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DIRECT SPECTROPHOTOMETRIC DETERMINATION OF SATRANIDAZOLE

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ABSTRACT

A direct spectrophotometric method was developed by the authors for the detection and determination of satranidazole in pure form as well in pharmaceutical formulations in the form of tablets and capsules. The method was based on the formation of a reddish-purple color dye, due to the diazotization reaction between the nitro group of the drug sample, sulphanilamide and NEDA. The drug sample dissolved in hot water, followed by the addition of 2ml each of 0.5% Sulphanilamide and 0.3% NEDA. It exhibited a stable instantaneous reddish purple, colour, which showed maximum absorbance at 540nm. Beer's law was found to be obeyed in the range 50-300 μgmL^{-1}, with a limit of detection of 0.09 μgmL^{-1}. The method was found to be simple, accurate and rapid.

INTRODUCTION: In continuation to our earlier studies [3-5], on the spectrophotometric determination of 5-nitro imidazoles, a new drug of the same class, namely satranidazole was under study in the present paper. 5-Nitroimidazoles, such as metronidazole and ornidazole, are extensively used as antiamoebic, antiprotozoal and specific antibacterial drugs. In clinical tests, metronidazole is active against amoebiasis in rats and hepatic amoebiasis in hamsters and is also active *in vitro* against *E. histolytica*. Subsequent clinical tests have established metronidazole, as the effective drug of choice, in the treatment of all forms of amoebiasis in humans [3-5]. As such satranidazole also found to have the same effect as metronidazole.

Variation of the structure of metronidazole, principally to improve trichomonacidal activity and metabolic stability, led to the discovery of other antiamaeobic agents. Satranidazole falls into the same category of drugs. Satranidazole, 2-Imidazolidinone, 1-(1-methyl-5-nitro-1H-imidazol-2-yl)-3-(methylsulfonyl)-2-di-azolidinone with molecular formula $C_8H_{11}O_5N_5S$.

This medication is an antiamoebic agent, prescribed for liver abscess, giardiasis and trichomoniasis. Its Side Effects includes palpitations, fast heart rate, elevated blood pressure, weakness, nervousness and headache [4].

Most of the above spectrophotometric methods found by the authors in the literature [6-9] for the determination of satranidazole in the visible region involve, initial reduction by treatment with Zn and HCl followed by the diazotisation and coupling of the resulting amine. All these methods time consuming involve tedious procedures such as heating and extraction, costly reagents and an additional diazotisation step detrimental to accuracy.

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The present one developed by the authors was a direct, accurate, precise and reproducible spectrophotometric method for the detection and determination of satranidazole in pure form and in pharmaceutical formulations. The author's method was devoid of reduction procedures and as such was found to increase the accuracy. Other methods include HPLC, RP HPLC and kinetic spectrophotometry.

EXPERIMENTAL:

Reagents: The pure form of sample of satranidazole was obtained commercially. These pure crystalline products were standardized by the standard method[1,2].

Satranidazole tablets: Ten tablets each of, satranidazole of different pharmaceutical firms under study, were weighed and ground into a fine powder. From this, a sample 500mg was weighed and dissolved in 150ml of double distilled water. This solution is heated to a temperature of 90^{o} C for 90minutes. After complete dissolution, the cooled solution was filtered through a Whatmann No 40 filter paper. The clear solution was made up to the mark into a 100 volumetric flask and standardized[1,2].

0.5% sulphanilamide in 20% (V/V) hydrochloric acid: A stock solution of 0.5% sulphanilamide was prepared by dissolving an accurate amount of 0.5g of sulphanilamide in 20% hydrochloric acid, and the solution was made up to the mark in a 100ml volumetric flask using 20% hydrochloric acid .

0.3% NEDA solution in 1% (V/V) hydrochloric acid: A stock solution of 0.3% NEDA was prepared by dissolving an accurate amount of 0.3g of NEDA in 1% hydrochloric acid, the solution was made up to the mark in a 100ml volumetric flask, using 1% hydrochloric acid. All the reagents used were of AnalaR grade only.

Apparatus: An ELICO SL-177, scanning visible spectrophotometer was used for all absorbance measurements. Matched set of 1cm glass cuvettes were used. Shimadzu-AUX 220, digital electronic balance was used for all weighing measurements. An ELICO LI-127; pH-meter was used for all pH measurements.

Recommended procedure for the determination of satranidazole: An aliquot (2.0ml) of drug sample of satranidazole was mixed with 2ml of each 0.5% sulphanilamide and 0.3% NEDA solution, to give an instantaneous, clear, stable reddish- purple coloured product. Each of the mixture was made unto 50ml in a volumetric flask and the spectra were taken for each of an aliquot of the solution which showed a λ_{max} at 540nm (**Fig. 1**).

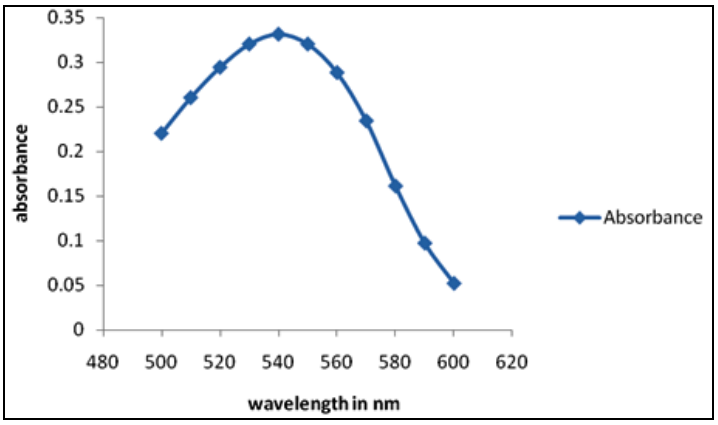

FIG. 1 ABSORPTION SPECTRUM OF THE REDDISH PURPLE COLOURED PRODUCT OBTAINED BY REACTION BETWEEN SATRANIDAZOLE, SULPHANILAMIDE AND NEDA. The λ_{max} is 540 nm

For the determination of satranidazole, an aliquot volume of the sample solution was mixed with 2ml each of 0.5% sulphanilamide and 0.3% NEDA solutions, to give a stable, clear reddish- purple coloured product. The mixture was made up to 50ml in a volumetric flask. The solution was taken in an optically matched cuvette of ELICO SL-177 spectrophotometer and the absorbances were measured at 540nm. The absorbances were compared with the standard curve (**Fig. 2**). Beer's law was found to be valid over the range 50-300µgmL^{-1} .

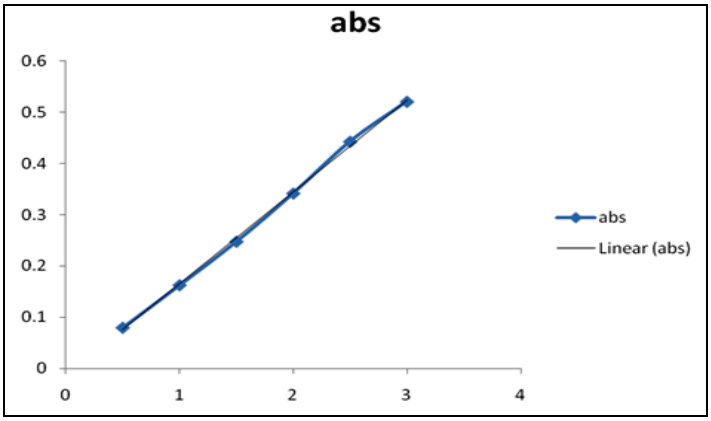

FIG. 2:CALIBRATION PLOT FOR ESTIMATION OF SATRANIDAZOLE. Beer's law obedience was 50-300µgmL^{-1} at λ_{max} 540nm

RESULTS AND DISCUSSION: The instantaneous, clear reddish purple colour obtained for satranidazole with sulphanilamide and NEDA was determined at a λ_{max} of 540nm. There is no overlap of spectra of other components used. It was observed that the reaction was dependent on the pH as well as the concentration of the reagents. Below and above the pH values of 3.5, the colour produced was found to be unstable. The reddish-purple colour of the product was obtained and stable with 0.5%sulphanilamide and 0.3% NEDA solutions.

Below the concentration level, the colour developed was found to be unstable and higher concentrations has no effect on the colour. Hence the concentrations of the reagents were fixed by the authors as 0.5% and 0.3% for sulphanilamide and NEDA respectively. All the observations are made after attaining stable absorbance in 15minutes.

TABLE 1: OPTICAL CHARACTERISTICS AND VALIDATION DATA

Parameters	SATRANIDAZOLE
λ_{max} (nm)	540
Beer's law limit (µgmL^{-1})	50-300
Molar absorptivity (cm^{-1} lit mole^{-1})	510.2
Stability (h)	>24
Correlation coefficient, r	0.9994
Relative standard deviation RSD*	0.7%
Limit of detection (µgmL^{-1})	0.09
Limit of quantification (µgmL^{-1})	0.30

***** 10 replicate analysis of 100µgmL^{-1}

Beer's law was found to be valid in the range 50-300µgmL^{-1}. The molar absorptivity (€) of satranidazole was 510.2 cm^{-1} lit mole^{-1}, detection limits (LOD) of was 0.09 µgmL^{-1} and the limit of quantitation (LOQ) 0.30µgmL^{-1}. The correlation factor for satranidazole was found to be as 0.9994. Relative standard deviation calculated for 10 measurements for the sample of drug was found to be in the limit prescribed, such as 0.7%. The lower values of RSD indicate the good precision and reproducibility of the method developed by the authors. From the data, it was found that the LOQ values were 3.3 times greater than the LOD values. LOD is well below the lower limit of the Beer's law range.

Commonly used excipients and other additives such as glucose, dextrose, lactose, starch, sodium alginate, talc, magnesium alginate, and magnesium stearate, and ascorbic acid had no interference. These results were found to be accurate, precise and reproducible.

TABLE 2 ANALYSIS FOR SATRANIDAZOLE FORMULATIONS

Commercial formulations analyzed	PM$^{\#}$	SM$^{@}$	RSD**
SATROGYL	98.7	99.8	1.9
SATROMAX	99.5	99.9	1.4

Proposed method; @Standard method; ** 10 replicate analysis

CONCLUSIONS: The solution of satranidazole gave an instantaneous, clear, stable reddish-purple coloured product with 0.5% sulphanilamide and 0.3% NEDA solutions. The λ_{max} for the reddish-purple colour product was 540nm, with molar absorptivitites of 510.2 M^{-1}cm^{-1} at 540nm. Beer's law was valid over the range 50-300µgmL^{-1}. The determination of the drug samples by author's method was rapid and accurate and hence recommended.

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