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Spectrophotometric Determination Of Nevirapine In Pharmaceuticals After Derivatization With 2,4-dinitro Phenylhydrazine

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ABSTRACT

The aim of present work is to develop a simple and sensitive spectrophotometric method for nevirapine in pharmaceutical tablet dosage forms and to validate the method. The method is based on the interaction of nevirapine (keto group) with 2,4 dinitro phenyl hydrazine in acidic ethanol to form red colored hydrazone. The absorption maximum in the visible range of the spectrum, for the product was found to be 470 nm. The pH (3-4) and reaction time scan for the assay were optimized. Spectrophotometric method has been developed for the determination of nevirapine in nevirapine tablets. A linear relation of concentration (10-50 µg/mL) of nevirapine against absorbance at 470 nm was established. The method was successfully applied to the determination of nevirapine in tablet dosage form and the proposed method can be used for the routine determination of nevirapine in simple and complex dosage forms.

INTRODUCTION

Nevirapine is a Non-Nucleoside Reverse Transcriptase Inhibitor used in HIV infection. Chemically it is 1-cyclopropyl-5,11-dihydro-4-methyl-6H-dipyrido (3,2-b:2',3'-e)(1,4) diazepin-6-one (Figure 1) [1,2]. The HPLC methods have been found in literature for its estimation alone and in fixed dose combination with other drugs [3-6]. In the present communication, a novel spectrophotometric methodfor the determination of nevirapine is described.

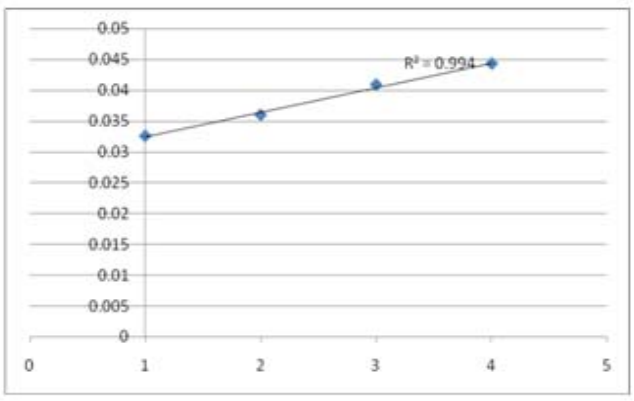


Fig 1 Linearity curve for nevirapine hydrazone

The Nevirapine hydrazone was prepared by reacting with 2,4 dinitro phenyl hydrazine in acidic ethanol and the reaction mixture was warmed at 60^0-63^0 C for 1 hour. This red colored reaction product nevirapine hydrazone showed the maximum absorption at 470 nm and it is used for determination of nevirapine in tablet dosage form.

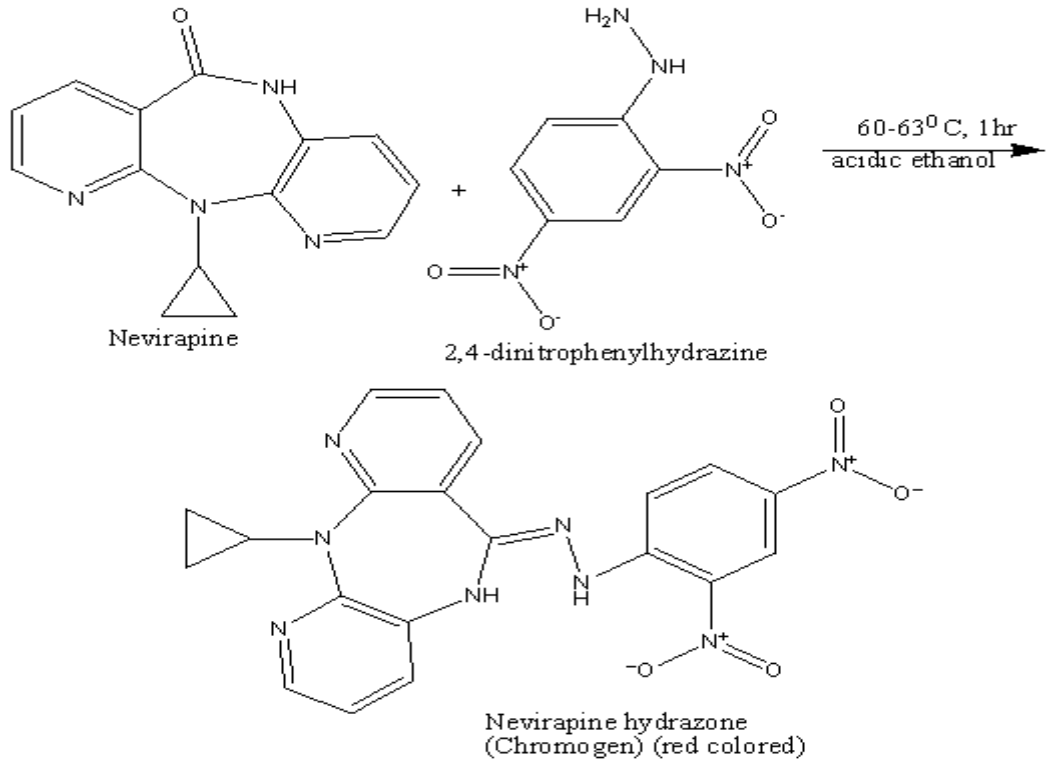
EXPERIMENTAL

3gm of Nevirapine and 1.84 gm of 2,4-di nitro phenyl hydrazine was dissolved in 100 ml of acid ethanol (25 ml H_2SO_4 : 75 ml ethanol), the reaction mixture was warmed at 60^0-63^0C for 1 hour, allowed to cool for some time. The red colored, needled shaped crystals were obtained. The formed Nevirapine hydrazones were filtered and washed with cold and dried.

TLC was performed using solvent system: CH_3OH: $CHCl_3$, single spot is observed under the UV light. The reference sample nevirapine Rf value (0.8548) and the sample (nevirapine hydrazones) Rf value (0.7064). The formed hydrazones where viewed under microscope. The needle shaped crystals were seen.

In the IR spectrum of the product the most outstanding feature was the absence of the bands characteristic of the keto group of nevirapine, namely combination vibrations at 2890 $cm^{-1}$and stretching vibrations C=O at 1639 cm^{-1} and the appearance of a new band at 1608 cm^{-1} associated with the C=N stretching vibration. The UV-vis spectrum of the derivative in absolute ethanol showed an absorption maximum at 470 nm (e = 24000 $I^{mol-1\ cm-1}$). The reaction between nevirapine and phenyl hydrazine is shown in Scheme 1.

Nevirapine hydrazone was dissolved in absolute ethanol and the λmax was obtained at 470 nm against the blank primary stock solution concentration of nevirapine hydrazone 1000 µg/ml was prepared. All measurements were made at room temperature. The standard solutions were prepared by proper dilutions of the primary stock solution with absolute ethanol to obtain working standards in the concentration range of 10-50 µg/ml of pure sample of nevirapine hydrazone. The tablet containing nevirapine, its hydrazone was also prepared similar to pure nevirapine. The concentration of nevirapine present in the tablet was obtained from the calibration curve.



Scheme 1: Derivatization of Nevirapine to Nevirapine hydrazone.

SUMMARY

The percentage recovery of nevirapine in tablet formulation was found to be 97.2 %. The linearity and range was in the range of 10-50 mg/ml for nevirapine. The correlation coefficient was found to be 0.994 (Figure 1) which indicates a perfect correlation. The developed method was validated for accuracy and precision. Thus, the proposed method can be used for the routine determination of nevirapine in simple and complex dosage forms.

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