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ORIGINAL ARTICLE

Analytical Method Development and Validation of Finerenone in Bulk and Formulation by HPLC

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ABSTRACT

A simple, rapid, precise, accurate, and robust reverse-phase high-performance liquid chromatographic (RP-HPLC) method was developed and validated for the quantitative determination of finerenone in bulk drug substance and pharmaceutical tablet formulation. Chromatographic separation was achieved on a C18 column employing an isocratic mobile phase composed of acetonitrile and 10 mM ammonium dihydrogen phosphate buffer (pH 4.5) at a flow rate of 1.0 mL/min, with UV detection at 238 nm. Finerenone exhibited a retention time of 7.24 min. The method was validated as per ICH Q2(R2) guidelines with respect to system suitability, specificity, linearity, accuracy, precision, robustness, and solution stability. Linearity was demonstrated over a concentration range of 50–150% of the working concentration (100.52–301.56 µg/mL), with a correlation coefficient of 1.00. Recovery studies at three spike levels (50%, 100%, and 150%) yielded mean percent recovery of 101.1% (%RSD 0.45), indicating excellent accuracy. Method precision studies showed %RSD of 0.27%, well within the NMT 2.0% acceptance criterion. Standard and sample solutions were stable for up to 65 hours and 58 hours, respectively, at 10°C. Specificity evaluation confirmed no interference from placebo excipients or known process-related impurities (acid impurity, aromatization impurity, dimethyl impurity). The validated method was successfully applied to the assay of marketed tablets and is suitable for routine quality control analysis of finerenone in pharmaceutical manufacturing environments.

Keywords: Finerenone, HPLC, Method validation, ICH Q2(R2), Analytical method development, Mineralocorticoid receptor antagonist

INTRODUCTION

Finerenone (INN: BAY 94-8862; chemical name: (4S)-4-(4-cyano-2-methoxyphenyl)-5-ethoxy-2,8-dimethyl-1,4-dihydro-1,6-naphthyridine-3(2H)-one; molecular formula: C24H23N3O3; molecular weight: 421.5 g/mol) is a novel, selective, third-generation non-steroidal mineralocorticoid receptor antagonist (MRA). Unlike first- and second-generation steroidal MRAs such as spironolactone and eplerenone, finerenone exhibits a higher binding selectivity for the mineralocorticoid receptor (MR), providing reduced off-target effects including hyperkalemia and antiandrogenic side effects[1,2]. Preclinical studies have demonstrated that finerenone offers 800-fold higher MR selectivity over androgen and progesterone receptors compared to spironolactone, minimizing hormonal interactions[3,4]. Its balanced distribution between cardiac and renal tissues reduces the risk of potassium retention and hyperkalemia that characterizes older MRAs[5].

Finerenone exerts its therapeutic benefit through potent anti-inflammatory and antifibrotic actions, blocking overactivation of the MR in both the kidneys and the cardiovascular system[6,7]. The drug received US Food and Drug Administration (FDA) approval on 9 July 2021, and European Medicines Agency (EMA) approval in February 2022, under the brand name Kerendia® (Bayer AG), for the treatment of chronic kidney disease (CKD) associated with

type 2 diabetes mellitus (T2DM)[8,9]. The landmark FIDELIO-DKD and FIGARO-DKD phase III clinical trials demonstrated that finerenone significantly reduced the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage renal disease (ESRD), cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure[10,11]. The pooled FIDELITY analysis further confirmed consistent cardiorenal benefits across more than 13,000 patients[12].

Approximately 40% of individuals with T2DM also have CKD, representing a substantial global disease burden[13]. Finerenone is commercially available as 10 mg and 20 mg film-coated tablets. Given its emerging clinical importance, the establishment of reliable, accurate, and reproducible analytical methods for the quantitative estimation of finerenone in pharmaceutical dosage forms is essential for quality control (QC), stability testing, and regulatory compliance. Currently, no official monograph for finerenone is published in any major pharmacopoeia such as the United States Pharmacopeia (USP), British Pharmacopoeia (BP), or Indian Pharmacopoeia (IP), underscoring the need for validated in-house analytical methods.

Several analytical methods have been reported in the literature for the determination of finerenone, including UV spectrophotometry[14,15], various RP-HPLC methods in dosage forms[16-20], stability-indicating RP-HPLC methods[21-23], liquid chromatography-tandem mass spectrometry (LC-MS/MS) for bioanalytical applications[24,25], fluorescence-based chemo-sensor approaches (26), and bioanalytical RP-HPLC methods in plasma[27]. Systematic reviews summarizing analytical approaches for finerenone have also been published[28]. However, a fully validated QC-grade RP-HPLC method incorporating stability-indicating capability, specificity toward known process-related impurities, comprehensive solution stability assessment, and filter validation studies—all critical requirements for regulatory-compliant QC methods—has not been comprehensively reported.

The present study describes the development and full ICH Q2(R2)-compliant[29] validation of an RP-HPLC method for the determination of finerenone in bulk drug substance and pharmaceutical tablet formulation, providing a reliable method suitable for routine pharmaceutical analysis and QC laboratory applications.

MATERIALS AND METHODS

Chemicals and Reagents

Reference standard of finerenone (purity ≥ 99.0%) was procured from a certified pharmaceutical manufacturer. Commercially available tablet formulations containing finerenone 20 mg were obtained from local pharmaceutical suppliers. Process-related impurities (acid impurity, aromatization impurity, dimethyl impurity) were used as reference substances for specificity evaluation. Acetonitrile (HPLC grade), methanol (HPLC grade), and ammonium dihydrogen phosphate (AR grade) were sourced from Merck (India). Water for HPLC use was produced in-house using a Milli-Q water purification system (Millipore). All chemicals and reagents were of analytical or HPLC grade and used without further purification.

Instrumentation

Chromatographic analysis was performed on an HPLC system equipped with a binary gradient pump, an auto-sampler, a column oven, and a UV-Vis photodiode array (PDA) detector. Chromatographic data acquisition and processing were carried out using compatible software. An analytical balance (readability 0.1 mg) was used for gravimetric operations. A pH meter was calibrated prior to mobile phase preparation. A sonicator was used for degassing all solutions.

Chromatographic Conditions

Separation was performed on a C18 reversed-phase column (250 × 4.6 mm, 5 µm particle size). The mobile phase consisted of acetonitrile and 10 mM ammonium dihydrogen phosphate buffer (pH 4.5) in an optimized ratio, delivered isocratically at a flow rate of 1.0 mL/min. The column oven temperature was maintained at 25°C (nominal). UV detection was performed at 238 nm. The injection volume was 10 µL and the run time was set to 15 minutes to allow elution of all relevant impurities.

Preparation of Mobile Phase

Ten millimolar ammonium dihydrogen phosphate buffer was prepared by dissolving an accurately weighed quantity of ammonium dihydrogen phosphate in water, adjusting pH to 4.5 ± 0.05 using dilute ammonia solution, and filtering through a 0.45 µm nylon membrane filter. The buffer and acetonitrile were mixed in the optimized ratio, degassed by ultrasonication for 15 minutes, and used as the mobile phase.

Preparation of Standard Stock Solution

An accurately weighed quantity of finerenone reference standard was dissolved in acetonitrile and diluted with mobile phase to produce a standard stock solution of approximately 1005 µg/mL. The working standard solution was prepared by further dilution with mobile phase to yield approximately 201.04 µg/mL, corresponding to the 100% working concentration.

Preparation of Sample Solution

Twenty tablets were weighed and the average tablet weight was calculated. A tablet mass equivalent to 20 mg of finerenone was accurately weighed, transferred to a 100 mL volumetric flask, and approximately 60 mL of acetonitrile was added. The mixture was sonicated for 30 minutes with

periodic shaking, diluted to volume with acetonitrile, and mixed thoroughly. An aliquot was filtered through a 0.45 µm PVDF syringe filter (discarding the first 3 mL of filtrate), and the clear filtrate was further diluted with mobile phase to obtain the sample solution at the working concentration.

System Suitability

System suitability was assessed by injecting the finerenone working standard solution six consecutive times. The USP tailing factor (NMT 2.0) and USP theoretical plate count (NLT 2000) were evaluated. The %RSD of peak areas from five consecutive standard injections (system precision) was required to be NMT 2.0%[30].

Method Validation

The method was validated in accordance with ICH Q2(R2) [29] for the following parameters:

Specificity: Evaluated by analyzing blank, placebo, standard, spiked sample (with known impurities), and as-such sample solutions. Peak purity was assessed by PDA detector. The purity index was compared against the single-point threshold[31].

Linearity: Standard solutions covering 50–150% of working concentration (100.52–301.56 µg/mL, five levels) were prepared. A calibration curve of peak area versus concentration was constructed. Acceptance criterion: Pearson $r \geq 0.99$.

Accuracy: Assessed at 50%, 100%, and 150% spike levels using spiked placebo solutions (n = 2 per level). Acceptance criterion: % recovery 97.0–103.0%[32].

Precision: Method precision was assessed from six independently prepared sample solutions. Acceptance criterion: %RSD NMT 2.0%.

Solution Stability: Evaluated at 10°C over 65 h (standard) and 63 h (sample). Acceptance criteria: %RSD NMT 2.0% (standard); % assay difference NMT ±2.0% (sample).

Filter Validation: 0.45 µm nylon and PVDF syringe filters tested with 3, 4, and 5 mL discard volumes. Acceptance criterion: % assay difference NMT ±2.0% vs unfiltered reference.

Robustness: Flow rate (±0.2 mL/min) and column oven temperature (+5°C) were deliberately varied. System suitability parameters and % assay differences were evaluated[33].

RESULTS

Method Development

The chromatographic conditions were optimized based on the physicochemical properties of finerenone (log P ≈ 2.6; UV absorption at 238 nm). Reversed-phase C18 chromatography was selected for adequate retention of the moderately lipophilic analyte. Acetonitrile was chosen as the organic modifier for its low UV absorbance and efficient solvating properties. Phosphate buffer adjusted to pH 4.5 was used to provide reproducible retention and ionization control. The optimized mobile phase provided adequate resolution of finerenone from placebo matrix components and all known process-related impurities within a 15-minute run time.

System Suitability: System suitability results are summarized in Table. 1. The USP tailing factor was 1.1 for both standard and sample solutions (NMT 2.0). USP theoretical plate count exceeded 9334 plates (NLT 2000). System precision %RSD was 0.17% (NMT 2.0%), confirming adequate system performance.

Table 1: System Suitability Results for Finerenone

Parameter	Finerenone Standard	Finerenone Sample
USP Tailing Factor (NMT 2.0)	1.1	1.1
USP Plate Count (NLT 2000)	9378	9334
Retention Time (min)	7.241	7.267
System Precision (%RSD, n=5)	0.17	—

Method Precision: Percent assay values from six replicate preparations ranged from 98.0–98.6%, mean 98.3%, SD 0.266, %RSD 0.27% (NMT 2.0%), confirming excellent repeatability Table. 2.

Table 2: Method Precision Results (Batch 05A, n = 6)

Sample No.	Weight (mg)	Avg Response	%Assay	%RSD
1	5	5,730,047	98.1	—
2	5	5,757,919	98.6	—
3	5	5,761,067	98.6	—
4	5	5,731,526	98.1	—
5	5	5,738,489	98.2	—
6	5	5,724,383	98.0	—
Mean / %RSD	—	—	98.3	0.27

Solution Stability: Standard solution stability %RSD remained within ±2.0% up to 65 hours at 10°C Table. 3. Sample solution percent assay difference remained within ±2.0% up to 58 hours at 10°C; the solution was deemed stable for 58 hours under specified storage conditions.

Filter Validation: Both nylon and PVDF 0.45 µm syringe filters yielded percent assay differences within ±2.0% Table.

4. The 0.45 µm PVDF filter with 3 mL pre-filtration discard was selected for routine use.

Table 3. Solution Stability of Finerenone Standard Solution at 10°C

Time (h)	Peak Area Response	%RSD	Limit
Initial	5,883,622	0.17	±2.0
5	5,916,338	0.21	±2.0
13	5,962,397	0.49	±2.0
27	6,053,274	1.10	±2.0
46	6,095,836	1.39	±2.0
65	6,126,483	1.60	±2.0

Table 4: Filter Validation Results

Filter Type	%Assay	%Diff	Limit
Unfiltered (reference)	98.5	—	±2.0
0.45 µm Nylon – 3 mL	98.3	0.2	±2.0
0.45 µm Nylon – 4 mL	98.1	0.4	±2.0
0.45 µm Nylon – 5 mL	98.3	0.2	±2.0
0.45 µm PVDF – 3 mL	98.1	0.4	±2.0
0.45 µm PVDF – 4 mL	98.4	0.1	±2.0
0.45 µm PVDF – 5 mL	98.1	0.4	±2.0

Linearity: Finerenone demonstrated linearity over 100.52–301.56 µg/mL (r = 1.00; slope 29,133.61; intercept 16,760.00; bias at 100% level = 0.3%). Results are summarized in Table. 5.

Table 5: Linearity Data for Finerenone

S. No.	Level (%)	Conc. (µg/mL)	Mean Peak Area	Remarks
1	50	100.52	2,962,126	50%
2	75	150.78	4,393,904	75%
3	100	201.04	5,877,385	100%
4	125	251.30	7,310,273	125%
5	150	301.56	8,825,218	150%
Correlation coefficient (r^2)			1.00	NLT 0.99
Slope			29,133.61	
Intercept			16,760.00	

Accuracy: Percent recovery values were 101.5%, 101.2%, and 100.6% at 50%, 100%, and 150% spike levels respectively; mean recovery 101.1% (%RSD 0.45%), within the 97.0–103.0% criterion Table. 6.

Specificity: No interfering peaks from blank, placebo, or process-related impurities (acid impurity RT 11.60 min; aromatization impurity RT 11.04 min; dimethyl impurity RT 4.90 min) were detected at the finerenone retention time. The %assay difference between as-such (99.2%) and spiked (98.8%) samples was 0.4% (NMT ±2.0%). Peak purity indices exceeded single-point thresholds in all solutions Table. 7.

Table 6: Accuracy Results for Finerenone

Level	Added (mg)	Found (mg)	Avg Response	%Recovery	Limit
50%	50.74	51.42	3,004,594	101.5	97–103%
100%	100.85	101.94	5,956,199	101.2	97–103%
150%	150.96	151.67	8,861,992	100.6	97–103%
Mean / %RSD	—	—	—	101.1 / 0.45	

Table 7: Specificity Results – As-Such vs. Spiked Sample Comparison

Sample Type	RT (min)	%Assay	Peak Purity Index	%Diff
As-Such Sample	7.267	99.2	1.000000	—
Spiked Sample	7.265	98.8	1.000000	0.4 (NMT ±2.0)
Blank Solution	ND	—	—	—
Placebo Solution	ND	—	—	—

Robustness: Under all tested conditions (flow rate ±0.2 mL/min; column temperature +5°C), system suitability parameters and %assay remained within acceptance criteria. The maximum absolute %assay difference was 0.3% Table. 8, confirming method robustness.

Table 8: Robustness Study Results

Condition	Plate Count	Tailing Factor	%Assay	%Diff
Nominal (1.0 mL/min, 25°C)	9378	1.1	98.3	0.0
+ Column Temp (30°C)	11187	1.1	98.1	0.2
- Flow Rate (0.8 mL/min)	11805	1.1	98.6	-0.3
+ Flow Rate (1.2 mL/min)	9573	1.1	98.1	0.2

DISCUSSION

The absence of a pharmacopoeial monograph for finerenone highlights the need for a validated in-house RP-HPLC method suitable for routine quality control. In the present study, chromatographic conditions were optimized to achieve adequate resolution, symmetrical peak shape, and satisfactory sensitivity. A C18 column was selected because

the moderate lipophilic nature of finerenone supports efficient reversed-phase separation. The mobile phase, consisting of ammonium dihydrogen phosphate buffer (pH 4.5) and acetonitrile, provided stable retention and effective separation of finerenone from its process-related impurities. The use of an isocratic elution further simplifies routine analysis and method transfer, in agreement with previously reported RP-HPLC methods[16-18].

Finerenone eluted at 7.24 min, which is comparable with reported C18-based methods employing phosphate buffer systems[18, 19]. Although published methods differ in column type, organic solvent, detection wavelength, and calibration range[16-19, 21, 22], the present method combines simple chromatographic conditions with reliable separation. All three known impurities, namely dimethyl, aromatization, and acid impurities, were resolved within a 15-minute run, demonstrating good method specificity.

System suitability parameters, including a tailing factor of 1.1, theoretical plates exceeding 9300, and system precision of 0.17% RSD, confirmed consistent chromatographic performance in accordance with USP recommendations and published reports[20, 21]. Method precision was equally satisfactory, with a %RSD of 0.27% for six replicate preparations, indicating excellent repeatability and solution stability during analysis. Similar precision has been reported in earlier studies[16, 17, 21].

The standard and sample solutions remained stable for 65 and 58 hours, respectively, when stored at 10°C, with assay responses remaining within the ±2.0% acceptance limit. This extended stability is advantageous for laboratories handling large analytical batches. A slight increase in standard response was observed over time, most likely because of minor solvent evaporation, emphasizing the importance of proper sample storage.

The method demonstrated excellent accuracy, with a mean recovery of 101.1% and a %RSD of 0.45%, which falls well within the accepted range of 97.0–103.0%. The low variability across all recovery levels indicates negligible interference from tablet excipients, consistent with previous reports[19, 20, 22]. Peak purity analysis using a PDA detector confirmed the absence of co-eluting peaks from blanks, placebo, or known impurities, with peak purity values of 1.000000. Likewise, the 0.4% difference between unspiked and impurity-spiked samples satisfied the predefined acceptance criterion.

Filter validation established that 0.45 µm PVDF syringe filters with a 3 mL pre-filtration discard can be reliably used for routine sample preparation. Robustness testing further showed that small variations in flow rate and column temperature did not significantly affect assay results or system suitability. The increase in theoretical plates at lower flow rates was consistent with the van Deemter relationship for reversed-phase chromatography[34].

Compared with LC-MS/MS methods[24, 25], the proposed RP-HPLC procedure is more economical and practical for routine pharmaceutical quality control. It also offers greater specificity than UV spectrophotometric methods by allowing simultaneous separation of process-related impurities[14, 15]. In addition, its stability-indicating capability, verified through impurity-spiking and peak purity evaluation, enhances its regulatory applicability over many previously published RP-HPLC assay methods[22, 23].

Overall, the method satisfied all ICH Q2(R2) validation requirements, demonstrating its suitability for the intended purpose. It compares favorably with recently published analytical methods for finerenone[21, 22, 35-37] and uniquely combines comprehensive filter validation with detailed solution stability studies, addressing important gaps in the existing literature.

CONCLUSION

A simple, precise, accurate, specific, and robust RP-HPLC method has been successfully developed and validated for the quantitative determination of finerenone in bulk drug substance and tablet formulation in compliance with ICH Q2(R2) guidelines. Chromatographic separation on a C18 column with an isocratic mobile phase comprising acetonitrile and ammonium dihydrogen phosphate buffer (pH 4.5) provides adequate resolution of finerenone from all known process-related impurities within 15 minutes. All validated parameters—linearity (r = 1.00; range 100.52–301.56 µg/mL), accuracy (mean recovery 101.1%; %RSD 0.45%), precision (%RSD 0.27%), solution stability (standard 65 h; sample 58 h at 10°C), specificity (no interference from placebo or three known impurities), filter validation (0.45 µm PVDF, 3 mL discard), and robustness—met their respective acceptance criteria. The method is suitable for routine quality control analysis of finerenone in pharmaceutical manufacturing and can serve as a reference for regulatory submissions in the absence of a pharmacopoeial monograph.

DISCLOSURE

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Conflict of Interest: The authors declare that there are no conflicts of interest regarding the publication of this manuscript.

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