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DEVELOPMENT AND VALIDATION OF A UV SPECTROPHOTOMETRIC METHOD FOR THE SIMULTANEOUS ESTIMATION OF IBUPROFEN AND PARACETAMOL IN TABLET FORMULATION

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ABSTRACT

The present review focuses on the development and preliminary validation of a UV-Visible spectrophotometric method for the simultaneous estimation of Paracetamol and Ibuprofen in combined pharmaceutical dosage forms. With the growing prevalence of fixed-dose combinations in therapeutic applications, there is an increasing demand for precise, economical, and rapid analytical techniques. The method employs the simultaneous equation approach based on absorbance measurements at 257 nm for Paracetamol and 221 nm for Ibuprofen, utilizing 0.1N NaOH as the solvent. Calibration curves were constructed over the concentration range of 5–25 µg/mL, demonstrating linearity in accordance with Beer-Lambert's law. Method validation was conducted in alignment with ICH guidelines, evaluating parameters such as linearity, accuracy, precision, limit of detection (LOD), limit of quantitation (LOQ), robustness, and ruggedness. The results affirm the method's reliability and suitability for routine quality control of pharmaceutical formulations containing these two active pharmaceutical ingredients.

KEYWORDS: Paracetamol, Ibuprofen, UV spectrophotometry, simultaneous estimation, 0.1N NaOH, method validation, ICH guidelines, fixed-dose combination.

INTRODUCTION

Paracetamol and Ibuprofen are widely used analgesic and antipyretic agents, often combined in pharmaceutical formulations to enhance therapeutic efficacy. Accurate and efficient analysis of such fixed-dose combinations is essential to ensure quality, safety, and compliance with regulatory standards. Among various analytical techniques, UV-Visible spectrophotometry is preferred for its simplicity, cost-effectiveness, and suitability for routine analysis.

Paracetamol, a centrally acting analgesic and antipyretic, works by inhibiting prostaglandin synthesis in the central nervous system, whereas Ibuprofen, a non-steroidal anti-inflammatory drug (NSAID), acts by non-selective inhibition of cyclooxygenase (COX-1 and COX-2) enzymes involved in prostaglandin synthesis.

In this study, a UV spectrophotometric method was developed for the simultaneous estimation of Paracetamol and Ibuprofen using 0.1N NaOH as a common solvent. The method is based on the simultaneous equation approach, with absorbance measurements taken at 257 nm and 221 nm, the respective λmax of Paracetamol and Ibuprofen. The aim is to establish a reliable, validated method that can be routinely applied for quality control of combined dosage forms.

REVIEW OF LITERATURE

(A) Paracetamol

Mavanga et al. (2025) developed and validated a UV-visible spectrophotometric method for the simultaneous assay of paracetamol and ibuprofen. Paracetamol exhibited absorption maxima at 249 nm, and the method demonstrated excellent linearity over the concentration range of 2.6–9.1 µg/mL, with a correlation coefficient (R^2) of 0.999. The method showed high precision, with coefficients of variation below 2%, and accuracy, with recovery rates between 98% and 102%.

Mugwiza et al. (2023) reported a UV spectrophotometric method for the simultaneous determination of paracetamol and ibuprofen in fixed-dose combination suspensions. Paracetamol showed a maximum absorbance at 243 nm. The method was validated as per USP and ICH guidelines, demonstrating linearity ($R^2 \geq 0.995$), precision (RSD ≤ 2%), and accuracy ranging between 98.1%–105%.

Gaikwad et al. (2017) proposed a UV spectrophotometric method for the simultaneous estimation of paracetamol and ibuprofen. Paracetamol showed absorption maxima at 257 nm. The method obeyed Beer's law in the concentration range of 10–50 µg/mL and demonstrated high accuracy and precision, with recovery rates of 96.9%.

(B) Ibuprofen

Mavanga et al. (2025) in their UV-visible spectrophotometric method, identified ibuprofen's absorption maxima at 219 nm. The method showed excellent linearity over the concentration range of 3.2–9.6 µg/mL, with a correlation coefficient (R^2) of 0.9996. Precision studies indicated coefficients of variation below 2%, and accuracy studies showed recovery rates between 98% and 102%.

Mugwiza et al. (2023) reported that ibuprofen exhibited a maximum absorbance at 222 nm in their simultaneous determination method. The method demonstrated linearity ($R^2 \geq 0.995$), precision (RSD ≤ 2%), and accuracy ranging between 109.8%–134.9%.

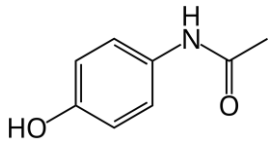
OBJECTIVES

1. To develop a simple, accurate, and rapid UV spectrophotometric method for the simultaneous estimation of Paracetamol and Ibuprofen in combined pharmaceutical formulations.
2. To utilize 0.1N NaOH as a common solvent for both drugs to ensure adequate solubility and spectral compatibility.
3. To determine the λmax of Paracetamol and Ibuprofen and apply the simultaneous equation (Vierordt's) method for quantitative analysis.

4. To validate the developed method in accordance with ICH guidelines by assessing parameters such as linearity, accuracy, precision, limit of detection (LOD), limit of quantification (LOQ), robustness, and ruggedness.
5. To apply the validated method to the analysis of commercial tablet formulations and confirm its suitability for routine quality control.

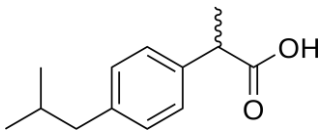
Drug Profile

1. Paracetamol



- **IUPAC Name:** N-(4-hydroxyphenyl)acetamide
- **Molecular Formula:** $C_8H_9NO_2$
- **Molecular Weight:** 151.16 g/mol
- **Melting Point:** 169 °C
- **Solubility:** Soluble in water; sparingly soluble in methanol
- **Category:** Analgesic and Antipyretic
- **Pharmacokinetics and Pharmacodynamics:** Paracetamol is a p-aminophenol derivative that exhibits central analgesic and antipyretic activity. It primarily acts through the inhibition of prostaglandin synthesis in the central nervous system, possibly via activation of descending serotonergic pathways. It has minimal anti-inflammatory activity and is well tolerated across all age groups. The bioavailability ranges from 63% to 89%. It is rapidly absorbed with peak plasma concentrations occurring within 30 minutes to 2 hours after administration. The drug is metabolized predominantly in the liver and excreted via the kidneys, mainly as glucuronide and sulfate conjugates.

2. Ibuprofen



- **IUPAC Name:** (RS)-2-(4-(2-Methylpropyl)phenyl)propanoic acid
- **Molecular Formula:** $C_{13}H_{18}O_2$
- **Molecular Weight:** 206.28 g/mol
- **Melting Point:** 75–78 °C
- **Solubility:** Practically insoluble in water; highly soluble in organic solvents (e.g., methanol, acetone)
- **Category:** Non-Steroidal Anti-Inflammatory Drug (NSAID)
- **Pharmacokinetics and Pharmacodynamics:** Ibuprofen is a non-selective cyclooxygenase (COX-1 and COX-2) inhibitor that reduces prostaglandin synthesis, thereby exerting analgesic, antipyretic, and anti-inflammatory effects. It is rapidly absorbed after oral administration, with peak serum concentrations reached within 1–2 hours. The drug is extensively protein-bound (>99%) and metabolized hepatically. It has a short half-life and is primarily excreted in the urine as inactive metabolites.

MATERIALS AND METHODS

Apparatus

A Shimadzu double beam UV-visible spectrophotometer (model No. 1601) bandwidth:2nm with 10 mm quartz cuvettes were used for all the absorbance measurements,Other equipment used included a digital weighing balance, ultrasonicator, volumetric flasks, and borosilicate glass pipettes.

Material and Methods

Paracetamol and Ibuprofenpure API, Combiflam tablet, NaOH, Distilled water.

Selection of common solvent

0.1N NaOH was used as common solvent for developing spectral characteristics. HPLC-grade distilled water was used to prepare the standard stock solution. 4 gm of NaOH is dissolved in 1000ml of distilled water to prepare 0.1N NaOH solution.

Determination of λ max

Preparation of Standard & Stock solution of Paracetamol

Paracetamol powder (10 mg) was weighed accurately and transferred in to the 100 ml volumetric flask and dissolved in 50 ml of 0.1N NaOH and made up the volume with 0.1N NaOH to get stock solution of 100µg/ml And then the working stock solution 10µg/ml was prepared from the stock solution.These Working solutions were scanned in the entire UV range (200-400 nm) to determine the λmax. The wavelength found for the analysis 257nm. The Calibration curve was plotted at the concentration range 5- 25 µg/ml absorbance vs concentration were plotted to obtain the calibration curve. The drugs obeyed Beer's law with the above concentration range.

Preparation of Standard & Stock solution of Ibuprofen

Ibuprofen powder (10 mg) was weighed accurately and transferred in to the 100 ml volumetric flask and dissolved in 50 ml of 0.1N NaOH and make up the volume with 0.1N NaOH to get stock solution of 100µg/ml and then the working standard stock solution 10 µg/ml was prepared from the stock solution these working solutions were scanned in the entire UV range (200-400 nm) to determine the λmax. The wavelength found for analysis 221nm. The calibration curve was plotted at the concentration range 5-25µg/ml. The drugs obeyed Beer's law with the concentration range 5-25µg/ml.

Preparation of calibration curves

The standard stock solution of Ibuprofen and Paracetamol were prepared. Working standard solution (5,10,15,20 & 25 µg for each drug) were prepared and scanned in the entire UV range of 400 -200 nm (figure 1). Calibrationcurve as concentration v/s Absorbance were constructed taking concentration on x- axis and absorbance on y-axis which showed a straight line obeyed Linearity in the concentration range of 5-25 µg/ml of both drugs. The correlation coefficient was found to be 0.9992 for Ibuprofen and 0.9981 for paracetamol.

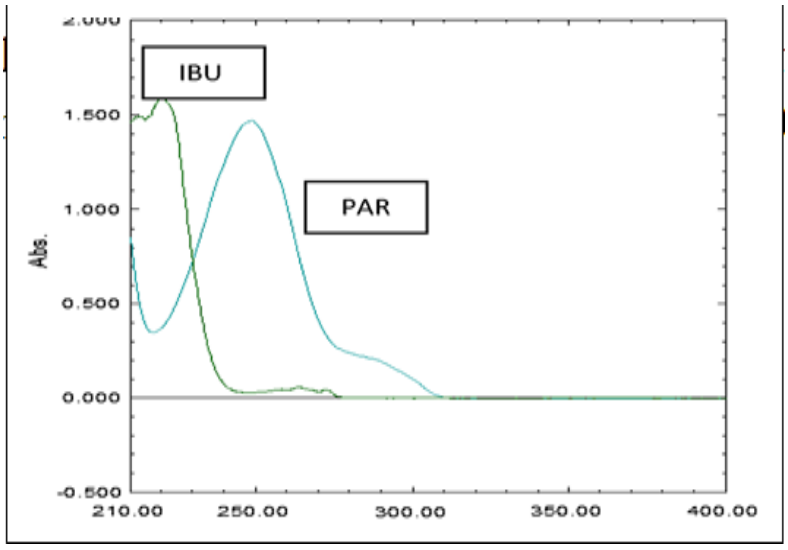


Fig. 1: Overlay spectra of Paracetamol and Ibuprofen.

Methodology

Analysis of tablet formulations 10 tablets were weighed and ground to fine powder. An accurately weighed powder equivalent to 32.5 mg of Paracetamol and 40 mg of Ibuprofen was transferred to a 100 ml of volumetric flask containing 0.1 N NaOH and ultrasonicated for about 15 min. The volume was made up to the mark with NaOH solution. The solution was filtered through Whatman filter paper no. 41. Appropriate aliquots were subjected to Method A. The amounts of PARA and IBU were determined.

Simultaneous determination

The standard solutions of PARA and IBU (10µg/ml) were scanned separatelyin the range of 200to 400 nm against NaOH solution as blank and wavelengths of maximum absorbance were determined. The absorbances of all dilutions were recorded at selected wavelengths (257 for PARA) and (221 for IBU) and calibration curves were plotted. The overlay spectrum of these drugs is shown. Drugs were determinedat both wavelengths. Simultaneous equations were formed. 257nm (**λ** max for PARA), 221 nm (**λ** max of Ibuprofen) and 225.3 nm (isobestic point)

The concentrations of drugs were determined using following equations.

Cx = (A2. ay1 – A1.ay2) / (ax2.ay1 – ax1.ay2)

Cy = (A1. ax2 – A2.ax1) / (ax2.ay1 – ax1.ay2)

Where

Cx = Concentration of Paracetamol in grs/lit

Cy = Concentration of Ibuprofenin grs/lit

ax_1 = 0.073720133 (Absorptivity of PCM at λ_1)

ax_2 = 0.0253508 (Absorptivity of PCM at λ_2)

ay_1 = 0.001649667 (Absorptivity of IBU at λ_1)

ay_2 = 0.045629867 (Absorptivity of IBU at λ_2)

A_1 = 1.3154 (Absorbance at λ_1)

A_2 = 1.34 (Absorbance at λ_2)

Validation of the developed method

1. Linearity

For each drug, appropriate dilution of standard stock solution were assayed as per the developed methods. The Beer-lambert's concentration range for both the, was found to be 5-25µg /ml. The Linearity data for method is presented in table1.

2. Accuracy

Accuracy refers to the closeness of the test results to the true value. To evaluate the accuracy of the proposed method, recovery studies were performed using the standard addition method at three concentration levels: 80%, 100%, and 120%. In this method, a known amount of standard drug solution was added to a previously analyzed sample solution, and the percentage drug content was calculated. The percentage recovery of the added pure drug was determined using the formula:

$$\% \text{ Recovery} = [(Ct - Cs) / Ca] \times 100$$

where Ct is the total drug concentration after the addition of the standard, Cs is the drug concentration in the original sample, and Ca is the concentration of the drug added. The results of the recovery studies are presented in Table 3.

3. Precision

Inter-day and Intra-day precision

The repeatability of the method was confirmed by analyzing the formulation six times at the same concentration, and the percentage relative standard deviation (% RSD) was calculated. Intermediate precision was evaluated through intra-day and inter-day studies. In the intra-day study, the formulation was analyzed three times within the same day at one-hour intervals. For the inter-day study, the analysis was repeated on three consecutive days. The amount of drug present was determined in each case, and the % RSD was calculated to assess the consistency of the method. The results of both inter-day and intra-day precision studies are presented in Table 4.

4. Ruggedness Study

It expresses the precision within laboratories variations like different analyst. Ruggedness of the method was assessed by for the standard 3 times with diff. analyst by using same equipment. The result was indicated as %RSD & given in Table5.

5. Limit of Detection (LOD) and Limit of Quantitation (LOQ)

LOD and LOQ were determined from the calibration curve using the standard deviation of the response (intercept) and the slope. They were calculated using the formulas: **LOD = 3.3 × (σ / S)** and **LOQ = 10 × (σ / S)**, where **S** is the slope and **σ** is the standard deviation of the response. The LOD and LOQ values for Ibuprofen and Paracetamol by the proposed method are shown in Table2.

RESULTS AND DISCUSSION

The developed UV spectrophotometric method for simultaneous estimation of Paracetamol and Ibuprofen was found to be simple, precise, and cost-effective. The method exhibited excellent linearity ($r^2 > 0.999$) over the concentration range of 5–25 µg/mL for both drugs.Recovery studies performed at different levels (80%, 100%, and 120%) yielded recovery rates within the acceptable range of 98%–102%, indicating high accuracy. Validation studies confirmed high accuracy, with recoveries ranging from 98% to 102%, and precision with %RSD below 2%. No interference from excipients was observed. The method met ICH validation criteria and is well-suited for routine quality control of combined pharmaceutical formulations.

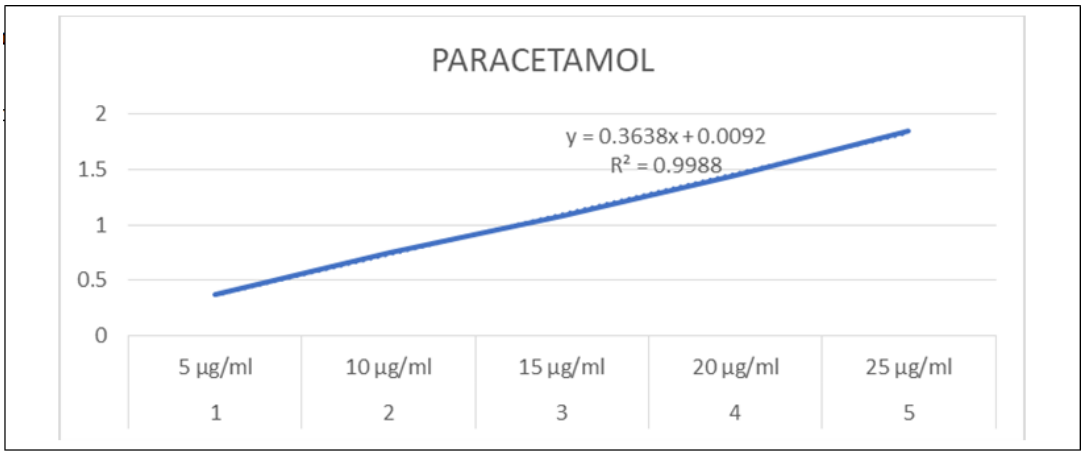


Fig. 2: Calibration curve of paracetamol.

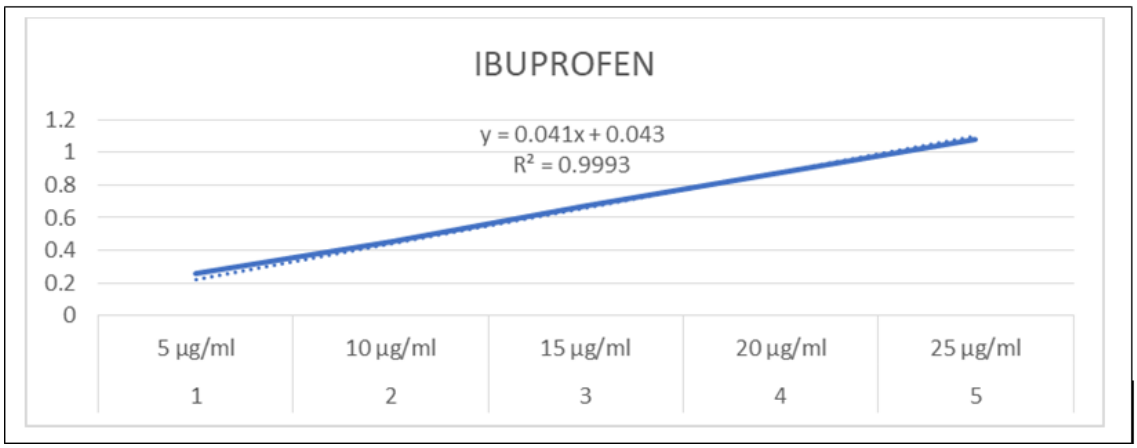


Fig. 3: Calibration curve of Ibuprofen.

Table 1: **Result of validation parameter.**

Parameter	Ibuprofen	Paracetamol
λmax (nm)	221 nm	257 nm
Linearity range (µg/mL)	5–25 µg/mL	5–25 µg/mL
Linearity equation	Y = 0.041x + 0.043	Y = 0.3638x + 0.0091
Correlation coefficient	0.9993	0.9988
Slope (b)	0.041	0.3638
Intercept (a)	0.043	0.0091
LOD	0.161 µg/mL	0.0825 µg/ml
LOQ	0.488 µg/mL	0.2501 µg/ml

Table 2: **Drug Recovery.**

Drug	Level (%)	Amount Added (µg/mL)	Total Amount Recovered (µg/mL)	% Recovered ± SD
Ibuprofen	80	8	7.80 µg/mL	97.5 ± 0.64
	100	10	9.82 µg/mL	98.2 ± 0.87
	120	12	11.82 µg/mL	98.5 ± 0.37
Paracetamol	80	8	7.84 µg/mL	98.01 ± 0.51
	100	10	9.90 µg/mL	99.00 ± 0.44
	120	12	11.88 µg/mL	99.00 ± 0.39

Table 3: Analysis of Tablet Formulation.

Drug	Labeled Amount (mg/tablet)	Amount Found (mg/tablet) ± SD	% Label Claim
Ibuprofen	400	397.81	99.45
Paracetamol	325	321.30	98.86

Table 4: **Precision Study (Paracetamol & Ibuprofen).**

Drug	Concentration (µg/ml)	Intraday precision % RSD(Mean three obs.)	Interday precision % RSD(Mean three obs.)
Ibuprofen	40	1.887	1.496
Paracetamol	32.5	0.685	0.663

Table 5: **Ruggedness Study (Analyst Variation).**

Analyst	Paracetamol (Mean ± SD)	% RSD	Ibuprofen (Mean ± SD)	% RSD
Analyst 1	1.3027 ± 0.0042	0.32%	1.3469 ± 0.0159	1.18%
Analyst 2	1.2660 ± 0.0052	0.41%	1.2774 ± 0.0079	0.62%

CONCLUSION

A simple and effective UV spectrophotometric method was developed and validated for the simultaneous determination of Paracetamol and Ibuprofen in both bulk and tablet formulations without interference from excipients. To the best of our knowledge, the present study is one of the few studies to demonstrate the successful application of the simultaneous equation method using 0.1N NaOH as a common solvent. The method employed a straightforward sample preparation procedure, resulting in satisfactory extraction efficiency and enabling its practical application in co-formulated pharmaceutical products.

The results of this study confirm that the developed method is simple, rapid, accurate, and precise. Statistical evaluations show that the method is repeatable, rugged, and selective for the quantitative analysis of Paracetamol and Ibuprofen. The method complies with ICH validation parameters and demonstrates strong linearity, reliability, and sensitivity. Therefore, it can be concluded that this UV spectrophotometric method is suitable for routine quality control analysis and can be confidently used in small laboratory setups due to its cost-effectiveness and ease of execution.

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