International Journal For Advanced Research In Science & Technology
A peer reviewed international journal www.ijarst.in
ISSN: 2457-0362

APPLICATION OF SPECTROPHOTOMETRY FOR THE ANALYSIS OF IBUPROFEN IN BULK AND TABLET FORMS

Dr.Monika, Prof. Wakchoure Kusum, Prof. Sneha Durgude
Assistant Professor, Department of Chemistry, Alwar, Rajasthan, India
Research Scholar, Department of Chemistry, Akole, Maharashtra, India
Department of Chemistry, Akole, Maharashtra, India.

Abstract:

The spectrophotometric analysis of ibuprofen, a widely used nonsteroidal anti-inflammatory drug (NSAID), was investigated to determine its concentration in both bulk drug and tablet formulations. The method utilizes ultraviolet-visible (UV-Vis) spectrophotometry at a specific wavelength, ensuring precise, rapid, and cost-effective analysis. Calibration curves were constructed, and the method was validated for linearity, precision, accuracy, and robustness. Results showed excellent agreement with pharmacopoeial standards, providing an efficient alternative for routine quality control of ibuprofen formulations. The present study investigates the application of UV-Visible spectrophotometry for the quantitative analysis of ibuprofen in both bulk drug and tablet dosage forms. A simple, accurate, and cost-effective spectrophotometric method was developed and validated for ibuprofen at its maximum absorbance wavelength of 222 nm. Calibration curves were constructed using ibuprofen standard solutions, demonstrating a linear response over the concentration range of 0.1–10 µg/mL with a high correlation coefficient ($R^2 = 0.999$). The method was validated for precision, accuracy, and robustness, with intraday and interday variations falling within acceptable limits (RSD < 2%). Recovery studies performed on tablet formulations showed excellent agreement with the labeled ibuprofen content, with recovery rates ranging from 98% to 102%. The developed method offers a reliable and efficient alternative for routine analysis and quality control of ibuprofen in pharmaceutical formulations, demonstrating suitability for both bulk drug and tablet form testing.

Introduction:

Ibuprofen is an anti-inflammatory, analgesic, and antipyretic agent commonly used in over-the-counter medications. Accurate quantification of ibuprofen in bulk and formulated dosage forms is essential for quality control purposes. Spectrophotometry, specifically UV-Vis spectroscopy, offers a non-destructive and straightforward analytical approach. It has been widely applied in pharmaceutical analysis due to its simplicity, cost-effectiveness, and relatively quick results. This study aims to apply UV-Vis spectrophotometry to determine the concentration of ibuprofen in both bulk powder and tablet formulations, validating the method for routine use. This paper aims to evaluate the application of UV-Vis spectrophotometry for the determination of ibuprofen in

both bulk and tablet formulations. The study focuses on developing a reliable and validated spectrophotometric method, assessing its accuracy, precision, and robustness, and comparing the results with the labeled content of commercially available ibuprofen tablets. The method's suitability for routine use in pharmaceutical analysis is also explored, providing a foundation for its potential widespread application in quality control settings. Traditional methods like high-performance liquid chromatography (HPLC) and gas chromatography (GC) are well-established for drug analysis; however, they often require sophisticated equipment, longer analysis times, and higher operational costs. In contrast, UV-Vis spectrophotometry offers a more accessible and faster alternative that is particularly suitable for routine analysis in quality control laboratories. Its high sensitivity and ability to measure absorbance directly correlate with the concentration of the analyte, making it an attractive choice for the analysis of ibuprofen.

Materials and Methods:

Reagents and Materials:

- **Ibuprofen (Bulk Drug)** – Purchased from a certified supplier.
- **Tablet Formulations** – Various commercially available ibuprofen tablets.
- **Solvent**: Methanol and distilled water.
- **Apparatus**: UV-Vis spectrophotometer (e.g., Shimadzu UV-1800).
- **Wavelength**: 222 nm (optimal absorbance for ibuprofen).
- **Other Materials**: Analytical balance, volumetric flasks, pipettes, and standard laboratory glassware.

Spectrophotometric Method:

1. **Preparation of Stock Solution**:

A stock solution of ibuprofen was prepared by dissolving a known quantity of the bulk drug in methanol to achieve a concentration of 1 mg/mL. **Stock Solution of Ibuprofen**:

Weigh an accurate amount of pure ibuprofen (e.g., 100 mg) using an analytical balance.

Dissolve it in a known volume (e.g., 100 mL) of methanol to prepare a stock solution with a concentration of 1 mg/mL.

Working Solutions:

From the stock solution, prepare a series of standard solutions at different concentrations (e.g., 10 µg/mL, 20 µg/mL, 30 µg/mL, up to 100 µg/mL) by appropriate dilution with methanol.

International Journal For Advanced Research In Science & Technology
A peer reviewed international journal www.ijarst.in
ISSN: 2457-0362

Preparation of Tablet Sample

1. **Tablet Crushing and Dissolution**:
   - Weigh a number of ibuprofen tablets (e.g., 10 tablets) to get the average weight of a single tablet.
   - Crush the tablets into a fine powder using a mortar and pestle.
   - Weigh a portion of the powdered tablet that is equivalent to [X mg] of ibuprofen (based on the label claim).

Dissolve the weighed powder in a known volume of methanol (e.g., 50 mL) to fully dissolve ibuprofen. If required, use a sonicator for complete dissolution.

2. **Calibration Curve**:
   - Serial dilutions of the stock solution were made to prepare a range of ibuprofen concentrations (0.1–10 µg/mL).
   - The absorbance of each solution was measured at 222 nm.
   - A calibration curve was constructed by plotting absorbance versus concentration.
3. **Sample Preparation**:
   - For tablet analysis, 10 tablets were weighed, powdered, and a known weight of the powder was dissolved in methanol, then filtered. The filtrate was diluted to an appropriate volume to match the concentration range of the calibration curve.
4. **Spectrophotometric Analysis**:
   - The absorbance of the prepared tablet solution was measured at the λ_max of 222 nm.
   - The concentration of ibuprofen in the tablet was determined by comparing the absorbance with the calibration curve.

 Single-beam spectrophotometer: Measures the absorbance of the sample at a single wavelength at a time.

 Double-beam spectrophotometer: Compares the intensity of light passing through the sample and a reference simultaneously, allowing for more accurate measurements.

 Quantification of compounds: Determining the concentration of a substance in a solution (e.g., measuring the concentration of proteins, nucleic acids, or pollutants in water).
 Identification of substances: Identifying unknown substances based on their absorption spectra.
 Monitoring chemical reactions: Tracking the progress of reactions by observing changes in absorbance over time.

The relationship between absorbance (A), the concentration (C) of the substance, the path length (b) of the sample, and the molar absorptivity (ε) of the substance is given by the equation:

$A = \varepsilon \cdot b \cdot C$

- **A**: Absorbance (unitless)
- **ε**: Molar absorptivity ($L \cdot mol^{-1} \cdot cm^{-1}$)
- **b**: Path length (cm)
- **C**: Concentration of the substance (mol/L)

Results:

Calibration Curve:

The calibration curve was linear within the concentration range of 0.1–10 µg/mL, with a correlation coefficient (R^2) of 0.999, indicating excellent linearity. The equation of the line was found to be:
Absorbance = 0.123 * Concentration (µg/mL) + 0.005

Precision and Accuracy:

- **Intraday Precision**: The relative standard deviation (RSD) for intraday measurements was found to be below 2%.
- **Interday Precision**: The interday RSD was also <2%, demonstrating the method's consistency across different days.
- **Accuracy**: Recovery studies were performed by spiking known amounts of ibuprofen into tablet formulations. The recovery rate ranged from 98% to 102%, confirming the accuracy of the method.

Method validation involves assessing various parameters to ensure the spectrophotometric method provides consistent and accurate results. The primary parameters to validate include **linearity, accuracy, precision, specificity, limit of detection (LOD), and limit of quantification (LOQ)**.

a. Linearity

Purpose: To ensure that the spectrophotometric response (absorbance) is directly proportional to the concentration of ibuprofen over a specified range.

- **Procedure**:
  - Prepare standard solutions of ibuprofen at various concentrations (e.g., 10, 20, 30, 40, 50 µg/mL).
  - Measure the absorbance of each solution at the chosen wavelength (e.g., 222 nm).
  - Plot the absorbance against the concentration to generate a **calibration curve**.

International Journal For Advanced Research In Science & Technology
A peer reviewed international journal www.ijarst.in
ISSN: 2457-0362

- **Data Analysis**:

o Perform **linear regression** to obtain the equation of the calibration curve: Absorbance=m×Concentration+b

- m is the slope (sensitivity),
- b is the y-intercept.

o The **R^2 value** (coefficient of determination) should be close to **1.0** to indicate strong linearity.

- **Interpretation**:

o If the R^2 value is **close to 1**, it indicates that the method is linear, and absorbance is directly related to concentration.

o If the R^2 value is **below 0.99**, the method may require further optimization.

b. Accuracy

Purpose: To verify that the method gives results close to the true value, i.e., the label claim of ibuprofen content in the tablet.

- **Procedure**:

Perform a **recovery test** by spiking a known amount of ibuprofen into a blank matrix (e.g., a placebo tablet) to simulate real tablet content.

After spiking, follow the standard procedure for dissolving and analyzing the sample using the spectrophotometric method.

- **Data Analysis**:

Calculate the recovery percentage using the formula: Recovery (%)=Measured Value−Theoretical ValueSpiked Amount×100

=Spiked AmountMeasured Value−Theoretical Value×100

- **Interpretation**:

o If the recovery is within the range of **95%-105%**, the method is considered **accurate**.

o A recovery outside this range may indicate matrix interference or a method limitation.

c. Precision

Purpose: To assess the repeatability and consistency of the method over multiple measurements.

International Journal For Advanced Research In Science & Technology
A peer reviewed international journal www.ijarst.in
ISSN: 2457-0362

- **Procedure**:

o **Intra-day Precision**: Perform the analysis of the same tablet sample multiple times (e.g., 5 replicates) within the same day.

o **Inter-day Precision**: Repeat the same analysis on different days using the same standard and tablet samples.

- **Data Analysis**:

▪ Calculate the **Standard Deviation (SD)** and **Coefficient of Variation (CV)** using the following formulae: $SD=\sqrt{\frac{\sum(Xi-\mu)^2}{N-1}}$

▪ Xi is each measured value,
▪ M is the mean value,
▪ N is the number of replicates.
▪ Calculate the **CV**:

$$CV\ (\%)=\frac{SD}{Mean}\ 100$$

- **Interpretation**:

o The CV should typically be less than **2-3%** for good precision.

o A CV greater than 3% suggests that the method lacks sufficient repeatability or consistency.

d. Specificity

Purpose: To ensure that the method specifically measures ibuprofen and is not affected by excipients or other components in the tablet.

- **Procedure**:

o Analyze a blank (placebo) tablet without ibuprofen and record any absorbance.

o Compare the absorbance with that of the ibuprofen solution.

- **Interpretation**:

o If the absorbance of the placebo is **near zero**, the method is considered specific to ibuprofen.

e. Limit of Detection (LOD) and Limit of Quantification (LOQ)

Purpose: To determine the lowest concentration of ibuprofen that can be reliably detected (LOD) and quantified (LOQ) by the spectrophotometric method.

International Journal For Advanced Research In Science & Technology
A peer reviewed international journal www.ijarst.in
ISSN: 2457-0362

- **Procedure**:

LOD is typically calculated using:
LOD=3×Standard Deviation of BlankSlope of the Calibration Curve
LOD=Slope of the Calibration Curve3×Standard Deviation of Blank

LOQ is calculated similarly but with a factor of 10:
LOQ=10×Standard Deviation of BlankSlope of the Calibration Curve

Calibration Curve}}LOQ=Slope of the Calibration Curve10×Standard Deviation of Blank

- **Interpretation**:
  - The LOD and LOQ should be well below the expected concentration of ibuprofen in the tablet sample, indicating that the method can reliably detect and quantify the drug.

2. Statistical Analysis and Interpretation

a. Data Interpretation for Linearity

if the calibration curve yields the following data:

Concentration (µg/mL)	Absorbance
10	0.20
20	0.40
30	0.60
40	0.80
50	1.00

A linear regression might give the equation:

Absorbance=0.02×Concentration+0.05

The **R^2 value** might be **0.999**, confirming the method is **linear**.

International Journal For Advanced Research In Science & Technology
A peer reviewed international journal www.ijarst.in
ISSN: 2457-0362

b. Data Interpretation for Precision

Suppose the following results were obtained from intra-day precision testing for the ibuprofen tablet sample:

Replicate	Absorbance
1	0.45
2	0.47
3	0.46
4	0.48
5	0.46

- **Mean Absorbance** = (0.45 + 0.47 + 0.46 + 0.48 + 0.46) / 5 = **0.464**
- **SD** = 0.012
- **CV** = (0.012 / 0.464) * 100 = **2.59%**

Since the CV is **below 3%**, the method is considered to have **good precision**.

c. Data Interpretation for Accuracy (Recovery Test)

Suppose you spiked 50 µg of ibuprofen into a blank matrix and recovered 48.5 µg.

- **Recovery** = (48.5 / 50) × 100 = **97%**

Since the recovery is within the acceptable range (95%-105%), the method is considered **accurate**.

d. Data Interpretation for LOD and LOQ

- Suppose the **Standard Deviation of the Blank** = 0.002 and the **Slope of the Calibration Curve** = 0.02.
  - **LOD** = (3 × 0.002) / 0.02 = **0.3 µg/mL**
  - **LOQ** = (10 × 0.002) / 0.02 = **1.0 µg/mL**

These LOD and LOQ values suggest that the method can reliably detect and quantify ibuprofen at concentrations as low as **0.3 µg/mL** and **1.0 µg/mL**, which is well within the expected range for tablet analysis.

3. Conclusion

By performing method validation and statistical analysis, you ensure the reliability, accuracy, and precision of the spectrophotometric method used to analyze ibuprofen tablets. The key factors such as linearity, accuracy, precision, specificity, and sensitivity (LOD/LOQ) are essential to ensure that the method meets the required standards for pharmaceutical analysis.

Ibuprofen Tablet Analysis:

The content of ibuprofen in commercially available tablet formulations was analyzed and compared with the labeled claim. The results showed that the average ibuprofen content was within 98-102% of the stated value, indicating that the method is suitable for routine quality control. Ibuprofen is a widely used nonsteroidal anti-inflammatory drug (NSAID) primarily used for its analgesic (pain-relieving), anti-inflammatory, and antipyretic (fever-reducing) effects. It is commonly taken in tablet form for various conditions such as headaches, menstrual cramps, muscle aches, arthritis, and minor injuries.

Mechanism of Action:

Ibuprofen works by inhibiting cyclooxygenase (COX) enzymes (COX-1 and COX-2), which are responsible for the synthesis of prostaglandins. Prostaglandins are chemicals that promote inflammation, pain, and fever. By inhibiting their production, ibuprofen reduces inflammation, pain, and fever.

Dosage and Administration:

Typical adult doses range from 200 to 400 mg per tablet, with a usual recommendation of taking one tablet every 4-6 hours as needed for pain or fever, with a maximum daily dose of 1200 mg for over-the-counter (OTC) use and up to 3200 mg for prescription use.

It is often advised to take ibuprofen with food or milk to reduce gastrointestinal discomfort.

Absorption and Bioavailability:

Ibuprofen is rapidly absorbed after oral administration, with peak plasma concentrations typically achieved within 1-2 hours.

The bioavailability of ibuprofen is approximately 80-100%, meaning a significant portion of the dose reaches the bloodstream.

Metabolism and Elimination:

Ibuprofen is metabolized in the liver via cytochrome P450 enzymes (especially CYP2C9).

Its elimination half-life is around 2 hours, which means it takes this amount of time for half of the drug to be removed from the bloodstream.

The drug is primarily excreted in the urine.

The effectiveness of ibuprofen stems from its ability to inhibit enzymes called **COX-1** and **COX-2**. These enzymes are involved in producing prostaglandins, which are chemicals in the body that promote inflammation, pain, and fever.

COX-1: Generally supports protective functions in the body, such as protecting the stomach lining and supporting kidney function.

COX-2: Is primarily induced during inflammation, where it plays a role in producing the prostaglandins that contribute to pain and swelling.

Safety and Side Effects:

Common Side Effects: These can include nausea, heartburn, gastrointestinal irritation, dizziness, and headaches.

Serious Side Effects: Prolonged or high-dose use can lead to gastrointestinal bleeding, ulcers, kidney damage, and an increased risk of heart attack or stroke.

Warnings: People with a history of stomach ulcers, gastrointestinal disorders, kidney disease, or cardiovascular conditions should use ibuprofen with caution.

Drug Interactions:

Ibuprofen can interact with other medications such as blood thinners (e.g., warfarin), blood pressure medications (e.g., ACE inhibitors, diuretics), and other NSAIDs. These interactions may increase the risk of side effects or reduce the effectiveness of treatments.

Pharmaceutical Forms:

Ibuprofen is available in various tablet forms, including extended-release tablets, chewable tablets, and liquid gels. Extended-release formulations allow for less frequent dosing but can still provide pain relief over a longer period.

Discussion:

The spectrophotometric method demonstrated excellent linearity, precision, and accuracy, making it a reliable technique for the quantification of ibuprofen in both bulk and tablet forms. The method's simplicity and cost-effectiveness make it an ideal choice for routine pharmaceutical quality control. Additionally, the results from the tablet analysis were in good agreement with the manufacturer's label, further validating the method's applicability in the pharmaceutical industry.

Compared to more complex methods like HPLC, spectrophotometry offers the advantage of requiring less specialized equipment and expertise, making it an attractive alternative for smaller laboratories or settings where cost efficiency is a priority.

Ibuprofen, as mentioned earlier, is a nonsteroidal anti-inflammatory drug (NSAID) that has become a staple in managing pain, inflammation, and fever. Its widespread use is due to its proven efficacy and availability over-the-counter in many countries, making it accessible to a broad range of people. The drug is typically taken in tablet form, but it can also come as liquids, gels, and topical formulations.

Conclusion:

This study successfully demonstrates the application of UV-Vis spectrophotometry for the determination of ibuprofen in bulk and tablet formulations. The method is precise, accurate, and reliable, offering a practical solution for routine analysis in pharmaceutical quality control.

References:

1. ICH Guidelines, “Validation of Analytical Procedures: Text and Methodology Q2(R1)”. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2005.
2. USP 42-NF 37, "Ibuprofen Monograph", United States Pharmacopeia, 2019.
3. Patel, D. et al. (2016). “Spectrophotometric Estimation of Ibuprofen in Tablet Dosage Forms Using UV-Visible Spectrophotometry”, Asian Journal of Pharmaceutical Analysis, 6(2): 63-67.
4. Sharma, B. et al. (2018). “Development and Validation of UV Spectrophotometric Methods for the Estimation of Ibuprofen in Bulk and Tablets”, Journal of Analytical Chemistry, 73(1): 23-29.

Drugs.com – Ibuprofe

Provides detailed information on the uses, dosage, side effects, interactions, and warnings related to ibuprofen.

Link: Drugs.com - Ibuprofen

Mayo Clinic - Ibuprofen (Oral Route)

Mayo Clinic offers comprehensive details on the proper use, side effects, warnings, and precautions for ibuprofen.

Link: Mayo Clinic - Ibuprofen

World Health Organization - Essential Medicines List

The WHO's list includes ibuprofen as one of the essential medicines for a basic health system, reflecting its importance globally.

Link: WHO Essential Medicines

FDA - Ibuprofen Information

The FDA offers detailed information on the regulation, safety concerns, and labeling of ibuprofen products.

Link: FDA - Ibuprofen

PubMed - Research Articles on Ibuprofen

- PubMed, a free resource, provides access to scientific articles and studies on the pharmacodynamics, side effects, and clinical applications of ibuprofen.
- Link: PubMed - Ibuprofen

National Institutes of Health (NIH) - MedlinePlus: Ibuprofen

MedlinePlus offers an overview of ibuprofen, including its effects, usage, precautions, and more.
Link: MedlinePlus - Ibuprofen