IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Research Article
May 2023 Vol.:27, Issue:2

Development and Validation of UV-Spectrophotometeric Method for Analysis of Fluvastatin Sodium in Bulk and in Pharmaceutical Formulation

IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Kalshetti M S, Bhosale D S, Mathpati S S, Bagewadi S M*, Londhe S S, Umate S U.

DSTS Mandal' College Of Pharmacy, Solapur, Maharashtra, India

Submitted: 20 April 2023
Accepted: 26 April 2023
Published: 30 May 2023

Keywords: Fluvastatin Sodium, Spectrophotometry, Ethanol, method development, validation

ABSTRACT

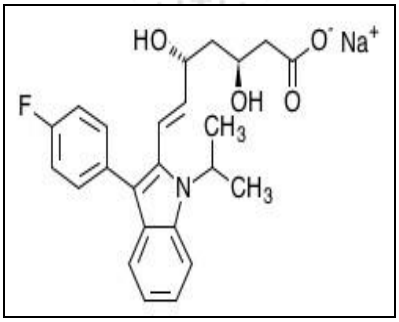
Objective: The current study aims to develop and validate a simple and economical UV spectrophotometeric method for Fluvastatin Sodium quantitative measurement in Ethanol detection. **Methods:** The UV spectrum of Fluvastatin Sodium in ethanol showed λ max at 304 nm. Beer's law is valid in the concentration range of 10-50 µg/ml. This method was validated for linearity, accuracy, precision, ruggedness and robustness. **Results:** The method has demonstrated excellent linearity in the range of 10-50 µg/ml with regression equation y = 0.0222x - 0.0195 and regression correlation coefficient r^2= 0.9994. The accuracy is between in the range of 91.75% to 91.85% And precision %RSD is 0.188696 Moreover, the method was found to be highly sensitive with LOD (0.018463 µg/ml) and LOQ (0.615432 µg/ml). **Conclusion:** Based on results the proposed method is validated for all the parameters according to ICH guidelines of Fluvastatin Sodium.

INTRODUCTION:

Fluvastatin Sodium (FSS) is chemically Sodium salt of (3S, 5R, 6E)-7-[3-(4-fluorophenyl)-1-(propan-2-yl)-1H-indol-2-yl]-3,5-dihydroxyhept-6-enoate which is synthetic lipid-lowering agent. Its molecular formula is $C_{24}H_{26}FNNaO_4$.

It is a member of the statin family and competes with hepatic 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase to prevent the conversion of HMG-CoA to mevalonate necessary for cholesterol biosynthesis. As a result, it lowers plasma lipoprotein and cholesterol levels to prevent cardiovascular disease. It is an almost white, crystalline powder with molecular weights of 433.455 g/mol, melting points of 191°C, and flash points of 366.1°C, respectively.

Various analytical techniques, including high performance liquid chromatography (HPLC), reverse phase high performance liquid chromatography (RP-HPLC), high performance thin layer chromatography (HPTLC), gas chromatography with flame ionisation detection, capillary electrophoresis, and UV-spectroscopy in 0.1 N NaOH and 0.1 N HCl, have been reported for FSS analysis, according to the literature.



However, a literature review has not yet reported on using a UV spectrophotometer to analyze FSS in ethanol. As a result, a new and economical UV spectrophotometer analytical procedure has been developed for the quantitative analysis and detection of FSS in ethanol.

MATERIAL AND METHODS:

Instruments:

An UV visible double beam spectrometer [systronics 2201] & Shimadzu 1800-UV spectrophotometer with 1cm quartz cuvettes was used for all absorbance measurement.

All weights were taken on analytical balance(Shimadzu AY220). Sonicator(OSCAR) was used for dissolving FSS in ethanol.

Reagents and Chemicals

Fluvastatin Sodium)was purchased from Aurobindo Pharma Limited Company, Telangana. Ethanol were procured from Laboratory. All ingredients employed were of analytical grade.

Experimental work:

Preparation of standard stock solution:

100 mg FSS was accurately weighed and dissolved in 100 ml ethanol to prepare a solution of 1000 µg/ml concentration. Pipette out 10ml from the previous stock solution and dilute to 100 ml to prepare a solution of 100 µg/ml concentration. Further, 1 ml of solution was diluted to 10ml using ethanol to obtain 10 µg/ml working standard solutions. All determinations were conducted in triplicate.

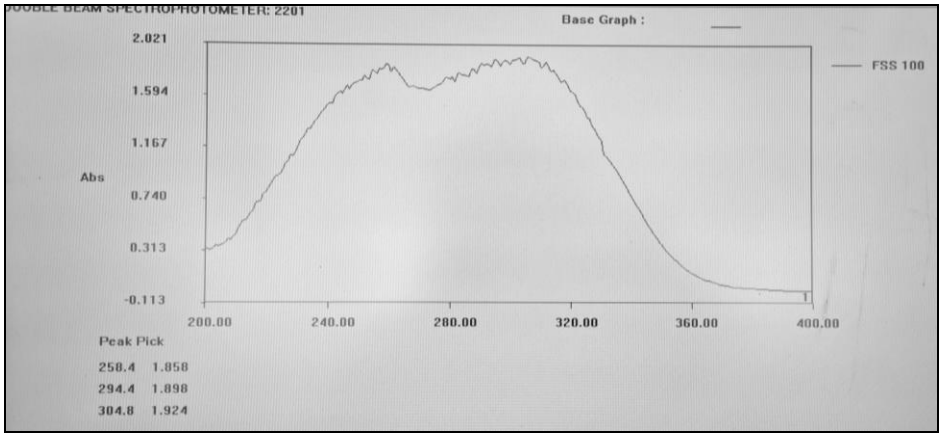
Procedure for plotting calibration curve:

10 µg/ml FSS was scanned over a range of 200-400 nm to determine λmax of FSS using ethanol as blank. From 100 µg/ml standard stock solution, aliquots of 1, 2, 3, 4 and 5 ml were diluted upto 10 ml with ethanol to obtain 10-50 µg/ml concentration.

RESULTS AND DISCUSSION:

The absorption spectra show result of wavelength at 304 nm.

UV VISIBLE SPECTRA OF FLUVASTATIN SODIUM



Linearity

The linearity was confirmed by taking aliquots of concentration of 10-50 µg/ml and absorbance was measured. It was performed in single day only. The obtained absorbance shows good regression coefficient at wavelength 304nm. The slope and intercept values were recorded. The linearity was plotted against absorbance of fluvastatin vs concentration of fluvastatin.

Table 1: Results for linearity

Sr No	Concentration (µg/ml)	Absorbance
1	10	0.213
2	20	0.417
3	30	0.639
4	40	0.870
5	50	1.098

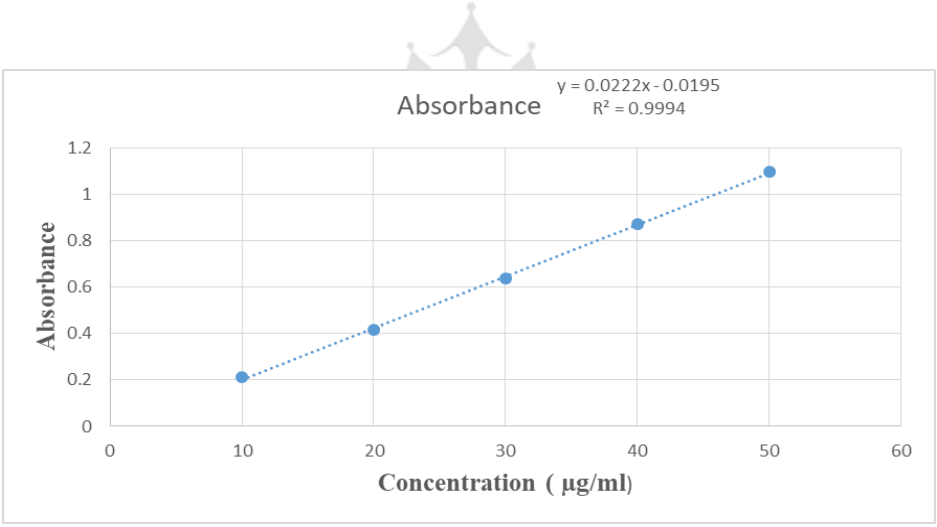


Figure 1: Calibration Curve for Dasatinib

Accuracy:

The accuracy is parameter of an analytical method which describes the closeness to the test results obtained by that method to the theoretical value. The standard addition method is used to analyze accuracy which is performed by using previously analyzed standard solutions. The percentage relative standard deviation and percentage recovery were analyzed by using standard solutions.

Range:

The range is the analytical parameter of interval between lower and upper concentration limit of an analyte i.e. 10-50 µg/ml.

Precision:

The precision is performed as inter-day and intra-day. Intra-day precision was performed in one day and inter-day precision was performed in three days. Fluvastatin Sodium was evaluated at concentration 30 µg/ml. The percentage RSD for intra-day precision was found to be 0.188% and inter-day precision was found to be 0.114%.

Limit of Detection (LOD):

The limit of detection (LOD) or lower limit of detection is the lowest quantity of a substance that can be able to distinguish from the absence of that substance with a stated experimental level.

$$\mathbf{LOD = 3\ Sa\ /\ b}$$

Limit of Quantitation (LOQ):

The limit of quantitation (LOQ) is the lowest concentration at which the performance of a method or measurement system is acceptable for a specified use.

$$\mathbf{LOQ = 10\ Sa\ /b}$$

Ruggedness:

The ruggedness is the study of degree of reproducibility of test results obtained by variety of external conditions like different analysts, laboratories, days and reagents. This study shown that there is no any influence of these conditions on test results.

Robustness:

The robustness is the small but deliberate variations in method parameters such as temperature and stability of analytical solution.

Table 2: Regression analysis of the calibration curve for proposed method

Parameters	**Method values**
λ max	304
Beer's law	A=abc
Correlation coefficient (r)	0.9994
Regression equation (Y = mx +c)	0.0222x-0.0195
Slope (m)	0.0222
Intercept (c)	0.0195
LOD(µg/ml)	0.018463
LOQ(µg/ml)	0.615432

Table 3: Result for precision (Intra-day)

Sr no	**Concentration (µg/ml)**	**Absorbance1**	**Absorbance2**	**Absorbance3**	**%RSD**
1	30	0.637	0.636	0.638	
2	30	0.639	0.639	0.637	
3	30	0.636	0.637	0.640	
4	30	0.637	0.639	0.639	
5	30	0.636	0.638	0.638	
6	30	0.639	0.637	0.638	
%RSD		0.214371	0.189921	0.161796	0.188696

Table 4: Result for precision (Inter day)

Sr No	Concentration (µg/ml)	Day 1	Day 2	Day 3	%RSD
1	30	0.638	0.639	0.638	
2	30	0.640	0.639	0.638	
3	30	0.639	0.638	0.638	
4	30	0.638	0.639	0.639	
5	30	0.638	0.640	0.637	
6	30	0.639	0.638	0.638	
%RSD		0.127844	0.117836	0.099131	0.114937

Table 5: Result for Robustness

Temperature	30ºC	25ºC
Concentration	30**(µg/ml)**	30**(µg/ml)**
Absorbance	0.637	0.638
	0.639	0.639
	0.638	0.639
	0.639	0.639
	0.639	0.638
	0.638	0.639
Average	0.638333	0.638667
SD	0.000816	0.000516

Table 6: Result of Ruggedness

Concentration	Analyst 1	Analyst 2
30(µg/ml)	0.639	0.638
	0.638	0.639
	0.639	0.640
	0.640	0.639
	0.638	0.639
	0.639	0.638
Average		0.638833
SD		0.000753

Linearity:

Five different concentrations of were prepared and analyzed. Then wavelength was found to be 304 nm. The regression coefficient was found to be 0.9994. The absorbance was found in limit i.e. 0-2. Hence the analyzed parameter was found to be validated (table 1).

Precision:

Intra-day precision:

Intra-day precision was found within limit i.e.30 µg/ml at 304nm. The relative standard deviation is less than 2%. Hence the parameter was found to be validated (table 3).

Inter-day precision:

Inter-day precision was performed in three days and the obtained results of concentration 30 µg/ml at 304 nm shown that the relative standard deviation is less than 2%. Hence the parameter was found to be validated (table 4).

Robustness:

The change in concentration i.e. 30 µg/ml and change in temperatures i.e. at 25 ºC and 30 ºC. And obtained results shown that there is negligible effect on results. The robustness was found to be in limit i.e. the relative standard deviation is less than 2%. Hence the performed parameter was found to be validated (table 5).

Ruggedness:

The change in analyst at concentration of 30µg/ml showed that the obtained result does not affected by it (table 6).

Limit of detection:

The limit of detection was found to be 0.018463 µg/ml (table 2).

Limit of quantification:

The limit of quantification was found to be 0.615432 µg/ml (table 2).

CONCLUSION:

Analytical method was developed and validated thoroughly for quantitative determination of fluvastatin Sodium. The developed method was found to be simple, accurate, precise,reproducible, rugged and gives an acceptable recovery of the analyte, which can be easily applied to the analysis of pharmaceutical tablet formulation of fluvastatin Sodium.

REFERENCES:

1. Gupta, S., T. Munjal, P. Bhatia and I. Kaur (2014). Fabrication and evaluation of fluvastatin Sodium loaded sustained release microspheres using polymer blends. International J. of Pharmacy & Pharmaceutical Sciences., 6(5): 365-371
2. Kamboj, A., M. Kaur, I. Bala and U.K. Jain (2016). Formulation and evaluation of fast dissolving oral films of fluvastatin Sodium by using taste masking techniques. Journal of Biomedical and Pharmaceutical Research., 5(3): 62-70.
3. Kukati, L., C.H. Archana, N.B. Shaik and P. Subrahmanyam (2015). Formulation and evaluation of fluvastatin Sodium bilayered osmotic tablets. Farmacia., 63(5): 700-709.
4. Borgmann, S.H.M., L.S. Bernardi and G.S. Gabriela Rauber et al., (2013) Solid-state characterization and dissolution properties of fluvastatin Sodium salt hydrates. Pharmaceutical Development and Technology., 18(2): 525-534.
5. El-Helw, A.R. and U.A. Fahmy (2015). Improvement of fluvastatin bioavailability by loading on nanostructured lipid carriers. International Journal of Nanomedicine., 10(1): 5797-5804.
6. Tank, C.J., G.K. Kapse and J.I. Sarvaiya (2013). Transdermal drug delivery of fluvastatin Sodium: Effect of permeation enhancers and pressure sensitive adhesive. Journal of Pharmacy Research., 6(5): 573-578.
7. Marakkarakath, H.C., G. Bannimath and P.P. Raikar (2019). Simultaneous estimation of lidocaine and prilocaine in topical cream by green gas chromatography. Journal of Applied Pharmaceutical Science., 9(3): 66-72.
8. Uyar, B., M. Celebier and S. Altinoz (2007). Spectrophotometric determination of rosuvastatin calcium in tablets. Pharmazie., 62(6): 411-413. Venkatesh, D.P., R. Karki, G.S. Andhal
9. Almasri, I.M., M. Ramadan and E. Algharably (2019). Development and validation of spectrophotometric method for determination of gabapentin in bulk and pharmaceutical dosage forms based on Schiff base formation with salicylaldehyde. Journal of Applied Pharmaceutical Science., 9(3): 21-26.

10. Belal, T.S., H.G. Daabees, M.M. Abdel Khalek, M.S. Mahrous and M.M. Khamis (2013). New simple spectrophotometric method for determination of the binary mixtures (atorvastatin calcium and ezetimibe; candesartan cilexetil and hydrochlorothiazide) in tablets. Journal of Pharmaceutical Analysis., 3(2): 118-126.
11. Breier, A.R., M. Steppe and E.E.S. Schapoval (2007). Validation of UV spectrophotometric method for fexofenadine hydrochloride in pharmaceutical formulations and comparison with HPLC. Analytical Letters., 40(12): 2329-2337.
12. Jain, R., N. Jain, D.K. Jain, V.K. Patel, H. Rajak and S.K. Jain (2013). Novel UV-spectrophotometer methods for quantitative estimation of metronidazole and furazolidone using mixed hydrotropy solubilisation. Arabian Journal of Chemistry., 10(2): 151-156.
13. Patil, D.D., M.S. Patil and Y.B. Wani (2015). Spectrophotometric method for pregabalin determination: An experimental design approach for method development. Journal of Association of Arab University for Basic and Applied Sciences., 21(1): 31-37.
14. Alamri, R.G., K. Mohsin, A. Ahmad, M. Raish and F.K. Alanazi (2016). Development and validation of bioanalytical UHPLC-UV method for simultaneous analysis of unchanged fenofibrate and its metabolite fenofibric acid in rat plasma: application to pharmacokinetics. Saudi Pharmaceutical Journal., 25(1): 128-135.
15. Divya, K., B. Narayana and S. Samshuddin (2013). New spectrophotometric methods for the determination of sulfadoxine by the formation of Co (II) Complexes. Journal of Saudi Chemical Society., 20: 536-540.
16. Prashant, K.N., K. Basavaiah and C.M. Xavier (2013). Development and validation of UV-spectrophotometric methods for the determination of sumatriptan succinate in bulk and pharmaceutical dosage form and its degradation behavior under varied stress conditions. Journal of Association of Arab University for Basic and Applied Sciences., 15(1): 43-52.
17. Divya, K. and B. Narayana (2014). A novel spectrophotometric approach for the determination of febantel in pure and dosage forms. Journal of Association of Arab University for Basic and Applied Sciences., 19(1): 23-28.
18. Christian, J., P. Shah, M. Patel, K. Patel and T. Gandhi (2017). 3370 Sukhbir Singh et al. Optimizing derivatization conditions using an experimental design and simultaneous estimation of artemether and lumefantrine by ratio first order derivative spectrophotometric method. Journal of Taibah University for Science., 11(5): 729-740.
19. Sukhbir Singh, Neelam Sharma*, Neha Kanojia, Gurpreet Kaur and Sandeep Arora, Development and validation of uv-spectrophotometer method for analysis of fluvastatin Sodium in polyethylene glycol 6000 and polyvinyl pyrollidone k30 solid dispersions, Plant Archives Vol. 20 Supplement 1, 2020 pp. 3365-3371