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A simple spectrophotometric determination of Nevirapine in pharmaceutical dosage form

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ABSTRACT

A simple and cost effective spectrophotometric method is described for the determination of Nevirapine in pure form and in pharmaceutical formulations. The proposed method was based on the formation of chloroform extractable complex of Nevirapine with wool fast blue. The absorbance of the extractable ion pair complex is measured at the wavelength of maximum absorbance 590 nm against the reagent blank and obeys beer's law in the concentration range 50 – 250 µg/ml. The results of analysis have been validated statistically and also by recovery studies. The method were found to be simple economical accurate and reproducible and can be adopted in routine analysis of Nevirapine in bulk drug and Pharmaceutical dosage form.

Key words: Nevirapine, spectrophotometry, wool fast blue.

INTRODUCTION

Nevirapine (Fig.1), 11-cyclopropyl-4-methyl-5, 11-dihydro-6*H*-dipyrido [3, 2-*b*: 2', 3'-*e*] [1, 4] diazepin-6-one is a reverse transcriptase (RT) inhibitor of human immunodeficiency virus type 1 (HIV-1)1-2.Nevirapine inhibits replication of HIV-1 by interfering with viral RNA-directed DNA polymerase (reverse transcriptase). It binds directly to herodimeric HIV-1reverse transcriptase and exerts a virustatic effect by acting as a specific, noncompetitive HIV-1 reverse transcriptase inhibitor; it appears to inhibit viral RNA and DNA-dependent DNA polymerase activities by disrupting the catalytic site of the enzyme.

Literature survey reveals that there are several analytical methods available for determination of nevirapine in pharmaceutical dosage forms which includes, Spectrophotometric method[1-2], HPLC[3], HPLC and ultraviolet spectrophotometric methods[4] and analytical methods for determination of nevirapine with combination of other antiviral drugs[5-7]. Literature survey further revealed that there are very few reported, for the analysis of nevirapine alone[8] and combination of other drugs in human plasma[9-12.]

The present investigation illustrates simple, sensitive and accurate spectrophotometricmethod for the analysis of Nevirapine in bulk drug and Pharmaceutical formulations.

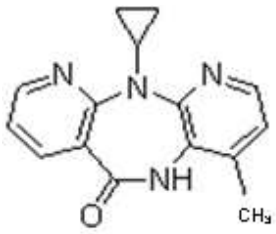

Fig No.1 Nevirapine

EXPERIMENTAL SECTION

Instrumentation

All absorbance measurements were made on a Spectronic 1001 plus spectrophotometer (Milton Roy Company, USA) with 1 cm matched quartz cells.

Chemical and reagents

All the solutions were freshly prepared. All solvents and other chemicals used through this study were of analytical grade. Wool fast blue solution (0.2%) was prepared in distilled water. Buffer solutions of required pH were prepared by mixing appropriate volumes of glycine, sodium chloride and 0.1M Hydrochloric acid

Preparation of Standard Solution

A stock solution of Nevirapine (1 mg/ml) was prepared in methanol. Standard solution was prepared by dilution of the stock solution with methanol to give solution in of 100 μg/ml.

Assay procedure

Into a series of 125 ml separating funnels containing aliquots of Nevirapine solution (0.5-2.5 ml) and 1.0 ml of buffer solution and 1.0 ml of wool fast blue solution were added. The total volume of aqueous phase in each separating funnel was adjusted to 15 ml with distilled water and 5.0 ml of chloroform was added. The contents were shaken for 2 min. the two phases were allowed to separate and the absorbance of the separated organic layer were measured at 590 nm against a reagent blank prepared under identical conditions. The amount of Nevirapine present in the sample was computed from calibration curve and calibration graph was shown in fig 2.

For the analysis of pharmaceutical formulations, ten tablets Nevirapine were weighed and powdered seperately. A quantity equivalent to 50 mg of Nevirapine was weighed and transferred

into conical flask and extracted with methanol, shaken thoroughly for about 20 minutes, and then it was filtered through whatman filter paper No.41 into a calibrated 10ml volumetric flask. Then the volume was made up to the mark with methanol. Appropriate aliquots were then taken in such a way that the final concentration in 10ml volumetric flask was with in the range used for calibration procedure.

The recovery studies were carried out by adding known amount of standard solution of Nevirapine to preanalyzed tablet solutions individually. The resulting solutions were then analysed by proposed method. The results of recovery studies were found to be satisfactory.

RESULTS AND DISCUSSION

The optimum conditions were established by varying one parameter at a time and keeping the others fixed and observing the effect on absorbance of chromogen for the proposed method. In the present work proposed method has been developed for the estimation of Nevirapine from tablet formulations. The developed method is based on formation of chloroform extractable colored complexes with wool fast blue. The absorption spectral analysis shows that the maximum of absorbance of Nevirapine was found to be 590 nm. The calibration graph of the absorbance versus concentration was found to be linear over the range of 50-250 µg/ml for proposed method. The percentage recovery values were close to 100% indicating the reproducibility and accuracy of the method. The optical characteristics such as absorption maxima, Beer´s law limits, molar absorptivity and Sandell´s sensitivity, regression analysis using method of least squares was made for the slope (b), intercept (a) and correlation (r) obtained from different concentrations and results incorporated in Table 1. The high molar absorptivities of the resulting colored complexes indicate the high sensitivity of the method. The percent relative standard deviation, standard deviation and student's 't' test values calculated from the five measurements of Nevirapine are presented in Table 2. Relative standard deviation values and standard deviation were low that indicates the reproducibility of the proposed methods. In the student's 't' tests, no significant differences were found between the calculated and theoretical values of both the proposed methods at 95% confidence level. This indicated similar precision and accuracy in the analysis of Nevirapine in its tablets

Table 1: Optical characteristics, precision and accuracy of Nevirapine

parameters	Proposed method
λmax (nm)	590
Beer's law limit (µg/ml)	50-250
Molar absorptivity (l mole-1 cm-1)	$3.6x10^3$
Sandell's sensitivity (µg cm-2 / 0.001 absorbance unit)	0..3649
Regression equation (Y = a + bC)	Y=0.001x+0.002
Slope (b)	0.001
Intercept (a)	0.002
Correlation coefficient (r)	0.999

**Y = a+bX, where Y is the absorbance and X concentration in µg / ml*

Table 2: Analysis of marketed formulations

Formulations	Label claim (mg)	*Amount found (mg)±S.D*	% Recovery	%RSD*	*t value
Nevir	200	200.16±0.65	100.2	0.3260	0.5481
Neve	200	200.2±0.56	100.04	0.0603	1.112
Nevivir	200	199.98±019	100.08	0.0971	0.2325

**Average of five determinations based on label claim*

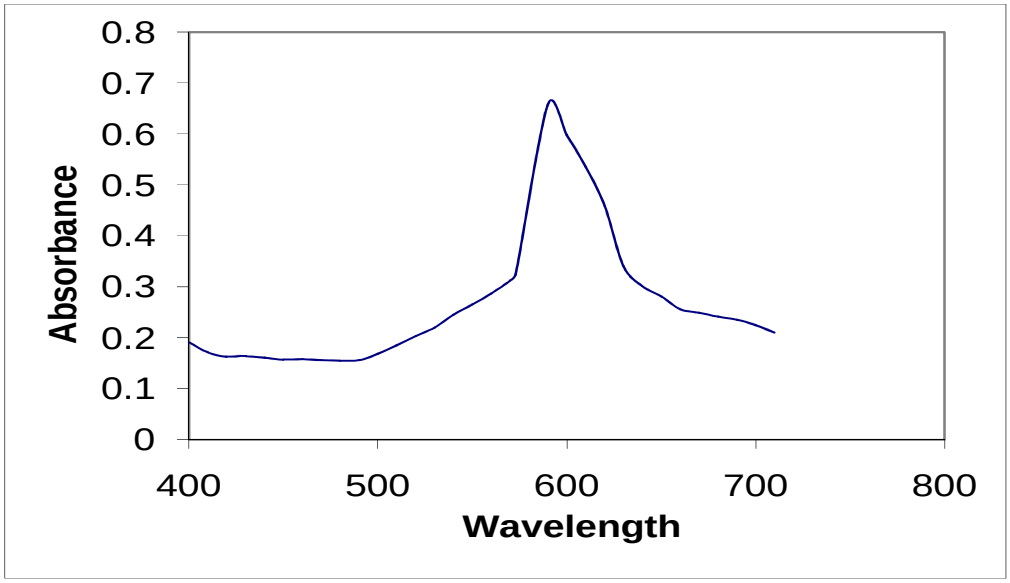

Fig 2. Absorption spectrum of Nevirapine with wool fast blue at 590 nm

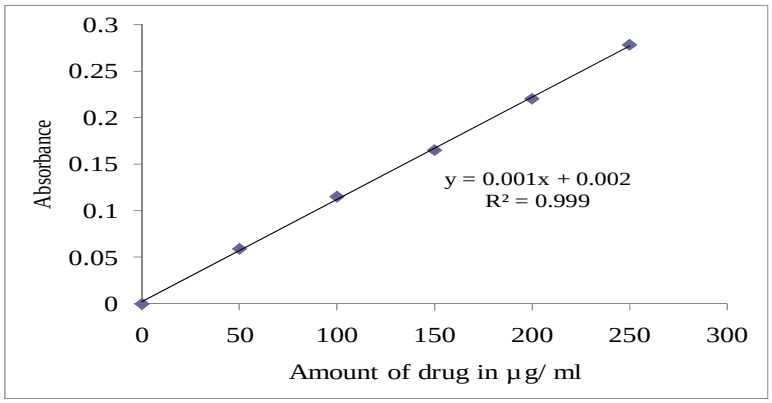

Fig 3. Calibration curve of Nevirapine

CONCLUSION

The proposed method was found to be simple, precise, accurate and rapid for determination of Nevirapine from pure and pharmaceutical formulations. Interference studies revealed that the common excipients and other additivies usually present in the dosage form did not interfere in the method

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