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ORIGINAL ARTICLE **OPEN ACCESS**

Analytical Process of Developments and Validation for the Estimations of Secnidazole in Bulk and Tablet Dosage Form by Using UV-Spectroscopy

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ABSTRACT
Secnidazole is a medicine from the group of 5-nitro-imidazole which is used in the treatment of protozoa and several bacterial infections. The goals of this study is to create as well as test a simple, cost effectives, and sensitive method, UV-Spectrophotometric methods for the analysis of Secnidazole. The quantification was performed using distilled water as solvent at 319 nm (wavelength maxima). The standardization graph was originated to be linear (r^2 =0.0999) over concentrations levels of 1-10µg/ml.When examined for characteristics like accuracy, precision, and ruggedness for routine determination of Secnidazole in bulk and tablet, the suggested procedures seem to be simple, sensitive, and repeatable. The suggested and developed UV-Spectrophotometric technique may be used to quantify Secnidazole in bulk drugs as well as pharmaceutical formulations.
Keywords: *Formulation, Pharmaceutical, Quantification, Secnidazole, Spectroscopy, Validation.*

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INTRODUCTION

Secnidazole is a nitroimidazole drug that is described chemically as One-(Two-hydroxypropyl)-2-methyl–5–nitroimidazole as shown in Figure 1[1].

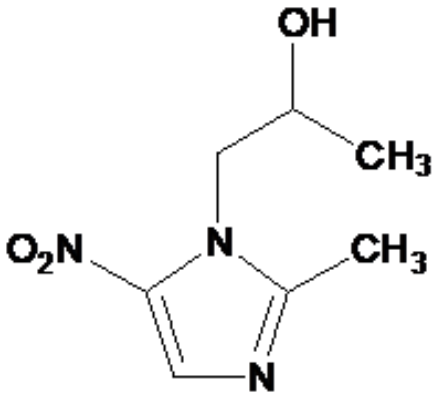

Figure 1: The above figure represents the Chemical structure of Secnidazole.

It is an antifungal and antiprotozoal medicine used to treat giardiasis, trichomoniasis, amoebiasis, as well as bacterial vaginal infections. After oral treatment, secnidazole is entirely absorbed [2][3]. Abdominal discomfort, disorientation, neurological disruption, and headache are all side effects of secnidazole[4][5]. The medicine is a crystalline powder that is white to off-white in color, odorless, and soluble in water, methanol, DMSO, and 1, 2-dichloroethane. Different techniques for quantifying Secnidazole have been described in the literature[6]. These include UV–Spectrophotometric [7],HPLC, UPLC, and other methods that have been performed for the determination in the organisation of protozoal infections as well as anaerobic bacterial infections.

The majority of the known methods for determining Secnidazole in the pharmaceuticalsdosage form are time-consuming, costly, and sophisticated [8]. Only a few strategies for pharmacological dose forms in economic form have been devised and confirmed.[9]. As a result, our research findings provide a straight

forward, accurate, and cost-effective UV Spectrophotometric technique for determining Secnidazole in bulk and tablet formulations.

MATERIAL AND METHODS

A Shimazdu twin beam UV-Visible Spectrophotometer model 1800 was used for the spectrophotometric measurements.

Reagents:

Balaji Drugs Ltd. in Gujarat provided the secnidazole. Throughout the test, distilled water was utilized as a solvent, which was provided from the Jaipur National University laboratory. A local pharmacy provided the pharmaceutical preparation.

Standard Solution:

To achieve a concentration of 100µg/ml, the pure medication was weighed properly and diluted in 100µg/ml triple distilled water. The calibration curve approach was used in this study. 1g/ml to 10g/ml was shown to be the linearity range.

Calibration Curve Method:

This approach involves measuring the absorbance of a series of standards solutions of references material at attentions that cover the sample concentration as well as creating a calibrations graph. For determining absorbance, which has a non-linear relationship with concentration, the calibration curve approach is required.

Preparation of Calibration Curve:

The highest absorption wavelength was found to be 319 nm. To obtain a calibration curve, the absorbance at 319 nm of six standard solutions with concentrations ranging from 1, 2, 4, 6, 8, 10 µg/ml was plotted versus concentration.

Preparation of standard stock solutions:

10 mg Secnidazole was weighed as well as placed to a 100 ml volumetric flask, where it was dissolved in distilled water and the quantity was brought up to mark using the same solvent to achieve a concentration of 100g/ml. The solution was further diluted suitably to obtain concentration range of 1, 2, 4, 6, 8, 10 µg/ml.

Method Validation:

Linearity:

For the spectrophotometric approach, the analytical curves were produced with six concentrations of reference solution in the range of 1-10 µg/ml. All of the experiments were done in duplicate. Linear regression analysis was utilized to determine the linearity by calculating the correlation coefficient and slope of the regression line.

Precision:

Repeatability (intra-day) and intermediate precision were used to measure precision (inter-day). Working standard Secnidazole solutions at the same concentration and on the same day were analyzed for repeatability. The assay's repeatability was investigated by comparing it to three independent replicas of each sample, for a total of five samples at a concentration of 6 g/ml. At 319 nm, the data was analysed. The percentages of the analytical response's relative standard deviation (percent R.S.D.) were computed.

Accuracy:

Recovery experiments were carried out at three distinct levels of 75 percent, 100 percent, and 125 percent to confirm the correctness of the procedure, and the results were tabulated.

Ruggedness:

The method's robustness was tested by having two separate analyzers detect 4 µg/ml of Secnidazole under identical experimental and ambient circumstances.

RESULTS AND DISCUSSION

The calibration curve was used to compute the sample solutions as well as measured at 319nm versus water are shown in Figure 2 and Figure 3.

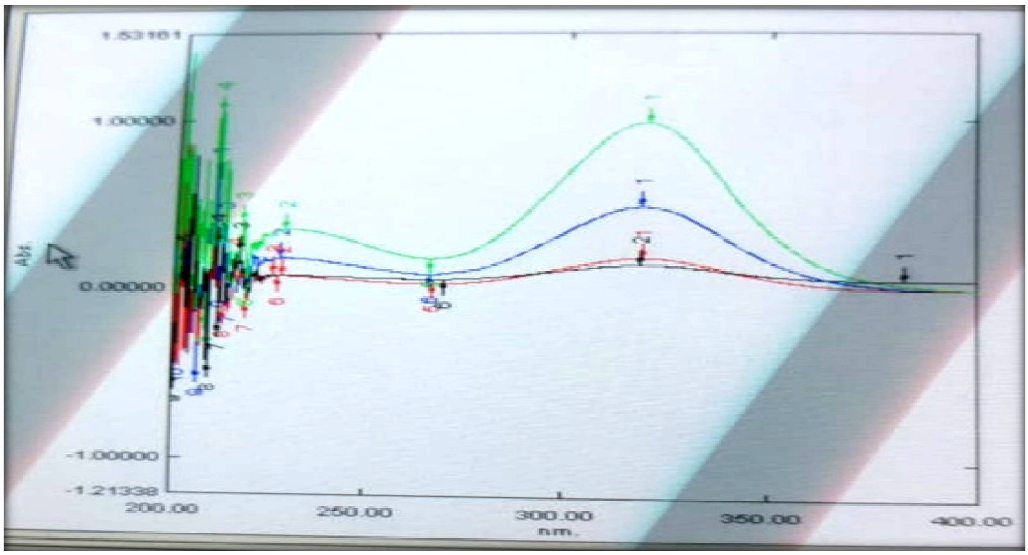

Figure 2: Illustrates the UV spectra of Secnidazole shows λ max at 319nm.

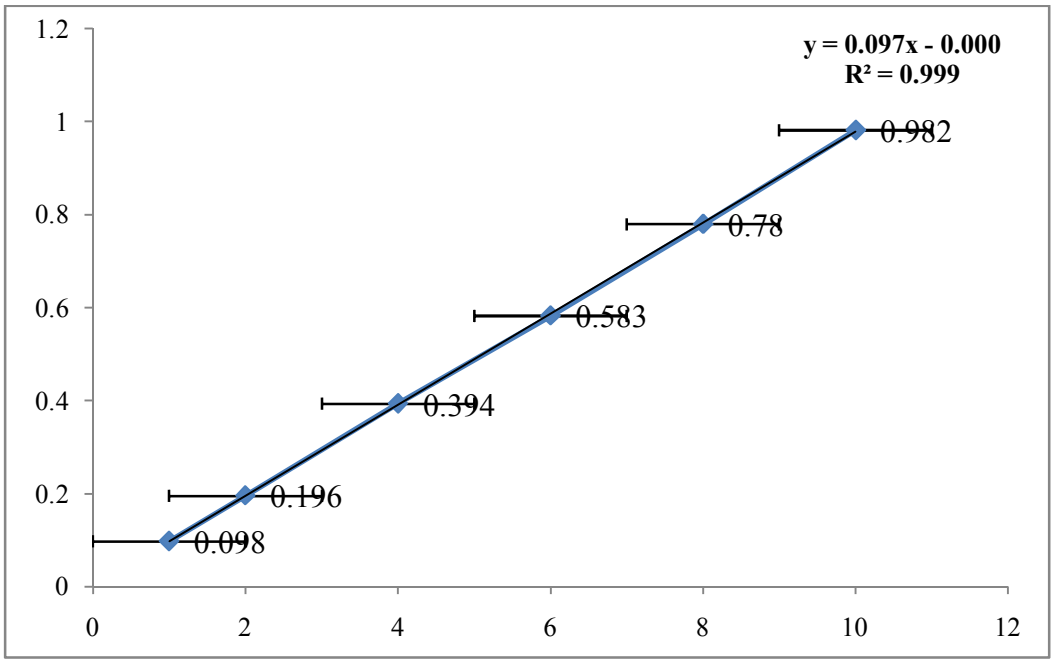

Figure 3: The Calibration Curve is a technique of determining a drug's concentration in an unknown compound by comparing it to a collection of known dosage reference samples.

Secnidazole is an antiprotozoal drug that belongs to the 5-nitroimidazole class of drugs. It has a lengthy serum half-life. Secnidazole is an anti-infective nitroimidazole. It is effective in the treatment of dientamoebiasis. It's also been shown to be effective against the Atopobiumvaginae. Secnidazole is licensed in the United States for the treatment of bacterial vaginosis in adult women, study of Secnidazole are shown in Table 1.

Table 1: The below Table Illustrates the Linearity Study of Secnidazole.

Concentrations (µg/mL)	Absorbance	SD*	%RSD
1	0.098	0.001	0.102
2	0.196	0.00115	0.587
4	0.394	0.00057	0.144
6	0.583	0.00057	0.0977
8	0.780	0.001	0.128
10	0.982	0.002	0.203

Optical Parameters:
The optical properties of the techniques, such as Beer's law limitations and correlation coefficient, were determined, and the findings were presented in Table 2.

Table 2: Optical Parameters, it is Material's Optical Characteristics Determine how it Interacts with Light.

S.No.	Parameters	Observation
1	λ max	319 nm
2	Beer's law limit (µg/mL)	1-10 µg/mL
3	Regression equation *	Y=0.0979x-0.0001
4	Correlation Coefficient (r^2)	0.9999
5	Slope	0.0979

Identification:
The FTIR result shows different peak ranges of Secnidazole which confirms the presence of the organic compounds init. Thus results confirmed the identification of $C_7H_{11}N_3O_3$ on analyzed samples (Figure 4).

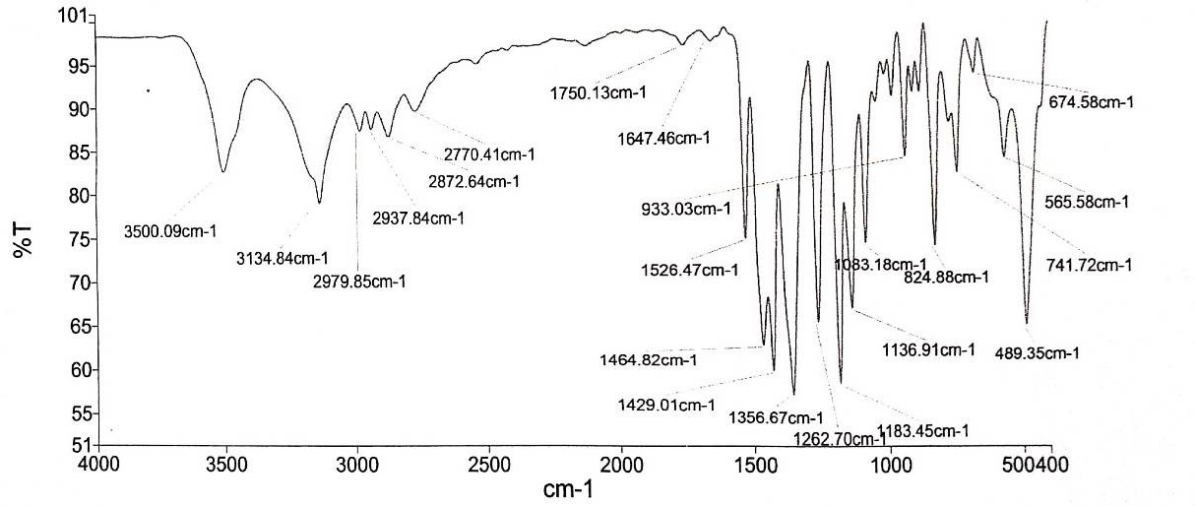

Figure 4:Illustrates the growth and validation of a novel maintainable analytical approach for identifying and quantifying secnidazole tablets using the Fourier-transforms infrared spectroscopy (FT-IR).

The frequency of molecular vibrations correlate to IR wavelengths. Because each vibration comprises a specific set of atoms and a specific motion such as stretching, bending, or wagging, molecules vibrate at a variety of frequencies are shown in Table 3.

Table 3: The below Table Represents the Peak data of IR (Infrared) Spectrum.

BOND	FREQUENCY RANGE(cm^{-1})	PEAK OBSERVED(cm^{-1})
C-H (alkane)	2850-2970 1340-1470	1356 1429 1464
C-H (aromatic)	3010-3100 690-900	824.88
C=C (aromatic)	1500-1600	1526.47
C-N	1180-1360	1183.45 1262.70 1356.67
O-H	3590-3650 3200-3600 3500-3650 2500-2700	3134.84 3500.09
C-O	1050-1300	1083.18 1136.91 1183.45 1262.70

Precision

Repeatability (intra-day) and intermediate precision were used to measure precision (inter-day). Working standard Secnidazole solutions at the same concentration and on the same day were analysed for repeatability. Precision refers to how near the measurements are to each other, while accuracy refers to how close they are to a particular value in a set of measurements. Precision was performed and the %RSD (Reflex Sympathetic Dystrophy) was found to be 0.344.

Repeatability:

Table 4 shows the repeatability precision data for secnidazole.

Table 4: Illustrates the Repeatability precision data for Secnidazole.

CONCENTRATION (µg/mL)	SAMPLE NO.	ABSORBANCE	AVERAGE ABSORBANCE	SD
6	1	0.580	0.581	0.003215
		0.585		
		0.579		
	2	0.583	0.581	0.002
		0.581		
		0.579		
	3	0.579	0.580	0.00152
		0.582		
		0.580		
	4	0.582	0.582	0.001528
		0.581		
		0.584		
	5	0.586	0.585	0.0020
		0.583		
		0.587		
AVERAGE OF ABSORBANCE	0.581			
AVERAGE SD	0.002			
%RSD	0.344%			

Intraday:

The percentage of RSD was found to be >1% for intra-day (Table 5).

Table 5: The Table shows the Intra-day precision data for Secnidazole.

Drug	Concentrations (µg/mL)	Absorbance	SD	%RSD
SECNIDAZOLE	2	0.194	0.000577	0.2974
	4	0.393	0.001	0.2544
	6	0.584	0.002	0.3424

Inter-day:

The %RSD was found to be >1% for inter-day(Table 6).

Table 6: Illustrates the Inter-day precision data for Secnidazole.

Drug	Concentrations (µg/mL)	Absorbance	SD	%RSD
SECNIDAZOLE	2	0.190	0.001	0.526
	4	0.389	0.00305	0.784
	6	0.581	0.00513	0.882

Ruggedness

The result for Ruggedness evaluation gives RSD below 1% suggest the method is rugged to changes (Table 7).

Table 7: The below Table Illustrates the Results for Ruggedness.

S No.	Conc.	Secnidazole	
		Analyst I	Analyst II
1	4 µg/Ml	0.390	0.393
2		0.394	0.397
3		0.392	0.393
4		0.391	0.394
5		0.390	0.391
6		0.391	0.395
Mean±SD		0.391±0.0015	0.393±0.0025
RSD		0.383%	0.636%

A: Mean of six purposes
B: Ruggedness study were carried out using diverse analysts.
Accuracy:
Accuracy was performed and % Recovery was found to be 98.42% to 100.33% for Secnidazole (Table 8).

Table 8: The below Table shows the Percentage of Recovery data for Secnidazole.

Recovery Level	Initial Sample Conc. (µg/L)	Conc. Of Standard Drug Added (µg/mL)	Total Conc. (µg/m)	Absorbance	Amounts of Drug Recovered (µg/mL)	%Recovery
75%	4	3	7	0.681	6.91	98.71%
				0.683	6.93	99.00%
				0.679	6.89	98.42%
100%	4	4	8	0.781	7.92	99.00%
				0.779	7.90	98.75%
				0.784	7.95	99.37%
125%	4	5	9	0.890	9.03	100.33%
				0.889	9.02	100.22%
				0.885	8.98	99.77%

CONCLUSION

Thus, after checking for criteria such as accuracy, precision, and ruggedness for routine determination of Secnidazole in bulk and tablet, it can be stated that the procedures used in this study were simple, sensitive, and repeatable. The recommended processes seem to be straightforward, sensitive, and repeatable when tested for features such as accuracy, precision, as well as ruggedness for routine assessment of secnidazole in bulk and tablet. The calibration curve was used to determine the sample solution, which was then measured at 319nm vs water. The calibration curve was used to compute the sample solutionas well as measured at 319nm versus water. For intra-day, the percent RSD (Reflex Sympathetic Dystrophy) was determined to be >1%. For inter-day, the percent RSD was determined to be >1%. The fact that the RSD for the Ruggedness assessment is less than 1% indicates that the approach is resistant to modification. Secnidazole was tested for accuracy, and the percent recovery was determined to be 98.42 percent to 100.33 percent.

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