

“UV- Spectrophotometry Method for Validation of Tinidazole Tablets”

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Abstract

Background: Pharmaceutical analysis plays a vital role in ensuring the quality, safety, and efficacy of drugs. UV-Visible spectroscopy, being simple, rapid, and economical, is widely used for routine drug estimation. This study aimed to develop and validate a UV spectrophotometric method for the estimation of tinidazole in bulk and tablet dosage forms.

Method: Tinidazole was dissolved in methanol, which was selected as the suitable solvent. The λ_{max} was determined at 282 nm. Calibration curves were prepared in the concentration range of 20–100 $\mu\text{g/mL}$. The developed method was validated according to ICH guidelines for linearity, precision, accuracy, robustness, LOD, and LOQ.

Results: Tinidazole exhibited good linearity with regression equation $y = 0.074x + 0.1209$ and correlation coefficient ($R^2 = 0.9961$). The method showed excellent precision with $\%RSD < 2\%$ for intra-day and inter-day studies. The LOD and LOQ were found to be 0.8 $\mu\text{g/mL}$ and 2.43 $\mu\text{g/mL}$, respectively. Accuracy studies revealed recovery values close to 100%, while robustness confirmed reliability. The assay of marketed tablets showed drug content of 99.84%.

Conclusion: The developed UV spectrophotometric method is simple, accurate, precise, robust, and cost-effective. It is suitable for routine quality control and quantitative analysis of tinidazole in pharmaceutical formulations, offering a reliable alternative to more complex techniques such as HPLC.

Keywords: Tinidazole, UV spectrophotometry, Method validation, ICH guidelines, Pharmaceutical analysis, Drug assay

Introduction:

Pharmaceutical analysis is a branch of practical chemistry concerned with the identification, quantification, purification, and structural determination of pharmaceutical substances, whether single compounds or mixtures. It employs both qualitative (identification of components) and quantitative (estimation of concentration) methods using techniques such as chemical reactions, spectrophotometry, and electrical measurements.

Among these, UV-Visible spectroscopy is widely used due to its simplicity, rapidity, and cost-effectiveness. It measures the absorption of light by molecules, governed by Beer-Lambert's Law, which relates absorbance to concentration. Different molecules exhibit characteristic absorption spectra, making this technique valuable in drug analysis.

Benzimidazole anthelmintics like albendazole and mebendazole are essential in treating helminthic infections, while tinidazole, a nitroimidazole derivative, is used for protozoal infections. Although HPLC is commonly employed for their analysis, it is expensive and requires skilled handling. In contrast, UV spectroscopic methods offer faster, simpler, and more accessible alternatives for routine pharmaceutical analysis.

Materials and Methods:**Materials:**

Tinidazole was gifted as a gift sample from Unique Chemicals Mumbai India. Analytical grade methanol (solvent) was procured from local market which is of Loba Chemie Pvt. Ltd.

Methods:**Selection of Solvent**

Drugs is dissolved in different solvent medium (Water, Acetonitrile, Methanol, Ethanol and Dimethyl sulfoxide). 100 mg of Tinidazole was weighed and taken to dissolve in each solvent from which Methanol is best suited and opted as the solvent medium for further procedure.

Preparation of Standard Stock Solution

100 mg of the reference drug Tinidazole was precisely weighed and then dissolved in 50

ml of solvent (methanol), which was then added to a 500 ml volumetric flask and subjected to a 10-minute sonication process. The volume is then brought up to the required level using the aforementioned solvent to obtain the desired stock solution concentration of 200 $\mu\text{g/ml}$.

Determination of λ_{max}

Tinidazole standard solutions were properly diluted with methanol, and solutions containing concentration of 20 $\mu\text{g/mL}$ of each drug were independently scanned in the 200–700 nm range against methanol as a blank. Tinidazole shows λ_{max} at 282m (Fig.1)

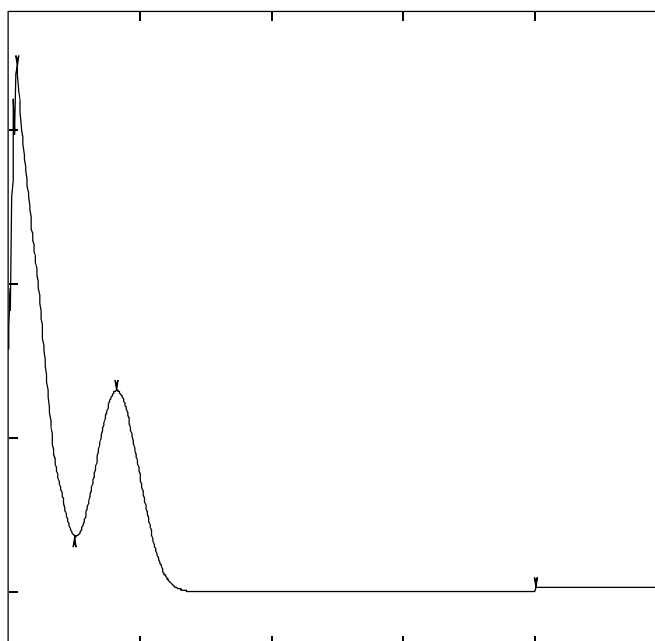


Figure 1: Spectrum of Tinidazole

Calibration curves of tinidazole

The tinidazole stock solution was diluted in distilled water serially to a concentration range of 20-100 $\mu\text{g/ml}$ tinidazole. A calibration curve of concentration versus measured absorbance was plotted. The spectral characteristics of tinidazole are given in Table 1.

Assay procedure

Twenty Amebamagma® -300 mg tablets were weighed and powder equivalent to 100 mg of tinidazole was transferred to a 100 ml volumetric flask followed by ultrasonication for 15 min. The resultant solution was filtered through Whatman filter paper no. 41 into a second 100 ml volumetric flask. The filter paper was washed several times with methanol. The washings were added to the filtrate and final volume was made up to 100

ml with methanol. 1 ml of filtrate of the sample solution was diluted to 10 ml with methanol. These were treated as per the procedure for preparation of a calibration curve and amount of the drug present in sample computed from respective calibration curve.

Validation of proposed method

The method was evaluated for linearity, sensitivity, accuracy, and precision for each analyte in accordance with ICH recommendations for the validation of analytical processes.

Results:

The developed method was validated as per ICH guidelines.

Linearity

The response of tinidazole was found to be linear in the concentration range of 20-100 µg /mL and linear regression equation was $y = 0.074x + 0.1209$ with correlation regression of 0.9961. Linearity tale and Calibration curve has been shown below.

Table 1: Linearity study of Tinidazole

Concentration (µg /ml)	Absorbance at 282 nm (n = 3)
20	0.5087
40	0.8280
60	1.2153
80	1.7553
100	1.9440

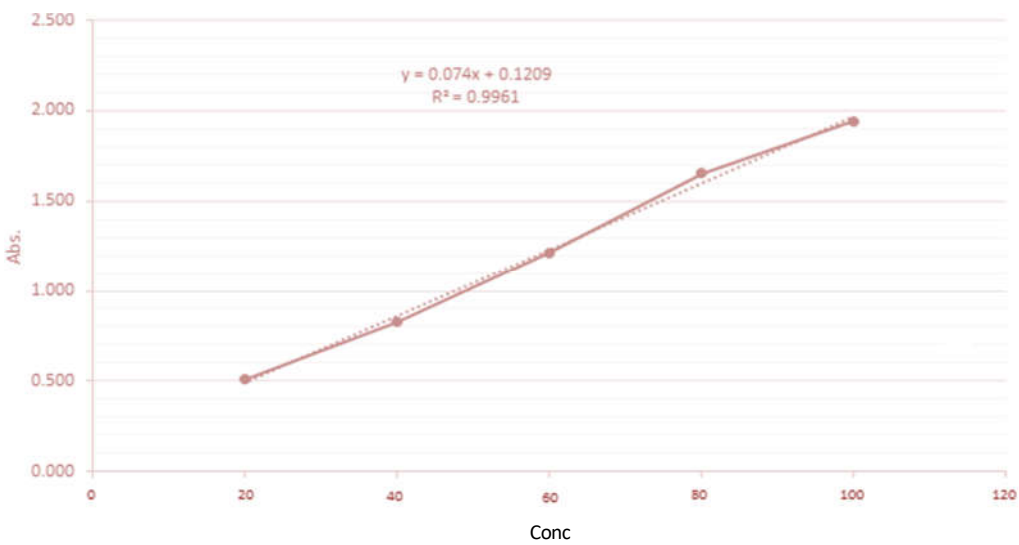


Figure 2: Calibration Graph of Tinidazole

Precision

Repeatability studies, intraday precision and inter day precision studies carried out for tinidazole and %RSD values were < 2%. Thus, the method developed was found to be precise.

Table 2: Precision study of Tinidazole (Intraday)

Parameter	Absorption at 0 Hr	Absorption at 2 Hr	Absorption at 4 Hr	Absorption at 8 Hr
Intraday (n = 6)	1.3354	1.3215	1.3321	1.3215
	1.3242	1.3321	1.3451	1.3568
	1.3520	1.3345	1.3214	1.3211
	1.3440	1.3541	1.3542	1.3112
	1.3200	1.3420	1.3421	1.3211
	1.3452	1.3501	1.3554	1.3102
Mean	1.3368	1.33905	1.341717	1.320983
SD	0.012621	0.012119	0.013114	0.011000
%RSD	0.944092	0.905023	0.977418	0.832705

Table 3: Precision study of Tinidazole (Interday)

Parameter	Absorption in Day 1	Absorption in Day 2	Absorption in Day 3
Interday (n = 6)	1.3354	1.3201	1.3136
	1.3242	1.3101	1.2994
	1.3520	1.3342	1.3216
	1.3440	1.3226	1.3147
	1.3200	1.3145	1.3201
	1.3452	1.3232	1.3105
Mean	1.3368	1.320783	1.313317
SD	0.012621	0.008285	0.007978
%RSD	0.944092	0.627300	0.607456

LOD and LOQ

LOD and LOQ were determined using the response and slope of the regression equation. The LOD 0.8 µg/ml and LOQ was found to be 2.43 µg/ml.

Accuracy

The mean recovery for Tinidazole was found to be respectively and %RSD was <2%. The method was found to be accurate as per the results obtained.

Table 4: % Recovery of Tinidazole Tablet

Level	Set No.	% Recovery	%Mean Recovery	SD	% RSD
80%	1.	99.81	99.75	1.72	1.72
	2.	101.5			
	3.	98.06			
100%	1.	98.85	98.98	0.16	0.16
	2.	99.15			
	3.	98.9			
120%	1.	98.75	98.54	0.23	0.24
	2.	98.29			
	3.	98.62			

Robustness

Wavelength was altered and checked for the robustness of the developed method. Results obtained showed % RSD <2% indicating the method to be robust.

Table 5: Robustness of Tinidazole

Parameter	Absorbance at 281nm	Absorption at 282nm	Absorption at 283nm
(n = 6)	1.3254	1.3201	1.3236
	1.3142	1.3101	1.3194
	1.3239	1.3242	1.3216
	1.3240	1.3226	1.3147
	1.3201	1.3192	1.3201
	1.3250	1.3232	1.3105
Mean	1.322	1.320	1.318
SD	0.004	0.005	0.005
%RSD	0.326	0.391	0.367

Assay of formulation

The drug content of the formulation is found to be 99.84%.

Table 6: Drug content of formulation

Sl. No.	Content (%)
1.	100.09
2.	99.77
3.	99.68
Mean	99.84
S.D.	0.215
%RSD	0.215

Conclusion:

For the determination of tinidazole in bulk and tablet dosage forms, the current work effectively developed a straightforward, accurate, precise, and economical UV spectrophotometric approach. The medication showed a clear absorption maximum at 282 nm, and methanol was found to be an ideal solvent. With a correlation coefficient (R^2) of 0.9961, the method showed excellent linearity throughout the concentration range of 20–100 $\mu\text{g/mL}$ and was verified in accordance with ICH criteria. Studies on precision, accuracy, robustness, LOD, and LOQ validated the method's sensitivity and dependability. The laboratory findings showed a 99.84% drug content, confirming that the devised approach can be used for regular tinidazole formulation quality control. Thus, especially for regular pharmaceutical examination, the suggested UV spectroscopic method offers a quick and affordable substitute for more complex methods like HPLC.

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