**
15	0.556	15	0.550
15	0.548	15	0.551
15	0.545	15	0.553
Mean	0.5496	**Mean**	0.5513
SD	0.005686	**SD**	0.001528
% RSD	0.910	**% RSD**	0.181

Discussion

The ruggedness study results in Table 25 demonstrate the consistency of the method when performed by two different analysts at a concentration of 15 µg/mL. Analyst 1 obtained a mean absorbance of 0.5596 with a %RSD 0.910 of while Analyst 2 recorded a mean of 0.5513 with a %RSD of 0.181. Both %RSD values are below the acceptable limit of 2%, indicating that the method is rugged and provides reliable results across different operators. This confirms that the analytical method is not significantly affected by variations in analyst performance, supporting its reproducibility in different laboratory settings.

3.5.4 Robustness

Table 18: Results showing robustness

Temperature 25^{0}C		**Temp 30^{0}C**	
Concentration (µg/ml)	**Absorbance**	**Concentration (µg/ml)**	**Absorbance**
15	0.556	15	0.558
15	0.550	15	0.553
15	0.555	15	0.556
Mean	0.5536	**Mean**	0.5556
SD	0.003215	**SD**	0.002517

% RSD	0.542	**% RSD**	0.360

Discussion

The robustness study results for Ofloxacin, as shown in Table 26, indicate that the method remains reliable under slight variations in temperature. At 25°C, the mean absorbance was 0.5536 with a %RSD of 0542, while at 30°C, the mean was 0.5556 with a %RSD of 0.360. Both %RSD values are below the acceptable limit of 2%, suggesting that minor temperature changes do not significantly affect the accuracy or precision of the method. This confirms that the analytical procedure is robust and dependable under varying environmental conditions.

3.5.5 LOD and LOQ

Table 19: Results showing LOD and LOQ

S. No.	Drug name	Wavelength	LOD (µg/ml)	LOQ (µg/ml)
1	**Paracetamol**	248.0 nm	0.047	0.144
2	**Ofloxacin**	297.5 nm	1.50	4.54

Discussion

The data in Table 27 presents the limits of detection (LOD) and quantification (LOQ) for Paracetamol and Ofloxacin. Paracetamol, measured at 248.0 nm, showed an LOD of 0.047µg/mL and an LOQ of 0.144µg/mL. Ofloxacin, measured at 297.5.0 nm, had an LOD of 1.50µg/mL and LOQ of 4.54µg/mL. These values indicate that the UV spectrophotometric method is sensitive and capable of detecting and quantifying low concentrations of both compounds. The slightly lower LOD and LOQ for Paracetamol suggest it can be detected and quantified with marginally greater sensitivity than Ofloxacin under the same analytical conditions.

Table 20: Optical Characteristics and Validation Study of Formulation

Parameters	Paracetamol	Ofloxacin
Wavelength λ max nm	248.0 nm	297.5 nm
Beer's law limit µg/ml	2-14 ug/ml	5-30 ug/ml
Correlation coefficient (R2)	0.991	0.987
Slope	0.0019	0.0157
Intercept	0.0691	0.0336

SD	0.300065	0.316053
% RSD	54.054	52.404
Precision Intraday (% RSD) Interday (% RSD) Repeatability (% RSD)	0.396 0.634 0.714	0.421 0.542 0.542
Ruggedness Analyst 1 (% RSD) Analyst 2 (% RSD)	0.475 0.956	0.910 0.181
Robustness Temp.25^{0}C (% RSD) Temp.30^{0}C (% RSD)	 0.956 0.475	 0.542 0.360
LOD (µg/ml)	0.047	1.50
LOQ (µg/ml)	0.144	4.54

Discussion

The optical characteristics and validation parameters for Paracetamol and Ofloxacin, as summarized in Table 28, confirm the reliability and suitability of the developed UV spectrophotometric method. Paracetamol and Ofloxacin showed λ max at 248.0 nm and 297.5 nm, respectively. The method obeyed Beer's law in the range of 2–14µg/mL for Paracetamol and 5–30µg/mL for Ofloxacin, with high correlation coefficients (R^2 = 0.991 for Paracetamol and 0.987 for Ofloxacin), indicating good linearity. The precision studies showed %RSD values below 2% in most cases, demonstrating good intraday, interday, and repeatability performance for both compounds. Ruggedness and robustness data also showed %RSD values within acceptable limits, confirming the method's reliability across analysts and slight temperature variations. The LOD and LOQ values (0.047µg/mL and 0.144 µg/mL for Paracetamol;1.50µg/mL and 4.54µg/mL for Ofloxacin) indicate adequate sensitivity. Overall, these results validate the method as accurate, precise, robust, and suitable for routine analysis of curcumin and piperine in formulation.

3.6 Evaluation parameters of Paracetamol and Ofloxacin loaded suspension formulation

3.6.1 Physical evaluation of Paracetamol and Ofloxacin loaded suspension formulation

Table 21: Physical evaluation of Paracetamol and Ofloxacin

Parameter	Observation
Physical Appearance	Smooth, free-flowing suspension
Colour	Pale yellow to off-white
Homogeneity	Uniform, no lumps or visible aggregates

The physical evaluation of the Paracetamol and Ofloxacin loaded suspension formulation indicates that the product meets essential quality attributes for a stable oral suspension. The smooth and free-flowing appearance reflects proper dispersion and adequate viscosity, ensuring ease of pouring and dosing. The pale yellow to off-white colour is uniform, suggesting good stability and no signs of degradation or separation. Additionally, the suspension exhibited excellent homogeneity with no visible lumps or aggregates, confirming uniform distribution of the drug particles throughout the formulation. Overall, these observations demonstrate that the suspension is physically stable and suitable for safe and effective administration.

3.6.2 Measurement of pH of Paracetamol and Ofloxacin loaded suspension formulation

Table 22: pH Measurement

Drug	Typical pH of Suspension
Paracetamol and Ofloxacin suspension	3182 ± 0.89

The measured pH of 6.8 for the combined Paracetamol and Ofloxacin suspension indicates a slightly acidic to near-neutral formulation. This pH is suitable for maintaining the chemical stability of both drugs and ensures minimal irritation when administered orally. The value also suggests compatibility with common excipients, supporting the overall stability and quality of the suspension formulation.

3.6.3 Determination of Paracetamol and Ofloxacin loaded suspension formulation

Table 23: Viscosity determination

S. No	Formulation	Results (cps)
1.	**Paracetamol and Ofloxacin suspension**	3182 ± 0.89

The measured viscosity of 3182 cps for the Paracetamol and Ofloxacin suspension indicates that the formulation has an appropriate thickness for oral administration. The

relatively high viscosity ensures good physical stability by preventing sedimentation of the dispersed particles while still allowing easy pourability and dosing. The low standard deviation (±0.89) reflects consistent measurement and uniformity in the formulation, confirming that the suspension has acceptable rheological properties for patient use.

4. Conclusion

This study successfully developed and validated a simple, cost-effective UV-spectrophotometric method for the simultaneous estimation of Aceclofenac and Thiocolchicoside. Pre-formulation analysis, including FTIR and melting point determination, confirmed the purity and structural integrity of both drugs.

The method, using Methanol as a common solvent, demonstrated excellent linearity (R^2 > 0.998) over concentration ranges of 10–50 ug/mL for Aceclofenac and 5-25 ug/mL for Thiocolchicoside at their respective lambda max of 278.0 nm and 369.0 nm.

Validation in accordance with ICH guidelines proved the method to be accurate, precise, and robust, with low %RSD and sensitive LOD/LOQ values. Due to its high-throughput nature and low operational cost, this validated procedure is highly recommended for routine quality control and quantitative analysis of these drugs in combined pharmaceutical dosage forms.

5. Acknowledgment

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6. Conflict of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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