Analytical Method Development and Validation for simultaneous estimation of Finerenone and Empagliflozin by RP-HPLC in prepared tablets

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Abstract **—A simple, fast and economic reversed phase high performance liquid chromatographic (RP-HPLC) method has been developed and validated for simultaneous and quantitative analysis of Finerenone and Empaglifozin in laboratory prepared tablets. The method was developed using the mobile phase comprising of methanol, water and trifluoroacetic acid in the ratio of 68:32:0.05 (v/v) over C-18 hypersil column (250 x 4.6 mm, 5 um) at ambient temperature. The flow rate was at 1.0 ml/min and the eluent was monitored by UV detection at 245 nm. The retention times for the nephroprotective drugs- Finerenone & Empagliflozin were found to be 3.2 and 4.6 minutes, respectively, with good resolution and symmetric peaks. The recoveries were found to be >99% for both Finerenone and Empaglifozin, demonstrative of accuracy of the protocol. Inter-day and intra-day precision of the new method were less than the maximum allowable limit (RSD%>2.0) according to ICH, USP and FDA guidelines. The method showed linear response with correlation coefficient (r^2) values of 0.99999 for finerenone and 0.99995 for empagliflozin. The LOD & LOQ of finerenone and empagliflozin were found to be 0.03 ug/ml, 0.09 ug/ml & 0.27 ug/ml, 0.81 ug/ml respectively. Therefore, the method was found to be accurate, reproducible, sensitive and less time consuming and can be successfully applied for the assay of finerenone and empagliflozin in combined formulations.**

***IndexTerms*— HPLC, finerenone, empagliflozin, analysis, tablets**

I. INTRODUCTION

The incidence of chronic kidney disease (CKD), type 2 diabetes mellitus (T2DM), and cardiovascular diseases is rapidly increasing worldwide, leading to a significant rise in morbidity, mortality, and healthcare costs. These conditions are interrelated, with T2DM being a leading cause of CKD and a major risk factor for cardiovascular complications. In recent years, there has been a paradigm shift in the management of such comorbidities with the introduction of novel drug classes that not only manage glycemic levels but also offer cardio-renal protection. Among these, finerenone and empagliflozin have emerged as promising agents, both approved for use in patients with CKD and heart failure, particularly those with coexisting T2DM.

Finerenone is a non-steroidal selective mineralocorticoid receptor antagonist (MRA). It acts by blocking the overactivation of mineralocorticoid receptors in the kidney, heart, and vasculature, which contributes to inflammation, fibrosis, and progression of kidney and cardiovascular diseases [1]. Unlike traditional MRAs such as spironolactone and eplerenone, finerenone offers greater receptor selectivity and a reduced risk of hyperkalemia and hormonal side effects [2]. Its therapeutic efficacy and safety have been demonstrated in large-scale randomized controlled trials such as the FIDELIO-DKD and FIGARO-DKD, which showed that finerenone significantly reduces the risk of CKD progression and cardiovascular morbidity in patients with T2DM [3,4].

Empagliflozin is a sodium-glucose co-transporter 2 (SGLT2) inhibitor that lowers blood glucose levels by reducing renal glucose reabsorption and promoting glycosuria. Beyond its antidiabetic effect, empagliflozin has shown substantial cardiovascular and renal benefits, including reductions in hospitalization for heart failure and slowing of CKD progression [5]. Major clinical trials such as EMPA-REG OUTCOME, EMPEROR-Reduced, and EMPA-KIDNEY have established empagliflozin's protective role in patients with or without diabetes [6,7]. As a result, it has been approved not only for the treatment of T2DM but also for heart failure with reduced ejection fraction (HFrEF) and CKD, highlighting its multifaceted therapeutic potential [8].

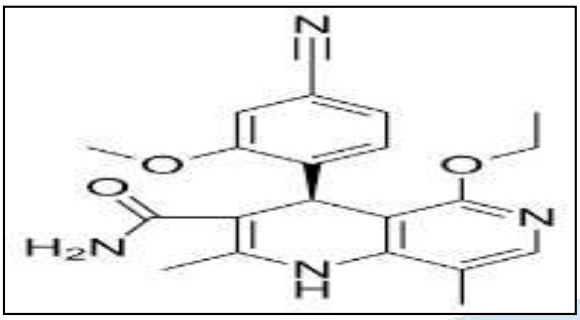


Fig 1: Chemical structure of Finerenone

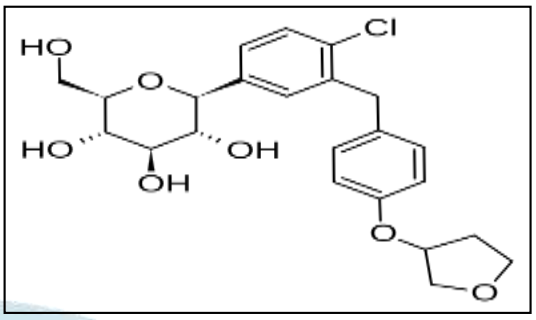


Fig 2: Chemical structure of Empagliflozin

The combination of finerenone and empagliflozin is an emerging therapeutic strategy for patients with T2DM and CKD, as both drugs exert complementary mechanisms of action. While empagliflozin reduces intraglomerular pressure and modulates tubuloglomerular feedback through osmotic diuresis and natriuresis, finerenone directly antagonizes the pro-inflammatory and pro-fibrotic effects of aldosterone. This combination may provide additive or even synergistic renal and cardiovascular protection [9].

Given their recent clinical importance and potential future use in fixed-dose combinations, there is a growing need for robust, reliable, and validated analytical methods to estimate both drugs simultaneously in pharmaceutical formulations and biological matrices. However, literature on simultaneous estimation of finerenone and empagliflozin is limited, and no official method has been included in pharmacopoeias to date.

Reverse-phase high-performance liquid chromatography (RP-HPLC) is one of the most widely used analytical techniques in pharmaceutical analysis due to its high accuracy, sensitivity, and reproducibility. It plays a crucial role in routine quality control, dissolution testing, and stability studies of drug products. The International Council for Harmonisation (ICH) guidelines Q2(R1) outline the essential parameters for method validation, including specificity, linearity, accuracy, precision, limit of detection (LOD), limit of quantitation (LOQ), and robustness [10].

Hence, the present study was undertaken to develop and validate a simple, precise, accurate, and stability-indicating RP-HPLC method for the simultaneous estimation of finerenone and empagliflozin in laboratory-prepared tablet formulations. This method aims to provide a reliable analytical tool for future formulation development and quality assurance purposes.

II. Materials and Methods

1. Chemicals and Reagents

Finerenone and empagliflozin reference standards were purchased from Bulat pharmaceuticals pvt ltd, Haryana. HPLC-grade methanol, water and trifluoroacetic acid were procured from Merck (India). Potassium dihydrogen phosphate and acetonitrile (analytical grade) were procured from S. D. Fine Chem Pvt. Ltd. All solvents and reagents used were of analytical or HPLC grade.

2. Instrumentation and Chromatographic Conditions

Chromatographic analysis was performed on a [YOUNG LIN ACME9000] HPLC system equipped with a UV-visible detector (730D) and auto-injector. Data acquisition and processing were carried out using Lab Solutions software.

- **Column**: Hypersil BDS C18 column (250 mm × 4.6 mm, 5 µm)
- **Mobile phase**: Methanol, water and trifluoroacetic acid (68:32:0.05 v/v)
- **Flow rate**: 1.0 ml/min
- **Detection wavelength**: 245 nm
- **Injection volume**: 20 µL
- **Column temperature**: Ambient (25 ± 2°C)
- **Run time**: 08 minutes

3. Determination of the λmax

The standard solutions of Fine and Empa having strengths 10 µg/ml were prepared in methanol. These solutions were scanned individually and in combination using a UV-visible spectrophotometer (range 200–400 nm) to determine the wavelength of maximum absorbance (λmax). Both drugs showed satisfactory absorbance at 245 nm, which was selected as the detection wavelength for RP-HPLC analysis due to good response and minimal baseline noise.

4. Preparation of Laboratory Tablets

Tablets were prepared using the direct compression method. Each tablet contained 20 mg of finerenone and 25 mg of empagliflozin. The APIs were blended with suitable excipients, and the mixture was compressed using a single-punch tablet machine. These tablets were used for analytical purposes only.

5. Preparation of Standard Stock Solutions

Accurately weighed 20 mg of Finerenone & 25 mg of Empagliflozin were transferred into a 100 mL volumetric flask, dissolved in the diluent, and the volume was made up to the mark to obtain a stock solution with a concentration of 200 & 250 µg/mL. From this stock solution, 2 mL was pipetted into a separate 20 mL volumetric flask and diluted to volume with the same diluent to achieve a final concentration of 20 & 25 µg/mL. The solution was shaken well and filtered through a 0.2 µm nylon syringe filter before injecting into the HPLC system (20µg/ml & 25 µg/ml).

6. Preparation of Sample Solution

10 tablets were weighed individually and then crushed into a fine powder using a mortar and pestle. An accurately weighed quantity of the powdered tablet, equivalent to the required amount of active pharmaceutical ingredients (APIs), was transferred to a 100 mL volumetric flask. The contents were dissolved in the diluent with vigorous shaking and sonicated for 2 minutes to ensure complete dissolution. From this solution, 2 mL was pipetted into a 20 mL volumetric flask, diluted to volume with the same diluent, shaken, and sonicated. The final solution was filtered through a 0.2 µm membrane filter prior to HPLC analysis.

7. Method Validation

The method was validated as per ICH Q2(R1) guidelines for the following parameters:

7.1 System Suitability

System suitability was assessed by injecting five replicates of a standard solution before sample analysis. Parameters evaluated included: Retention time (Rt), Theoretical plates (N), Tailing factor (T), Resolution (Rs), %RSD of peak areas. All values were within acceptable limits, confirming suitability of the system.

7.2 Specificity

Specificity was confirmed by analyzing placebo and sample solutions to check for interference at the retention times of the analytes.

7.3 Accuracy (Recovery Studies)

Accuracy was assessed by recovery studies at 80%, 100%, and 120% levels. Known quantities of standard drugs were added to pre-analyzed samples, and percentage recovery was calculated.

7.4 Precision

Precision was evaluated in terms of:

- **Intra-day precision**: Four replicates of sample solutions were analyzed on the same day.
- **Inter-day precision**: The same procedure was followed on two different days. Results were expressed as %RSD (Relative Standard Deviation).

7.5 Linearity

Linearity was evaluated by preparing standard solutions of finerenone (5–30 µg/mL) and empagliflozin (12.5–75 µg/mL). Calibration curves were plotted between peak area and concentration, and correlation coefficients (R^2) were determined.

7.6 Limit of Detection (LOD) and Limit of Quantification (LOQ)

LOD and LOQ were calculated using the formula:

- **LOD** = 3.3 × (σ/S)
- **LOQ** = 10 × (σ/S)

where σ is the standard deviation of the response and S is the slope of the calibration curve.

7.7 Robustness

Robustness was evaluated by making small, deliberate changes in method parameters:

- Flow rate (±0.1 mL/min)
- Mobile phase composition (±5%)

The effect on retention time, peak area, and resolution was observed.

7.8 Ruggedness

Ruggedness was evaluated by analyzing the same sample under different conditions like change in batch or lot no of solvent. The %RSD of results was calculated to assess reproducibility under varied conditions.

7.9 Analysis of formulated tablet

The formulated tablet test preparation was prepared as described earlier, with 2 injections made from the tablet solution. The active pharmaceutical ingredient (API) content was determined by comparing the observed amount (in mg) of Finerenone and Empagliflozin to the label claim. The assay was calculated based on the peak area from the chromatograms, and the percentage assay of the formulated tablet was determined, ensuring the method's accuracy and suitability for routine analysis.

III. Results and Discussions

1. Method Development

A reverse-phase HPLC method was successfully developed for the simultaneous estimation of finerenone and empagliflozin in prepared tablet formulations. After evaluating various solvent systems and detection wavelengths, a mobile phase of methanol, water and trifluoroacetic acid in the ratio of 68:32:0.05 (v/v) and detection at 245 nm provided well-resolved, sharp, and symmetrical peaks for both analytes.

- **Retention time**: Finerenone ~ 3.2 min; Empagliflozin ~ 4.6 min
- The method showed good peak symmetry and baseline separation.

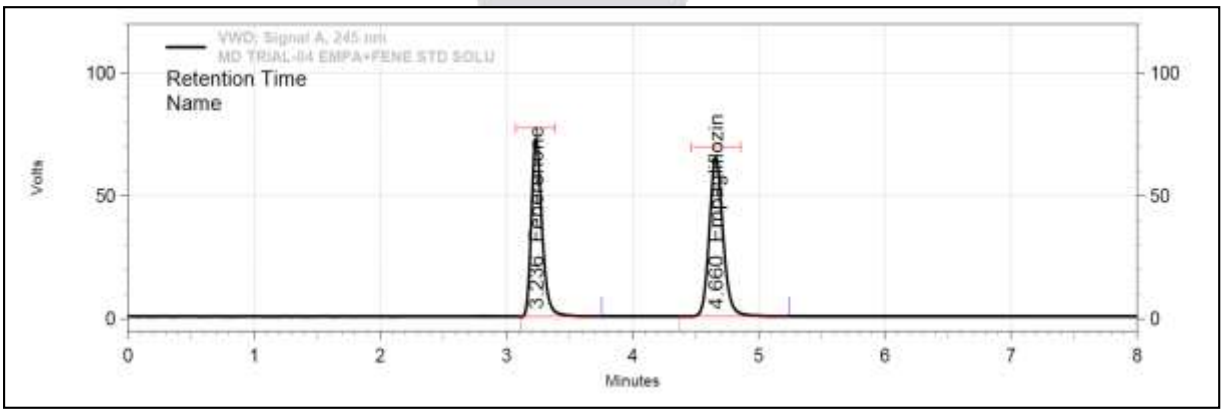


Fig no 3: Chromatogram showing resolved peaks of FINE & EMPA

2. System Suitability

System suitability parameters were assessed before validation. The results are summarized below:

Table no 1: System Suitability studies for Finerenone

Name	Area	RT (min)	TP (NLT 2000)	TF (NMT 2)	Resolution (NLT 2)
Standard_Inj_01	7108544	3.236	7312	1.46	8.33
Standard_Inj_02	7111600	3.241	7336	1.48	8.30
Standard_Inj_03	7109782	3.241	7309	1.32	8.31
Standard_Inj_04	7131815	3.241	7324	1.47	8.32
Standard_Inj_05	7085455	3.241	7359	1.43	8.34
Mean	7109439	3.240			
SD	16443.1310	0.0022			
%RSD (NMT 2)	**0.23**	**0.07**			

Table no 2: System Suitability studies for Empagliflozin

Name	Area	RT (min)	TP (NLT 2000)	TF (NMT 2)	Resolution (NLT 2)
Standard_Inj_01	8126697	4.679	9188	1.17	8.33
Standard_Inj_02	8098063	4.689	9209	1.25	8.30
Standard_Inj_03	8109951	4.679	9250	1.18	8.31
Standard_Inj_04	8146813	4.679	9282	1.26	8.32
Standard_Inj_05	8129539	4.679	9317	1.22	8.34
Mean	8122213	4.681			
SD	18791.7247	0.0045			
%RSD (NMT 2)	**0.23**	**0.10**			

Remark: Theoretical plates, resolution and Tailing factor observed within acceptance criteria, also %RSD of replicate injections for area and retention time observed within acceptance criteria, hence system is suitable for analysis of both finerenone & empagliflozin. Hence System Suitability is justified.

3. Specificity

There was no interference from the blank or excipients. Well-resolved and pure peaks confirmed the method's specificity.

4. Accuracy (Recovery Studies)

Accuracy was evaluated by spiking known quantities of drugs into the matrix. The recovery was within acceptable limits.

Table no 3: Accuracy studies of Finerenone & Empagliflozin

Level (%)	Finerenone			Empagliflozin		
	Mean % recovery	SD	%RSD (NMT 2)	Mean % recovery	SD	%RSD (NMT 2)
80%	100.70	1.0708	**1.06**	100.48	0.6372	**0.63**
100%	99.41	0.2742	**0.28**	99.44	0.7323	**0.74**
120%	99.69	0.3926	**0.39**	99.34	0.1159	**0.12**

5. Assay

%Assay of Finerenone & Empagliflozin in test solutions 1 & 2 was found to be 99.05%, 99.77% & 99.71%, 99.49% respectively.

Table no 4: %Assay of Finerenone

Name	Area	RT(min)	% Assay
Test solutions-1	7112070	3.241	**99.05**
Test solutions-2	7092937	3.241	**99.77**

Table no 5: %Assay of Empagliflozin

Name	Area	RT(min)	% Assay
Test solutions-1	8130714	4.679	**99.71**
Test solutions-2	8080716	4.679	**99.49**

6. Precision

Precision was evaluated by intra- and inter-day repeatability studies. The %RSD values were below 2% for both drugs, confirming the method's reproducibility under normal laboratory conditions.

Table no 6: Intraday precision data of Finerenone & Empagliflozin

Name	Preparations	% Assay	
		Finerenone	Empagliflozin
Set-1	prep-1	99.05	99.71
	prep-2	99.77	99.49
Set-2	prep-1	99.46	100.18
	prep-2	99.92	99.50
Mean		99.55	99.72
SD		0.3844	0.3230
% RSD (NMT 2)		**0.39**	**0.32**

Table no 7: Interday precision data of Finerenone & Empagliflozin

Name	Preparations	% Assay	
		Finerenone	Empagliflozin
Day-1	prep-1	99.05	99.71
	prep-2	99.77	99.49
Day-2	prep-1	99.26	98.84
	prep-2	98.89	99.28
Mean		99.24	99.33
SD		0.3829	0.3709
% RSD (NMT 2)		**0.39**	**0.37**

7. Linearity

Linearity was evaluated by analyzing five different concentrations within the expected working range. A strong correlation between concentration and peak area was observed, with correlation coefficients (R^2) greater than 0.999 for both drugs. This confirms the method's reliability across the tested concentration range.

8. LOD & LOQ

LOD and LOQ were determined based on standard deviation and slope of the calibration curve. These values indicate the method's high sensitivity, capable of detecting and quantifying trace levels of both drugs.

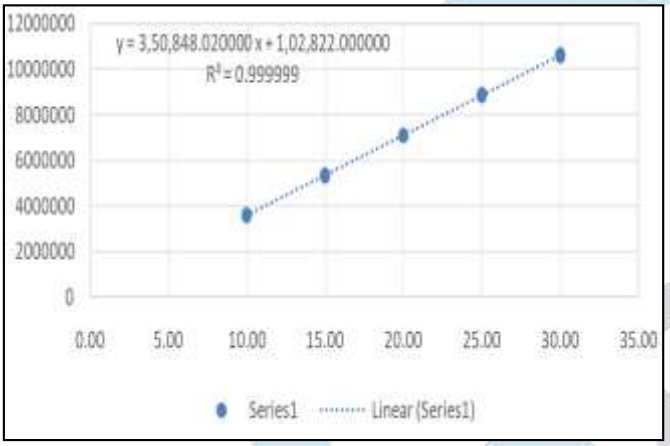


Fig no 4: Linearity curve for Finerenone

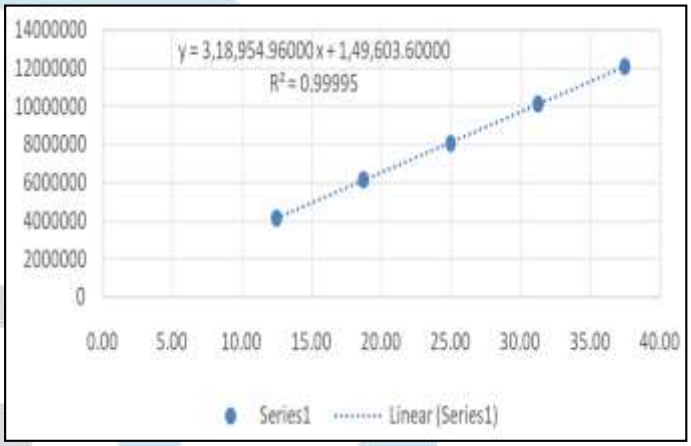


Fig no 5: Linearity curve for empagliflozin

Table no 8: Linearity standards peak area along with LOD & LOQ for finerenone & empagliflozin

Con. (ppm or ug/ml)	Area	Con. (ppm or ug/ml)	Area
10.00	3608312	12.50	4139568
15.00	5369436	18.75	6147878
20.00	7119228	25.00	8084756
25.00	8875411	31.25	10128673
30.00	10626525	37.50	12116513
Correlation coefficient (NLT 0.995)	**0.99999**	**Correlation coefficient (NLT 0.995)**	**0.99995**
Intercept	**102822**	**Intercept**	**149604**
SLOPE	**350848**	**SLOPE**	**318955**
STEYX	**3128.19**	**STEYX**	**25836.25**
LOD (ug/ml)	**0.03**	**LOD (ug/ml)**	**0.27**
LOQ (ug/ml)	**0.09**	**LOQ (ug/ml)**	**0.81**

9. Robustness

The robustness of the method was confirmed by deliberately altering flow rate & mobile phase. No significant variations were observed in retention time or peak area, proving that the method is reliable under slight changes in conditions.

10. Ruggedness

Ruggedness was evaluated by changing batch/lot no. of solvent and performing the analysis on different days. The %RSD remained below 2%, indicating that the method is reproducible and rugged across varying operational environments.

Table no 9: Robustness changes in method parameters of finerenone & empagliflozin

Name	Preparations	%Assay	
		Finerenone	Empagliflozin
Original method parameters	Test prep-1	99.05	99.71
Original method parameters	Test prep-2	99.77	99.49
Pump, Flow 0.90 ml/min	Test prep	100.25	99.88
Pump, Flow 1.1 ml/min	Test prep	98.87	100.91
MeOH:Water:TFA, 63:37:0.05	Test prep	99.41	100.35
MeOH:Water:TFA, 73:27:0.05	Test prep	98.94	98.76
Mean		99.38	99.85
SD		0.5427	0.7365
%RSD (NMT 2)		**0.55**	**0.74**

Table no 10: Ruggedness data for finerenone & empagliflozin

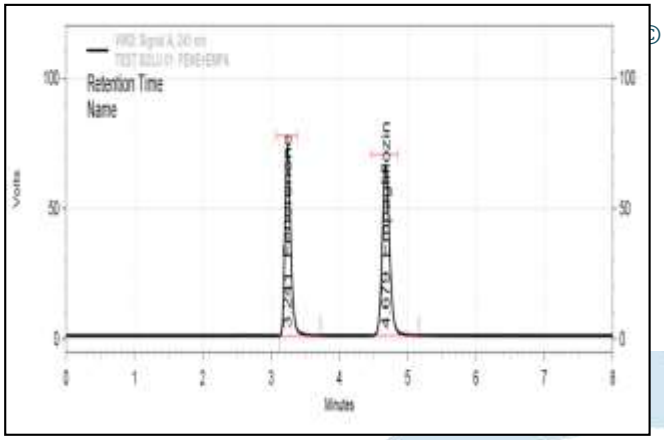
Name	Preparations	%Assay	
		Finerenone	Empagliflozin
Original method parameters	Test prep-1	99.05	99.71
Original method parameters	Test prep-2	99.77	99.49
Change in time	Test prep	100.98	99.72
change in day	Test prep	99.73	100.33
Change in Batch or Lot of solvent	Test prep	99.89	99.60
Mean		99.88	99.77
SD		0.6953	0.3267
%RSD (NMT 2)		**0.70**	**0.33**

11. Analysis of formulated tablet

The developed and validated RP-HPLC method was applied for the quantitative estimation of finerenone and empagliflozin in the prepared tablet formulation. The sample was analyzed in triplicate, and the assay results were calculated based on the peak areas from the standard calibration curve. The percentage of the labeled amount found in the tablet was within the acceptable range of 98% to 102%, confirming that the method is suitable for routine analysis of these drugs in formulation. These results indicate that the prepared tablets complied with assay specifications and the method can reliably quantify both APIs without interference.

Table no 11: Formulated tablet test analysis (Finerenone & Empagliflozin)

Name	Finerenone		Empagliflozin	
	Test solution-1	Test solution-2	Test solution-1	Test solution-2
Area	7112070	7092937	8130714	8080716
RT (in min)	3.241	3.241	4.679	4.679
API obs in mg	19.49	19.47	24.38	24.27
Label claim	20	20	25	25
% Assay	**97.44**	**97.37**	**97.51**	**97.10**



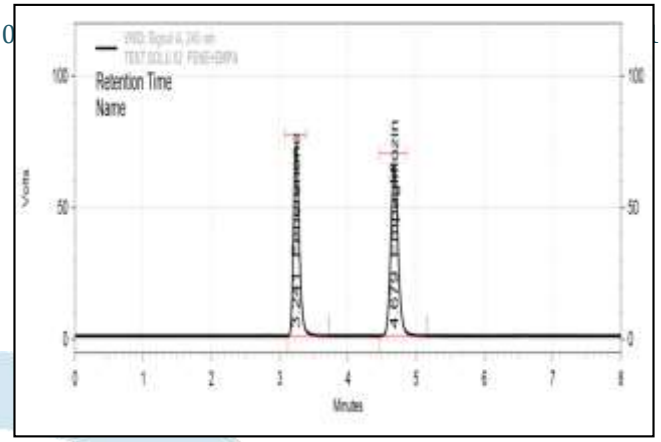


Fig no 6: Chromatogram of formulated tablet test solution-1 Fig no 7: Chromatogram of formulated tablet test solution-2

IV. CONCLUSION

A simple, precise, accurate, and robust reverse-phase HPLC method was successfully developed and validated for the simultaneous estimation of finerenone and empagliflozin in prepared tablet formulations. The method demonstrated excellent linearity, precision, accuracy, specificity, and system suitability as per ICH guidelines. Low values of LOD and LOQ indicate the method's high sensitivity. The developed method was effectively applied to the analysis of formulated tablets, and the assay results were within acceptable limits. Overall, the method is reliable and suitable for routine quality control analysis of finerenone and empagliflozin in pharmaceutical dosage forms.

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VI. REFERENCES

1) Bakris GL, Agarwal R, Anker SD, Pitt B, Ruilope LM, Rossing P, Kolkhof P, Nowack C, Schloemer P, Joseph A, Filippatos G. Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. New England journal of medicine. 2020 Dec 3;383(23):2219-29.
2) Filippatos G, Anker SD, Agarwal R, Pitt B, Ruilope LM, Rossing P, Kolkhof P, Schloemer P, Tornus I, Joseph A, Bakris GL. Finerenone and cardiovascular outcomes in patients with chronic kidney disease and type 2 diabetes. Circulation. 2021 Feb 9;143(6):540-52.
3) Filippatos G, Bakris GL, Pitt B, Agarwal R, Rossing P, Ruilope LM, Butler J, Lam CS, Kolkhof P, Roberts L, Tasto C. Finerenone reduces new-onset atrial fibrillation in patients with chronic kidney disease and type 2 diabetes. Journal of the American College of Cardiology. 2021 Jul 13;78(2):142-52.
4) Pitt B, Filippatos G, Agarwal R, Anker SD, Bakris GL, Rossing P, Joseph A, Kolkhof P, Nowack C, Schloemer P, Ruilope LM. Cardiovascular events with finerenone in kidney disease and type 2 diabetes. New England Journal of Medicine. 2021 Dec 9;385(24):2252-63.
5) Zinman B, Wanner C, Lachin JM, Fitchett D, Bluhmki E, Hantel S, Mattheus M, Devins T, Johansen OE, Woerle HJ, Broedl UC. Empagliflozin, cardiovascular outcomes, and mortality in type 2 diabetes. New england journal of medicine. 2015 Nov 26;373(22):2117-28.
6) Packer M, Anker SD, Butler J, Filippatos G, Pocock SJ, Carson P, Januzzi J, Verma S, Tsutsui H, Brueckmann M, Jamal W. Cardiovascular and renal outcomes with empagliflozin in heart failure. New England Journal of Medicine. 2020 Oct 8;383(15):1413-24.
7) Herrington WG, Staplin N, Agrawal N, Wanner C, Green JB, Hauske SJ, Emberson JR, Preiss D, Judge P, Zhu D, Dayanandan R. Long-term effects of empagliflozin in patients with chronic kidney disease. The New England journal of medicine. 2024 Oct 25:10-56.
8) Heerspink HJ, Berger S, Gansevoort RT, Renal Life Cycle Trial Investigators. Will SGLT2 inhibitors be effective and safe in patients with severe CKD, dialysis, or kidney transplantation. Clinical Journal of the American Society of Nephrology. 2023 Nov 1;18(11):1500-2.
9) Green JB, Mottl AK, Bakris G, Heerspink HJ, Mann JF, McGill JB, Nangaku M, Rossing P, Scott C, Gay A, Agarwal R. Design of the COmbinatioN effect of FInerenone anD EmpaglifloziN in participants with chronic kidney disease and type 2 diabetes using a UACR Endpoint study (CONFIDENCE). Nephrology Dialysis Transplantation. 2023 Apr;38(4):894-903.
10) Ermer J. ICH Q2 (R2): validation of analytical procedures. Method validation in pharmaceutical analysis: a guide to best practice. 2025 Apr 7:351-72.
11) Hanouneh M, Le D, Jaar BG, Tamargo C, Cervantes CE. Real-Life Experience on the Effect of SGLT2 Inhibitors vs. Finerenone vs. Combination on Albuminuria in Chronic Kidney Disease. Diagnostics. 2024 Jun 26;14(13):1357.
12) Chepyala S, Medidi S, Malik JK. Development of a Robust and Reliable RP-HPLC Method for the Estimation of Finerenone in Tablet Dosage Form. International Journal of Drug Delivery Technology. 2024;14(2):703-708.

13) Badawal Rajnandani , Pooja J. Vyas, Shilpa Rathwa , Bhoomika Malete, Chainesh N Shah, Umesh Upadhyay, Development And Validation Of UV Spectroscopy Method For Simultaneous Estimation Of Finerenone And Empagliflozin In Synthetic Mixture, Int. J. of Pharm. Sci., 2024, Vol 2, Issue 9, 584-594. https://doi.org/10.5281/zenodo.13749520
14) Imran SJ, Kini SG, Kumar V, Sonawane B, Chaudhari J, Warde S. Validated stability indicating reversed-phase high-performance liquid chromatography (RP-HPLC) for the estimation of FINERENONE in Pharmaceutical tablet dosage form.
15) Siridevi MP, Kumar HT, Rao SY, Rao VP. RP-HPLC method for quantification of Empagliflozin in pharmaceutical formulation. Asian Journal of Pharmacy and Technology. 2019;9(3):208-11.
16) Kumar DV, Rao JS. A new validated stability indicating RP-HPLC method for simultaneous estimation of metformin hydrochloride and empagliflozin in tablet dosage forms. IRJPMS. 2018;1:16-22.
17) Patil SD, Amurutkar SV, Upasani CD. Development and validation of stability indicating RP-HPLC method for empagliflozin. Asian Journal of Pharmaceutical Analysis. 2016;6(4):201-6.
18) Armstrong NA. Tablet manufacture by direct compression. Encyclopedia Pharmaceut Technol. 2007;6:3673-83.
19) Bushra R, Shoaib MH, Aslam N, Hashmat D, Rehman M. Formulation development and optimization of ibuprofen tablets by direct compression method. Pak. J. Pharm. Sci. 2008 Apr 1;21(2):113-20.