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Formulation and Evaluation of Sustained Release Tablet of Finerenone using Tamarind Seed Polysaccharide as Excipient

[1]*Deepika V, [1]Dr.Manjula Devi A.S, [2]Sethu Raman A.

[1*]Post graduate scholar, Department of Pharmaceutics, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore-641044, Tamil Nadu, India
[1]Professor, Department of Pharmaceutics, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore-641044, Tamil Nadu, India
[2]Post graduate scholar, Department of Pharmaceutics, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore-641044, Tamil Nadu, India

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Corresponding author:
Sethu Raman A.
[2]Post graduate scholar, Department of Pharmaceutics, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore-641044, Tamil Nadu, India
Email id: ganesharumugam2001@gmail.com

ABSTRACT

Finerenone, a novel non-steroidal mineralocorticoid receptor antagonist, has emerged as an effective therapeutic agent for managing chronic kidney disease (CKD) linked to type 2 diabetes mellitus. Despite its clinical potential, the drug suffers from poor aqueous solubility and pronounced first-pass metabolism, leading to reduced oral bioavailability. The present investigation was undertaken to design and evaluate a sustained-release (SR) tablet of Finerenone utilizing Tamarind Seed Polysaccharide (TSP), a natural, biodegradable polymer, as a rate controlling excipient. Tablets were formulated by the wet granulation technique with different concentrations of TSP and subjected to comprehensive evaluation for pre-compression and post compression characteristics, drug content uniformity, and in-vitro dissolution performance. Among all the developed batches, the optimized formulation (F5) displayed desirable physicochemical attributes, consistent drug distribution, and sufficient mechanical strength. The *in-vitro* release profile indicated a prolonged and controlled drug release of approximately 92% over 24 hours, adhering to Higuchi kinetics with a non-Fickian diffusion mechanism. Hence, the developed Finerenone SR tablets employing TSP as a release- modifying polymer can effectively prolong drug release, minimize dosing frequency, and enhance therapeutic efficiency and patient adherence in the long-term management of CKD.

Keywords: Finerenone, Tamarind Seed Polysaccharide, Sustained Release, Controlled Drug Delivery, Chronic Kidney Disease.

INTRODUCTION

Oral dosage forms continue to dominate global pharmaceutical therapy owing to their convenience, cost-effectiveness, and high patient acceptance.[1] Recent innovations in formulation science emphasize the development of sustained and controlled-release systems, which play a vital role in the long-term management of chronic conditions such as diabetes and kidney disorders.[2] These systems ensure consistent therapeutic drug levels, minimize dosing frequency, and enhance treatment adherence.[3] Finerenone, a novel non-steroidal mineralocorticoid receptor antagonist, has shown significant organ-protective benefits in patients with type 2 diabetes-associated chronic kidney disease by mitigating inflammation and fibrosis.[4]

Growing interest in natural excipients—particularly plant-derived polysaccharides—reflects a shift toward environmentally sustainable, biocompatible, and multifunctional drug delivery systems.[5] Among these, tamarind seed polysaccharide (TSP) has attracted attention for its superior swelling ability, mucoadhesive nature, and controlled-release properties. Its incorporation as a binder and matrix former in sustained-release formulations offers improved drug stability, patient compliance, and aligns with the principles of green pharmacy. Overall, the use of plant-based excipients such as TSP highlights a promising direction in pharmaceutical innovation, promoting safer, more sustainable, and patient-centered drug delivery approaches.[6]

MATERIALS AND METHODS

Finerenone (Active Pharmaceutical Ingredient) was procured from Hangzhou Jinlan Pharmaceutical Co., Ltd., China. Various excipients used in the formulation of sustained-release tablets included Tamarind Seed Polysaccharide (TSP) obtained from Tokyo Chemical Industry Pvt. Ltd., Chennai, Microcrystalline Cellulose (MCC) and Magnesium Stearate supplied by Loba Chemie Pvt. Ltd., Mumbai, and Polyvinylpyrrolidone K30 (PVP K30) purchased from Yarrow Chem Products, Mumbai. Lactose Monohydrate and Talc were kindly provided by SD Fine Chem Ltd., Mumbai and Isochem Laboratories, Kochi, respectively.

For buffer preparation, Potassium Dihydrogen Phosphate (KH_2PO_4) and Sodium Hydroxide (NaOH) were obtained from Merck Pvt. Ltd., Mumbai and Himedia Laboratories Pvt. Ltd., Mumbai, respectively, while Hydrochloric Acid (HCl) was procured from SRL Chemicals, Mumbai. Distilled Water used throughout the study was freshly prepared in the laboratory.

METHODS

Preparation of Finerenone Sustained-Release Tablets (Wet Granulation Method)

Table.1 Sustained release tablet formulations of Finerenone

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Finerenone	400	400	400	400	400	400
Tamarind Seed Polysaccharide (TSP)	900	1100	1300	1100	1400	1600
Microcrystalline Cellulose (MCC)	2300	2100	1950	1700	1800	1700
Lactose Monohydrate	900	900	850	1300	900	800
PVP K30 (Binder)	300	300	300	300	300	300
Talc	100	100	100	100	100	100
Magnesium Stearate	100	100	100	100	100	100
Total (mg per 20 tablets)	5000	5000	5000	5000	5000	5000

- **Step 1: Preparation of Materials**

Finerenone (API) and excipients including Tamarind Seed Polysaccharide (TSP), Microcrystalline Cellulose (MCC), Polyvinylpyrrolidone K30 (PVP K30), Lactose Monohydrate, Talc, and Magnesium Stearate were accurately weighed according to the formulation design. All materials were passed through a #40 mesh sieve to obtain a uniform particle size.

- **Step 2: Preparation of Binder Solution**
  PVP K30 was dissolved in a small quantity of purified water to form a clear binder solution under continuous stirring.
- **Step 3: Granulation Process**
  The weighed drug and excipients were blended thoroughly, and the binder solution was gradually added with gentle mixing until a damp, cohesive mass was formed. The wet mass was passed through a #20 mesh sieve to form granules.
- **Step 4: Drying of Granules**
  The wet granules were dried in a hot air oven at 40–50°C until the moisture content was below 5%. The dried granules were then passed through a #20 mesh sieve to ensure uniformity.
- **Step 5: Lubrication and Blending**
  Dried granules were mixed with Talc and Magnesium Stearate for 5 minutes to improve flow and compression properties.
- **Step 6: Compression**
  The lubricated granules were compressed into tablets using a Rimek Mini Press-II rotary tablet machine fitted with round punches (8–10 mm diameter). The compression force was adjusted to maintain uniform hardness and thickness.[7]

Evaluation of Finerenone Sustained-Release Tablets

Hardness Test

Tablet hardness was determined using a Monsanto Hardness Tester, and the mean of six readings was reported in kg/cm^2.

Thickness and Diameter

Ten tablets were measured using a digital Vernier caliper, and average values were calculated.

Friability

Ten tablets were tested in a Roche Friabilator at 25 rpm for 4 minutes. Percent friability was calculated from the weight loss before and after rotation.

Weight Variation

Twenty tablets were individually weighed using a digital balance; the average weight and percentage deviation were calculated.

Drug Content Uniformity

Powder equivalent to one tablet was dissolved in phosphate buffer (pH 6.8) and analyzed spectrophotometrically at λmax 249 nm using a UV–Visible Spectrophotometer (JASCO V-750).[8]

In-vitro Dissolution Study

Dissolution Conditions: The release profile of Finerenone sustained-release tablets was evaluated using a USP Type II (Paddle) Dissolution Apparatus at 50 rpm, 37 ± 0.5°C with a medium volume of 900 mL.

Stage 1: Simulated Gastric Fluid (pH 1.2)

The study was initiated in 900 mL of pH 1.2 buffer for the first 2 hours to simulate gastric conditions.

Stage 2: Simulated Intestinal Fluid (pH 6.8)

After 2 hours, the medium was replaced with 900 mL of pH 6.8 phosphate buffer to simulate intestinal conditions for the remaining 22 hours.

At each interval, 5 mL of the sample was withdrawn, filtered, and replaced with an equal volume of fresh medium to maintain sink conditions. The absorbance of the samples was measured at 249 nm using a UV spectrophotometer, and the cumulative percentage of drug release was calculated.

Kinetic Modelling of Drug Release

The obtained dissolution data were analyzed using different kinetic models to understand the mechanism of drug release from the matrix system:

- **Zero-order model** – to evaluate constant drug release independent of concentration.
- **First-order model** – to analyze concentration-dependent release kinetics.
- **Higuchi model** – to determine diffusion-controlled release through the matrix.
- **Korsmeyer-Peppas model** – to identify the mechanism of release (Fickian diffusion, anomalous transport, or erosion).

The model showing the highest correlation coefficient (R^2) was considered the best fit, indicating the predominant release mechanism of Finerenone from the sustained-release matrix tablets.[9]

RESULTS AND DISCUSSION

Physical Characterization of Finerenone

Physical Appearance

Finerenone was observed as a pure white to off-white amorphous powder, consistent with pharmacopeial specifications.

Solubility

The solubility profile of Finerenone in various solvents is summarized below.

Table 2. Solubility data of pure drug finerenone in different solvents

Solvent	Solubility
Ethanol	Soluble
DMSO (Dimethyl sulfoxide)	Soluble
Water	Insoluble
Phosphate Buffer (pH 6.8)	Poorly soluble

Determination of λmax

Finerenone exhibited maximum absorbance (λmax) at 251 nm when analyzed using a UV-Visible spectrophotometer, indicating its characteristic wavelength for further analytical studies.

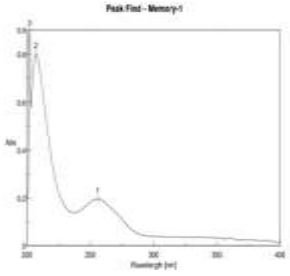

Fig 1. λ max of finerenone at 251nm

Calibration Curve

A calibration curve of Finerenone in phosphate buffer (pH 6.6) showed excellent linearity within the concentration range of 10–50 µg/mL, with a correlation coefficient (R^2 = 0.9995).

Table 1. Concentration and absorbance values for the calibration curve of finerenone at 251nm

Concentration(µg/ml)	Absorbance
10	0.515
20	0.972
30	1.426
40	1.881
50	2.335

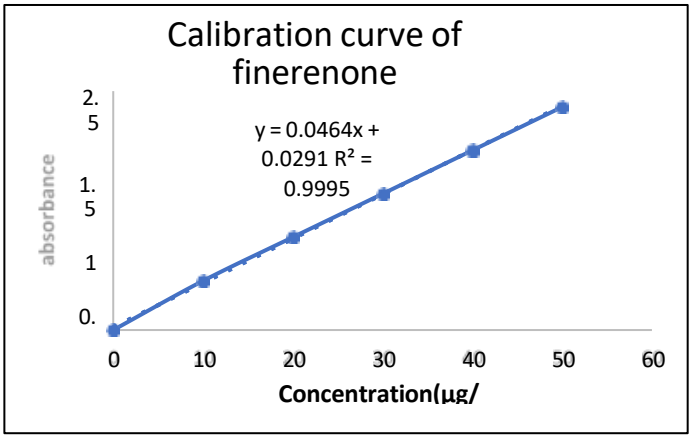

Fig 2. Calibration curve of finerenone

FT-IR Finerenone

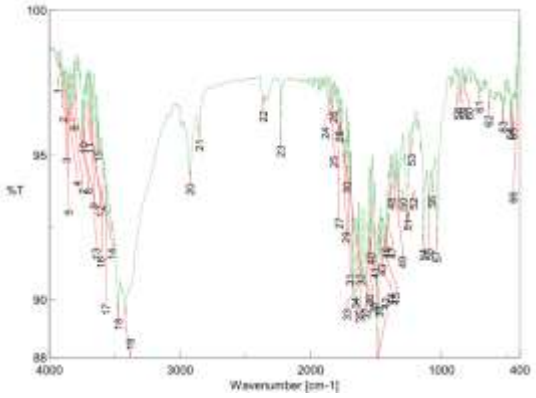

Fig 3. FT-IR spectrum of pure drug Finerenone

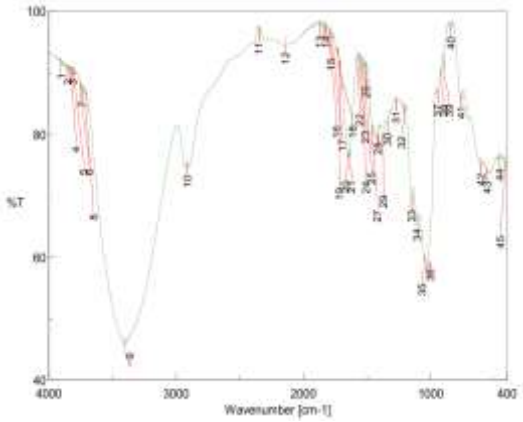

Fig 4. FT-IR spectrum of tamarind seed polysaccharide

Table 4. FT-IR interpretation for pure drug finerenone

S. NO	FUNCTIONAL GROUP	TEST ABSORPTION (cm^{-1})
1	O-H (alcohol/phenol) or N-H (amine)	3419.17
2	C-H (alkane)	2923.56
3	C=O (carbonyl)	1733.69
4	C=C (aromatic ring)	1609.31
5	C-O (ether/ester)	1137.80

Table 5. FT-IR interpretation for tamarind seed polysaccharide

S. NO	FUNCTIONAL GROUP	TEST ABSORPTION (cm^{-1})
1	O-H (Hydroxyl)	3399.89
2	C-H (Alkane)	2913.91
3	C=O (Carboxylic acid/Amide)	1732.73
4	C=C (Aromatic ring)	1646.91
5	C-O (Alcohol/Ether)	1205.29

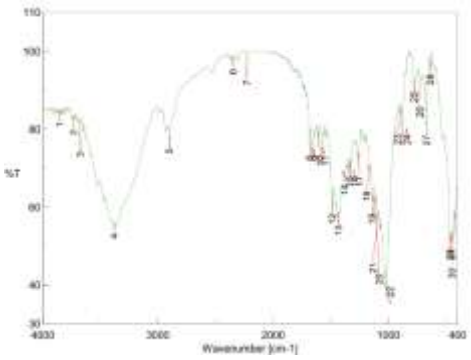

Fig 5. FT-IR spectrum of drug + all excipients

Table 6. FT-IR interpretation for drug + all excipients

S. NO	FUNCTIONAL GROUP	TEST ABSORPTION (cm^{-1})
1	O-H (alcohol/phenol)	3379.64
2	C-H (alkane)	2900.41

3	C=O (carbonyl)	1655.59
4	C=C (aromatic ring)	1608.34
5	C–O (ether/ester)	1019.19

Pre-Compression Evaluation

Table 7. Pre compression evaluation of sustained release tablet formulations of finerenone

Parameter	F1	F2	F3	F4	F5	F6
Bulk Density (g/cm³)	0.46 ± 0.01	0.45 ± 0.02	0.47 ± 0.01	0.46 ± 0.01	0.48 ± 0.01	0.47 ± 0.02
Tapped Density (g/cm³)	0.52 ± 0.01	0.51 ± 0.02	0.53 ± 0.01	0.53 ± 0.02	0.55 ± 0.01	0.54 ± 0.02
Carr's Index (%)	11.5	11.8	11.3	13.2	12.7	13.0
Hausner's Ratio	1.13	1.13	1.12	1.15	1.14	1.15
Angle of Repose (°)	29.6 ± 0.5	28.4 ± 0.6	27.8 ± 0.4	27.1 ± 0.5	25.3 ± 0.4	26.0 ± 0.6

The powder blends showed good flowability and compressibility, with Carr's index values between 11.3–13.2% and Hausner's ratios below 1.25. The angle of repose values (25.3°–29.6°) indicated excellent flow characteristics suitable for tablet compression.

FORMULATION OF SUSTAINED RELEASE TABLETS

Fig 6. Sustained release tablet formulations of finerenone

Post-Compression Evaluation

Table 8. Post compression evaluation of sustained release tablet formulations of finerenone

Parameter	F1	F2	F3	F4	F5	F6
Hardness (kg/cm²)	5.3 ± 0.1	5.6 ± 0.1	5.8 ± 0.1	6.0 ± 0.1	6.2 ± 0.1	6.5 ± 0.2
Thickness (mm)	3.15 ± 0.02	3.16 ± 0.02	3.14 ± 0.01	3.13 ± 0.02	3.12 ± 0.01	3.18 ± 0.02
Friability (%)	0.40	0.35	0.30	0.26	0.20	0.18
Weight Variation (%)	±2.4	±2.3	±2.1	±2.0	±1.9	±2.0

Drug Content (%)	97.6 ± 0.3	98.0 ± 0.4	98.3 ± 0.2	98.7 ± 0.3	99.1 ± 0.2	98.8 ± 0.3

All formulations complied with pharmacopeial limits. F5 exhibited optimal characteristics with the highest hardness (6.2 kg/cm²), lowest friability (0.20%), and uniform drug content (99.1%), indicating it as the optimized batch.

In-vitro Drug Release Study

The dissolution study was performed using a USP Type II (Paddle) Dissolution Apparatus at 50 rpm and 37 ± 0.5°C with 900 mL of phosphate buffer (pH 6.8) as the medium. Samples were withdrawn at predetermined intervals (1–24 hours), filtered, and analyzed spectrophotometrically at 249 nm.

Table 9. In vitro drug release of sustained release tablet formulations of finerenone

Time (h)	F1	F2	F3	F4	F5	F6
1	17.6	14.1	12.2	13.0	**11.8**	9.6
2	28.4	22.1	23.6	23.6	**18.6**	14.6
4	44.5	35.1	33.4	29.6	**27.6**	21.4
6	60.1	43.4	42.6	33.4	**33.7**	32.6
8	72.2	54.2	57.4	44.6	**40.6**	39.4
10	81.2	66.8	63.2	52.3	**46.2**	47.6
12	89.4	75.3	68.1	61.4	**54.9**	54.9
14	92.1	83.7	74.6	68.6	**60.8**	61.9
16	94.6	87.5	79.5	73.5	**74.5**	67.4
18	97.8	89.9	83.6	77.6	**79.6**	74.9
20	100	93.2	86.3	79.6	**85.4**	78.6
22	–	96.2	89.2	82.3	**94.6**	82.3
24	–	96.3	90.1	85.4	**98.8**	84.6

Among all batches, **F5 exhibited the most controlled and prolonged release (98.8% at 24 hours)**, confirming its suitability as an optimized sustained-release formulation.

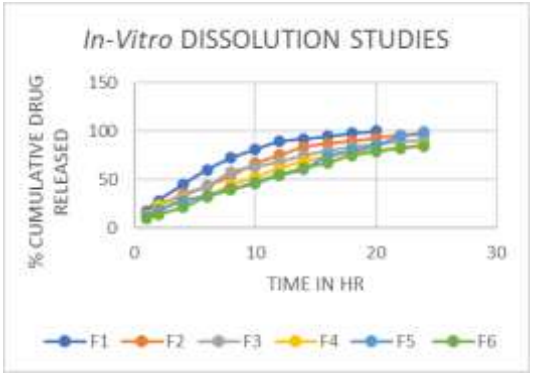

Fig 7. Percentage cumulative drug release for all different formulations

Drug Release Kinetics

Table 10. Release kinetics of F5 formulation

Time (h)	Log T	% Drug Release	% Remaining Drug	Log Unreleased	√T	Log % Release
1	0.0000	11.80	88.20	1.945	1.000	1.072
2	0.3010	18.60	81.40	1.911	1.414	1.270
4	0.6021	27.60	72.40	1.859	2.000	1.441
6	0.7782	33.70	66.30	1.821	2.449	1.528
8	0.9031	40.60	59.40	1.774	2.828	1.609
10	1.0000	46.20	53.80	1.731	3.162	1.665
12	1.0792	54.90	45.10	1.654	3.464	1.740
14	1.1461	60.80	39.20	1.593	3.742	1.784
16	1.2041	74.50	25.50	1.406	4.000	1.872
18	1.2553	79.60	20.40	1.309	4.243	1.901
20	1.3010	85.40	14.60	1.164	4.472	1.931
22	1.3424	94.60	5.40	0.732	4.690	1.976
24	1.3802	98.80	1.20	0.079	4.899	1.995

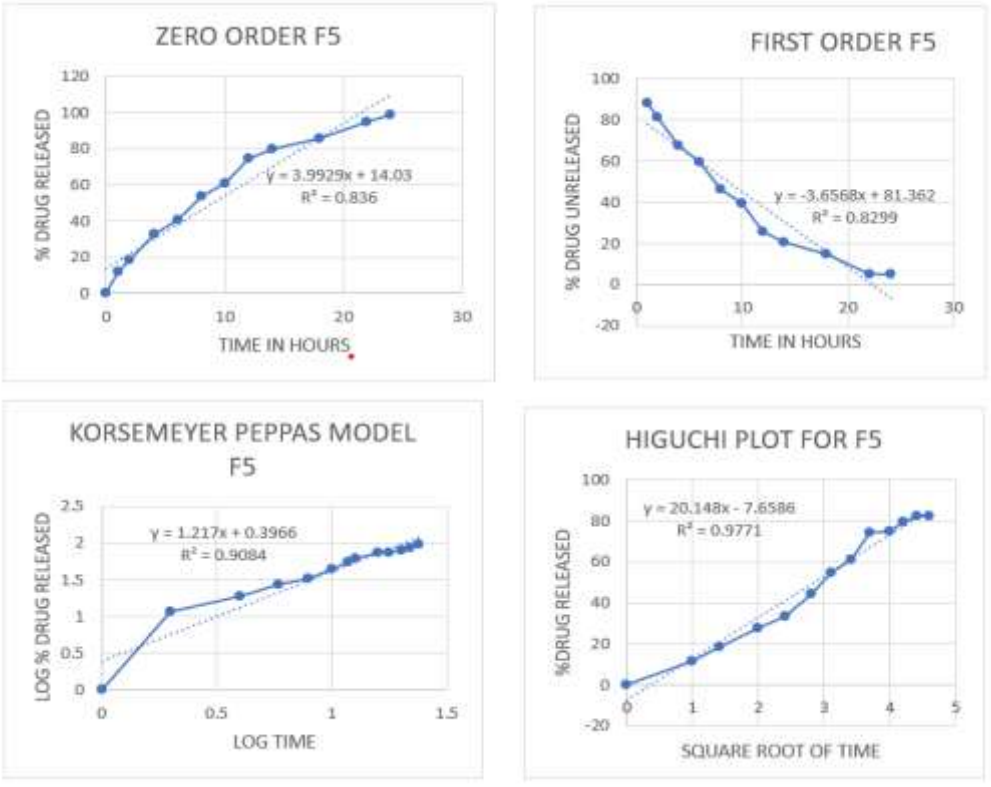

Fig 7. *In vitro* release kinetics of F5

The drug release data were fitted into various kinetic models—Zero-order, First-order, Higuchi, and Korsmeyer–Peppas—to determine the mechanism of release. The optimized batch (F5) followed Higuchi kinetics (R^2 > 0.99), indicating a diffusion-controlled release process. The release exponent (n) from the Korsmeyer–Peppas model revealed a non-Fickian (anomalous) diffusion, suggesting a combination of polymer swelling and drug diffusion as the dominant mechanism.

DISCUSSION

The study successfully developed Finerenone sustained-release tablets using Tamarind Seed Polysaccharide (TSP) as a natural polymer to achieve prolonged drug release and improved patient compliance. Pre-formulation results confirmed that Finerenone is a white, amorphous powder with a melting point of 259.8°C, insoluble in water but soluble in ethanol and DMSO. The calibration curve showed excellent linearity (R^2 = 0.9995) at 251 nm, validating the analytical method. All formulations exhibited good flow and compressional properties, with acceptable hardness, friability, and uniform drug content. Among the batches, F5 showed optimal physical characteristics and provided controlled drug release up to 24 hours (98.8%). Kinetic analysis indicated that the optimized formulation followed Higuchi diffusion kinetics with a non-Fickian release mechanism, suggesting drug diffusion combined with polymer swelling. Overall, TSP proved to be an effective, natural, and eco-friendly matrix former, capable of sustaining Finerenone release and serving as a potential alternative to synthetic polymers in sustained-release formulations.

CONCLUSION

The present study successfully formulated Finerenone sustained-release tablets using Tamarind Seed Polysaccharide (TSP) as a natural polymeric excipient. The preformulation and evaluation results confirmed the suitability of TSP for controlled drug delivery, ensuring good flow, compressibility, and stability of the formulation. Among all formulations, F5 exhibited excellent mechanical strength, uniform drug content, and a sustained release of 98.8% over 24 hours, following Higuchi diffusion kinetics with a non-Fickian mechanism. These findings demonstrate that TSP serves as a promising natural, biodegradable, and cost-effective polymer for developing sustained-release formulations. The optimized Finerenone tablets have the potential to enhance therapeutic efficacy, reduce dosing frequency, and improve patient adherence in the management of chronic kidney disease associated with type 2 diabetes.

CONFLICT OF INTEREST

Authors declare for none conflict of interest.

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