Research Article

Development of New UV Spectroscopic Method for the Estimation of Nelfinavir as Bulk Drug and in Solid Dosage Forms

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ABSTRACT

A simple and sensitive spectroscopic method in ultraviolet region was developed for the estimation of Nelfinavir in Bulk and pharmaceutical dosage forms. The method is based on Nelfinavir, showing absorbance at 220 nm for zero order spectroscopy in distilled water. The method obeys Beers law in the concentration range of 10 to 100µg/ml. The proposed method is precise, accurate, linear, stable and reproducible and can be extended to the analysis of Nelfinavir in bulk and pharmaceutical formulations.

Keywords: Nelfinavir, U.V spectroscopic, U.V estimation.

INTRODUCTION

Nelfinavir is chemically (3S,4aS,8aS)-N-tert-butyl- 2-[(2R,3R)-2-hydroxy-3-[(3-hydroxy-2-methylbenzoyl)amino]-4-phenylsulfanylbutyl]-3,4,4a,5,6,7,8,8a-octahydro-1H-isoquinoline-3-carboxamide (Fig. 1). It is a white powder form and used as antiretroviral agent, for the treatment of HIV infection. It has an empirical formula of $C_{32}H_{45}N_3O_4S$ and molecular weight of 567.7820. Nelfinavir belongs to a class of antiretroviral drugs known as protease inhibitor with activity against Human Immunodeficiency Virus Type 1 (HIV-1)[1]. Literature survey reveals that very few analytical methods has been established for the determination of Nelfinavir viz. Nelfinavir (Viracept) is a potent and orally bioavailable human immunodeficiency virus HIV-1 protease inhibitor and is being widely prescribed in combination with HIV reverse transcriptase inhibitors for the treatment of HIV infection[2], Spectrophotometric estimation of nelfinavir in tablet dosage forms[3],Spectrophotometric Methods for the Determination of Nelfinavir in either bulk form or dosage forms[4], HIV-1 Protease Inhibitors Nelfinavir and Atazanavir Induce MalignantGlioma Death by Triggering Endoplasmic Reticulum Stress[5], Evaluation of an Internationalnelfinavir by liquid chromatography[6], Stress degradation studies of nelfinavir by Fourier transform infrared spectroscopy[7], Stability indicating high performance thin-layer chromatographic determination of Nelfinavir as bulk drug and in pharmaceutical dosage form[8].

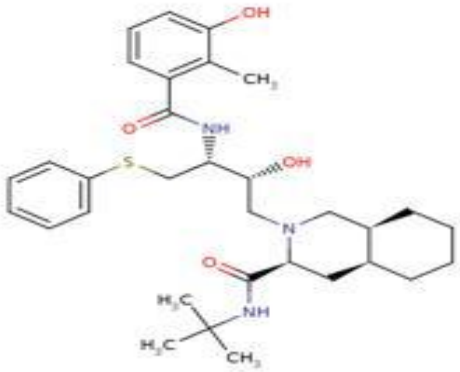

Fig. 1: Chemical structure of Nelfinavir

The objective of this work was to develop a new, simple, economic, rapid, precise, and accurate U.V spectroscopic method for quantitative analysis of Nelfinavir as bulk drug and in pharmaceutical formulations.

MATERIAL AND METHODS

Instrument

Elico SL 164 double beam spectrophotometer was used for all the spectroscopic measurements. The spectral bandwidth was 1 nm.

Prepartion of standrad solution and sample solution

A stock solution of 1mg/ml Nelfinavir in water was used. The working solutions were (0.1 mg/ml) prepared by transferring 5.0 ml from

respective stock solution to a 50 ml volumetric flask and completing to volume with water.

Determination of Nelfinavir in tablets
Brand name
Viracept (625mg)
Company name
Pure standard of Nelfinavir (Assigned purity 99.98%) was obtained as a gift sample from Hetero Drugs Ltd, Hyderabad, Andhra Pradesh, India.

Procedure
A total of 20 tablets were accurately weighed and powdered in a mortar. An amount equivalent to 100 mg (129.189mg) was taken and dissolved in 50 ml of water and stirred on magnetic stirrer for five minutes. About 10 ml of water was added and stirred for further 5 minutes. Then transferred into a 100 ml volumetric flask through a Whatman No. 40 filter paper. The residue was washed thrice with water and the combined filtrate was made up to the mark.

Determination of Nelfinavir
100 mg of pure Emtricitabine was taken and dissolved in 50 ml of water and stirred on magnetic stirrer for five minutes, finally make up the volume up to 100 ml with distilled water. The procedure with standard solution of drug has same concentration as test solution. The absorbance of test and standard solutions were measured at 220 nm against reagent blank. The experiment was performed for bulk drug and formulation and we get standard plot at a wavelength of 220 nm given in fig. 1 with optical activity given in table 1.

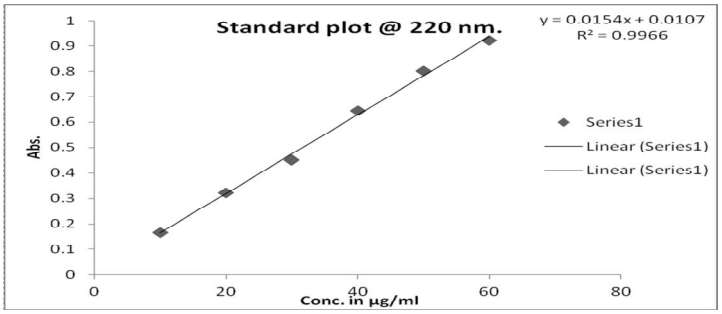

Fig. 1: Standard plot for zero order spectra

Table 2: Optical characteristic of Zero order

Sl.NO.	Parameters	Results
1	Absorption maxima (nm)	220
2	Beer's law limits (mcg/ml)	10-100
3	Molar extinction coefficient ($mole^{-1}$ cm^{-1})	0.016116
4	Sandell,s sensitivity (mcg/cm/0.001 absorbance units)	0.06205
5	Regression equation (y)* Slope (b) Intercept (a)	0.9966 0.0154 0.0107
6	Coefficient of variance	0.004653
7	Standard deviation**	0.003

*y = a + bx; when x is the concentration in µg/ml and y is absorbance unit.
**Three replicate samples.

RESULTS AND DISCUSSION
In the present study attempts shall be made to develop specific spectroscopic method for the estimation of Nelfinavir in bulk and in Pharmaceutical formulation (Tablets).The method involves UV spectroscopic estimation of Nelfinavir using distilled water as solvent in bulk and in formulation. The absorption maximum was measured at 220 nm and calibration curve was plotted with linearity in the concentration range 10-100µg/ml. The sandells sensitivity was found out to be 0.06205 mcg/cm/0.001 absorbance units and molar absortivity 0.016116 mol^{-1} cm^{-1}. The regression equation for the proposed method is calculated by Least Square method as Y= a + bx and found to be 0.9966, intercept (a) was found to be 0.0107 and slope (b) was found to be 0.0154 of the line. The standard deviation of 0.003 indicated accuracy and reproducibility of the method. The method was extended for the determination of Nelfinavir in tablet

formulation. It was observed that the recovery was found to be 98.42 to 101.89% indicating practically no interference of formulation excipients with the proposed method. The accuracy, precision and recovery studies prove that the method is the best for further analysis of the drug. So the developed spectroscopic methods were found to be simple, accurate, economical and reproducible for the estimation of Nelfinavir in bulk and in Pharmaceutical formulation (Tablets).

CONCLUSION

The proposed UV spectroscopic method is found to be accurate, precise, linear, stable, specific, and simple, for quantitative estimation of Nelfinavir in raw material and pharmaceutical formulations. Hence the present UV spectroscopic method is suitable for routine assay of Nelfinavir in raw materials and in pharmaceutical formulations in the quality control laboratories.

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