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DEVELOPMENT AND VALIDATION OF FIRST-ORDER DERIVATIVE UV-SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF FLUVASTATIN SODIUM IN FORMULATION

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Keywords:

Fluvastatin sodium, First order derivative, UV spectrophotometry, Method development, Validation

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ABSTRACT: A simple, accurate, precise and sensitive first-order UV - Spectrophotometric assay method has been developed and validated for the quantitative estimation of fluvastatin sodium in pharmaceutical dosage forms. The solvent to dissolve the drug and for dilutions, methanol was used. The absorption maxima of fluvastatin sodium in methanol after derivatized into the first-order derivative was found to be 306nm. The drug obeyed Beer's law in the concentration range of 1 - 5µg/mL with correlation coefficient of 0.9997. The developed method was validated as per the ICH guidelines. The % recovery values were found to be within limits, which showed that the method was accurate. The % relative standard deviation values were less than 2, indicating the method was found to be precise. Limit of detection and limit of quantitation were calculated using statistical methods. The developed method can be used for the quality control of fluvastatin sodium in pharmaceutical dosage formulations.

INTRODUCTION: Fluvastatin sodium **Fig. 1**, chemically designated as [R*,S*-(E)]-(±)-7-[3-(4-fluorophenyl)-1-(1-methylethyl)-1H-indol-2-yl]-3,5-dihydroxy-6-heptenoic acid, mono-sodium salt, is a white to pale yellow, hygroscopic powder soluble in water, ethanol and methanol and has a pKa of 5.5. It is a water-soluble cholesterol lowering agent which acts through the inhibition of 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) [1, 2]. According to the literature survey, very few methods [3] HPLC methods [4-6], UV Spectro-photometry [7, 8] and HPTLC [9] were developed.

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The proposed method aimed to develop and validate first order derivative UV- spectro-photometric method for the determination of fluvastatin sodium in formulation.

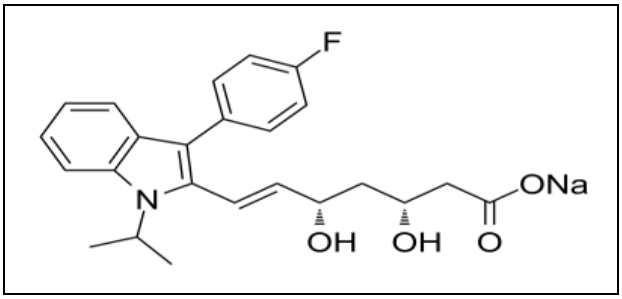

FIG. 1: CHEMICAL STRUCTURE OF FLUVASTATIN SODIUM

MATERIAL AND METHODS:

Reagents and Chemicals: Fluvastatin sodium standard drug was supplied as a gift sample by spectrum labs, Hyderabad (India).

The fluvastatin capsules (Lescol) were purchased from a local pharmacy. All the solvents used were purchased from Merck, Mumbai, India.

All the chemicals used for developing the method were of AR grade and purchased from Sigma Aldrich, Bangalore, India.

Instruments and Chromatographic Conditions: A JASCO V-530 UV/VIS double beam spectrophotometer with 1 cm matched quartz cells was used for the determination of fluvastatin sodium in the pharmaceutical dosage form. All the parameters were controlled by UV Win software. Other instruments used were electronic balance and Ultrasonic bath sonicator.

Preparation of Standard Solution and Sample Solution: Dissolve 10 mg of accurately weighed fluvastatin working standard in 100 mL volumetric flask with methanol (100 µg/mL). Dilute 0.3 mL of above stock solution with same solvent to 10 mL (3 µg/mL).

Twenty capsules (Lescol) were weighed accurately, and the average weight was calculated. The capsules were opened, and fine powder was collected. Dissolve an amount equivalent to 10 mg of fluvastatin in 100 mL volumetric flask with methanol and sonicated for 30 min with intermediate shaking. The final volume was made up of the same solvent. The above solution was filtered, and 0.3 mL of the solution was diluted with the same solvent in 10 mL volumetric flask.

Method Validation:

Linearity: Serial dilutions of standard Fluvastatin sodium in the range of 1 µg/mL and 5 µg/mL were prepared and placed in the system. A linearity graph was plotted between concentration and absorbance.

Accuracy: The solutions were prepared in three different concentration levels of 50%, 100% and 150%, placed in the system and % recoveries were calculated.

Precision: The precision of the method was determined by Intra and Inter-day precision studies. The standard solution was placed six times on the same day (intra-day) as well as on different day (inter-day) and the % RSD was calculated.

Specificity: The specificity of the method was determined by placing the placebo solution and comparing with standard solution for the interference with Fluvastatin sodium peak.

Limit of Detection (LOD) and Limit of Quantitation (LOQ): LOD and LOQ are determined by the standard deviation (SD) and slope of the calibration curve.

The limiting values are calculated as per the following equations:

$$LOD = (3.3 \times SD)/ Slope \text{ and } LOQ = (10 \times SD)/ Slope.$$

RESULTS AND DISCUSSION: The main aim of the study was to develop a first-order derivative UV spectrophotometric method for the determination of Fluvastatin sodium in capsule dosage form and to validate the method.

Solvent Selection: In order to select suitable solvent for determination of Fluvastatin, various solvents were selected for the solubility studies and it was found that Fluvastatin was freely soluble in methanol.

In the present investigation, methanol was used for all the dilutions due to greater solubility and reproducible readings of maximum absorbance.

Selection of Wavelength: The absorbance of the solutions containing Fluvastatin at 10 mcg/ml was determined in the UV range 400-200 nm using an appropriate blank. λ_{max} of solution of Fluvastatin was found to be 306 nm **Fig. 2**.

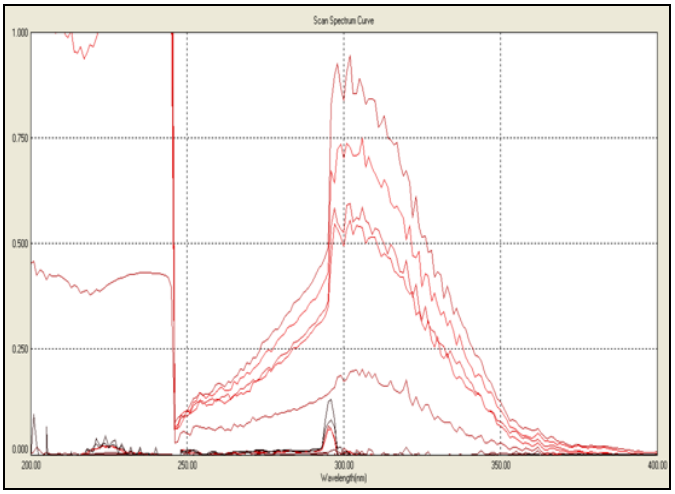

FIG. 2: OVERLAY UV SPECTRUM OF FLUVASTATIN SODIUM

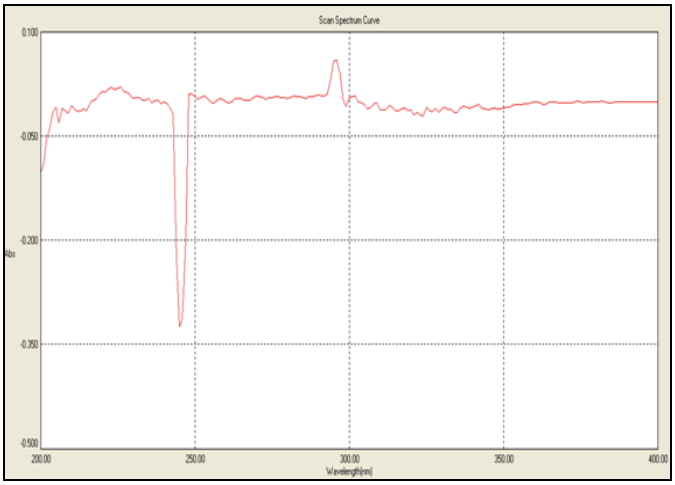

FIG. 3: FIRST ORDER DERIVATIVE UV SPECTRUM OF FLUVASTATIN SODIUM

TABLE 1: OPTICAL CHARACTERISTICS

S. no.	Parameters	Results
1	Absorption maximum	306 nm
2	Linearity Range	1 – 5µg/mL
3	Regression Equation	y=0.187x+0.006
4	Slope	0.187
5	Intercept	0.006
6	Correlation coefficient (r)	0.9994
7	Molar extinction coefficient ($L.mol^{-1} cm^{-1}$)	0.0878
8	Sandell's sensitivity (µg/cm^2 - 0.001absorbance units)	0.0049
9	Accuracy (% recovery)	99.12% - 99.72%
10	Precision (Intra-day) %RSD (Inter-day) %RSD	0.4 0.3
11	LOD (µg/mL)	0.157
12	LOQ (µg/mL)	0.476
13	Standard error	0.0047
14	Specificity	Specific, No interference

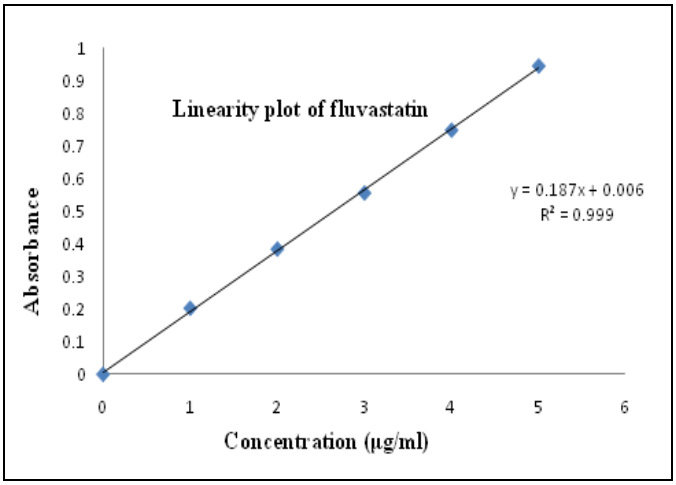

FIG. 4: LINEARITY PLOT OF FLUVASTATIN SODIUM

For the estimation of linearity of method, concentrations ranging from 1 µg/mL to 5 µg/mL were prepared and a linearity graph **Fig. 3** was plotted using concentration against absorbance. The regression equation was found to be y = 0.187x + 0.006, with a correlation coefficient of 0.9994, indicating that good linearity was observed.

The % recovery of Fluvastatin sodium was found to be 99.12% - 99.72%, and % RSD was found to be 0.4 for intra-day precision and 0.3 for inter-day precision. As the results were found to be within limits, which indicates that the method was accurate and precise. The LOD and the LOQ for Fluvastatin sodium were found to be 0.157 µg/mL and 0.476 µg/mL, respectively. The method was also found to be specific.

CONCLUSION: A specific, accurate first-order derivative UV spectrophotometric method was developed for the determination of Fluvastatin sodium in the pharmaceutical dosage form. The method was validated by using various validation parameters and the method was found to be linear, precise, accurate and specific. The method is economical, rapid and does not require any sophisticated instruments in contrast to the chromatographic method. Hence it can be effectively applied for the routine analysis of fluvastatin in bulk drugs. Its advantages are the low cost of reagents, speed, and simplicity of sample treatment, satisfactory precision, and accuracy.

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CONFLICTS OF INTEREST: The authors declare that there is no conflict of interest.

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