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Research Article

SPECTROPHOTOMETRIC ESTIMATION OF SATRANIDAZOLE IN BULK AND IN DOSAGE FORM

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ABSTRACT

A simple, precise and accurate spectrophotometric method has been developed for the determination of Satranidazole in bulk drug and in pharmaceutical dosage form. This method was based on reduction of nitro group followed by diazotization and coupling reaction with phloroglucinol forming yellow coloured chromogen exhibiting absorbance maximum at 430nm. The molar absorptivity value of Satranidazole was found to be 1.76 x 10^3 $mole^{-1}$ cm^{-1}. Beer's law was obeyed in the concentration range of 10 – 50µg/ml. The results obtained were statistically evaluated and were found to be accurate and reproducible.

Keywords: Satranidazole, Spectrophotometry.

INTRODUCTION

Satranidazole is an antiprotozoal agent[1-2]. It is nitro imidazole derivative and most effective against giardiasis, amoebiasis and anaerobic infections. It is chemically 1-(1-methyl-5-nitro-imidazol-2-yl)-3'-methyl sulfonyl – imidazolidin-2'-one.

Literature survey revealed that only few chromotagraphic methods[3-5] and spectrophotometric methods[6-8] have been reported for the determination of Satranidazole and its formulations.

EXPERIMENTAL

Materials and instrument

Pure drug was obtained from Alkem pharmaceuticals, as a gift sample. Satrogyl was the tablet formulation purchased from the market. Methanol was used as solvent for entire experiment. Perkin Elmer Ez 301, a double beam UV-Spectrophotometric with 1cm matched Quartz cells were used for the measurement of absorbance. Dhona 1600 – analytical single pan balance was used for weighing.

PROCEDURE

Preparation of standard solution

Satranidazole standard stock solution (1mg/ml) was prepared in methanol. From this stock solution, working standard solution 30mcg/ml was prepared by appropriate dilution with methanol.

Determination of λ_{max} and A (1%, 1cm) value:

Working standard solution of Satranidazole was scanned in the entire UV visible range of 370-470nm. The λmax and A (1%, 1cm) of Satranidazole were found to be 430nm (Fig. No: 1) and 61 respectively.

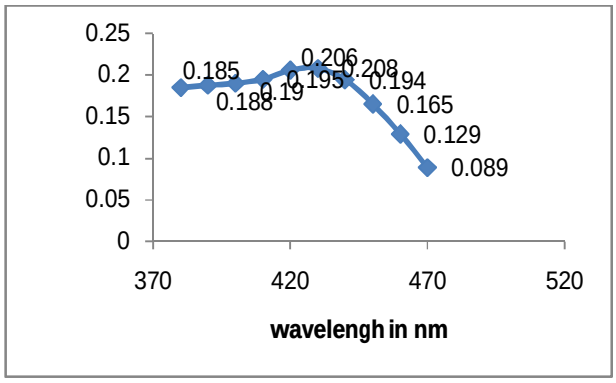

Fig. 1: Spectrum of Satranidazole

Preparation of calibration curve

Standard stock solution was prepared in methanol and diluted suitably with methanol to obtain concentrations in the range of 10-50mcg/ml. Absorbance of resulting solutions was measured at 430nm. Absorbance was plotted versus concentration to obtain the calibration curve (Fig. No: 2). From the calibration curve the linearity range was found out and LOD and LOQ values were calculated using the relation, LOD=3.3 σ/s and LOQ=10 σ/s where σ = standard derivation of residuals from the curve, s = slope of the curve.

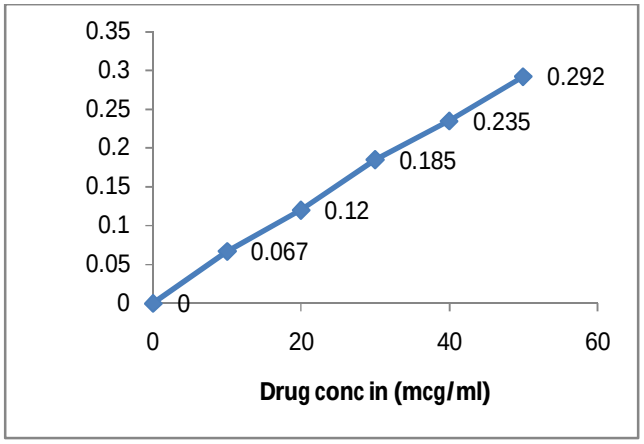

Fig. 2: Calibration curve of Satranidazole

Analysis of the marketed formulation

Twenty tablets were weighed and its average weight was determined. An accurately weighed tablet powder equivalent to 25mg of Satranidazole was transformed into 25ml volumetric flask, dissolved with little methanol and then volume was made up to 25ml with methanol. This methanolic solution was filtered using Whatmann filter paper (Grade – I). 5ml of this filterate was taken and suitably diluted with methanol to obtain 30mcg/ml solution. The absorbance of the resulting solution was compared to the absorbance of standard solution (30mcg/ml) to estimate the Satranidazole content in the tablets. Results of assay were shown in table No.1.

Table 1: Results of Analysis in Marketed Formulation

Drugs	Parameters	% labeled claim*	% recovery*
Satrogyl	Mean	99.46	100.42
	±SD	0.427	0.344
	%RSD	0.427	0.342

* Mean of five determination
SD – standard deviation
RSD – relative standard deviation

Recovery studies

To determine the accuracy of the method, recovery study was performed by standard addition method. To the tablet powder equivalent to 25mg known quantity of standard drug (5mg) was added and total drug contents were determined as per assay method. The percentage of recovery was determined and the results were given in Table No.1.

RESULTS AND DISCUSSION

The λ_{max} of Satranidazole was found to be 430nm from its spectrum. The A (1%, 1cm) value found to be 61. Satranidazole showed linear absorption from 10-50mcg/ml. the correlation coefficient (r) was found to be 0.9994. The LOD and LOQ values were determined from the slope of linearity plot and standard deviation of y-intercept and found to be 1.98mcg/ml and 5.91mcg/ml respectively. The stability of solution of formulation was determined by measuring the absorbance at 430nm at periodic intervals. There was no considerable change in the absorbance at this wavelength up to 3hrs.

Commercial formulations containing Satranidazole was analysed by proposed method. Five replicate analysis of the formulation were carried out and the mean assay values in tablet formulation SATROGYL was found to be 99.46±0.42. The corresponding RSD value was found to be 0.43% indicating that the method has required precision. The accuracy of the method was determined by recovery studies. 5mg of pure Satranidazole was added to the preanalysed tablet powder and the mean recovery of Satranidazole was found to be 100.42±0.34 indicating that the method has required accuracy. The validation results were given in Table No.2.

Table 2: Optical characteristics, Data, Precision and accuracy of the Prepared Method for Satranidazole

Parameter	Method
λmax (nm)	430
Beer's law limits (µg/ml)	10-50
Molar absorptivity (Lit. mole^{-1} cm^{-1})	1.76 x 10^3
Sandall's sensitivity (µg/cm^2/0.001 abs. unit)	0.177
Regression equation (y=a+bc) slope (b)	0.00565
Correlation coefficient	0.9994
% relative standard deviation*	0.43%

* - average of five determinations

CONCLUSION

Thus the developed method is simple, accurate, precise, reproducible, less time consuming and effective. Hence it could be used for routine analysis of Satranidazole in pharmaceutical formulation.

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