

## Research Article

# Development of New UV Spectroscopic Method for the Estimation of Efavirenz in Bulk and Solid Dosage Forms

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## ABSTRACT

A simple and sensitive spectroscopic method in ultraviolet region was developed for the estimation of Efavirenz in Bulk and pharmaceutical dosage forms. The method is based on Efavirenz, showing absorbance at 247 nm for zero order spectroscopy in distilled water. The method obeys Beers law in the concentration range of 10 to 100 $\mu$ g/ml. The proposed method is precise, accurate, linear, stable and reproducible and can be extended to the analysis of Efavirenz in bulk and pharmaceutical formulations.

**Keywords:** Efavirenz, U.V spectroscopic, U.V estimation.

## INTRODUCTION

Efavirenz is chemically (4S)-6-chloro-4-(2-cyclopropylethynyl)-4-(trifluoromethyl)-1H-3, 1-benzoxazin-2-one (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<sub>14</sub>H<sub>9</sub>ClF<sub>3</sub>NO<sub>2</sub> and molecular weight of 315.6750. Efavirenz belongs to a class of antiretroviral drugs known as non-nucleoside reverse transcriptase inhibitor (NNRTI) and is used as part of highly active antiretroviral therapy (HAART) for the treatment of a human immunodeficiency virus (HIV) type-1<sup>1</sup>. Literature survey reveals that very few analytical methods has been established for the determination of Efavirenz viz. Development of Rapid UV Spectrophotometric Method for the Estimation of Efavirenz in Formulations<sup>2</sup>, High-performance liquid chromatographic method for the determination of HIV-1 non-nucleoside reverse transcriptase inhibitor efavirenz in plasma of patients during highly active antiretroviral therapy<sup>3</sup>, Development of a competitive immunoassay for efavirenz: Hapten design and validation studies<sup>4</sup>, Simultaneous quantification of a non-nucleoside reverse transcriptase inhibitor efavirenz, a nucleoside reverse transcriptase inhibitor emtricitabine and a nucleotide reverse transcriptase inhibitor tenofovir in plasma by liquid chromatography positive ion electrospray tandem mass spectrometry<sup>5</sup>, Determination of efavirenz, a selective non-nucleoside reverse transcriptase inhibitor, in human plasma using HPLC with post-column photochemical derivatization and fluorescence

detection<sup>6</sup>, Quantitative Estimation of Efavirenz by High Performance Thin Layer Chromatography<sup>7</sup>, Development and validation of stability indicating HPTLC method for determination of efavirenz as bulk drug and in pharmaceutical formulation<sup>8</sup>.

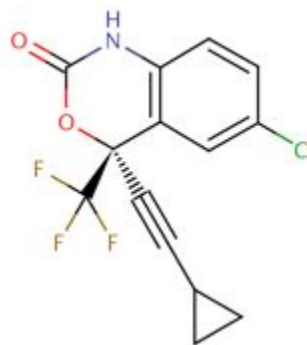


Fig. 1: Chemical structure of Efavirenz

The objective of this work was to develop a new, simple, economic, rapid, precise, and accurate U.V spectroscopic method for quantitative analysis of Efavirenz 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.

### Preparation of standard solution and sample solution

A stock solution of 1mg/ml Efavirenz 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 Efavirenz in tablets

#### Brand name

Sustiva (600mg)

#### Company name

Pure standard of Efavirenz (assigned purity 99.98%) was obtained as a gift sample from Ranbaxy labs Pvt. Ltd. Gurgaon, India.

### Procedure

A total of 20 tablets were accurately weighed and powdered in a mortar. An amount equivalent to 100 mg (123.18mg) 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 Efavirenz

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 247 nm against reagent blank. The experiment was performed for bulk drug and formulation and we get standard plot at a wavelength of 247 nm given in fig. 1 with optical activity given in table 1.

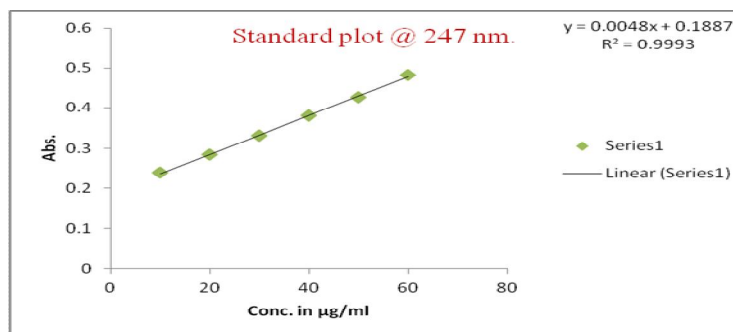


Fig. 1: Standard plot for zero order spectra

Table 2: Optical characteristic of Zero order

S.NO.	Parameters	Results
1	Absorption maxima (nm)	247
2	Beer's law limits (mcg/ml)	10-100
3	Molar extinction coefficient ( $\text{mole}^{-1} \text{cm}^{-1}$ )	0.009508
4	Sandell,s sensitivity (mcg/cm/0.001 absorbance units)	0.10517
5	Regression equation (y)*	0.9993
	Slope (b)	0.0048
	Intercept (a)	0.1887
6	Coefficient of variance	0.002629
7	Standard deviation**	0.001

\* $y = a + bx$ ; 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 Efavirenz in bulk and in Pharmaceutical formulation (Tablets). The method involves UV spectroscopic estimation of Efavirenz using distilled water as solvent in bulk and in formulation. The absorption maximum was measured at 247 nm and calibration curve was plotted with linearity in the concentration range 10-100µg/ml. The

sandells sensitivity was found out to be 0.10517 mcg/cm/0.001 absorbance units and molar absorptivity  $0.009508 \text{ mol}^{-1} \text{cm}^{-1}$ . The regression equation for the proposed method is calculated by Least Square method as  $Y = a + bx$  and found to be 0.9993, intercept (a) was found to be 0.1887 and slope (b) was found to be 0.0048 of the line. The standard deviation of 0.001 indicated accuracy and reproducibility of the method. The method was extended for the determination of Efavirenz in tablet

formulation. It was observed that the recovery was found to be 98.66 to 101.24% 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 Efavirenz 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 Efavirenz in raw material and pharmaceutical formulations. Hence the present UV spectroscopic method is suitable for routine assay of Efavirenz in raw materials and in pharmaceutical formulations in the quality control laboratories.

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