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Development and Validation of Simple UV Spectrophotometric Methods for Simultaneous Estimation of Ofloxacin and Tinidazole in Combined Tablet Dosage Form

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Abstract:

The present study aimed to develop and validate two simple, rapid, economical, and accurate UV-visible spectrophotometric methods for the simultaneous estimation of Ofloxacin (OFLOX) and Tinidazole (TZ) in combined tablet dosage forms. Two analytical approaches, namely Vierordt's simultaneous equation method (Method I) and the absorbance ratio (Q-analysis) method (Method II), were developed using 0.1 N sodium hydroxide as the solvent. The absorption maxima of Ofloxacin and Tinidazole were observed at 288 nm and 319 nm, respectively, while an isoabsorptive point was identified at 298 nm. Calibration curves exhibited excellent linearity within the concentration ranges of 2–14 µg/mL for Ofloxacin and 4–20 µg/mL for Tinidazole, with correlation coefficients ranging from 0.998 to 0.999. The developed methods were validated according to International Council for Harmonisation (ICH) guidelines with respect to linearity, accuracy, precision, limit of detection (LOD), limit of quantification (LOQ), and assay. Recovery studies performed at 80%, 100%, and 120% concentration levels yielded recoveries between 99.76% and 100.41%, confirming the accuracy of both methods. Precision studies demonstrated %RSD values below 2%, indicating excellent repeatability and intermediate precision. Assay results showed drug contents ranging from 99.92% to 100.90%, demonstrating the applicability of the proposed methods for routine quality control analysis. The developed UV spectrophotometric methods are simple, reliable, cost-effective, and suitable for simultaneous estimation of Ofloxacin and Tinidazole in combined pharmaceutical dosage forms without prior separation.

Keywords: Ofloxacin, Tinidazole, UV-visible spectrophotometry, Simultaneous equation method, Method validation

Introduction

Bacterial and protozoal infections continue to pose a significant public health challenge worldwide despite substantial advances in antimicrobial therapy. Mixed aerobic and anaerobic infections are frequently encountered in gastrointestinal, urinary tract, gynecological, and dental infections, requiring combination antimicrobial therapy for effective management. Pharmaceutical combinations containing antibacterial agents with complementary mechanisms of action have therefore become an important therapeutic strategy to enhance

clinical efficacy while reducing microbial resistance and improving patient compliance (World Health Organization, 2023).

Ofloxacin is a second-generation fluoroquinolone antibiotic possessing broad-spectrum antibacterial activity against both Gram-positive and Gram-negative microorganisms. It acts by inhibiting bacterial DNA gyrase (topoisomerase II) and topoisomerase IV, enzymes responsible for DNA replication, transcription, and repair, ultimately leading to bacterial cell death. Due to its excellent oral bioavailability, favorable pharmacokinetic profile, and broad antimicrobial spectrum, Ofloxacin is widely prescribed for respiratory tract infections, urinary tract infections, skin infections, gastrointestinal infections, and sexually transmitted diseases (Brunton et al., 2023).

Tinidazole, a 5-nitroimidazole derivative, exhibits potent activity against anaerobic bacteria and protozoa, including Entamoeba histolytica, Giardia lamblia, and Trichomonas vaginalis. Following intracellular reduction of its nitro group under anaerobic conditions, reactive intermediates interact with microbial DNA, resulting in inhibition of nucleic acid synthesis and subsequent cell death. Owing to its prolonged half-life and improved tolerability compared with earlier nitroimidazole derivatives, Tinidazole is extensively employed in the treatment of mixed anaerobic bacterial and protozoal infections (Sweetman, 2023).

The fixed-dose combination of Ofloxacin and Tinidazole has gained widespread clinical acceptance because it offers synergistic antimicrobial activity against mixed infections involving aerobic bacteria, anaerobic bacteria, and protozoa. Such combinations are commonly prescribed for infectious diarrhea, dysentery, pelvic inflammatory disease, postoperative infections, intra-abdominal infections, and various gastrointestinal disorders. Since both active pharmaceutical ingredients are present in a single dosage form, reliable analytical methods capable of simultaneously quantifying both drugs are essential for ensuring product quality, efficacy, and regulatory compliance (Indian Pharmacopoeia Commission, 2022).

Analytical method development plays a vital role in pharmaceutical quality assurance. The availability of simple, rapid, precise, and economical analytical methods facilitates routine quality control during manufacturing and post-marketing surveillance. Although advanced chromatographic techniques such as HPLC, HPTLC, LC-MS/MS, and capillary electrophoresis provide excellent sensitivity and selectivity, these techniques require sophisticated instrumentation, expensive solvents, highly skilled personnel, and longer analytical times. Consequently, they may not always be suitable for routine analysis in many industrial and academic laboratories, particularly in resource-limited settings (Skoog et al., 2018).

UV-visible spectrophotometry remains one of the most widely employed analytical techniques in pharmaceutical analysis because of its simplicity, affordability, reproducibility, and minimal sample preparation requirements. Simultaneous estimation using spectrophotometric techniques is particularly advantageous for multicomponent formulations where overlapping spectra can be mathematically resolved without physical separation. Among these techniques, Vierordt's simultaneous equation method utilizes absorptivity coefficients measured at selected wavelengths to calculate the concentration of each component, whereas the absorbance ratio (Q-analysis) method employs measurements at an isoabsorptive point together with the absorption maximum of one component for simultaneous quantification (Beckett & Stenlake, 2002).

Validation of analytical methods according to International Council for Harmonisation (ICH) guidelines is an indispensable requirement before routine application. Validation establishes that an analytical procedure consistently produces reliable, reproducible, and accurate results for its intended purpose. Parameters including linearity, accuracy, precision, specificity, limit of detection, limit of quantification, and robustness collectively demonstrate the suitability of an analytical method for pharmaceutical quality control (ICH Q2(R2), 2023).

Several analytical methods have previously been reported for the estimation of Ofloxacin and Tinidazole individually or in combination using chromatographic and spectrophotometric techniques. However, many of these methods involve complex sample preparation, expensive instrumentation, gradient mobile phases, or lengthy analytical procedures. Therefore, there remains a need for a simple, rapid, validated, and cost-effective UV spectrophotometric method suitable for routine quality control analysis of combined tablet dosage forms.

Accordingly, the present investigation was undertaken to develop two simple UV-visible spectrophotometric methods based on Vierordt's simultaneous equation method and the absorbance ratio method for the simultaneous estimation of Ofloxacin and Tinidazole in combined tablet formulations. The developed methods were validated according to ICH guidelines with respect to linearity, precision, accuracy, assay, limit of detection, and limit of quantification. The proposed methods are intended to provide reliable, economical, and efficient analytical tools for routine quality control laboratories involved in pharmaceutical analysis.

Materials and Methods

Materials

Reference standards of Ofloxacin (OFLOX) and Tinidazole (TZ) were obtained as gift samples from a Zee Laboratories Pvt. Ltd. and used without further purification. Commercial tablet formulations containing Ofloxacin and Tinidazole were procured from the local pharmaceutical market. Analytical reagent (AR) grade chemicals and solvents were used throughout the study. Sodium hydroxide (NaOH) was procured from Merck (India) and prepared as 0.1 N NaOH, which served as the solvent for preparation of standard and sample solutions. Distilled water was used for cleaning glassware and preparation of reagents whenever required.

Instrumentation

Absorbance measurements were carried out using a double-beam UV–Visible spectrophotometer equipped with 1 cm matched quartz cells and UV analysis software. An electronic analytical balance with an accuracy of ±0.1 mg was employed for weighing all chemicals. Ultrasonication was performed using a laboratory ultrasonic bath to facilitate complete dissolution of the drug samples.

Preparation of Standard Stock Solution

A standard stock solution containing 1000 µg/mL of Ofloxacin and Tinidazole was prepared separately by accurately weighing an appropriate quantity of each drug and dissolving it in a small volume of 0.1 N NaOH. The solutions were sonicated for 10 minutes to ensure complete dissolution and then diluted to volume with the same solvent in a 100 mL volumetric flask. The prepared solutions were filtered through Whatman No. 41 filter paper before further dilution for analysis (Beckett & Stenlake, 2002).

Table 1. Preparation of Standard Stock Solution

Drug Combination	Solvent	Stock Concentration (µg/mL)
Ofloxacin + Tinidazole	0.1 N NaOH	1000

Selection of Analytical Wavelengths

Working standard solutions (10 µg/mL) of each drug were prepared by appropriate dilution of the stock solution with 0.1 N NaOH. The solutions were scanned over the wavelength range of 200–400 nm against solvent blank to obtain their absorption spectra. The wavelengths corresponding to maximum absorbance (λmax) of Ofloxacin and Tinidazole and the isoabsorptive point were selected for simultaneous estimation.

Table 2. Selected Analytical Wavelengths

Drug Combination	λmax of Ofloxacin (nm)	λmax of Tinidazole (nm)	Isoabsorptive Point (nm)
Ofloxacin + Tinidazole	288	298	319

Preparation of Calibration Curves

Working standard solutions of different concentrations were prepared by suitable dilution of the stock solutions using 0.1 N NaOH. The absorbance of each solution was recorded at 288 nm, 298 nm, and 319 nm. Calibration curves were constructed by plotting absorbance against concentration, and linear regression equations were obtained to establish Beer–Lambert's law over the selected concentration ranges (Skoog et al., 2018).

Simultaneous Equation (Vierordt's) Method

The simultaneous equation method is based on Beer–Lambert's law, which states that absorbance is directly proportional to concentration within the linearity range. Absorbance values of the mixed drug solution were measured at 288 nm and 319 nm, corresponding to the λmax of Ofloxacin and Tinidazole, respectively. Using the absorptivity coefficients of each drug at the selected wavelengths, simultaneous equations were constructed and solved to determine the concentration of each component in the tablet formulation (Beckett & Stenlake, 2002).

Absorbance Ratio (Q-Analysis) Method

The absorbance ratio method utilizes the isoabsorptive wavelength (298 nm) together with the λmax of one of the components. Absorbance measurements were recorded at 298 nm and 319 nm, and concentration of each drug was calculated using absorptivity values and absorbance ratios according to the standard Q-analysis equations (Jeffery et al., 1989).

Determination of Absorptivity

The absorptivity coefficients of Ofloxacin and Tinidazole at 288 nm, 298 nm, and 319 nm were determined using Beer–Lambert's equation:

$$A=\varepsilon bc$$

where

- **A** = Absorbance
- **ε** = Absorptivity coefficient
- **b** = Path length (1 cm)
- **c** = Concentration of the solution

The calculated absorptivity values were subsequently employed in both analytical methods for simultaneous estimation (Beckett & Stenlake, 2002).

Analysis of Tablet Formulation

Twenty tablets containing Ofloxacin and Tinidazole were accurately weighed, and their average weight was calculated. The tablets were finely powdered using a

mortar and pestle. A quantity of powder equivalent to the labeled amount of drug was transferred into a volumetric flask containing a small quantity of 0.1 N NaOH. The mixture was sonicated for 10 minutes to ensure complete extraction of both drugs and then diluted to the required volume with the same solvent. The solution was filtered through Whatman No. 41 filter paper, and suitable dilutions were prepared to obtain a working concentration of 10 µg/mL. Absorbance was measured at the selected analytical wavelengths, and drug contents were calculated using both developed methods.

Method Validation

The developed analytical methods were validated according to the International Council for Harmonisation (ICH) Q2(R1) guideline with respect to linearity, accuracy, precision, limit of detection (LOD), and limit of quantification (LOQ) (ICH, 2005).

Linearity

Linearity was evaluated by analyzing standard solutions over the concentration range of 2–14 µg/mL for Ofloxacin and 4–20 µg/mL for Tinidazole. Calibration curves were constructed, and regression equations and correlation coefficients (R^2) were calculated.

Accuracy

Accuracy was determined by the standard addition method at 80%, 100%, and 120% concentration levels. Pre-analyzed tablet samples were spiked with known amounts of standard drug solutions. Each concentration level was analyzed in triplicate, and percentage recovery along with percentage relative standard deviation (%RSD) was calculated. Recovery values within 98–102% and %RSD less than 2% were considered acceptable according to ICH guidelines.

Precision

Precision was evaluated as:

- Repeatability (Intraday Precision)
- Intermediate Precision (Interday Precision)

Three replicate measurements of selected concentrations were analyzed within the same day and over three consecutive days. Results were expressed as mean ± SD and %RSD. A %RSD value less than 2% indicated acceptable precision.

Limit of Detection (LOD) Limit of Quantification (LOQ)

The limit of detection was calculated using the equation:

$DL=3.3\ \sigma S$

$QL=10\ \sigma S$

where

- **σ** = Standard deviation of the response
- **S** = Slope of the calibration curve

Results and Discussion

Selection of Analytical Wavelengths

The UV absorption spectra of Ofloxacin and Tinidazole were recorded individually in 0.1 N NaOH over the wavelength range of 200–400 nm. Ofloxacin exhibited maximum absorbance (λmax) at 288 nm, whereas Tinidazole showed maximum absorbance at 319 nm. An isoabsorptive point was observed at 298 nm, where both drugs exhibited identical absorptivity. These wavelengths were selected for the development of the simultaneous equation (Vierordt's) method and absorbance ratio (Q-analysis) method. The well-resolved absorption spectra enabled simultaneous quantification of both drugs without prior separation, confirming the suitability of the selected analytical wavelengths.

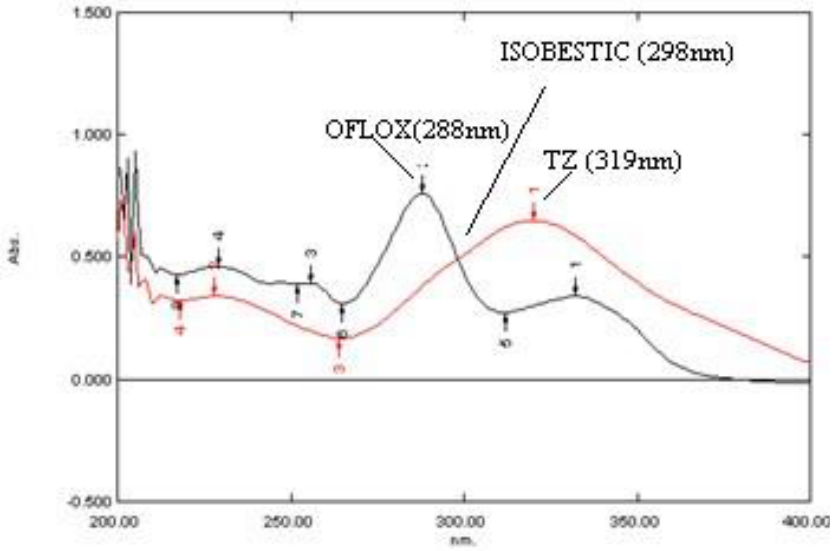

Figure 1: Overlain spectrum of OFLOX and TZ showing λmax at 288 nm and 319 nm respectively and isobestic point at 298 nm in 0.1N NaOH

Table 3: Absorbance for Ofloxacin at 288 nm, 319nm and 298nm in 0.1N NaOH

Concentration (µg/mL)	288 nm		319 nm %RSD		298 nm %RSD	
	Absorbance ± SD	%RSD	Absorbance ± SD	%RSD	Absorbance ± SD	%RSD
0	0.000 ± 0.000	0	0.000 ± 0.000	0	0.000 ± 0.000	0
2	0.156 ± 0.001	0.641	0.064 ± 0.002	3.125	0.118 ± 0.002	1.695
4	0.304 ± 0.002	0.657	0.127 ± 0.002	1.574	0.219 ± 0.006	2.739
6	0.465 ± 0.001	0.215	0.184 ± 0.005	2.717	0.318 ± 0.001	0.314
8	0.619 ± 0.001	0.162	0.234 ± 0.000	0	0.412 ± 0.007	1.699
10	0.752 ± 0.002	0.266	0.285 ± 0.001	0.35	0.502 ± 0.011	2.191
12	0.882 ± 0.000	0	0.348 ± 0.007	2.011	0.595 ± 0.002	0.336
14	1.025 ± 0.001	0.098	0.407 ± 0.006	1.474	0.687 ± 0.001	0.145

Table 4: Absorbance for Tinidazole at 288 nm, 319nm and 298nm in 0.1N NaOH

Concentration (µg/mL)	288 nm		319 nm %RSD		298 nm %RSD	
	Absorbance ± SD	%RSD	Absorbance ± SD	%RSD	Absorbance ± SD	%RSD
0	0.000 ± 0.000	0	0.000 ± 0.000	0	0.000 ± 0.000	0
4	0.165 ± 0.000	0	0.265 ± 0.000	0	0.102 ± 0.000	0
8	0.315 ± 0.002	0.634	0.525 ± 0.002	0.38	0.187 ± 0.002	1.069
12	0.441 ± 0.001	0.227	0.778 ± 0.003	0.385	0.281 ± 0.000	0
16	0.558 ± 0.004	0.716	1.016 ± 0.000	0	0.375 ± 0.003	0.8
20	0.755 ± 0.000	0	1.268 ± 0.002	0.158	0.489 ± 0.000	0

Calibration Curve and Linearity

Calibration curves for Ofloxacin and Tinidazole demonstrated excellent linearity within the investigated concentration ranges of 2–14 µg/mL and 4–20 µg/mL, respectively. The absorbance increased proportionally with concentration at all selected wavelengths, confirming compliance with Beer–Lambert's law.

Regression coefficients (R^2) ranging from 0.998 to 0.999 indicated an excellent linear relationship between concentration and absorbance. The low standard deviation values observed throughout the calibration study demonstrated good reproducibility of absorbance measurements. These findings confirm that the developed methods possess adequate sensitivity and are suitable for quantitative determination of both drugs within the selected analytical range.

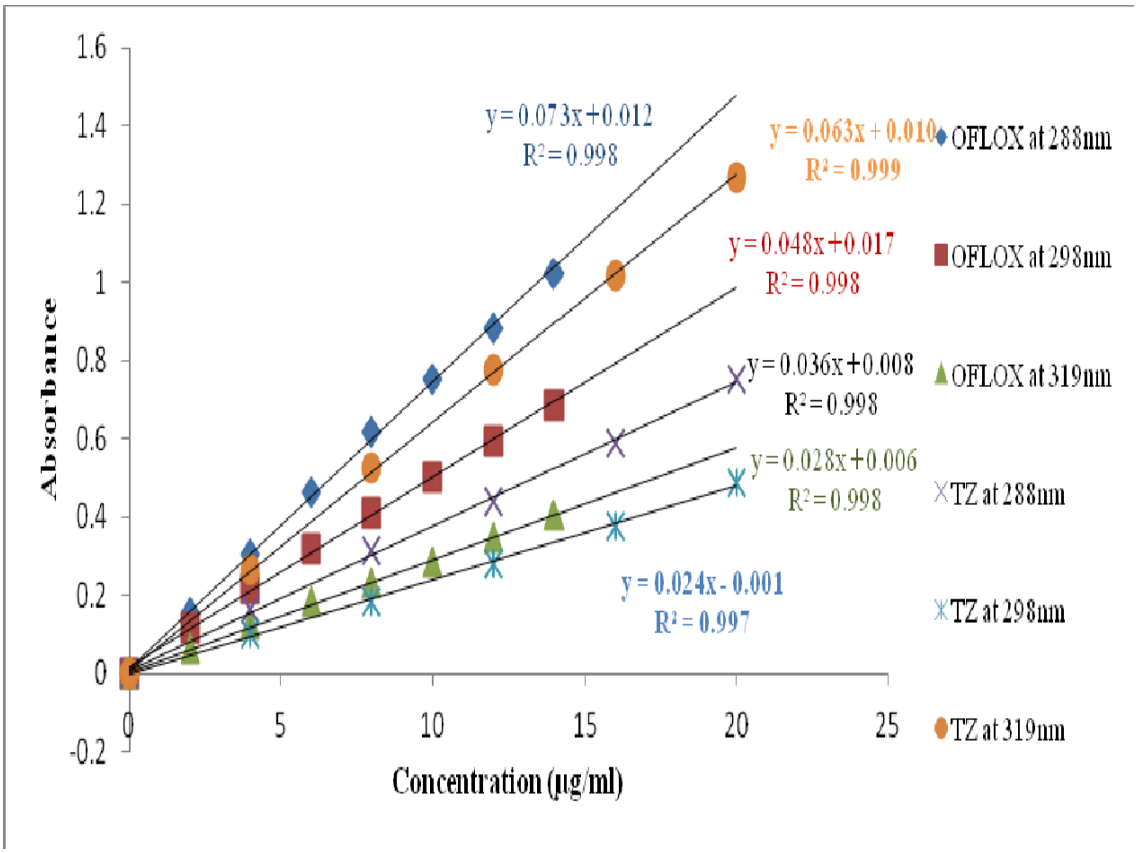

Figure 2: Linearity graphs of OFLOX and TZ plotted between concentration (µg/mL) on X-axis and absorbance on Y-axis

Optical Characteristics

The optical characteristics, including Beer's law limits, regression equations, slope, intercept, correlation coefficient, standard deviation, limit of detection (LOD), and limit of quantification (LOQ), were evaluated for both drugs at all selected wavelengths.

Both drugs exhibited high regression coefficients, indicating excellent linearity. The slopes of the calibration curves reflected adequate analytical sensitivity, while the small intercept values suggested negligible systematic error. The calculated LOD and LOQ values were sufficiently low, demonstrating that the proposed methods are capable of detecting and quantifying very small concentrations of both analytes. These parameters collectively confirm the reliability and sensitivity of the developed UV spectrophotometric methods.

Table 5: Optical Characteristics of OFLOX and TZ

Parameters	288 nm		298 nm		319 nm	
	OFLOX	TZ	OFLOX	TZ	OFLOX	TZ
Beer's law limit (µg/mL)	2–14	4–20	2–14	4–20	2–14	4–20
Regression equation	Y = mX + c	Y = mX + c	Y = mX + c	Y = mX + c	Y = mX + c	Y = mX + c
Slope (m)	0.073	0.036	0.048	0.024	0.028	0.063
Intercept (c)	0.012	0.008	0.017	0	0.006	0.01
Correlation coefficient (R^2)	0.998	0.998	0.998	0.998	0.998	0.999
Standard deviation (SD)	0.001	0.002	0.004	0.001	0.002	0.001
Limit of detection (LOD, µg/mL)	0.045	0.183	0.275	0.137	0.235	0.052
Limit of quantification (LOQ, µg/mL)	0.137	0.556	0.833	0.417	0.714	0.159

Absorptivity Studies

The absorptivity coefficients of Ofloxacin and Tinidazole were determined at 288 nm, 298 nm, and 319 nm to facilitate simultaneous estimation using both analytical methods.

Ofloxacin exhibited maximum absorptivity at 288 nm, whereas Tinidazole showed the highest absorptivity at 319 nm. At the isoabsorptive wavelength (298 nm), both drugs produced suitable absorptivity values, allowing accurate application of the absorbance ratio method. The distinct absorptivity differences at the selected wavelengths ensured accurate mathematical resolution of both components in the combined dosage form.

Table 6: Absorptivity Values of Ofloxacin and Tinidazole at Selected Analytical Wavelengths

Component	Absorptivity at 288 nm	Absorptivity at 319 nm	Absorptivity at 298 nm
Ofloxacin (OFLOX)	75.8	30	52.4
Tinidazole (TZ)	38.4	64.7	24

Assay of Commercial Tablet Formulation

The developed analytical methods were successfully applied for simultaneous estimation of Ofloxacin and Tinidazole in marketed tablet formulations.

Method I estimated the drug content as 100.90 ± 0.070% for Ofloxacin and 99.92 ± 0.050% for Tinidazole. Similarly, Method II produced assay values of 100.40 ± 0.048% and 100.10 ± 0.022% for Ofloxacin and Tinidazole, respectively.

All assay values were within the pharmacopeial acceptance limit of 98–102%. Furthermore, the low %RSD values (<2%) indicated excellent repeatability and consistency of both methods. These results demonstrate that both spectrophotometric methods are suitable for routine quality control analysis of combined tablet formulations.

Table 7: Assay of OFLOX and TZ in tablets

Drug	Amount Taken	Absorbance (Mean, n = 3)		Amount Found (mg)		Drug Content (% ± SD, n = 3)		%RSD	
		Method I	Method II	Method I	Method II	Method I	Method II	Method I	Method II
Ofloxacin (OFLOX)	10 mg	1.175	1.012	10.09	10.04	100.90 ± 0.070	100.40 ± 0.048	0.069	0.048
Tinidazole (TZ)	10 mg	0.984	0.763	9.992	10.01	99.92 ± 0.050	100.10 ± 0.022	0.05	0.022

Accuracy (Recovery Studies)

Accuracy was evaluated using the standard addition method at 80%, 100%, and 120% concentration levels.

Percentage recovery values ranged from 99.76% to 100.41% for both drugs using both analytical methods. The recovery values were close to 100%, indicating that tablet excipients did not interfere with the estimation process.

Moreover, all %RSD values remained below 2%, satisfying ICH acceptance criteria for analytical accuracy. The recovery results clearly demonstrate that both methods accurately estimate Ofloxacin and Tinidazole in pharmaceutical formulations without significant analytical bias.

Table 7: Recovery Studies for OFLOX and TZ

Drug	Amount Present (mg/mL)	Standard Drug Added (mg/mL)	Method I			Method II		
			Amount Recovered (mg/mL)	% Recovery ± SD (n = 3)	%RSD	Amount Recovered (mg/mL)	% Recovery ± SD (n = 3)	%RSD
OFLOX	10	80% (8 mg)	18.02	100.09 ± 0.711	0.71	18.06	100.35 ± 0.930	0.927
	10	100% (10 mg)	20.02	100.10 ± 0.701	0.701	20.09	100.41 ± 0.017	0.017
	10	120% (12 mg)	22	100.00 ± 0.448	0.448	22.09	100.41 ± 0.434	0.432
TZ	10	80% (8 mg)	17.96	99.76 ± 0.945	0.947	18.06	100.31 ± 0.431	0.43
	10	100% (10 mg)	19.99	99.97 ± 0.777	0.777	19.99	99.93 ± 0.666	0.667
	10	120% (12 mg)	21.96	99.83 ± 0.914	0.916	22.04	100.17 ± 0.233	0.233

Precision Studies

Precision was evaluated by determining intra-day and inter-day variability.

The intra-day precision study produced %RSD values ranging from 0.392 to 1.330%, while inter-day precision values ranged from 0.256 to 0.776%. Since all %RSD values were well below the acceptable limit of 2%, both methods demonstrated excellent repeatability and intermediate precision.

The small variation between repeated measurements confirms that the proposed analytical procedures are highly reproducible and suitable for routine laboratory analysis.

Table 8: Precision Studies for OFLOX and TZ

Parameter	Method I		Method II	
	Intra-Day (n = 3)	Inter-Day (n = 3)	Intra-Day (n = 3)	Inter-Day (n = 3)
	OFLOX	TZ	OFLOX	TZ
Mean (% ± SD)	102.96 ± 0.0404	102.50 ± 0.137	103.00 ± 0.0264	101.00 ± 0.0435
Precision (%RSD)	0.392	1.33	0.256	0.425

Comparison of Method I and Method II

Both the simultaneous equation method (Method I) and the absorbance ratio method (Method II) produced comparable analytical results for assay, recovery, and precision studies.

Method I showed slightly higher assay values for Ofloxacin, whereas Method II demonstrated marginally better precision with lower %RSD values. However, the differences between the two methods were statistically insignificant and remained within acceptable validation limits. Therefore, both analytical approaches can be employed interchangeably for routine quality control depending on laboratory requirements and instrument availability.

Conclusion

The present investigation successfully developed two UV spectrophotometric methods for simultaneous estimation of Ofloxacin and Tinidazole in combined tablet dosage forms. The selected analytical wavelengths (288 nm, 298 nm, and 319 nm) enabled accurate quantification of both drugs without prior separation. Calibration studies demonstrated excellent linearity with correlation coefficients exceeding 0.998, confirming compliance with Beer–Lambert's law.

Validation studies performed according to ICH guidelines established the reliability of the developed methods. Recovery values close to 100%, assay values within pharmacopeial specifications, and precision studies with %RSD below 2% demonstrated excellent accuracy and reproducibility. The low LOD and LOQ values further confirmed the sensitivity of the methods for quantitative pharmaceutical analysis.

Compared with chromatographic techniques such as HPLC, the proposed UV spectrophotometric methods offer several advantages, including simplicity, rapid analysis, low operational cost, minimal sample preparation, and absence of expensive solvents or complex instrumentation. Consequently, the developed methods are highly suitable for routine quality control of combined Ofloxacin and Tinidazole tablet formulations in pharmaceutical industries, quality control laboratories, and academic research settings.

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