Development And Validation of a UV–Visible Spectrophotometric Method for the Estimation of Ornidazole in Tablet Dosage Form

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Abstract- The present study was undertaken to develop and validate a simple, accurate, and economical UV–Visible spectrophotometric method for the quantitative estimation of Ornidazole in pharmaceutical tablet dosage form. Ornidazole is a nitroimidazole derivative widely used for the treatment of infections caused by anaerobic bacteria and protozoa. The analytical method was developed using methanol as the solvent system. The standard solution of Ornidazole was scanned over 200–400 nm to determine the wavelength of maximum absorption. The drug exhibited maximum absorbance at 277 nm, which was selected as the analytical wavelength for further analysis. A calibration curve was constructed in the concentration range of 2–12 µg/mL, and the method showed good linearity with a correlation coefficient of 0.999. The developed method was validated in accordance with ICH guidelines for linearity, accuracy, precision, limit of detection, limit of quantification, and robustness. The recovery values obtained during accuracy studies were within the acceptable range, indicating that the method is accurate. Precision studies showed percentage relative standard deviation values below 2%, confirming the reproducibility of the analytical procedure. The developed method was successfully applied for the estimation of Ornidazole in tablet formulation. The results demonstrated that the proposed UV spectrophotometric method is simple, reliable, and suitable for routine pharmaceutical analysis of Ornidazole in tablet dosage forms.

Keywords: Ornidazole, UV spectrophotometric method, ICH guidelines.

I.INTRODUCTION

1.1. Infectious Diseases and the Need for Antimicrobial Therapy

Infectious diseases continue to represent a significant challenge to public health worldwide. Microbial infections caused by bacteria, protozoa, and other pathogenic organisms are responsible for a large number of illnesses and deaths, particularly in developing countries. The widespread occurrence of gastrointestinal infections, parasitic diseases, and anaerobic bacterial infections necessitates the continuous development and effective use of antimicrobial drugs. The success of antimicrobial therapy depends not only on the drug's therapeutic activity but also on the quality, purity, and correct dosage of pharmaceutical formulations.

Pharmaceutical quality control plays an essential role in ensuring that drugs used in medical treatment meet the required standards of safety and efficacy. Analytical methods are therefore required to evaluate the quality of pharmaceutical products during manufacturing and throughout their shelf life. Accurate determination of the active pharmaceutical ingredient present in a dosage form is essential to ensure that patients receive the correct therapeutic dose.

Modern pharmaceutical analysis involves the application of a range of analytical techniques to qualitatively and quantitatively evaluate drugs. These analytical techniques are used in research laboratories, pharmaceutical industries, and regulatory agencies to ensure that pharmaceutical products comply with established standards. Reliable analytical methods are essential for determining drug content, identifying impurities, and monitoring stability during storage.

1.2. Nitroimidazole Derivatives as Antimicrobial Agents

Nitroimidazole derivatives are important antimicrobial drugs used to treat infections caused by anaerobic bacteria and protozoa. They contain a nitro group attached to an imidazole ring, which is essential for their activity. Common drugs include metronidazole, tinidazole, secnidazole, and ornidazole.

These drugs are effective against organisms like Entamoeba histolytica, Giardia lamblia, and Trichomonas vaginalis. Their mechanism involves reduction of the nitro group inside microbial cells, producing reactive intermediates that damage DNA and inhibit cell replication, leading to cell death.

They are widely used for gastrointestinal, reproductive, and systemic infections and are available in various dosage forms such as tablets, capsules, injections, and suspensions.

1.3 Ornidazole

Ornidazole is a synthetic nitroimidazole derivative with potent antimicrobial and antiprotozoal activity. Chemically, it is known as 1-chloro-3-(2-methyl-5-nitroimidazol-1-yl)-2-propanol. Its activity is mainly due to the presence of the nitroimidazole group.

It is widely used to treat infections caused by anaerobic bacteria and protozoa such as Entamoeba histolytica, Giardia lamblia, and Trichomonas vaginalis. Compared to other nitroimidazoles, Ornidazole has a longer half-life, making it effective for sustained therapy. It is commonly available in tablet and injectable forms, with tablets being preferred for ease of administration and patient compliance. Accurate analytical methods are essential to ensure proper drug content and maintain therapeutic efficacy and safety.

1.4 Mechanism of Action of Ornidazole

Ornidazole exerts its antimicrobial effect through the reduction of its nitro group inside anaerobic microorganisms. This reduction produces reactive intermediates that interact with microbial DNA, causing strand breakage and inhibition of nucleic acid synthesis. As a result, cell replication is halted, leading to cell death. Since this process mainly occurs in anaerobic organisms, Ornidazole shows selective toxicity, making it highly effective against anaerobic pathogens.

1.5 Pharmaceutical Analysis of Antimicrobial Drugs

Pharmaceutical analysis ensures that drug formulations contain the correct amount of active ingredient and meet quality standards. Various analytical techniques are used, including chromatographic, spectroscopic, electrochemical, and titrimetric methods. High-performance liquid chromatography (HPLC) is highly sensitive and selective but requires expensive equipment. In contrast, spectroscopic methods such as UV spectrophotometry are simple, rapid, and cost-effective, making them suitable for routine analysis in pharmaceutical laboratories.

1.6 Spectroscopic Techniques in Pharmaceutical Analysis

Spectroscopic techniques are based on the interaction between electromagnetic radiation and matter. These methods measure absorption, emission, or scattering of radiation to provide information about the structure and concentration of compounds. Common techniques include UV–Visible spectroscopy, infrared spectroscopy, nuclear magnetic resonance (NMR), and fluorescence spectroscopy. Among these, UV–Visible spectroscopy is widely used due to its simplicity, sensitivity, and low cost. Many pharmaceutical compounds absorb UV radiation because of chromophores such as double bonds and aromatic rings, enabling their quantitative determination.

1.7 Ultraviolet–Visible Spectroscopy

UV–Visible spectroscopy measures the absorption of radiation in the ultraviolet (200–400 nm) and visible (400–800 nm) regions. When radiation passes through a solution, part of it is absorbed, promoting electrons from lower to higher energy levels. The absorbed energy is measured as absorbance, which is directly proportional to concentration. The wavelength at which maximum absorption occurs (λmax) is used for analysis to ensure accuracy and sensitivity. This technique is widely applied for the quantitative estimation of drugs due to its reliability, simplicity, and efficiency.

1.2. chromophores and Auxochromes

A chromophore is a group of atoms within a molecule that is responsible for absorbing ultraviolet or visible radiation. Chromophores usually contain unsaturated bonds, such as double bonds or aromatic rings, that enable electronic transitions.

Auxochromes are functional groups that do not absorb radiation by themselves but can influence the absorption properties of a chromophore when attached to it. Auxochromes can shift the absorption wavelength or increase absorption intensity.

1.3. Beer–Lambert Law

Quantitative determination of pharmaceutical compounds by UV spectroscopy is based on the Beer–Lambert law. This law describes the relationship between the absorbance of light and the concentration of the absorbing species in a solution.

According to Beer–Lambert law, the absorbance of a solution is directly proportional to the concentration of the absorbing species and the path length of the sample cell.

The mathematical expression of the Beer–Lambert law is given as:

$$A = \varepsilon bc$$

Where
A = Absorbance
ε = Molar absorptivity
b = Path length of the cuvette
c = Concentration of the solution
If the system follows the Beer–Lambert law, a linear relationship between absorbance and concentration will be observed. This relationship allows the determination of drug concentration by measuring the solution's absorbance at a specific wavelength.

1.11. Instrumentation of UV–Visible Spectrophotometer

A UV–Visible spectrophotometer measures the absorption of ultraviolet and visible radiation by a substance to determine its concentration. It operates on the principle that molecules absorb specific wavelengths based on their structure.

The instrument consists of key components:
Radiation source: Deuterium lamp (UV region) and tungsten lamp (visible region) provide continuous radiation.

Monochromator: Isolates the required wavelength using prisms or diffraction gratings.

Sample holder: Contains the sample in a cuvette (usually quartz, 1 cm path length for UV analysis).

Detector: Converts transmitted light into an electrical signal proportional to intensity.

Data system: Processes and records absorbance, generating spectra for analysis.
Together, these components enable accurate and rapid quantitative analysis of substances.

1.12. Applications of UV Spectrophotometry in Pharmaceutical Analysis

UV spectrophotometry is widely used for quantitative estimation of drugs in bulk and dosage forms using the Beer–Lambert law. It aids in compound identification through characteristic spectra, detection of impurities and degradation products, stability studies, and dissolution testing. Its simplicity and rapid analysis make it a common technique in pharmaceutical laboratories.

1.13. Analytical Method Development

Analytical method development involves selecting appropriate conditions for accurate drug estimation. Key factors include solvent selection, wavelength selection (λmax), and sample preparation. Standard solutions are used to construct calibration curves. The method should be simple, precise, accurate, and reproducible.

1.14. Analytical Method Validation

Method validation confirms the suitability of an analytical procedure as per International Council for Harmonisation guidelines. Key parameters include linearity, accuracy, precision, limit of detection, limit of quantification, and robustness, ensuring r1.15.

1.4. Electronic Transitions in UV Spectroscopy

The absorption of ultraviolet radiation by molecules excites electrons from lower-energy molecular orbitals to higher-energy orbitals. These excitations are known as electronic transitions.

In organic molecules, several types of electronic transitions may occur depending on the nature of the chemical bonds present in the molecule. The most common electronic transitions observed in UV spectroscopy include sigma to sigma star ($\sigma \rightarrow \sigma^*$), n to sigma star ($n \rightarrow \sigma^*$), pi to pi star ($\pi \rightarrow \pi^*$), and n to pi star ($n \rightarrow \pi^*$) transitions.

Sigma-to-sigma star transitions occur in molecules containing single bonds and require high-energy radiation, typically in the far ultraviolet region. Pi to pi star transitions occur in molecules containing double bonds or aromatic rings and require relatively lower energy radiation.The type of electronic transition in a molecule determines the wavelength at which absorption occurs. Understanding these transitions helps in selecting appropriate analytical wavelengths for spectrophotometric analysis.

II.DRUG PROFILE

Ornidazole is a synthetic antimicrobial agent belonging to the class of nitroimidazole derivatives. Drugs in this class are widely used to treat infections caused by anaerobic bacteria and protozoa. Nitroimidazole derivatives are particularly effective in the treatment of gastrointestinal infections and parasitic diseases because they can penetrate microbial cells and interfere with nucleic acid synthesis. Ornidazole is considered an important member of the nitroimidazole group due to its broad-spectrum antimicrobial activity and relatively long half-life compared with other drugs in the same class. Because of these properties, the drug has gained significant importance in clinical therapy for the treatment of protozoal and anaerobic bacterial infections.

The drug is widely used in medical practice for the treatment of diseases such as amoebiasis, giardiasis, trichomoniasis, and infections caused by anaerobic bacteria. Ornidazole is available in several pharmaceutical dosage forms, including tablets, injections, and suspensions. Because of its therapeutic importance, accurate determination of Ornidazole in pharmaceutical formulations is necessary to ensure the drug's quality, safety, and effectiveness. Analytical methods such as UV spectrophotometry are commonly used to quantify Ornidazole in pharmaceutical dosage forms.

2.1 Chemical Information

Ornidazole is chemically known as 1-chloro-3-(2-methyl-5-nitro-1H-imidazol-1-yl)-2-propanol. The presence of a nitroimidazole ring in the structure is responsible for its antimicrobial activity. The nitro group in the molecule plays an essential role in the drug's pharmacological action. During microbial metabolism, this nitro group is reduced, generating reactive intermediates that bind to microbial DNA, thereby inhibiting nucleic acid synthesis. The chemical structure of Ornidazole contains both hydrophilic and lipophilic functional groups, which allow the drug to penetrate microbial cell membranes effectively.

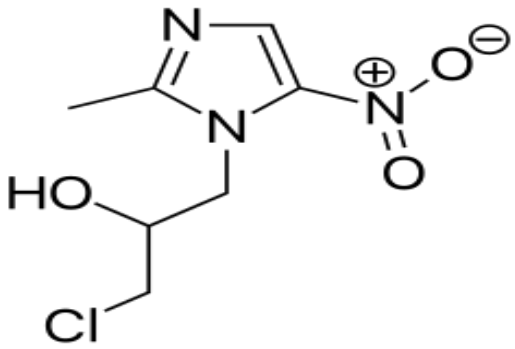

Figure 2.1: Chemical Structure of Ornidazole

2.2 Molecular Characteristics

Molecular formula: $C_7H_{10}ClN_3O_3$

Molecular weight: 219.63 g/mol

The compound appears as a white to pale yellow crystalline powder. Ornidazole exhibits good solubility in organic solvents such as methanol and ethanol, but limited solubility in water. Because of these solubility characteristics, suitable solvents are selected during analytical method development to ensure complete drug dissolution. The compound exhibits characteristic ultraviolet absorption due to the nitroimidazole chromophore, enabling its determination by UV spectrophotometry.

2.3 Pharmacological Classification

Ornidazole belongs to the pharmacological class known as antiprotozoal and antibacterial agents. More specifically, it is classified as a nitroimidazole antimicrobial drug. Nitroimidazole drugs are primarily effective against anaerobic microorganisms and protozoan parasites. These drugs are widely used to treat infections caused by organisms that thrive in low-oxygen environments. Members of this class include metronidazole, tinidazole, secnidazole, and ornidazole. These drugs share similar mechanisms of action and are frequently used to treat protozoal and anaerobic bacterial infections.

2.4 Mechanism of Action

The antimicrobial activity of Ornidazole is mainly due to the reduction of its nitro group by microbial

enzymes. In anaerobic microorganisms, the nitro group is enzymatically reduced, forming reactive intermediates. These intermediates interact with microbial DNA and other essential biomolecules, disrupting nucleic acid synthesis. As a consequence, the replication and growth of the microorganism are inhibited. The formation of these toxic intermediates damages the microorganism's DNA, ultimately leading to cell death. Because this reduction process occurs mainly in anaerobic microorganisms, Ornidazole selectively targets these organisms without significantly affecting aerobic cells.

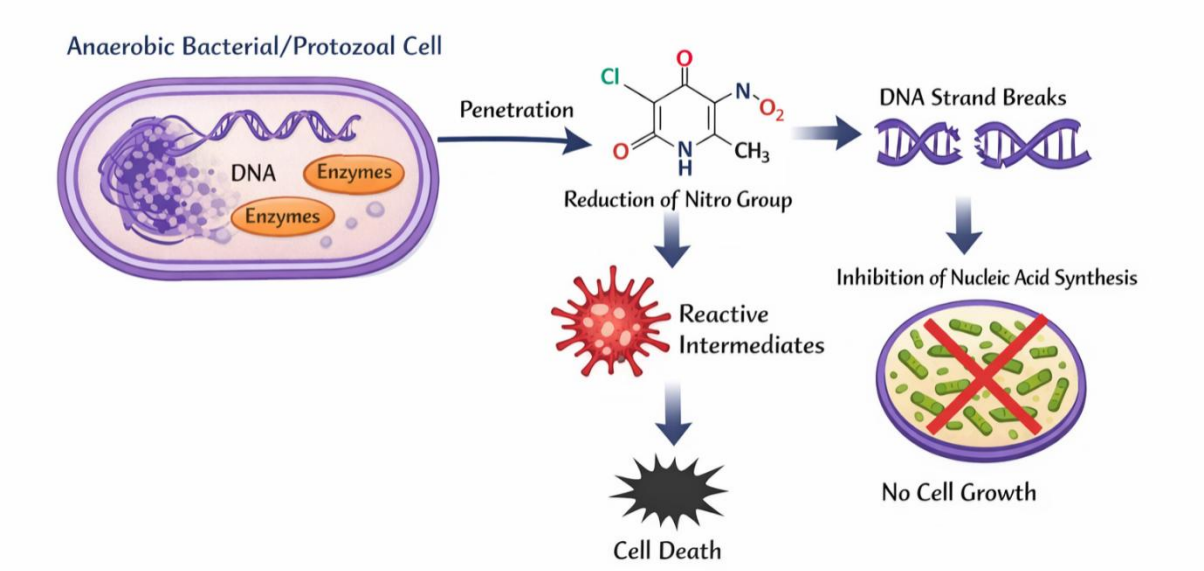

Figure 2.2: Mechanism of Antimicrobial Action of Ornidazole

2.5 Pharmacokinetics

After oral administration, Ornidazole is rapidly absorbed from the gastrointestinal tract. The drug exhibits good bioavailability and reaches peak plasma concentrations within a few hours after administration.

Ornidazole is widely distributed throughout body tissues and fluids, including bile, saliva, cerebrospinal fluid, and vaginal secretions. The drug is metabolized in the liver via multiple pathways.

The elimination half-life of Ornidazole is relatively long compared with other nitroimidazole derivatives, which allows less frequent dosing in clinical therapy. The metabolites and the unchanged drug are primarily excreted through urine.

2.6 Therapeutic Uses

Ornidazole is widely used in the treatment of various protozoal and anaerobic bacterial infections. The drug is effective against several pathogenic microorganisms responsible for gastrointestinal and systemic infections.

It is commonly used to treat amoebiasis, a disease caused by the protozoan parasite *Entamoeba histolytica*. The drug is also effective against giardiasis, an intestinal infection caused by *Giardia lamblia*.

Another important clinical use of Ornidazole is in the treatment of trichomoniasis, a sexually transmitted infection caused by *Trichomonas vaginalis*. In addition to protozoal infections, the drug is used to treat infections caused by anaerobic bacteria.

2.7 Adverse Effects

Although Ornidazole is generally well tolerated, some patients may experience mild adverse effects during treatment. Common side effects include nausea, headache, dizziness, and gastrointestinal disturbances. In some cases, patients may experience a metallic taste in the mouth or mild neurological symptoms such as dizziness or fatigue. These adverse effects are usually temporary and resolve after discontinuation of the drug. Serious adverse reactions are rare but may include allergic reactions or neurological disturbances in sensitive individuals.

2.8 Storage Conditions

Ornidazole should be stored in a cool, dry place, away from direct sunlight and moisture. The drug should be stored in tightly sealed containers to

protect it from environmental factors that may affect its stability. Proper storage conditions are necessary to maintain the quality and potency of the pharmaceutical formulation throughout its shelf life

III.EXPERIMENTAL WORK

31. Drug Sample

A pure Ornidazole working standard was obtained and used to develop the analytical method. The drug sample was used without further purification.

3.2 Pharmaceutical Formulation

Commercially available Ornidazole tablet formulation containing 500 mg of Ornidazole per tablet was used for the analysis.

3.3 Chemicals and Reagents

All chemicals and reagents used during the experimental work were of analytical reagent grade.

The following chemicals were used in the study:

Methanol, Distilled water ,Ornidazole standard, Ornidazole tablet formulation

Methanol was selected as the solvent because Ornidazole exhibits good solubility in methanol, yielding clear solutions suitable for UV spectrophotometric analysis.

3.4 Instrumentation

The absorbance measurements were carried out using a UV–Visible spectrophotometer equipped with UVWin software.

Table 3.1: Instrument Details

Instrument	UV–Visible Spectrophotometer
Software	UVWin Software
Wavelength range	200–800 nm
Cuvette	Quartz cuvette
Path length	1 cm

Matched quartz cells of 1 cm path length were used for all spectrophotometric measurements.

3.5 Preparation of Solvent

Methanol was used as the solvent for the preparation of all standard and sample solutions. The solvent was used as a blank solution during spectrophotometric measurements.

3.6 Preparation of Standard Stock Solution

An accurately weighed quantity of 10 mg of Ornidazole was transferred into a 100 mL volumetric flask. The drug was dissolved in methanol with gentle shaking, and the volume was made up to the mark with methanol to obtain a standard stock solution of concentration 100 µg/mL.

3.7 Determination of Wavelength of Maximum Absorption (λmax)

A suitable aliquot of the stock solution was diluted with methanol to obtain an appropriate concentration for spectral scanning. The prepared solution was scanned in the UV region from 200 nm to 400 nm using methanol as the blank. The absorption spectrum of Ornidazole showed a maximum absorption peak at approximately 277 nm, which was selected as the analytical wavelength for quantitative estimation.

3.8 Preparation of Working Standard Solutions

From the standard stock solution, different aliquots were transferred into a series of 10 mL volumetric flasks and diluted with methanol to obtain solutions of varying concentrations. The concentration range selected for the study was 2–12 µg/mL.

Table 3.2: Preparation of Calibration Standards

S.No	Volume of Stock Solution (mL)	Final Concentration (µg/mL)
1	0.2	2
2	0.4	4
3	0.6	6
4	0.8	8
5	1.0	10
6	1.2	12

3.9 Construction of Calibration Curve

The absorbance of the prepared standard solutions was measured at 277 nm against methanol as a blank. A calibration curve was constructed by plotting absorbance versus concentration. The calibration curve showed a linear relationship within the selected concentration range, indicating that the method obeys Beer–Lambert law.

3.10 Analysis of Tablet Formulation

Twenty tablets of Ornidazole were weighed and finely powdered. A quantity of powder equivalent to 10 mg of Ornidazole was accurately weighed and transferred into a 100 mL volumetric flask. Approximately 50 mL of methanol was added, and the mixture was shaken thoroughly to dissolve the

drug completely. The solution was then filtered to remove insoluble excipients, and the volume was made up to 100 mL with methanol. Appropriate dilutions of this solution were prepared to obtain concentrations within the calibration range. The absorbance of the sample solution was measured at 277 nm, and the drug content was calculated using the calibration curve.

3.11 Method Validation

The developed UV spectrophotometric method was validated in accordance with ICH guidelines.

The following validation parameters were evaluated:

Linearity, Accuracy, Precision

Limit of detection, Limit of quantification & Robustness

3.11.1 Linearity

Linearity of the method was evaluated by measuring the absorbance of Ornidazole standard solutions over the concentration range of 2–12 µg/mL.

3.11.2 Accuracy

50%, 100%, and the method's accuracy was determined by performing recovery studies at three levels: 150%.

3.11.3 Precision

The method's precision was evaluated by analyzing replicate samples and calculating the percentage relative standard deviation (%RSD).

3.11.4 Limit of Detection (LOD)

The limit of detection was calculated using the formula:

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

Where

σ = standard deviation

S = slope of calibration curve

3.11.5 Limit of Quantification (LOQ)

The limit of quantification was calculated using the formula:

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

3.11.6 Robustness

The method's robustness was evaluated by introducing small variations in the analytical wavelength and observing the resulting changes in absorbance.

IV. RESULTS AND DISCUSSION

4.1 Introduction

The developed UV spectrophotometric method for the estimation of Ornidazole in tablet dosage form was evaluated and validated in accordance with the International Conference on Harmonisation guidelines. The validation of the developed analytical method included evaluating parameters such as wavelength selection, linearity, accuracy, precision, limit of detection, limit of quantification, and robustness.

The results obtained from the experimental work are presented and discussed in the following sections.

4.2 Determination of λmax

The standard solution of Ornidazole prepared in methanol was scanned in the ultraviolet region between 200 nm and 400 nm using a UV–Visible spectrophotometer.

The recorded absorption spectrum showed a prominent peak at approximately 277 nm, indicating the wavelength of maximum absorption for Ornidazole in methanol. The presence of this absorption peak is attributed to electronic transitions in the nitroimidazole chromophore within the drug's molecular structure.

Selection of the analytical wavelength at λmax is important because it provides maximum sensitivity and minimizes analytical errors during quantitative estimation. Therefore, 277 nm was selected as the analytical wavelength for further spectrophotometric analysis.

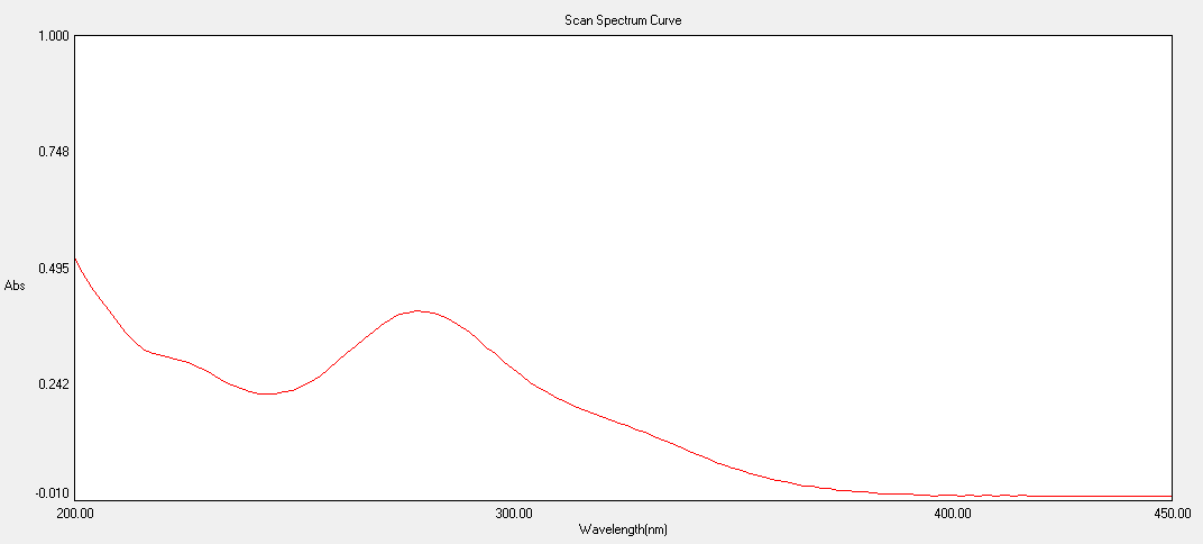

Figure 6.1: UV Spectrum of Ornidazole Showing λmax at 277 nm

4.3 Validation

4.3.1 Linearity

Linearity of the proposed analytical method was evaluated by preparing a series of standard solutions of Ornidazole within the concentration range of 2–12 µg/mL. The absorbance of these solutions was measured at 277 nm using methanol as a blank. A calibration curve was constructed by plotting absorbance against concentration. The calibration plot showed a straight-line relationship, indicating that the developed method obeys Beer–Lambert law within the studied concentration range.

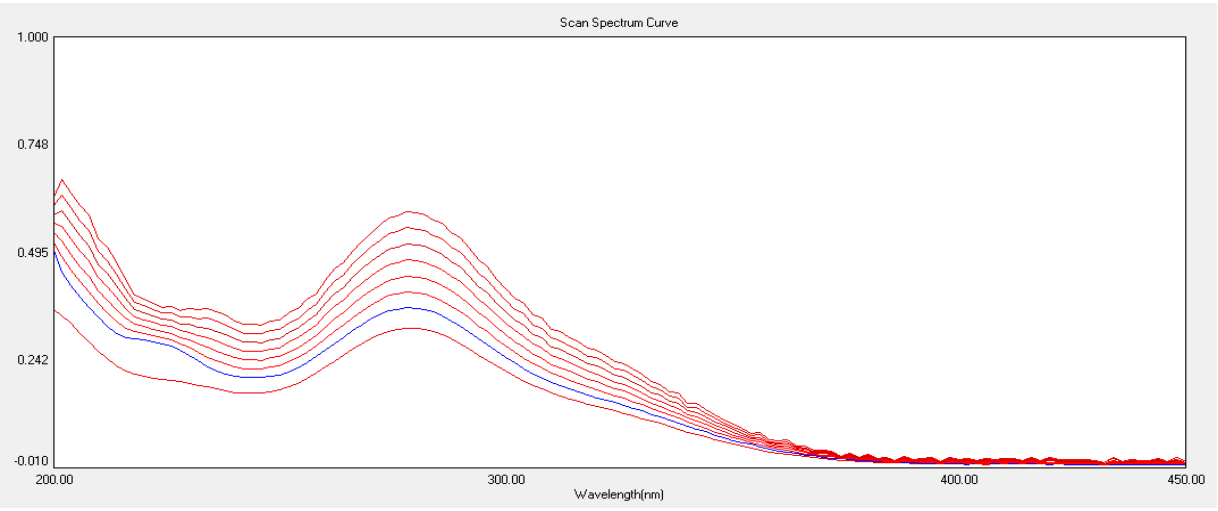

Figure 6.2: Overlay Spectra of Ornidazole at Different Concentrations

4.3.2 Accuracy

The accuracy of the developed analytical method was determined by performing recovery studies at three different levels: 50%, 100%, and 150% of the target concentration. Known quantities of Ornidazole standard were added to previously analyzed tablet sample solutions, and the percentage recovery was calculated.

Table 4.1: Results for Accuracy for the Ornidazole

Level	Amount Added (µg/mL)	Amount Recovered (µg/mL)	% Recovery
50%	4	3.98	99.50
100%	8	8.05	100.62
150%	12	11.94	99.50

4.3.3 Precision

The precision of the analytical method was evaluated by performing intra-day (repeatability) and inter-day precision studies. The precision of the method was assessed by analyzing six replicates of a standard solution containing 8 µg/mL of Ornidazole on the same day. The same concentration was analysed on three different days.

Table 4.2: Results for Interday and Intraday for the Ornidazole

Trial	Absorbance
1	0.462
2	0.461
3	0.463
4	0.462
5	0.460
6	0.463
Mean absorbance	0.4618
Standard deviation	0.0011
%RSD	0.24%
Day 1	0.462
Day 2	0.460
Day 3	0.463
Mean absorbance	0.4618
%RSD	0.24%

The %RSD values for intra- and inter-day precision were less than 2%, indicating good precision and reproducibility of the developed method.

4.3.4 Limit of Detection (LOD)

The calculated LOD was 0.18 µg/mL, indicating that the method can detect very low concentrations of Ornidazole.

4.3.5 Limit of Quantification (LOQ)

The calculated LOQ value was 0.55 µg/mL, indicating adequate sensitivity of the developed method for quantitative determination.

4.3.6 Robustness

The robustness of the analytical method was evaluated by making small variations in the analytical wavelength (±2 nm) and observing the effect on absorbance values.

Table 4.3: Robustness results for Ornidazole

Wavelength	% Assay
275 nm	99.4
277 nm	100.0
279 nm	99.6

The results indicated that minor variations in wavelength did not significantly affect the analytical results. This demonstrates that the developed method is robust and reliable under normal laboratory conditions.

Table 4.4: Summary of Validation Parameters

Parameter	Result
λmax	277 nm
Linearity range	2–12 µg/mL
Regression equation	y = 0.0578x + 0.0006
Correlation coefficient	0.9992
Precision (%RSD)	< 2%
Accuracy (% recovery)	99.50 – 100.62%
LOD	0.18 µg/mL
LOQ	0.55 µg/mL

4.9 Assay of Ornidazole Tablets

The developed analytical method was applied to the determination of Ornidazole in a commercial tablet formulation.

Table 4.5: Assay Results of Tablet Formulation

Parameter	Result
Label claim	500 mg
Amount found	498.6 mg
% Assay	99.72%

The assay results indicate that the tablet formulation contains Ornidazole within acceptable limits set by pharmaceutical standards.

4.10 Discussion

The developed UV spectrophotometric method for the estimation of Ornidazole in tablet dosage form demonstrated satisfactory analytical performance. The absorption spectrum obtained for Ornidazole showed a distinct peak at 277 nm, which was selected as the analytical wavelength for quantitative determination.

The linearity study indicated that the method obeys the Beer–Lambert law over the concentration range of 2–12 µg/mL, with a correlation coefficient of 0.999. The precision study showed a low percentage relative standard deviation, indicating good reproducibility of the analytical procedure.

The method's accuracy was confirmed by recovery studies, which yielded recovery values close to 100%. The calculated LOD and LOQ values indicate that the method is sensitive enough to detect and quantify low concentrations of Ornidazole.

Robustness studies indicated that small variations in wavelength did not significantly affect the analytical

results. The assay of the tablet formulation confirmed that the developed method can be successfully applied for the routine analysis of Ornidazole in pharmaceutical dosage forms.

VI.SUMMARY AND CONCLUSION

5.1 Summary

The present investigation was carried out to develop and validate a simple and reliable ultraviolet spectrophotometric method for the estimation of Ornidazole in pharmaceutical tablet dosage form. Ornidazole is an antimicrobial drug in the nitroimidazole class and is widely used for the treatment of protozoal and anaerobic bacterial infections. Because of its therapeutic importance, accurate determination of Ornidazole content in pharmaceutical formulations is necessary to ensure quality, safety, and efficacy.

In the present study, a UV spectrophotometric method was developed using methanol as the solvent system. The standard solution of Ornidazole was scanned over 200–400 nm to determine the wavelength of maximum absorption. The absorption spectrum obtained during scanning showed that Ornidazole exhibited a maximum at 277 nm, which was selected as the analytical wavelength for further analysis.

A series of standard solutions of Ornidazole was prepared within the concentration range of 2–12 µg/mL. The absorbance of these solutions was measured at 277 nm, and a calibration curve was constructed by plotting absorbance against concentration. The calibration curve showed a linear relationship between absorbance and concentration, indicating that the method obeys Beer–Lambert law within the selected concentration range.

The developed analytical method was validated in accordance with the International Conference on Harmonisation guidelines. Validation parameters, including linearity, accuracy, precision, limit of detection, limit of quantification, and robustness, were evaluated.

The correlation coefficient obtained from the calibration curve was 0.999, indicating excellent linearity for the developed method. Precision studies showed that the percentage relative standard deviation was less than 2%, confirming the reproducibility of the analytical procedure. Accuracy studies conducted through recovery experiments yielded recovery values close to 100%, indicating that the method is accurate and reliable.

The limit of detection and limit of quantification values demonstrated that the developed method possesses adequate sensitivity for the detection and quantification of Ornidazole in pharmaceutical formulations. Robustness studies indicated that small variations in analytical wavelength did not significantly affect the results.

The developed UV spectrophotometric method was successfully applied for the analysis of Ornidazole in tablet formulation. The assay results indicated that the drug content in the tablet formulation was within acceptable pharmaceutical limits.

5.2 Conclusion

From the results obtained in the present investigation, it can be concluded that the developed UV spectrophotometric method for the estimation of Ornidazole in tablet dosage form is simple, accurate, precise, and economical.

The method showed good linearity within the concentration range of 2–12 µg/mL and satisfied all validation parameters according to ICH guidelines. The developed analytical method requires minimal sample preparation and does not require complex instrumentation, making it suitable for routine pharmaceutical analysis.

Therefore, the proposed UV spectrophotometric method can be successfully applied for the quantitative determination of Ornidazole in pharmaceutical tablet formulations for quality control purposes.

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