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RP-HPLC Method Development and Validation for Estimation of Rosuvastatin Calcium in Bulk and Dosage Form

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ABSTRACT:

Rp –Hplc Method Development And Validation For Estimation Of Rosuvastatin Calcium In Bulk and Dosage Form In this proposed method the linearity was observed in the concentration range of 40-140µg/ml with co-efficient of correlation, r^2 = 0.9982. The result of the analysis by the proposed method was found to be highly reproducible and reliable. The additive present in the formulation of the assayed samples did not interfere with determination of ROS. So, the developed RP-HPLC method was simple, precise, accurate and reproducible and can be used for determination of ROS bulk and in pharmaceutical dosage forms. The method was validated as per International Conference on Harmonization (ICH) guidelines. The work was planned on conventional line of procedure in development of the analytical methods for the multiple drugs is as follows:

Development of Spectrophotometric Method for Determination of Drugs from their Formulation.

The work will be performed on following lines: Procurement of pure drug samples of Fenofibrate And Rosuvastatin Selection of suitable solvent Study of spectra and selection of wavelength Development and Validation of RP-HPLC Method for Determination of Fenofibrate Pure and Tablet Dosage Form.: Selection of solven ,Optimization of mobile phase ,Preparation of standard stock solution Linearity study ,Estimation of the drug in pure sample, Application of the proposed method for estimation drug in tablets, Validation of the proposed method

Keyword: Rp –Hplc Method, Rosuvastatin Calcium, Bulk and Dosage Form

INTRODUCTION

The efficient analytical method development and its validation are critical elements in the development of pharmaceuticals. An analytical method is selected on the basis of criteria such as accuracy, precision, sensitivity, selectivity, robustness, ruggedness, and the amount of available sample, the amount of analyte in the sample, time, cost, and availability of equipment.[1]

1. METHOD DEVELOPMENT: [2]

Today developing a method for analysis is usually based on a prior art or existing literature, The development of any new or improved method usually tailors existing approaches and instrumentation to the current analyte, as well as to the final needs or requirements of the method. Method development usually requires selecting the method requirements and deciding on what type of the instrumentation to utilize and why. In the development stage, decision regarding drug solubility, choice of column, mobile phase, detectors and method of quantization must be addressed. In this way, development considers all the parameters pertaining to any methods.

There are several valid reasons for developing new method of analysis.

- There may not be a suitable method for a particular analyte in the specific sample matrix.
- Existing method may be inaccurate, artifact, and/or contamination prone, or they may be unreliable (have poor accuracy or precision), if available.
- Existing method may be too expensive, time consuming or energy intensive, or they may not be easily automated.
- Existing method may not provide adequate sensitivity or analyte selectivity in samples of interest.

- Newer instrumentation and techniques may have evolved methods, including improve analyte identification or detection limits, greater accuracy or precision, or better return on investment.

There may be a need for an alternative method to confirm for legal or scientific reasons analytical data originally obtained by existing methods. One the instrumentation has been selected, based on the criteria suggested above, it is important to determine, "analyteparameters" of interest. To develop a method it is necessary to consider the properties of the analytes of interest that may be advantageous to establish optimal ranges of analyte parameters values. It is important that methods development be performed using only analytical standards that have been well identified and characterized, and whose purity is already known. Such precaution will prevent problems in the future and will remove variables when one is trying to optimize or improve initial conditions during method development.

- **STRATEGY FOR METHOD DEVELOPMENT IN HPLC[24]**

- Selection of suitable chromatography method for organic compounds:
- First reverse phase should be tried,
- If not successful, Normal-phase should be taken into consideration.
- Before making experimentation with Ion Exchange or Ion-Pair chromatography, ion suppression by pH controls and reverse–phase chromatography should be tried. For ion-forming organic compounds Ion-pair chromatography should be preferred to Ion-Exchange chromatography.

- **Reverse phase HPLC:**

Phase chromatography is usually a method of first choice of convenience, wide applicability, and good understanding of operating principles. In the reverse–phase partition HPLC the relative polarities of the stationary phase is less polar than the mobile phase and consequently the solutes are eluted in order of their decreasing polarities. These phases are

AIM

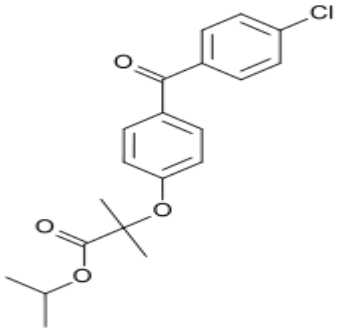
RP –HPLC METHOD DEELOPMENT AND VALIDATION FOR ESTIMATION OF ROSUVASTATIN CALCIUM IN BULK AND DOSAGE FORM

OBJECTIVE

From literature review it was observed that very few methods were reported for the quantitative analysis of selected drugs and its formulations. Hence it was thought worthwhile to develop fast, precise, sensitive different UV methods and HPLC methods for quantitative determination of the selected drugs from its formulation.

DRUG PROFILE [1-10] 1.1

FENOFIBRATE:

PARAMETER	DESCRIPTION
Name of Drug	**Fenofibrate**
Chemical Structure	
IUPAC names	Propan-2-yl2-{4-[(4-chlorophenyl)carbonyl]phenoxy}-2methylpropanoate.
Chemical Formula	C20H21CLO4

CAS Registry No.	49562-28-9
Molecular Weight	360.8 g/mol
PHYSICOCHEMICAL PROPERTIES OF DRUG	
State & Colour	A white to off white powder
Solubility	Practically insoluble in water, 0.1 M Hcl and 0.1 M NaOH, soluble in methanol.
Melting Range	79 - 820C
pKa	4.9
PHARMACOLOGICAL DATA	
Therapeutic Category	Antihyperlipidemic drug
Pharmacological Uses	For use as adjunctive therapy to diet to reduce elevated LDLC, Total-C, Triglycerides and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia.
Mechanism of Action	Fenofibrate exerts its therapeutic effects through activation of peroxisome proliferator activated receptor a (PPARa). This increases lipolysis and elimination of triglyceride- rich particles from plasma by activating lipoprotein lipase and reducing production of apoprotein C-III. The resulting fall in triglycerides produces an alteration in the size and composition of LDL from small, dense particles, to large buoyant particles. These larger particles have a greater affinity for cholesterol receptors and are catabolized rapidly
Dose	120-160mg/day
STABILITY AND STORAGE DATA	
Stability	Drug is stable
Storage	Store protected from light and moisture, at a temperature not exceeding 30^0C.

Experimental Work and Results

Method 1

6.1 RP-HPLC METHOD DEVELOPEMT AND VALIDATION FOR ESTIMATION OF ROSUVASTATIN CALCIUM IN BULK AND DOSAGE FORM.

6.1.1 MATERIALS AND INSTUMENTS

6.1.1.1 Materials and Reagents

- Analytically pure Rosuvastatin Calcium was procured as gift samples from Torrent Research Centre, Ahmedabad, Gujarat, India.
- All other chemicals and reagents used were analytical grade and purchased from Merck Chemicals, India. Tablets were procured from the local market.

Instruments and Apparatus

- High Performance Liquid Chromatograph

- Model: Series 600
- Make: Perkin Elmer, USA.
- Column: Brownlee Analytical C18 column 250×4.6 mm, 5µm particle size
- software –Turbo chrome
- Pump: quaternary gradient system.
- Flow rate 1.0ml/min
- Injector: Rhenodyne valve with 20µl fixed loop. Detector: Diode array detector (UV-visible).

PREPARATION OF SOLUTIONS

Preparation of ROS standard stock solution (1000µg/ml)

Accurately weighed 100mg of ROS was transferred into 100ml volumetric flasks, dissolve and diluted up to mark with methanol to get stock solution having concentration of 1000µg/ml.

6.1.2.2 Preparation of working standard solution (200µg/ml)

20 ml of each of standard stock solution of ROS was transferred to 100 ml volumetric flask and diluted to 100ml with methanol to get ROS working standard solution having concentration of 200µg/ml.

Preparation of solution for calibration curves (40-140µg/ml)

To obtain calibration curve, aliquots form working standard solutions was taken (2.0ml- 7.0ml) and diluted up to the mark with methanol to get the range of 40-140µg/ml.

Preparation of sample solution of ROS

Powder mixture equivalent to 10mg of ROS was transferred in 100ml volumetric flask containing 50mL methanol, sonicated for 10 min and diluted to mark with methanol to obtain 100 µg /ml. The resulting solution was filtered using whatman filter paper and injected for the quantification.

Preparation of mobile phase:

Mobile phase Acetonitrile : Buffer in proportion of 68:32v/v, buffer was

10mM Ammonium acetate (pH 4 adjusted with Formic acid), Filtered through

0.45µm filter paper, sonicated for 10 minutes to degas the mixture and used as mobile phase.

OPTIMIZATION OF CHROMATOGRAPHIC CONDITION

Chromatographic estimation was performed using an equilibrated Brownlee analytical C18 column (250mm×4.6mm i.d.), mobile phase consisting of Acetonitrile: Buffer in proportion of 68:32v/v, buffer was 10mM Ammonium acetate (pH 4 adjusted with Formic acid) Detection was done at 243nm. The sample was injected using a 20µl fixed loop, flow rate 1ml/min and the total run time was 10 minutes.

Selection of wavelength for measurement

2 ml of working standard solution of ROS (200 µg/ml) was diluted to 10 ml with Methanol to get 40 µg/ml of ROS and solution was scanned between 200-400 nm. Data were recorded at an interval of 1 nm. 244nm was selected as a detection wavelength for ROS. (Figure 7.1)

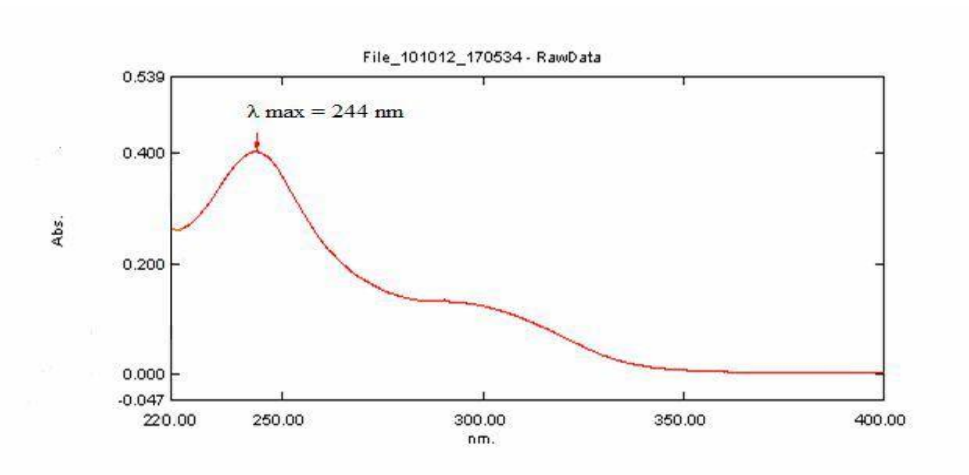


Figure UV Spectra of ROS (40 µg/ml)

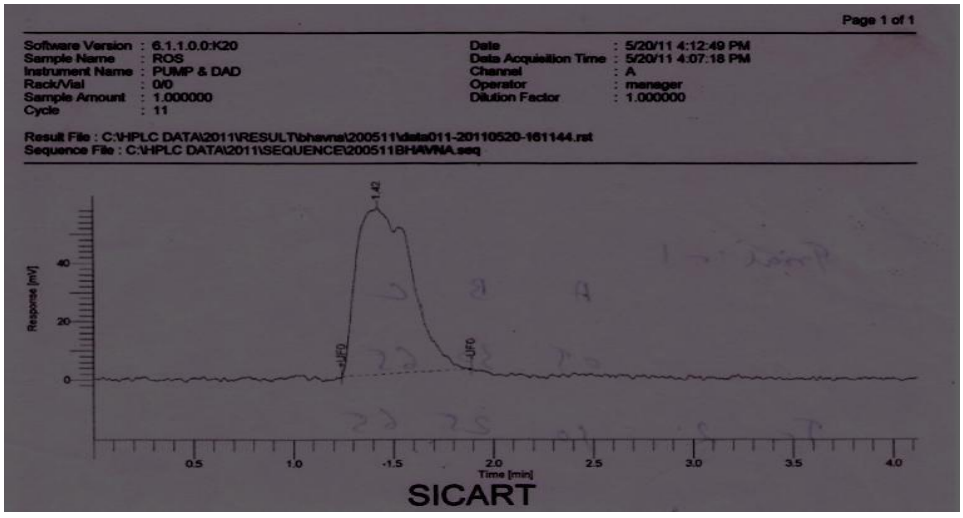
Optimization of Mobile phase

Standard solution of ROS was prepared in methanol and used for evaluation.

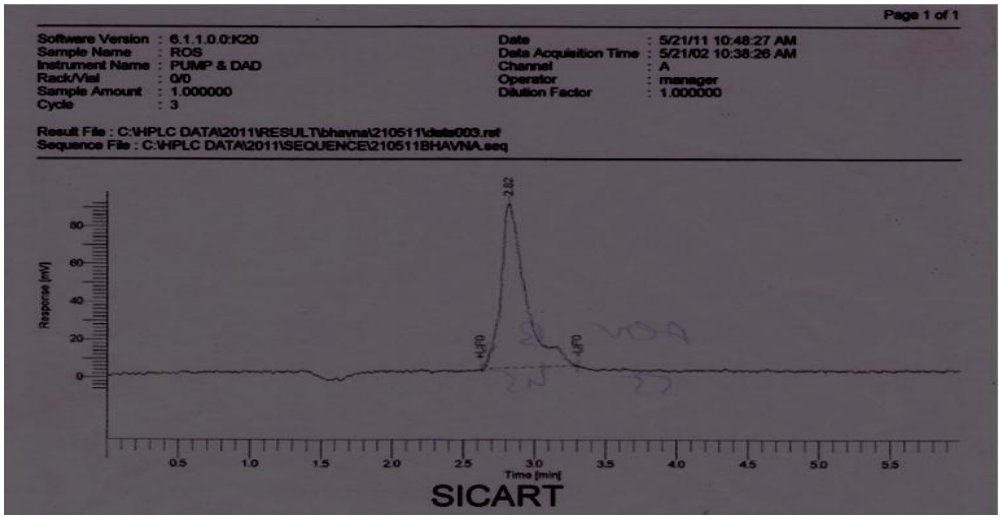
Various mobile phase are tried which are listed below in Table 7.1.

Table: Selection of mobile phase for ROS

Sr. no.	Mobile phase	Ratio v/v	Remark
1	Acetonitrile: Methanol	50:50	Poor resolution was observed [Fig.7.2 a]
2	Acetonitrile: Methanol	60:40	peak shape was asymmetrical [Fig.7.2b]
3	Acetonitrile: Buffer	70:30	Peak splitting [Fig.7.2c]
4	Acetonitrile: Buffer [10mM Ammonium acetate pH 4 adjusted with Formic acid]	60:40 (v/v)	Good resolution, but sharp peak was not found. [Fig.7.2 d]
5	Acetonitrile: Buffer [10mM Ammonium acetate pH 4 adjusted with Formic acid]	68:32 (v/v)	Very good resolution, symmetric sharp peak was found. [Fig.7.2 e]



7.2 a.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Instrument Name : PUMP & DAD
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Sample Amount : 1.000000
Cycle : 3
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Data Acquisition Time : 5/21/02 10:38:26 AM
Channel : A
Operator : manager
Dilution Factor : 1.000000
Result File : C:\HPLC DATA\2011\RESULT\bhavna\210511\data003.rst
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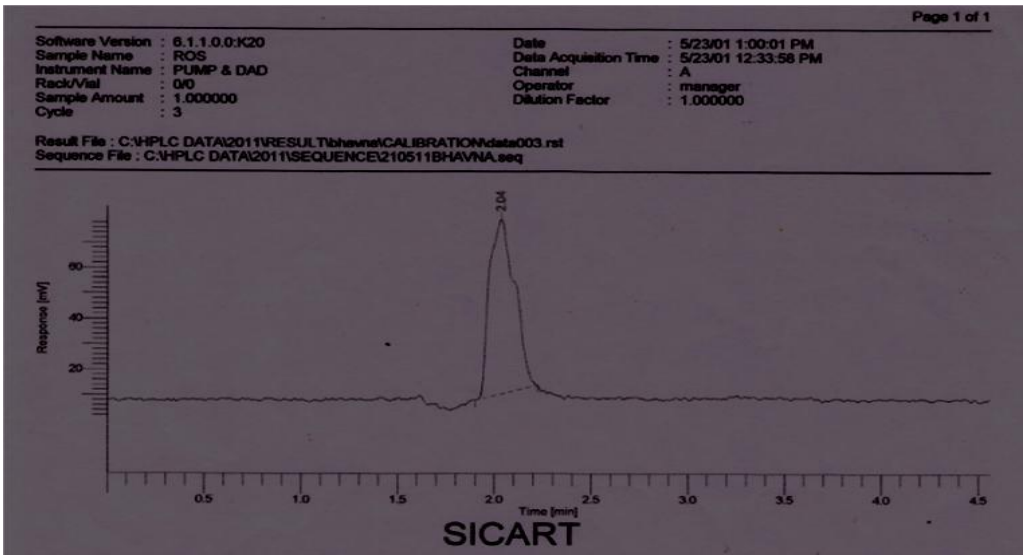
2.82
Response [mV]
Time [min]
SICART

7.2 b.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Instrument Name : PUMP & DAD
Rack/Vial : 0/0
Sample Amount : 1.000000
Cycle : 3
Date : 5/23/01 1:00:01 PM
Data Acquisition Time : 5/23/01 12:33:58 PM
Channel : A
Operator : manager
Dilution Factor : 1.000000
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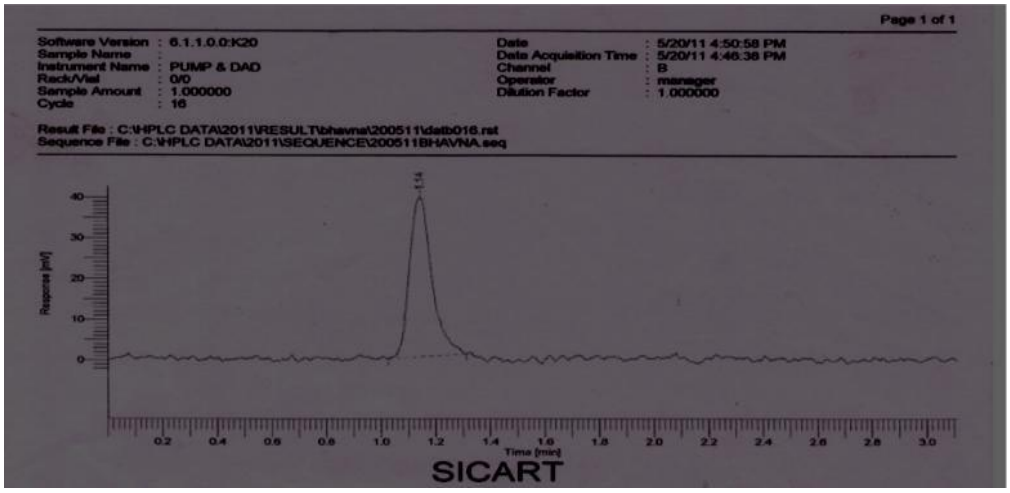
Response [mV]
Time [min]
SICART

7.2 c.


Page 1 of 1
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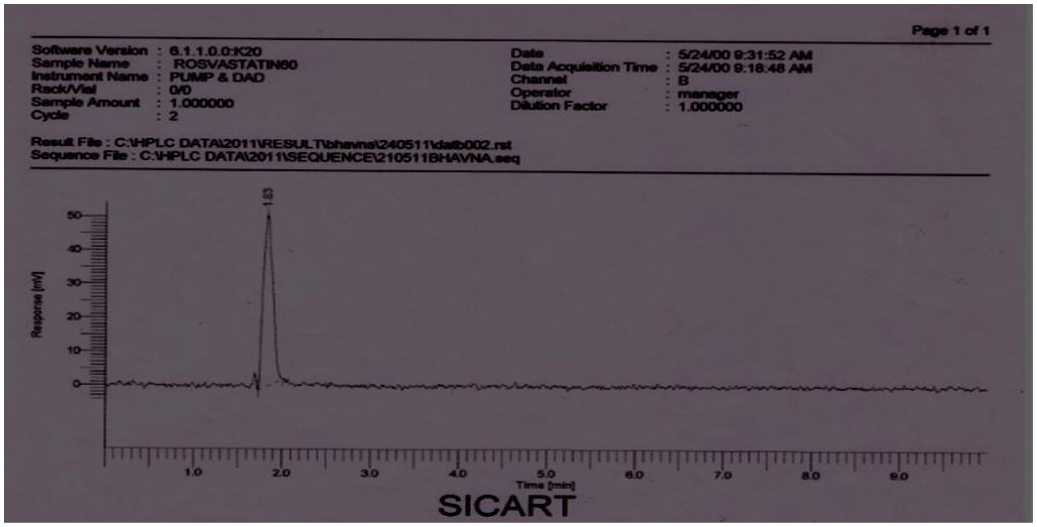
Response [mV]
Time [min]
SICART

7.2 d.



7.2 e

Figure (a-e): Trial Chromatograms of STD ROS

The mobile phase consisting of Acetonitrile: Buffer in proportion of 68:32v/v, buffer was 10mM Ammonium acetate (pH 4 adjusted with Formic acid) was selected for evaluation of ROS. The optimized chromatographic condition is shown in Table

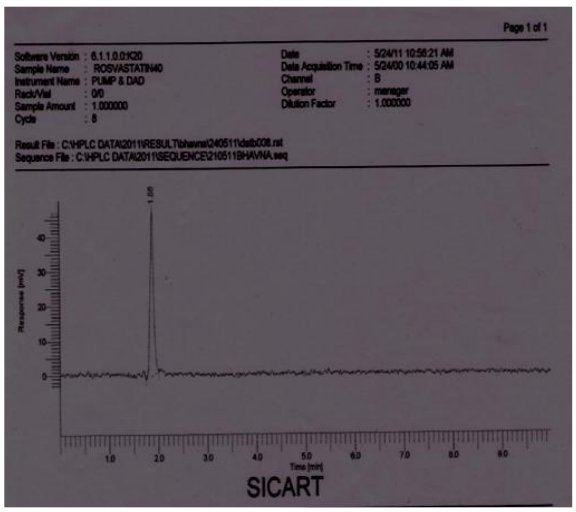
Table: Optimized Chromatographic Conditions

Parameter	**Optimized conditions**
Instrument	Perkin Elmer, Turbo chrome software, Series 600
Column	Brownlee analytical C18 column (250mm X 4.6mm, 5µm)
Mobile phase	Acetonitrile: Buffer in proportion of 68:32v/v, buffer was 10mM Ammonium acetate (pH 4 adjusted with Formic acid)
Flow rate	1.0 ml/min
Detection	244nm
Injection volume	20 µl
Temperature	Ambient

6.1.3.4 Calibration Curve

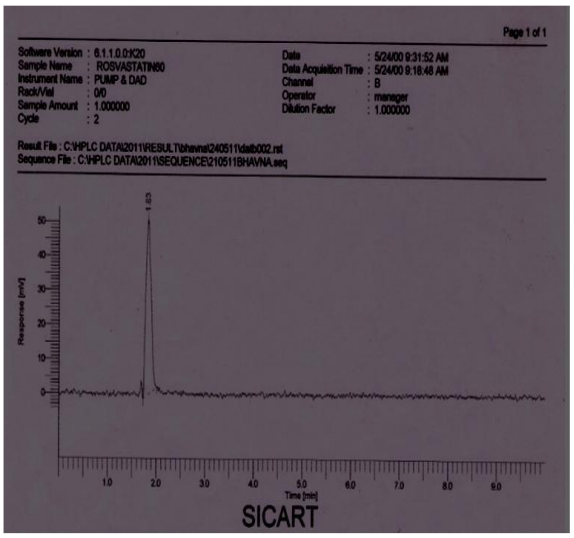
To obtain calibration curve, aliquots form working standard solutions was taken (2.0ml- 7.0ml) and diluted up to the mark with methanol to get the range of 40-140µg/ml.

The chromatogram of all the concentration was shown in Figure 7.3(a-f) and the data is mentioned in Table 7.3 and Figure 3 shows the calibration curve.

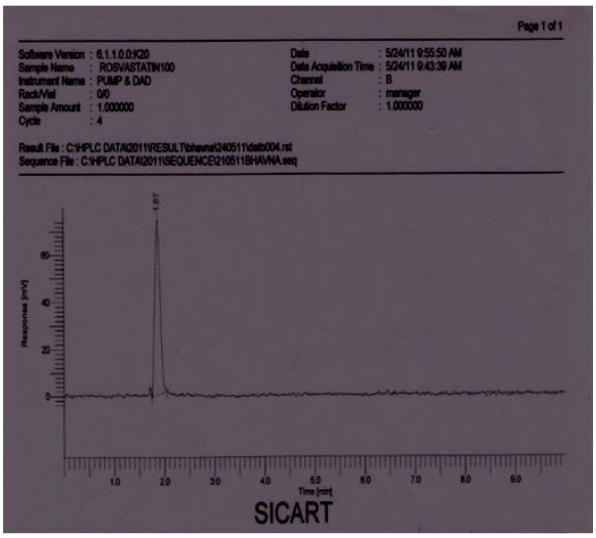


7.3 a

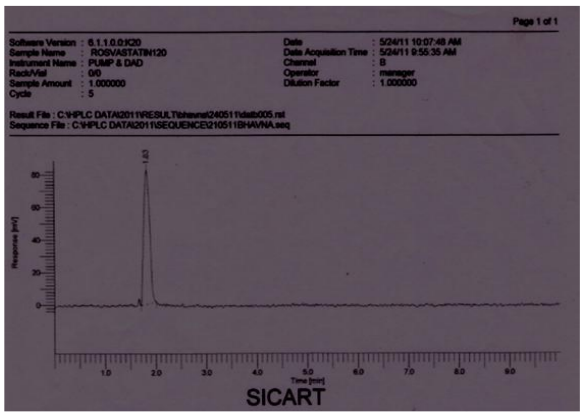
7.3 b.



7.3 c.



7.4 d



7.3 e.

7.3 f.

Figure 7.3 (a-f): Standard Chromatogram of ROS (40-140 µg/ml) Table 7.3: Result of Calibration Curve for ROS

Concentration (µg/ml)	**Area Mean (n=5) ± SD**	**%RSD**
40	262841.2±4637.3	1.76
60	376124.2 ± 5567.7	1.48

80	495075.6 ± 5478.231	1.10
100	555404 ± 6401.196	1.15
120	657122.4 ± 6881.455	1.04
140	752428.8 ± 8306.037	1.10

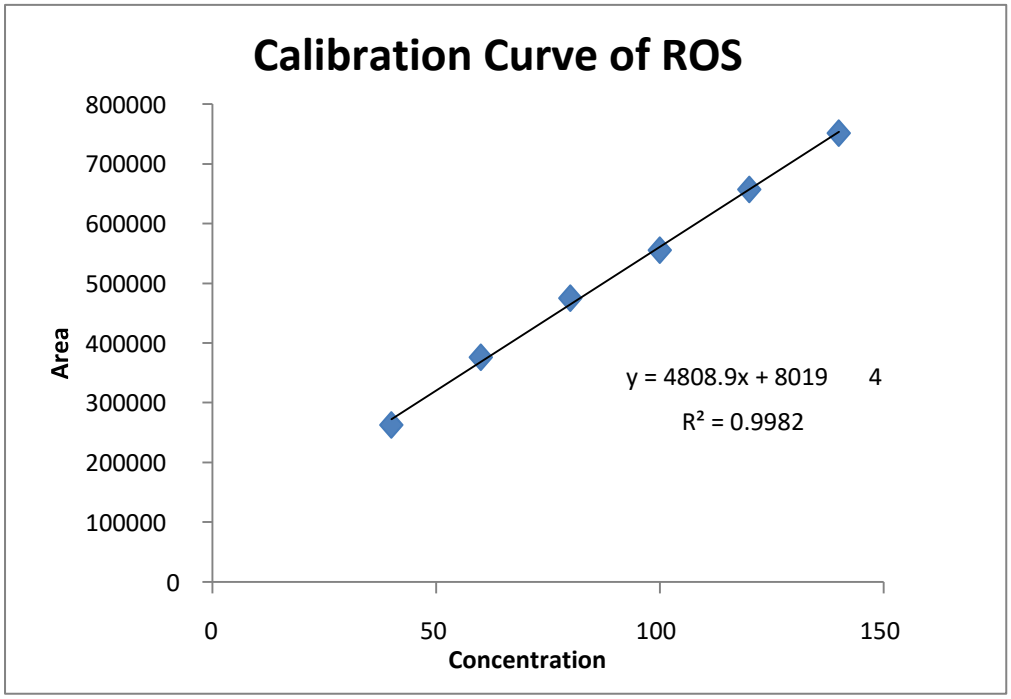


Figure 7.4: Calibration curve of ROS (40 -140µg/ml)

METHOD VALIDATION

Linearity

The linearity is express in term of correlation co-efficient of linear regression analysis. 2-7 ml from working standard solution of ROS and transfer into a 10 ml volumetric flask and diluted up to the mark with HPLC grade Methanol to get the concentration range 40-140 µg /ml of ROS. The standard solution was chromatographed for 10 minutes using mobile phase at a flow rate of 1.0 ml/min. The graph was plotted for peak area vs. concentration for the drug. Data of the calibration plot revealed good linear relationship between area and concentration over the range 40 -140 µg/ml. The linear equations for the calibration plots was y = 4808.9x + 80194 with Regression (r^2) being 0.9982 and statistical data is shown in Table 7.4.

Table : Statistical Data of ROS

Parameters	**Results**
Linear Range(µg/ml)	40 -140 µg/ml
Slope	4805.9
Intercept	80194
Regression Equation	y = 4808.9x + 80194
Co-efficient of Determination (r^2)	r^2 = 0.9982

Precision

 Method Repeatability- The precision of the method was checked by repeated injecting and measuring the area of ROS (40 -140 µg/ml) solutions (n = 5) without changing the parameters is shown in Table

Table Repeatability data of ROS

Conc.	**40**	**60**	**80**	**100**	**120**	**140**
Area	269686	382785	493528	551797	656053	751966
	258425	370355	498874	559524	663568	741853
	265142	381298	502357	545897	649875	754828
	259214	372327	488765	561148	664857	764521
	261739	373856	491854	558654	651259	748976
Mean	262841.2	376124.2	495075.6	555404	657122.4	752428.8
S D	4637.327	5567.351	5478.231	6401.639	6881.455	8306.037
RSD	0.017643	0.014802	0.011065	0.011526	0.010472	0.011039
%RSD	1.76	1.48	1.10	1.15	1.04	1.10

Instrument Repeatability: The precision was checked by repeated measuring of the area of ROS (80µg/ml) solution (n = 6) without changing the parameters of the proposed method. The %RSD values for ROS is found to be 1.17%

(Table 7.6).

Table : Instrument repeatability study of ROS

Conc.	**ROS 80 (µg/ml)**
Area	496843
	493528
	497583
	484395
	501659
	495623
Mean	494938.5
± SD	5820.809
RSD	0.011761
%RSD	1.17

 Intermediate precision a) Intra-day precision

The intra-day precisions of the proposed method were determined by analyzing corresponding responses in triplicate on the same day for 3 different concentrations of standard solutions of ROS (80,100 and 120 µg/ml). % RSD for ROS is 1.05-1.09% shown in Table 7.7. b) Inter-day precision

The inter-day precisions of the proposed method was determined by an1alyzing corresponding responses in triplicate on 3 different days over a period of 1 week for 3 different concentrations of standard solutions of ROS (80,100 and 120µg/ml). Results were reported in terms of % RSD.

The %R.S.D. values for inter-day study 1.12-1.44. The %RSD values listed in Table 7.given below, was <2.0%, confirming that the method was sufficiently precise.

Table : Intra-Day and Inter-Day study of ROS

Conc. (µg/ml)	**Intra-Day Area Mean (n=3) ± SD**	**%RSD**	**Inter-Day Area Mean (n=3) ± SD**	**%RSD**
80	495728± 5280.2	1.06	496665.3 ± 7060.0	1.4
100	552523 ± 6423.0	1.16	548856.3 ± 9538.7	1.7
120	655459 ± 7190.9	1.09	659433.3 ± 8302.8	1.2

Accuracy

Accuracy was estimated by spiking the known analyte sample at three different levels (50%, 100% and 150% of analyte sample) with standard ROS and calculating the percentage recovery of added standard drug. The mean recovery was 99.8% - 100.1%. Results of recovery studies are shown in Table 7.8.

Table 7.8: Determination of Accuracy for ROS

Amt. Of sample (Formulation) µg/ml (*n*=3)	Amt. Of Std drug added µg/ml (*n*=3)	Amt. recovered µg/ml	% Recovery
100	50	149.8	99.8%
100	100	200.2	100.1%
100	150	249.9	99.96%

Sensitivity

The sensitivity of measurement of ROS by the use of proposed method was estimated in terms of Limit of Detection (LOD) and Limit of Quantitation (LOQ). Based on the standard deviation of the response and the slope, LOD and LOQ were estimated.

LOD and LOQ were determined from the standard deviations of the responses for six replicate, shown in Table 7.9 below.

Table 7.9: Result of sensitivity data for ROS

Parameter	ROS
LOD (µg/ml)	4.26
LOQ (µg/ml)	11.62

System suitability

Five replicate injections of standard preparation were injected and resolution, asymmetry, number of theoretical plates and capacity factor were determined. It was carried out using standard solution of ROS (60µg/ml). Results of System suitability study is shown in Table10.

Table 7.10: System suitability parameters

Parameter	ROS
Retention time	1.88±0.02 min
No. of theoretical plate	2513
Asymmetrical factor	0.8
Capacity Factor	2.13

Analysis of ROS in marketed formulation

Powder mixture equivalent to 10mg of ROS was transferred in 100ml volumetric flask containing 50mL methanol, sonicated for 10 min and diluted to mark with same solvent to obtain 100µg/ml of ROS. The resulting solution was filtered using whatman filter paper and injected to get the chromatogram which is shown in Figure 7.5.

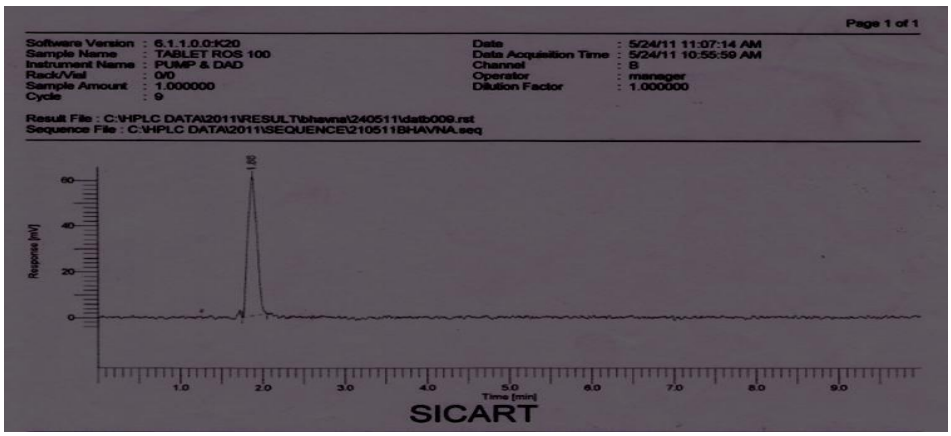


Figure: Chromatogram of Marketed formulation of ROS

Average content of ROS (three times) found in the Marketed formulation from the proposed method was found 99.8%, as shown in Table 7.11.

Table 7.11: Assay Result of Marketed formulation

Formulation	Labelled claim	Avg. Amt. Recovered ROS	Avg. % Assay
TABLET	20mg per tablet	19.98 mg	99.8

SUMMARY AND CONCLUSION

Development and Validation of RP-HPLC Method for Determination ROS AND FEN in Tablet Dosage Form.

SUMMARY OF VALIDATION PARAMETER

The RP-HPLC method for determination of ROS was developed. The results for each validation parameters confirmed linearity, accuracy, precision and selectivity of the developed analytical method. The method showed good linearity over the selected linearity range of 40-140µg/ml. The summary of the developed analytical method is shown in Table 7.12.

Table : Summary of validation parameters for RP-HPLC method

Parameters	ROS
Linearity (µg/ml)	40-140 µg/ml
LOD (µg/ml)	4.26 µg/ml
LOQ (µg/ml)	11.62 µg/ml
%Recovery	99-100.5
Repeatability (%RSD, n = 6)	1.17
Precision (%RSD)	
Inter-day (n = 3)	1.06-1.16
Intra-day (n = 3)	1.2-1.7

SUMMARY OF VALIDATION PARAMETER

The UV spectrophotometric method for simultaneous estimation of ROS and FEN from pharmaceutical dosage form was developed. The developed method was validated as per ICH guidelines. The result obtained for each validation parameters confirmed linearity, precision, accuracy and selectivity of the developed analytical method. The marketed pharmaceutical formulation containing ROS and FEN was subjected to quantitative analysis using the developed method, yielded nearly 100% assay result for ROS and FEN. The summary of the developed method is shown in Table

Table: Summary of Validation Parameter for ROS and FEN

Parameters	Simultaneous method	
	ROS	**FEN**
Linearity (µg/ml)	4-12 µg/ml	16-48 µg/ml
LOD (µg/ml)	0.76 µg/ml	1.96 µg/ml
LOQ (µg/ml)	2.32 µg/ml	5.96 µg/ml
%Recovery	100.9-103.2 %	100.9-101.3 %
Precision (%RSD),		
Inter-day (n = 3)	0.76-1.82 % RSD	0.42-1.47% RSD
Intra-day (n = 3)	0.76-1.05 % RSD	0.32-1.16 % RSD

CONCLUSION

The proposed UV spectrometric method for quantitative determination of FEN and ROS in combined dosage form is found to be simple, rapid, precise, accurate and sensitive. The excipients of the commercial sample analyzed did not interfere in the analysis, which proved the specificity of the method for this formulation. The developed method was found to be more reproducible and sensitive. The method was validated as per International Conference on Harmonization (ICH) guidelines.

	ROS	**FEN**
Linearity (µg/ml)	2-16 µg/ml	14-112 µg/ml
LOD (µg/ml)	0.12	0.67
LOQ (µg/ml)	0.77	2.05
%Recovery	99.99-100.49 %	99.78-100.78 %
Repeatability (%RSD, n = 6)		
Precision (%RSD),		
Inter-day (n = 3)	1.29-1.57 %	0.89-1.88 %
Intra-day (n = 3)	0.80-1.63 %	0.45-1.23 %

CONCLUSION

The proposed HPLC method for quantitative determination of ROS and FEN in combined tablet dosage form was found to be simple, rapid, precise, accurate and sensitive. The excipient of the tablet sample was analyzed and did not interfere in the analysis, which proved the specificity of the method for the estimation of formulations. The developed method was found to be reproducible. The method was validated as per International Conference on Harmonization (ICH) guidelines.

REFERENCES:

1. The Indian pharmacopoeia. New Delhi. The Controller of Publication, Vol-III, p 2071-2073.
2. The British pharmacopoeia. London. HMSO Publication Centre; Vol-I, p 867.
3. The United State Pharmacopoeia XXIV, National formulary, Vol-II, p 2802.
4. www.drugbank.ca/drugs/DB1098 (accessed on 15/12/2011)
5. www.drugbank.ca/drug/DB01039 (accessed on 16/1/2011)
6. http://www.mims.com/india (accessed on 16/12/2011)
7. www.rxlist.com (accessed on 03/12/2011)
8. www.drugsupdate.com (accessed on 03/12/2011)
9. www.nlm.nih.gov/medlineplus/druginfo/meds/a601052.html (accessed on 1/1/2012)
10. www.nlm.nih.gov/medlineplus/druginfo/meds/a603033.html (accessed on 1/1/2012)
11. C. B. Pandya, K.P. Channabasavaraj, J. D. Chudasama, T.T. Mani. "Development and Validation of RP-HPLC Method For Determination Of Rosuvastatin Calcium In Bulk And Pharmaceutical Dosage Form", International Journal of Pharmaceutical Sciences Review and Research 2010; 5(1): 82-86.
12. V. V. Rajkondwar, P. Maini and M. Vishwakarma. "Characterization and method development for estimation and validation of Rosuvastatin Calcium by UV – visible spectrophotometry", International Journal of Theoretical & Applied Sciences, 2009 1(1): 48-53.
13. A. Gupta, P. Mishra, K. Shah. "Simple UV Spectrophotometric Determination of Rosuvastatin Calcium in Pure Form and in Pharmaceutical Formulations", E-Journal of Chemistry 2009; 6(1): 89-92.
14. H. O. Kaila, M. A. Ambasana, R. S. Thakkar, H. T. Saravaia, and A. K. Shah. "A New Improved RP-HPLC Method for Assay of Rosuvastatin Calcium in Tablets", Indian J Pharm Sci. 2010 Sep-Oct; 72(5): 592–598.
15. B.G. Chaudhari, N.M. Patel, P.B. Shah. "Determination of Simvastatin, Pravastatin sodium and Rosuvastatin calcium in tablet dosage forms by HPTLC", Indian J Pharm Sci 2007; 69: 130-132.
16. Journal of Chemtech Research 3(2): 629-635