INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA):IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Review Article

Development And Validation Of RP-HPLC Method For Determination Of Fimasartan In Bulk And Their Dosage Form – A Review

Gayatri Sunil Holkar*, Sonali A. Waghmare

Department of Quality Assurance, S.N.D. College of Pharmacy, Babhulgaon, Yeola, Nashik, Maharashtra, India.

ARTICLE INFO

Received: 04 June 2024
Accepted: 08 June 2024
Published: 01 July 2024
Keywords:
Fimasartan, Precision, RP-HPLC, Development, Validation
DOI:
10.5281/zenodo.12602482

ABSTRACT

Fimasartan is an angiotensin II receptor antagonist used in the treatment of hypertension. Chromatography, particularly RP-HPLC, is critical for separating and studying fimasartan and other related chemicals in pharmaceutical formulations. The development and validation of RP-HPLC techniques for fimasartan is critical to ensuring accurate and reliable quantification. Method validation includes parameters such as accuracy, precision, specificity, linearity, range, limit of detection, limit of quantification, robustness, and system suitability testing, as specified by organizations such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Adherence to these principles ensures that the method is reliable and suitable for use in drug research, development, and manufacturing procedures.

INTRODUCTION

An example of a typical antihypertensive drug is fimasartan. When renin is released from the kidney, the kidney's rennin-angiotensin cascade begins, breaking down angiotensinogen into angiotensin I. This is how fimasartan acts on the kidney. Vasoconstriction is reduced and vasodilation is encouraged when fimasartan binds to the AT1 receptor. 2-(2-Butyl-4-methyl-6-oxo-1-{[2'-(1H-tetrazol-5-yl)-4-biphenylyl] methyl}-1,6-dihydro-5-pyrimidinyl)-N, N-dimethylethanethioamide is chemical name of fimasartan as shown in fig. 1.1

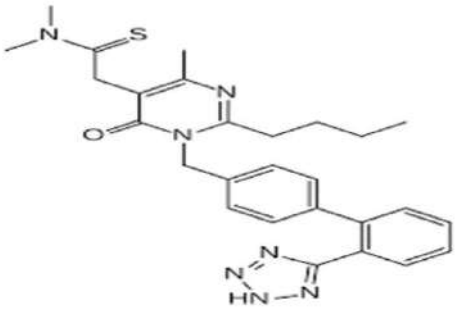

Fig. 1: Chemical structure of Fimasartan

***Corresponding Author:** Gayatri Sunil Holkar
Address: *Department of Quality Assurance, S.N.D. College of Pharmacy, Babhulgaon, Yeola, Nashik, Maharashtra, India.*
: gayatriholkar429@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Few methods, such as ultraviolet (UV), high-performance liquid chromatography (HPLC), and LC-MS, appear to be available for biological fluids and pharmaceutical dosage forms, according to a study of the literature [1–16]. Using a UV detector at 265 nm, the current method offers precise information about the development and validation of Fimasartan in pharmaceutical dosage form and bulk. It is easy to use, precise, quick, repeatable, and sensitive, meeting acceptance criteria based on ICH and FDA guidelines.

METHODS:

Fimasartan Potassium Trihydrate was obtained as sample from pharmaceutical company in Maharashtra, India. The pharmaceutical tablet formulation is obtained from the pharmaceutical firm. HPLC grade water, orthophosphoric acid, and acetonitrile of HPLC grade were used. Analytical grade chemical reagents were the other chemicals used.

Selecting a wavelength

Fimasartan was dissolved in an appropriate solvent (acetonitrile) to determine the wavelength, and the resulting solution was scanned in the ultraviolet (UV) area, or between 200 and 400 nm. According to Fimasartan, the greatest absorption at 265 nm was chosen, as seen in Fig. 2.

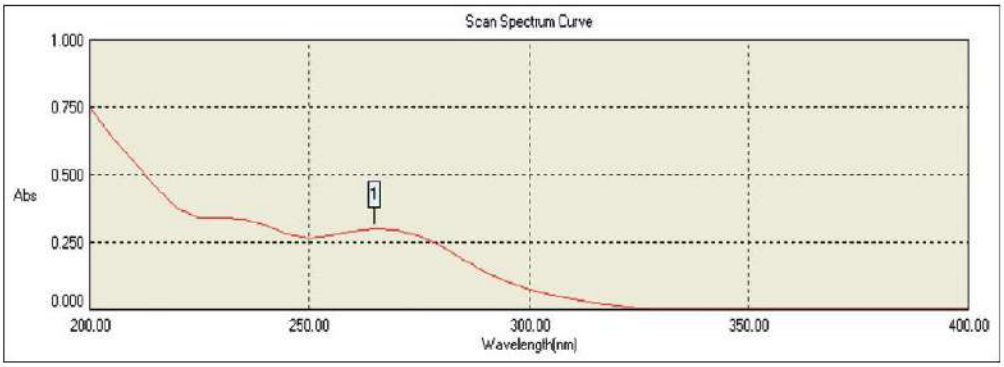

Fig. 2: Ultraviolet spectra of Fimasartan

Conditions for chromatography

An HPLC from Shimadzu was used to examine the entire process. Acetonitrile:0.1% OPA (80:20, v/v) at a flow rate of 0.8 ml/min was used as the mobile phase and a Primacel C18 (150 mm × 4.6 mm i.d., 5 µm) column as the stationary phase. A rheodyne injector with a 25 µl loop was used to inject the samples. Finally, the sample was analysed at 265 nm after the mobile phase had been sonicated, filtered, and degassed. Acetonitrile and 0.1% OPA were used in the mobile phase at an 80:20 v/v ratio to prepare it for the current experiment. This was accomplished by dissolving in a reservoir 20 millilitres of 0.1% OPA and 80 millilitres of acetonitrile. 0.1% orthophosphoric acid was produced by carefully measuring 0.1 ml of OPA and dissolving it in 100 ml of HPLC-grade water. The mobile phase that was prepared earlier is sonicated and degassed.

Preparation of the standard solution

100 mg of fimasartan were precisely weighed and then transferred into a 100 ml volumetric flask to create the standard solution. Add a few milliliters of acetonitrile to this to fully dissolve the medication. Lastly, add acetonitrile (1000 µg/ml) to the solution to make it up to 100 ml.

Preparation of a sample solution

The tablet powder to 100 mg of fimasartan was carefully weighed, then put into a 100 ml volumetric flask, with the volume being raised to 100 ml using acetonitrile. Following around fifteen minutes of sonication, pour the mixture into a second 100 ml volumetric flask (1000 µg/ml) and strain it using Whatman filter paper (No. 1). The solution was further diluted with the diluent until

it reached the working concentration range of the calibration curve.

Curve of calibration

A 100 milliliter volumetric flask was filled with ten milliliters of the standard solution. The remaining volume was increased to 100 milliliters by adding 100 µg/ml of acetonitrile. From this solution, several dilutions with concentrations ranging from 5 µg/ml to 30 µg/ml were made. Following three more injections of these concentrations into the system, the calibration curve was made by plotting the concentration on the X-axis and the peak area on the Y-axis.

How the commercial formulation is assayed

Fimasartan, a film-coated tablet containing a similar amount of potassium trihydrate, is sold. Locally, fimasartan is available under the trade name FIMANTA (120 mg, Ajanta Pharma Limited, India). A sample solution was prepared and diluted to 10 µg/ml, and then 1000 µg/ml was injected into the HPLC apparatus. After determining the percentage assay, the outcomes are shown in Table 1.

Table 1: Assay of tablet formulation

Drug	Fimanta ®tablet label claim (mg)	Amount found (mg)	% Label claim±% RSD (n=3)
Fimasartan	120	119.95	99.96±0.13

END RESULTS AND TALK

Specificity

The system was injected with the blank after the formulation excipients were prepared. The specificity of the developed procedure is shown by an absence of peaks in the retention period that match the analyte peak, suggesting that the excipients in the formulation are not interfering. A blank and standard chromatogram are displayed in Fig. 3

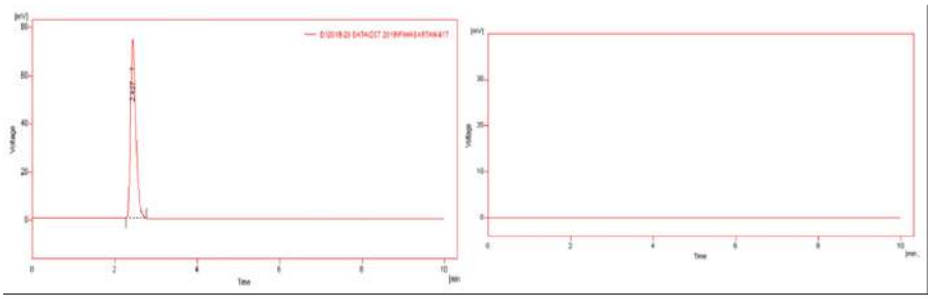

Fig. 3: Blank and standard chromatogram of Fimasartan

Linearity

A 100 ml volumetric flask was filled with ten ml of the standard solution. The remaining volume was increased to 100 ml by adding 100 µg/ml of acetonitrile. From this solution, several dilutions with concentrations ranging from 5 µg/ml to 30 µg/ml were made. These concentrations were injected into the system three more times, and the calibration curve was made by graphing the concentration of fimasartan on the X-axis and the mean peak area on the Y-axis. The method has strong linearity (r2 = 0.9995). The linearity graph and table were supplied by Table 2 and Fig.

Table 2: Linearity table of Fimasartan

Concentration (µg/ml)	Peak area (mV)
5	317.684
10	625.400
15	894.706
20	1176.303
25	1476.828
30	1749.634

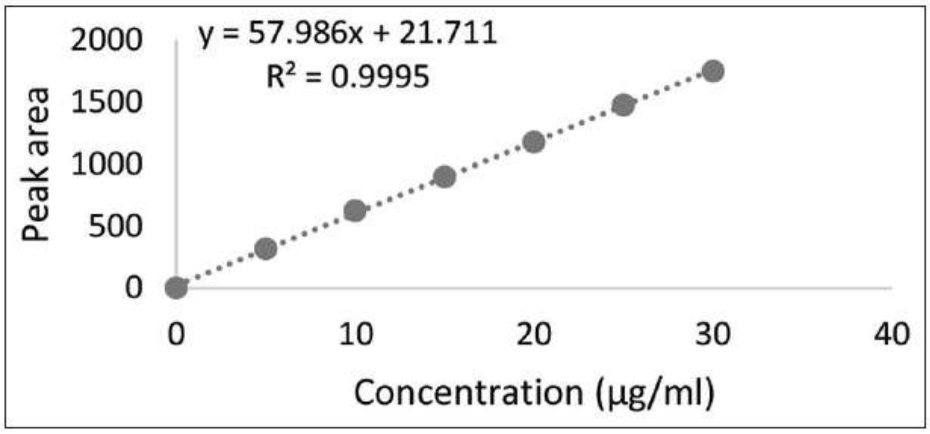

Fig. 4: Linearity curve of Fimasartan

Determination limit (LOD)

This represents the lowest detectable analyte concentration. The formula below can be used to compute this:

LOD = 3.3 × SD/slope.

It was calculated and determined to 1.3 µg/ml.

Quantification limit (LOQ)

This represents the lowest quantifiable analyte concentration. The formula below can be used to compute this:

LOD = 10 × SD/slope.

It was calculated and determined to be 4 µg/ml.

Accuracy

There is a consensus between the measured and true values. Three injections of 50%, 100%, and 150% levels into the HPLC apparatus are required to achieve accuracy. As a conclusion, Table 3 provides a clear representation of the computed amounts found, added, recovered percentage, mean recovery, percentage SD, and percentage RSD, all of which indicate good agreement between the findings.

Table 3: Results showing accuracy of Fimasartan

Level (%)	Amount added (µg/ml)	Amount found (µg/ml)	% Recovery	% Avg recovery	% SD	%RSD
50	5	4.98	99.6	99.6	0.2	0.200
50	5	4.97	99.4			
50	5	4.99	99.8			
100	10	9.97	99.7	99.7	0.1	0.100
100	10	9.96	99.6			
100	10	9.98	99.8			
150	15	14.95	99.6	99.70	0.173	0.173
150	15	14.94	99.6			
150	15	14.95	99.6			

Precision

Repeatability

System Precision

The procedure is as follows: an HPLC system is filled with 10 µg/ml of standard solution six times; the peak regions are noted, and the average, standard deviation, and percent RSD are computed, as indicated in Table 4 and Figure 5.

Method precision

This involves injecting 10 µg/ml of sample solution six times into an HPLC machine, noting

peak regions, and calculating % assay, average, SD, and %RSD, as shown in Table 5 and Fig. 6.

Intermediate Precision/Ruggedness

It is conducted in two different laboratories under two different analysts' conditions on two different days, as shown in Fig. 7. The two laboratories are kept similar.

Analyst-1:

Inject the sample six times into the HPLC system at a concentration of 100% (10 µg/ml). Take note of the area after every injection and compute the SD and % RSD values, as indicated in Table 6.

Analyst 2:

Inject the sample six times into the HPLC system at a concentration of 100% (10 µg/ml). Take note of the area after every injection and compute the SD and % RSD values, as indicated in Table 6.

Day 1:

Inject 100% concentration of sample (i.e., 10 µg/ml) into HPLC system 6 times. Note the area for each injection and calculate the SD and% RSD values, as given in Table 6. On Day 2, inject the sample at 100% concentration (10 µg/ml) into the HPLC system six times. Record the area for each injection and calculate the SD and percentage RSD values, as shown in Table 6.

Reproducibility

This is generally considered as the laboratories' precision. In two different laboratories, inject 100% of the sample (10 µg/ml) six times into separate HPLC systems to carry out the test. As indicated in Table 7 and Figure 8, note the area for each injection and calculate the SD and% RSD values.

Table 5: Results showing method precision values of Fimasartan

Concentration (µg/ml)	Retention time	Peak area (mV)	%Assay	Average %Assay	S. D	%RSD
10	2.4	627.497	100.10	99.96	0.120	0.120
10	2.4	626.364	99.90			
10	2.4	625.443	99.81			
10	2.4	627.184	100.00			
10	2.4	626.287	99.90			
10	2.4	627.360	100.10			

Table 4: Results showing system precision values of Fimasartan

Concentration (µg/ml)	Retention time	Peak area (mV)	Average peak area (mV)	SD	%RSD
10	2.4	625.410	626.33	1.34	0.21
10	2.4	626.675			
10	2.4	625.054			
10	2.4	628.253			
10	2.4	627.430			
10	2.4	625.138			

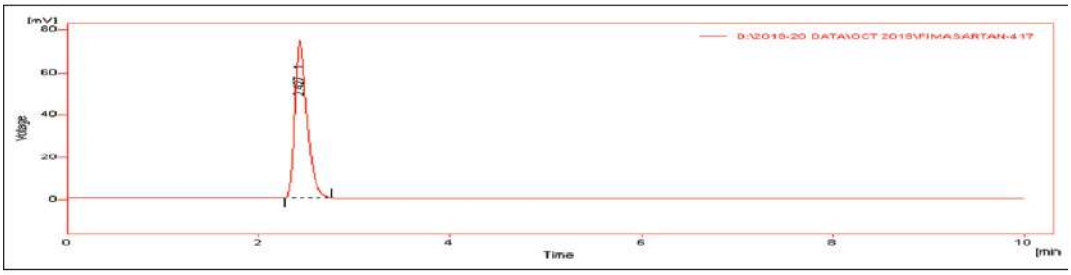

Fig. 5: System precision peak of Fimasartan

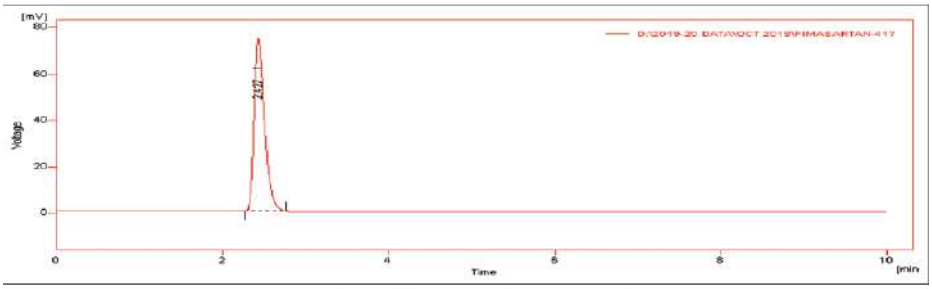

Fig. 6: Method precision peak of Fimasartan

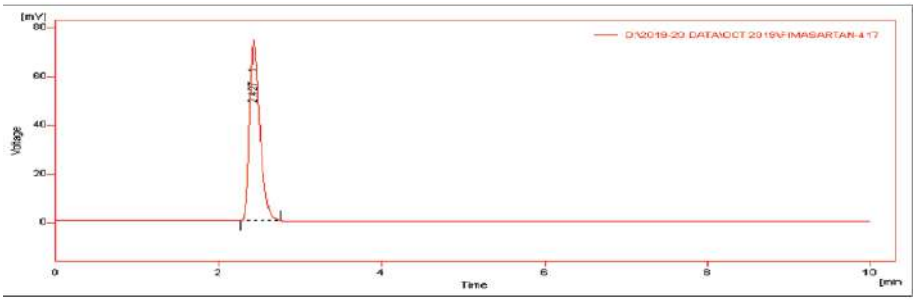

Fig. 7: Intermediate precision peak of Fimasartan

Table 6: Results showing intermediate precision values of Fimasartan

Lab-1 (%Assay)					Lab-2 (%Assay)			
Conc. (µg/ml)	Day-1		Day-2		Day-1		Day-2	
	A-1	A-2	A-1	A-2	A-1	A-2	A-1	A-2
10	100.60	100.10	100.40	100.30	100.40	100.30	100.00	100.10
10	100.20	100.30	99.90	100.00	100.60	100.00	100.30	100.60
10	100.40	100.60	100.30	100.30	100.60	100.30	100.40	100.30
10	100.30	100.30	100.10	100.50	100.30	100.30	100.10	99.90
10	100.50	100.40	100.30	100.60	100.20	100.50	100.10	100.40
10	100.00	100.00	100.60	100.30	100.10	100.00	100.30	100.30
Avg	100.33	100.28	100.27	100.33	100.37	100.23	100.20	100.21
SD	0.22	0.21	0.24	0.21	0.21	0.20	0.15	0.24
%RSD	0.22	0.21	0.24	0.21	0.21	0.20	0.15	0.24
Intermediate precision within laboratory variations (n=6)								
Avg		100.30			Avg		100.27	
SD		0.032			SD		0.072	
%RSD		0.032			%RSD		0.072	

Table 7: Results showing reproducibility values of Fimasartan

Lab-1 (%Assay)		Lab-2 (%Assay)	
Avg	100.30	Avg	100.27
SD	0.032	SD	0.072
%RSD	0.032	%RSD	0.072
Reproducibility between laboratories (n=48)			
Avg		100.29	
SD		0.021	
%RSD		0.021	

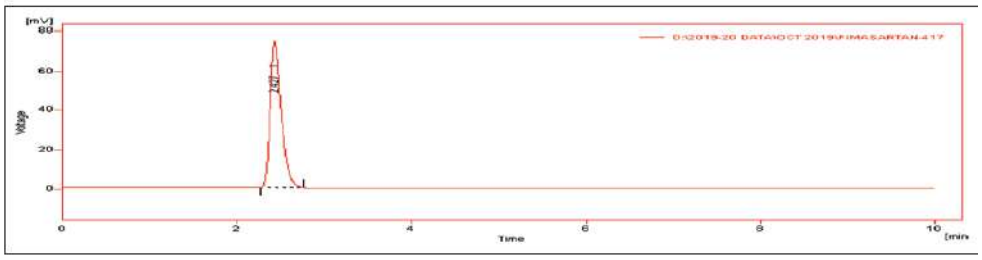

Fig. 8: Reproducibility peak of Fimasartan

Robustness

A purposeful or accidental change of a parameter shouldn't impact any method. In order to

accomplish this, adjust the mobile phase (± 10%) and flow rate (± 10%).

Change in flow rate

The flow rate can be adjusted by ± 10% (0.7 ml/min and 0.9 ml/min) to achieve this. Six injections at 0.7 and 0.9 ml/min flow rates should be made with the 100% concentration (10 µg/ml). Table 8 and Figures 9 and 10 illustrate this process. Take note of the peak location and compute the percentage assay, average, SD, and % RSD for both flow rates.

Table 8: Results showing change in flow rate values of Fimasartan

Flow rate (0.7 ml/min)				Flow rate (0.9 ml/min)			
Conc. (µg/ml)	Rt (mins)	Peak area (mV)	%Assay	Conc. (µg/ml)	Rt (mins)	Peak area (mV)	%Assay
10	2.7	625.767	99.81	10	2.1	625.296	99.61
10	2.7	623.134	99.41	10	2.1	623.590	99.51
10	2.7	624.620	99.61	10	2.1	625.337	99.71
10	2.7	624.178	99.61	10	2.1	625.176	99.71
10	2.7	623.111	99.41	10	2.1	624.659	99.61
10	2.7	625.376	99.71	10	2.1	623.535	99.51
Mean			99.59	Mean			99.61
SD			0.160	SD			0.089
%RSD			0.161	%RSD			0.089

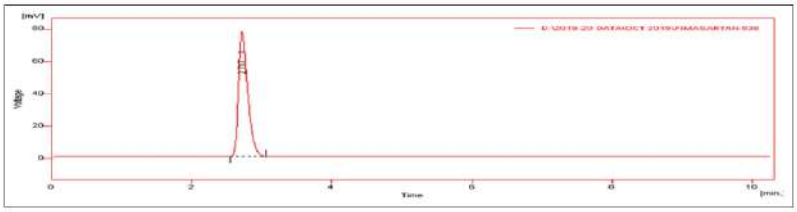

Fig. 9: Peak which was eluted at 0.7 ml/min of flow rate

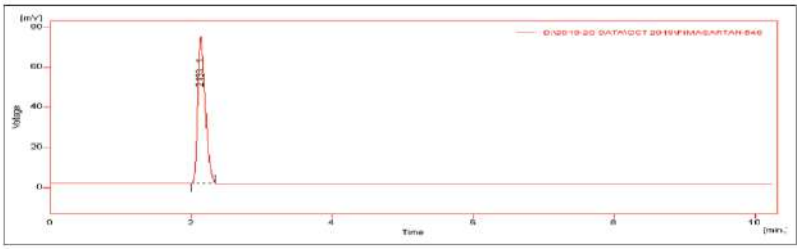

Fig. 10: Peak which was eluted at 0.9 ml/min of flow rate

Change in mobile phase (+10% organic phase).

The organic phase percentage (88:12 v/v and 72:28 v/v) is adjusted by ± 10% to achieve this. Using both mobile phase proportions (88:12 v/v and 72:28 v/v), inject the 100% concentration (10 µg/ml) six times. Table 9 and Figures 11 and 12 illustrate how to compute the % Assay, Average, SD, and % RSD for both mobile phase proportions while noting the peak area.

Table 9: Results showing change in mobile phase values of Fimasartan

Mobile phase −10%				Mobile phase +10%			
Conc. (µg/ml)	Rt (mins)	Peak area (mV)	%Assay	Conc. (µg/ml)	Rt (mins)	Peak area (mV)	%Assay
10	2.3	625.767	99.81	10	2.6	625.337	99.71
10	2.3	625.376	99.71	10	2.6	625.176	99.71
10	2.3	624.296	99.61	10	2.6	625.376	99.71
10	2.3	623.590	99.51	10	2.6	624.296	99.61
10	2.3	625.176	99.71	10	2.6	624.659	99.61
10	2.3	623.111	99.41	10	2.6	625.376	99.71
Mean			99.63	Mean			99.68
SD			0.147	SD			0.052
%RSD			0.148	%RSD			0.052

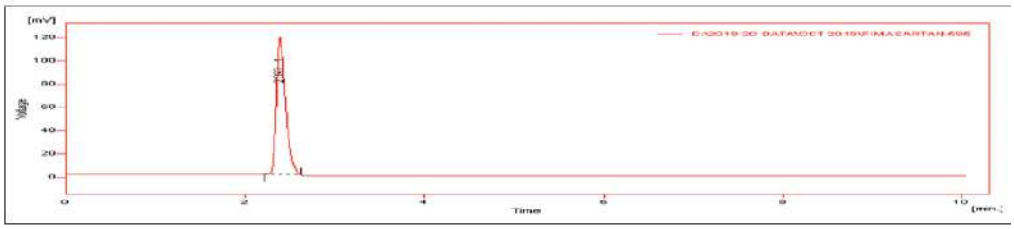

Fig. 11: Peak which was eluted at +10% of mobile phase

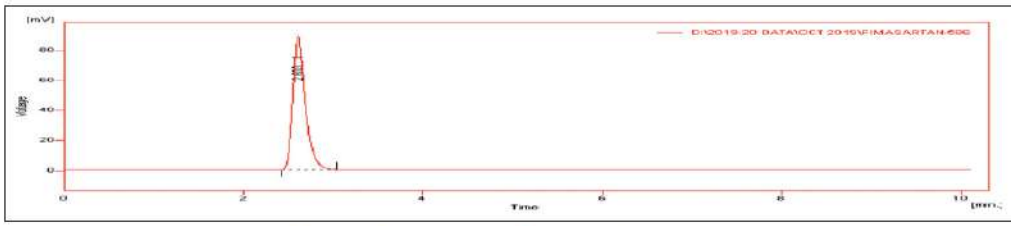

Fig. 12: Peak which was eluted at −10% of mobile phase

Solution Stability

This is carried out for 0, 24, and 48 hours. Inject 100% concentration (10 µg/ml) 6 times during 0, 24, and 48 hours. Table 10 and Figures 13–15 illustrate how to compute the percentage assay, average, SD, and %RSD for both mobile phase proportions while noting the peak area.

Force Degradation Studies

This includes acid and alkali degradation, oxidative deterioration, photolytic degradation, and thermal degradation, all of which are well illustrated in Table 11 and Figures 16-20.

Table 10: Results showing solution stability values of Fimasartan

0 h				24 h		48 h	
Concentration (µg/ml)	Retention time (mins)	Peak area (mV)	%Assay	Peak area (mV)	%Assay	Peak area(mV)	%Assay
10	2.4	625.405	99.81	625.402	99.81	623.524	99.51
10	2.4	627.537	100.10	624.785	99.81	625.510	99.81
10	2.4	624.381	99.61	623.607	99.51	624.462	99.61
10	2.4	628.216	100.20	624.324	99.61	623.180	99.41
10	2.4	626.422	99.91	625.924	99.81	624.989	99.71
10	2.4	629.979	100.51	623.170	99.41	625.917	99.81
Mean			100.02	Mean	99.66	Mean	99.64
SD			0.32	S. D	0.18	S. D	0.16
%RSD			0.32	%RSD	0.18	%RSD	0.16

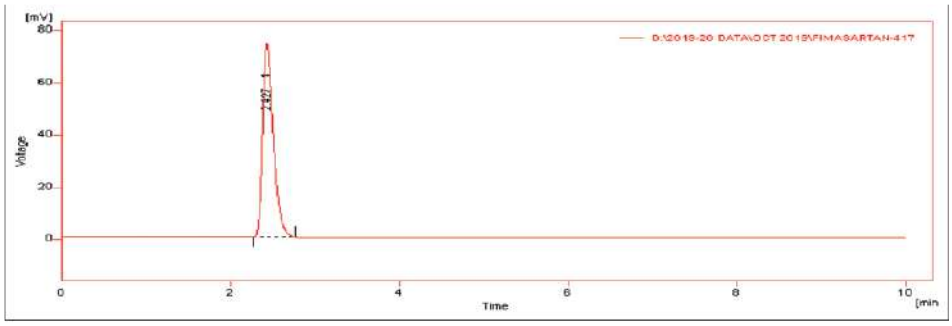

Fig. 13: Peak which was eluted at 0 h

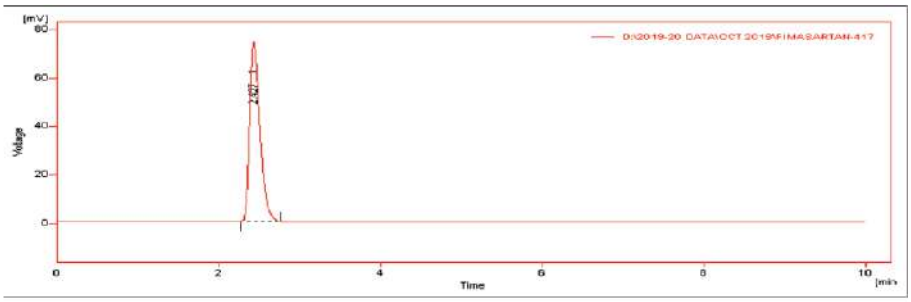

Fig. 14: Peak which was eluted at 24 h

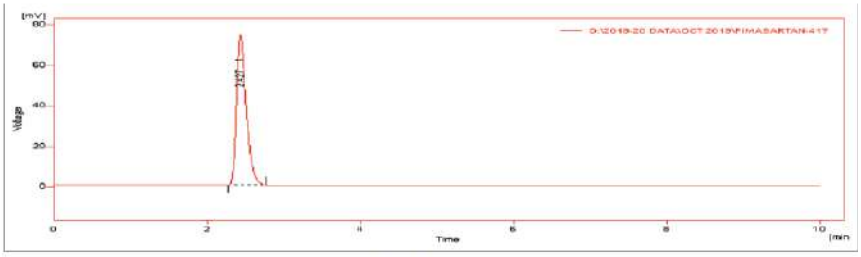

Fig. 15: Peak which was eluted at 48 h

Table 11: Results showing forced degradation values of Fimasartan

Degradation parameter (n=3)	Concentration (µg/ml)	Peak area (mV)	Average peak area (mV)	%Degraded	%Recovered
Acid	10	795.442	794.98	27.2	72.8
	10	794.251			
	10	795.254			
Alkali	10	698.982	698.25	11.6	88.4
	10	697.251			
	10	698.523			
Peroxide	10	983.123	982.83	57.1	42.9
	10	982.145			
	10	983.251			
Thermal	10	624.252	624.54	0.14	99.86
	10	625.124			
	10	624.251			
Photolytic	10	625.124	625.16	0.04	99.96
	10	625.231			
	10	625.145			

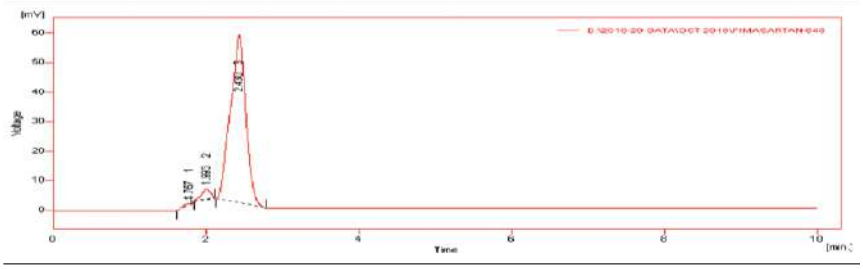

Fig. 16: Peak showing acid degradation

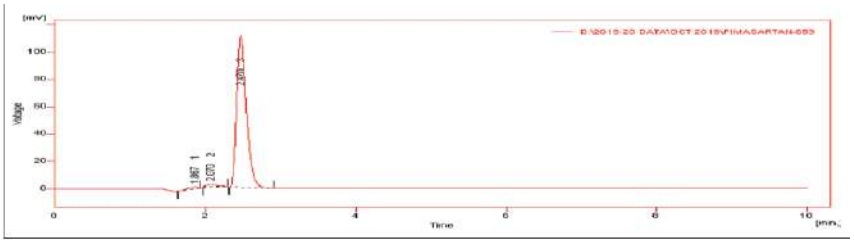

Fig. 17: Peak showing alkali degradation

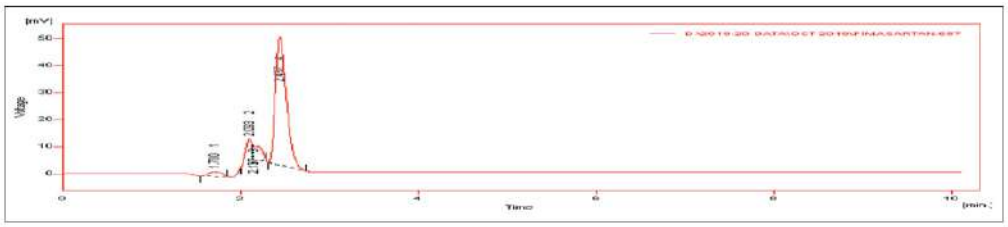

Fig. 18: Peak showing oxidative degradation

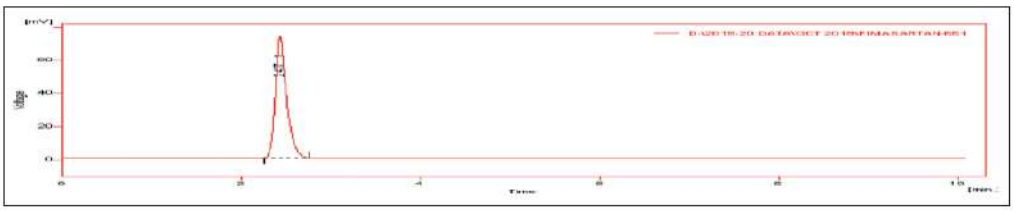

Fig. 19: Peak showing photolytic degradation

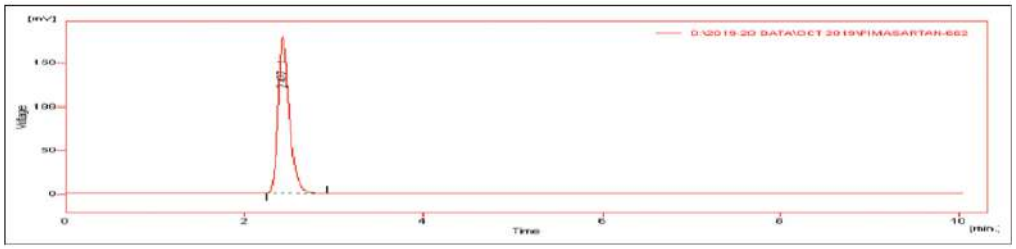

Fig. 20: Peak showing thermal degradation

Preparation of Solutions

a. Prepare 0.1N HCl for acid degradation.

Pipette 0.812 ml of HCl into a 100-ml volumetric flask, then fill with pure water (0.1N).

b. Prepare 0.1N NaOH for alkali degradation.

Weigh 0.4 g of sodium hydroxide pellets precisely, then transfer them to a 100 mL volumetric flask that's filled with distilled water (0.1N).

c. Prepare a solution of 3% hydrogen peroxide for oxidative testing.

Pipette 3 ml of hydrogen peroxide into a 100 ml volumetric flask, then fill with distilled water to make 3% solution.

Method for FDS studies

1. For investigations into acid deterioration- Pipette out 1 ml of Fimasartan stock solution, then add 1 ml of 0.1N Hydrochloric acid to make up to 10 ml of acetonitrile. After 60 minutes, evaluate the peak area by introducing the sample into the HPLC system with the optimal mobile phase.
2. For investigations into alkali deterioration- Pipette out 1 ml of Fimasartan stock solution, then add 1 ml of 0.1N Sodium hydroxide to make up to 10 ml of acetonitrile. After 60 minutes, evaluate the peak area by introducing the sample into the HPLC system with the optimal mobile phase.
3. For investigations into oxidative deterioration- Pipette out 1 ml of Fimasartan stock solution, then add 1 ml of 3% hydrogen peroxide to make up to 10 ml of acetonitrile. After 60 minutes, evaluate the peak area by introducing the sample into the HPLC system with the optimal mobile phase.
4. For investigations into photolytic deterioration- Pipette out 1 ml of Fimasartan stock solution, to this add acetonitrile to make it 10 ml. Put the solution in the UV cabinet for 60 minutes. Inject the sample into the optimized mobile phase of the HPLC instrument to determine the peak area.
5. For investigations into thermal deterioration- Pipette out 1 ml of Fimasartan stock solution, to this add acetonitrile to make the solution to 10 ml. Place the solution in a hot air oven at

60°C for 60 minutes. Inject the sample into the optimized mobile phase of the HPLC instrument to determine the peak area. The above figures clearly show that peroxide has the highest degradation rate, followed by acid and alkali. There is no deterioration in photolysis or thermal.

CONCLUSION

The article describes the development and validation of Fimasartan techniques using RP-HPLC (technique). Method development and validation are critical activities that ensure that parameters are measured accurately while meeting performance restrictions. Several factors influence separation selectivity, including column, buffer, detector, wavelength, organic solvent composition, and pH. RP-HPLC has several advantages, including good selectivity, sensitivity, cost-effectiveness, reduced time consumption, and low limits of detection. The optimization of RP-HPLC entails modifying parameters such as temperature, flow rate, and mobile-phase modifier type/concentration. These modifications are intended to improve separation efficiency and analytical performance. Validation entails evaluating several criteria such as specificity, precision, accuracy, detection limit, and linearity, among others, in order to ensure the method's dependability and robustness.

CONFLICTS OF INTEREST

The author said that they have no conflict of interest.

AUTHOR'S FUNDING

The author(s) did not receive any specific support for this work.

REFERENCE

1. Sharma BK. Introduction to analytical chemistry. In: Instrumental Methods of Chemical Analysis. Vol. 23. Meerut: Goel Publishing House; 2012. p. 9-303.
2. Pandya CP, Rajput SJ. Validated stability indicating RP-HPLC method for the determination of fimasartan in presence of degradation products. Indo Am J Pharm Res 2017; 7:929-46.
3. Moon HW, Yousaf AM, Cho KH, Yong CS. Evaluation of stability and simultaneous determination of fimasartan and amlodipine by a HPLC method in combination tablets. Asian J Pharm Sci 2014; 9:123-8.
4. Mohammed AB, Rudwan EH. RP-HPLC method development and validation of stability indicating method a for estimation of losartan potassium under stress condition and tablet dosage form. Int J Pharm Sci Res 2016; 7:2343-51.
5. Sumithra M, Shanmugasundaram P, Sankar AS, Niharika. Method development and validation of losartan potassium by RP-HPLC. Res J Pharm Biol Chem Sci 2012; 3:463-78.
6. Paladugu ND, Rao GD, Satyanarayana B, Poloju D. Development and validation of RP-HPLC method for quantification of valsartan and its pharmaceutical formulations. Int J Drug Dev Res 2013; 5:199-205.
7. Pal R, Padma S, Bhargav Y, Reddy GR. RP-HPLC method development and validation of valsartan in bulk and its tablet dosage form. J Biomed Pharm Sci 2019; 2:122.
8. Vinzuda DU, Sailor GU, Sheth NR. RP-HPLC method for determination of valsartan in tablet dosage form. Int J ChemTech Res 2010; 2:1461-7.
9. Haque MA, Amrohi SH, Kumar KP, Nivedita G, Kumar TP, Mohanty D, et al. Stability indicating RP-HPLC method for the estimation of valsartan in pharmaceutical dosage form. IOSR J Pharm 2012; 2:12-8.
10. Siddiqui MM, Qasim SS, Abueida EY. Isocratic RP-HPLC method validation and verification of losartan potassium in pharmaceutical formulations with stress test

stability for drug substance. Der Pharm Lett 2011; 3:160-7.

11. Panigrahy UP, Kumari KN, Reddy T, Abbulu K. RP-HPLC method development and validation for simultaneous estimation of prazosin and polythiazide in bulk and pharmaceutical dosage form. Res J Pharm Technol 2020; 13:1779-89.
12. Masthanamma SK, Pradeepthi, Jahnavi. Stability indicating RP-HPLC method for determination of azilsartan medoxomil in pharmaceutical dosage form. Res J Pharm Technol 2014; 7:168-72.
13. Bhadoriya U, Dhaked H, Danodia AK. RP-HPLC method development and validation for estimation of telmisartan in bulk and tablet dosage form. Int J Drug Regul Aff 2013; 1:61-4.
14. Raghu Babu K, Sarma ES, Kumari NA, Raju GM, Sarma GV. Simple and stability indicating RP-HPLC assay method development and validation of telmisartan in bulk and dosage form. Der Pharm Lett 2015; 7:274-80.
15. Patro SK, Kanungo SK, Patro VJ, Choudhury NS. Stability indicating RP-HPLC method for determination of valsartan in pure and pharmaceutical formulation. J Chem 2009; 7:487197.
16. Kore RS, Mahaparale SP, Bhagat AP. Stability indicating RP-HPLC method development and validation for estimation of azilsartan medoxomil in tablet dosage form. World J Pharm Res 2019; 8:1023-35.
17. Indian Pharmacopoeia (2018) Government of India, Ministry of Health & Family Welfare, 8th edn. Indian Pharmacopoeia Commission, Ghaziabad, pp 4616–4618
18. Agrawal KS, Gandhi LR (2019) UV spectrophotometric method of fimasartan drug and its tablet formularion. Asian Journal of Pharmaceutical Research and Development 7(5):26–30.
19. ICH – Harmonized Tripartite Guideline (2005) Validation of analytical procedures: text and methodology Q2 (R1). In: International conference on harmonization, IFPMA, Geneva, Switzerland.
20. R. Achala, N. Khannuri, H. Pant, H. Khan, "Hypertension in India: A systematic review and metanalysis of prevalence awareness and control of hypertension," Journal of hypertension, vol.32, Issue 6, pp. 1170-1177, 20

HOW TO CITE: Gayatri Sunil Holkar, Sonali A. Waghmare, Development And Validation Of RP-HPLC Method For Determination Of Fimasartan In Bulk And Their Dosage Form – A Review, Int. J. of Pharm. Sci., 2024, Vol 2, Issue 7, 13-24. https://doi.org/10.5281/zenodo.12602482