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UV-SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF SECNIDAZOLE IN BULK AND TABLET DOSAGE FORM

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ABSTRACT

A simple, precise and accurate UV-Spectrophotometric method has been developed and validated for estimation of secnidazole in bulk and tablet dosage form. It shows maximum absorbance at 313 nm with methanol and water (30:70). Estimation was carried out by A(1%1cm) and by comparison with standard. Calibration graph was found to be linear (r^2 =0.09998) over concentration range of 1-4µg/ml. The proposed methods appear to be simple, sensitive, and reproducible when checked for parameters like accuracy, precision, limit of detection for routine determination of secnidazole in bulk as well as in tablet. The methods can be adopted in its routine analysis.

INTRODUCTION: Secnidazole which is an antifungal, antiprotozoal drug is used in treatment of amoebiasis, giardiasis, trichomoniasis, and bacterial vaginasis [1]. Chemically it is (RS)-1-(2-methyl-5-nitroimidazole-1yl) propane-2-ol [2]. Secnidazole interferes with electron transport in metabolic pathways. The drug is white to off white crystalline powder, odorless, soluble in water, methanol, ethyl acetate, and 1, 2-dichloroethane [3]. Literature survey revealed very few analytical methods which include only HPLC method for estimation of secnidazole. No validated UV-spectrophotometric studies on secnidazole individually in pharmaceutical preparation have been found in literature.

MATERIALS AND METHODS: The spectrophotometric measurements were carried out using a Schimadzu double beam UV-Visible Spectrophotometer model 1700 with 1cm matched quartz cell.

Reagents: Secnidazole was obtained as a gift sample from Agio pharmaceutical Pvt. Ltd., Pune, Maha rashtra. Methanol: double distilled water (30:70) used as solvents throughout the experimentation. Pharmaceutical preparation was purchased from local industry.

Standard Solution: The pure drug of about 10 mg was weighed accurately and dissolved in solvent methanol: water (30:70) to get the concentration of 100µg/ml.

Three different methods applied were calibration curve method, single point standardization and two point bracketing method. Solvent system selected was Methanol: Water (30:70). The linearity range was found to be 1µg/ml to 4µg/ml.

Calibration Curve Method [4]: In this method, absorbances of a set of standard solutions of reference substance at concentration encompassing the sample concentration are measured and calibration graph is constructed. Calibration curve method is essential for determination of absorbance which has a non-linear relationship with concentration.

Preparation of Calibration Curve: Wavelength of maximum absorption was found to be 313 nm. The absorbance at 313 nm of eight standard solutions

having the concentration range from 1 - 4µg/ml was plotted against concentration to get calibration curve.

Analysis of Tablet Formulation: The tablet solution was prepared in methanol AR grade (30ml) and was further diluted with double distilled water (70ml) as described earlier. The concentration of 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0 µg/ml. Solutions were prepared respectively and the absorbances were measured. The values of absorbance were kept in the calibration curve equation as started above and concentration was evaluated.

Single Point Standardization [4]: The single point standardization procedure involves the measurement of the absorbance of a sample solution and of a standard solution of a reference substance having same concentration. The concentration of substance in the sample is calculated from the proportional relationships that exist between absorbance and concentration.

$$C_{test} = \frac{A_{test} \times C_{std}}{A_{std}}$$

Where, C_{test} and C_{std} are the concentration in sample and standard solution respectively. A_{test} and A_{std} are the absorbance of the sample and standard solution respectively.

Analysis of Tablet Formulation: Tablet solution was prepared in methanol AR grade (30ml) and distilled water (70ml) as described earlier. The concentration of 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0 µg/ml solutions were prepared respectively and the absorbance were measured. The obtained absorbance value were put in above equation, concentration were calculated.

Double Point Bracketing Method [4]: Double point bracketing method is required to determine the concentration of sample solution. The concentration of one standard solution is greater than that of sample solution, while other standard solution has lower concentration than sample. The concentration of substance in sample solution is given by equation.

$$C_{test} = \frac{(A_{test}-A_{std1})(C_{std1}-C_{std2}) + C_{std1}(A_{std1}-A_{std2})}{A_{std1}-A_{std2}}$$

Where, Std_1 refers to standard solution with high concentration. Std_2 refers to standard solution with low concentration.

Analysis of Tablet Formulation [4]: Tablet solution was prepared in methanol AR grade (30ml) and distilled water (70ml) as described earlier. The concentration of 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0 µg/ml solutions were prepared respectively and the absorbance were measured. The obtained absorbance value were put in above equation, concentration were calculated.

Validation of Methods: The proposed methods were validated with respect to linearity, precision and accuracy.

RESULTS AND DISCUSSION: The absorbance was measured at 313nm against methanol and the sample solution was computed from calibration curve (**fig. 1 & fig. 2**).

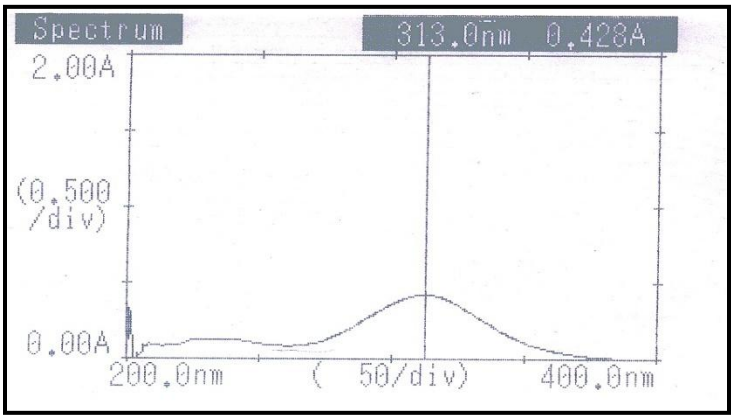

FIG. 1: λ_{max}

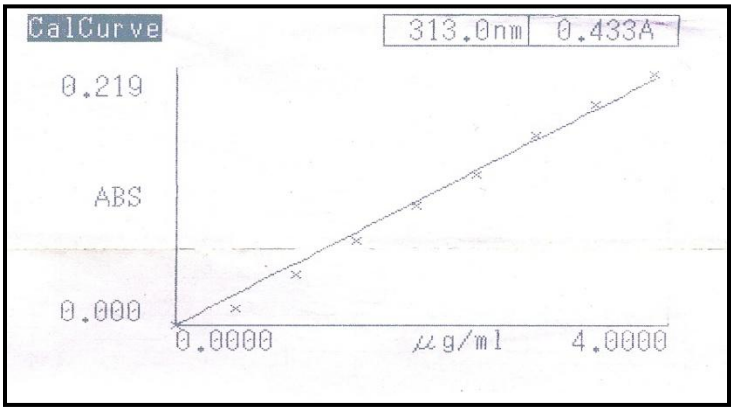

FIG. 2: CALIBRATION CURVE

Optical Parameters: The optical characteristics such as Beer's law limits, correlation coefficient were calculated for the methods and results are summarized in **Table 1**.

TABLE 1: OPTICAL PARAMETERS

Parameters	Value
λ max(nm)	313
Beer's range(µg/ml)	1- 4
Correlation coefficient	0.9928
Slope	0.0537

The methods were applied for the analysis of the drugs in the tablet formulation. To evaluate the validity and reproducibility of the methods, known amount of pure drug was added to the sample and mean recovery was found to be about 100%.

Validation of Methods: Statistical evaluation is displayed in the **table 2 and 3**.

TABLE 2: STATISTICAL EVALUATION

Method	Label claim (gm/tab)	Amount found (gm/tab)	% found
CCM	1	1.007	100.7
SPS	1	1.03	103.0
DPS	1	1.02	102.0

CCM (Calibration Curve Method), SPS (Single Point Standardization), DPS (Double Point Bracketing Standardization)

TABLE 3: RECOVERY STUDY DATA OF TABLET FORMULATION

Method	Level % Recovery	% Recovery Found	Standard Deviation	Coefficient of Variance	R.S.D
CCM	80	111.90	0.0352	1.83	0.0183
	90	113.32	0.0346	1.71	0.0171
	100	111.97	0.0522	2.45	0.0245
	120	109.91	0.0707	3.04	0.0304
SPS	80	115.25	0.352	1.83	0.0183
	90	113.88	0.036	1.75	0.0175
	100	113.7	0.053	2.4	0.0240
	120	110.41	0.070	3.04	0.0304
DPS	80	112.5	0.0311	1.61	0.0161
	90	113.33	0.0335	1.74	0.174
	100	116.0	0.0494	2.31	0.0231
	120	110.0	0.0789	3.05	0.0305

CONCLUSION: Thus, it can be concluded that the methods in present investigation were simple, sensitive and reproducible when checked for parameters like accuracy, precision and limit of detection for routine determination of secnidazole in bulk as well as in tablet.

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