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DERIVATIVE SPECTROPHOTOMETRIC ESTIMATION OF NEVIRAPINE IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

The first derivative spectrophotometric method in methanol have been developed for the determination of Nevirapine in bulk drug and its pharmaceutical formulations. Nevirapine exhibits absorption maxima at 295 nm. In the first derivative spectra of Nevirapine, the amplitude of positive maxima was measured at 291nm. Linearity in the concentration range was found to be 5-30µg/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.

KEYWORDS: Nevirapine, First Derivative Spectrophotometry, NRTI etc.

INTRODUCTION

Nevirapine [NVP] is (shown in fig no.1) 11-cyclopropyl-5,11-dihydro-4-methyl-6Hdipyrido[3,2-b:2′,3′-f][1,4]diazepin-6-one. Nevirapine is a non-nucleoside reverse transcriptase inhibitor (nNRTI) with activity against Human Immunodeficiency Virus Type 1 (HIV-1).Nevirapine binds directly to reverse transcriptase (RT) and blocks the RNA-dependent and DNA-dependent DNA polymerase activities by causing a disruption of the enzyme's catalytic site. It is use in HIV treatment as first generation drug. Literature survey revealed the availability of methods of estimation of the drugs by HPLC in plain solution and in human plasma either alone or a mixture of same drug category. No derivative

spectrophotometric method has been reported for routine quality control analysis of Nevirapine. The present investigation illustrates simple, sensitive and accurate derivative spectrophotometric method for the analysis of Nevirapine in bulk drug and Pharmaceutical formulations.[2,3]

Experimental Section

MATERIAL AND METHODS

Materials and Reagents: Nevirapine (NAV) generous gift sample from Cipla Ltd.(Mumbai, India).A commercial NEVIMUNE (Cipla) tablet containing 200 mg were purchased from a local market and used within their shelf-life period. All chemicals used were of analytical reagent grade.

Instrumentation: Systronic 2201 UV-Visible double beam spectrophotometer with 1cm matched quartz cell was used to measure absorbance of the resulting solution.

Preparation of stock solution and sample solution

Stock solution of Nevirapine (100µg/ml) was prepared separately by dissolving in 0.1N HCL and sonicate for 15 min. having a concentration of 100 µg/ml. The prepared stock solution was stable in 0.1N HCL at room temperature for 6 days.

In first derivative spectrum, aliquots of working solution of NVP, 100 µg/ml was taken separately from which 0.5 to 3.0 ml were transferred into a series of 10ml volumetric flasks and made up to the mark with 0.1N HCL. The amplitude of positive maximum adjacent to 295nm was measured for NVP.

Preparation of standard calibration curve for 0.1N HCL

The standard calibration curves of Nevirapine was plotted to check the linearity between concentration and absorbance i.e. up to which concentration Beer's law is followed. This is useful to ascertain concentration range of the drug to utilized for difference spectrophotometric analysis. Standard solution 0.5,1,1.5,2,2.5 and 3ml from stock(100ug) of Nevirapine were transferred into six 10ml volumetric flasks and diluted with 0.1N HCL solution in order to get final concentration 05,10,15,20,25 and 30ug/ml of Nevirapine respectively. Each solution is scanned between 200nm to 400nm using spectrum mode of instrument to determine λmax of nevirapine in 0.1N HCL was found at 295nm. The linearity

data of Nevirapine is given in the below table. The linear regression equation for Nevirapine in 0.1N HCL was found to be Y=o.o33x+0.072, and r^2=0.9995.

Nevirapine tablets containing 200 mg NVP were analysed by the proposed method. For the analysis of pharmaceutical formulations, Six tablets NVP were weighed and powdered Seperately. A quantity equivalent to labeled amount was weighed and transferred into conical flask and dissolved in 0.1N HCL and sonicate for about 15 minutes, then it was filtered through whatman filter paper no.41 into a calibrated 10ml volumetric flask. Filter paper was rinsed twice with 1ml each of 0.1N HCL and was made upto 10ml with 0.1N HCL. Appropriate aliquots was then taken in such a way that the final concentration in 10ml volumetric flask were within the range used for testing the drug.

RESULTS AND DISCUSSION

The optical characteristics such as Beers' law limit, molar extinction coefficient, LOD, LOQ, percent relative standard deviation and percentage range of error at 95% confident limit of all the methods were incorporated in Table 2.

Method Validation: The method was validated as per ICH guide lines25.

Linearity and Range: 10 to 30µg/mL.

Precision: Intra-day and inter-day precision of the assay samples containing Nevirapine (10, 15, and 200 µg/ml) were analyzed four times in the same day (intraday), and for three consecutive days by different analysts. Precision was calculated and given in terms of mean % ± S.

Accuracy: It was found out by recovery study using standard addition method. Known amounts of standard Nevirapine was added to pre-analyzed samples at a level from 80% to 120% and then subjected to the proposed method. Results of recovery studies are shown.

Sensitivity: LOD and LOQ decide about the sensitivity of the method. LOD is the lowest detectable concentration of the analyte by the method while LOQ is the minimum quantifiable concentration. LOD and LOQ were calculated by the equations as given in ICH guidelines.

$$\mathbf{LOD=3.3\sigma/s \quad LOQ=10\sigma/s}$$

LOD and LOQ for Nevirapine were found to be 0.057 and 0.1748 µg/ml, respectively, these data show high sensitivity of the method

Linearity of Nevirapine

Using standard addition technique, the validity of the methods was further confirmed, the Standard addition technique was carried out by spiking placebo (starch, lactose and magnesium stearate) with addition of NVP at 50%, 100%, and 150% respectively in the sample solution. the linearity of nevirapine- lderi percentage recoveries of the three concentrations were found to be close to 100%. This implies the high percentage recoveries and no interference from excipients and ingredients. In the first derivative spectra, good amplitude was observed and therefore, derivative spectroscopy methods was selected for analysis.

Ruggedness of the proposed methods was studied with the help of two analysts. Robustness of the methods was studied in two different laboratories using UV- visible spectrophotometer. The results did not show any statistical difference between operators and environmental conditions, suggesting that methods developed were rugged and robust. The results from validation studies.

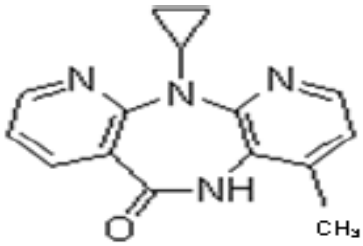

Fig. No.1 Nevirapine.

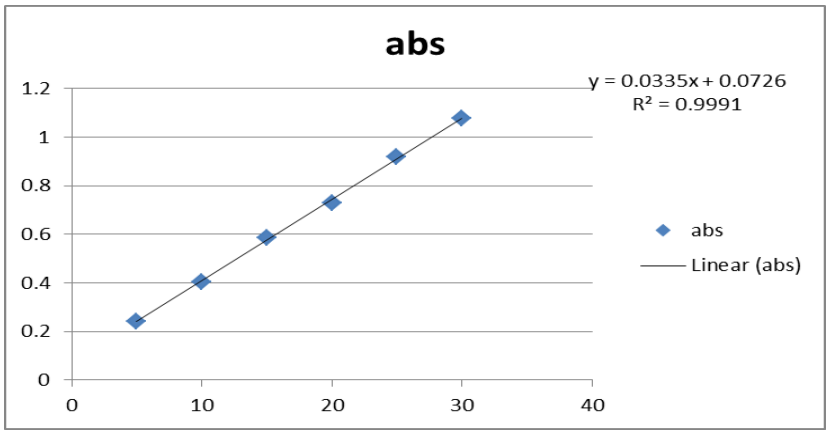

Figure. No. 2: Calibration Curve of Nevirapine.

Table. 1: Concentration Vs Absorbance.

Concentration (µg/ml)	Absorbance
5	0.241
10	0.404
15	0.585
20	0.727
25	0.917
30	1.078

Table. 2: Optical characteristics, precision and accuracy of Nevirapine (NVP).

Sr. No.	Parameter	NVP
1	Absorption Maxima (nm)	295 nm
2	Linearity range (µg/ml)	5-30
3	Molar Absorptivity (L/mol/cm)	$1.33x10^{-1}$
4	Correlation Coefficient (r)	0.999
5	Slope (B)	0.033
6	Intercept (A)	0.072

Table. 3: Analysis of marketed formulations.

Methods	Label claim (mg)	Amount Estimated (mg)	Standard deviation	%RSD	% recovered
NVP (Nevimune)	200	200.5	0.000577	0.0791	100.25

Intraday

Table. 4: SD and %RSD for Intraday.

Concentration (µg/ml)	Abs	Abs	Abs	Mean	SD	%RSD
10	0.40	0.402	0.403	0.401	0.00147	0.366
15	0.585	0.589	0.579	0.584	0.00503	0.86
20	0.740	0.728	0.729	0.732	0.0066	0.687

Interday

Table. 5 SD and %RSD for Interday.

Concentration (µg/ml)	Abs	Abs	Abs	Mean	SD	%RSD
10	0.403	0.401	0.402	0.401	0.00147	0.366
15	0.581	0.576	0.582	0.579	0.00321	0.554
20	0.726	0.725	0.727	0.726	0.001	0.137

Table. 6: SD,%RSD,LOD and LOQ.

Analyte	Formulation	Pure drug added	% Level of recovery	SD	%RSD	LOD	LOQ
Nevirapine	200mg	180	80%	0.000577	0.0539	0.0577	0.1748
	200mg	200	100%	0.001528	0.1368	0.1528	0.4636
	200mg	220	120%	0.002646	0.230	0.2646	0.8081

Table. 7: Ruggedness (%RSD) (n = 3).

Analyst I (% label claim)	0.331
Analyst II(% label claim)	0.332

Table. 8: Robustness (% RSD) (n = 3).

Laboratory- I	0.275
Laboratory - II	0.274

CONCLUSION

The proposed method was found to be simple, precise, accurate and rapid for determination of Nevirapine from pure and pharmaceutical formulations. All the proposed methods produce comparable results and can be used for precise and accurate analysis of NVP in its pure and in Tablet dosage forms. Interference studies revealed that the common excipients and other additives usually present in the dosage form did not interfere in the method. The values of standard deviations were satisfactory and percentage recovery was close to 100% indicating the reproducibility and accuracy of the methods can be employed as a quality control tool for the analysis of Nevirapine in dosage forms.

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