

FORMULATION AND EVALUATION OF SPIRONOLACTONE FAST DISSOLVING TABLETS: A STUDY ON RAPID DRUG DELIVERY

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ABSTRACT

Spironolactone is a potassium-sparing diuretic essentially utilized in the therapeutic management of hypertension, congestive heart failure, and oedema. Despite its clinical prevalence, the drug exhibits poor water solubility, which presents significant challenges in developing dosage forms with optimal bioavailability. The present study was aimed at the formulation and evaluation of spironolactone immediate-release tablets to achieve rapid drug release and acceptable physicochemical properties utilizing the direct compression method. Various formulations were prepared using distinct super disintegrants, specifically Cross Povidone, Croscarmellose sodium, and Sodium starch glycolate. The prepared powder blends were subjected to pre-compression evaluation for parameters including bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio, with results indicating satisfactory flow properties. Subsequently, compressed tablets were evaluated for post-compression quality attributes such as weight variation, hardness, thickness, friability, disintegration time, drug content uniformity, and in vitro dissolution profiles. All evaluated parameters fell within the limits specified by the Indian Pharmacopoeia (IP). Among the developed formulations (F1-F9), formulation F7 was identified as the optimized candidate, exhibiting rapid disintegration and a maximum in vitro drug release of 99.82%, a statistically significant improvement over comparative formulation. These results demonstrate that spironolactone immediate-release tablets with enhanced dissolution characteristics can be successfully formulated via direct compression, potentially improving therapeutic efficacy and patient compliance.

Keywords: Spironolactone, Immediate Release, Direct Compression, Sodium Starch Glycolate, Super disintegrants.

INTRODUCTION

Oral drug delivery remains the most preferred route due to its ease of administration, cost-effectiveness, and high patient compliance.¹ Immediate-release (IR) dosage forms are designed to disintegrate and

release their medication rapidly without any special rate-controlling features.¹ Such systems are particularly beneficial for drugs requiring a quick onset of action, thereby improving therapeutic outcomes.² Spironolactone is a lipophilic drug with a half-life of 1.4 hours, categorized as a potassium-sparing diuretic. It acts by competitively inhibiting aldosterone in the distal renal tubules, leading to increased sodium and water excretion while conserving potassium.³ Spironolactone is a steroid-like compound that functions pharmacologically as a mineralocorticoid receptor (MR) antagonist. By blocking the binding of aldosterone to the MR, it prevents sodium reabsorption and potassium excretion in the distal renal tubules, making it a cornerstone therapy for conditions such as primary aldosteronism, essential hypertension, and severe heart failure (Katsu et al., 2024). Despite its established efficacy, the clinical utility of spironolactone is often hampered by its physicochemical classification; it is a Biopharmaceutics Classification System (BCS) Class II drug, characterized by high permeability but low aqueous solubility. This low solubility often leads to variable absorption and bioavailability, necessitating robust formulation strategies to ensure immediate and consistent therapeutic effects.

The rate-limiting step in drug absorption can be either disintegration (for highly soluble drugs) or dissolution (for poorly soluble drugs).⁴ This study focuses on overcoming the dissolution challenge by using super disintegrants to enhance the disintegration and subsequent release of Spironolactone.⁵ The primary objective was to formulate and evaluate Spironolactone IR tablets using different super disintegrants (Cross Povidone, Croscarmellose sodium, and Sodium starch glycolate) and to identify an optimized formulation that complies with pharmacopeial standards.⁶ The scope of this study is focused on the development of an immediate-release tablet dosage form that ensures rapid onset of action. By utilizing super disintegrants, the study aims to enhance the wettability and disintegration of the tablet matrix, thereby accelerating dissolution. The study provides a systematic comparison of three distinct superdisintegrants (Cross Povidone, Croscarmellose sodium, and Sodium starch glycolate), identifying validated formula for immediate therapeutic intervention. The research demonstrates the feasibility of formulating spironolactone tablets using direct compression, a cost-effective and streamlined manufacturing process, by validating the flow properties of powder blends through pre-compression analysis.

MATERIALS AND METHODS

Materials

Spironolactone was procured from Hetero labs, Hyderabad. Superdisintegrants including Cross Povidone, Croscarmellose sodium, and Sodium starch glycolate, along with other excipients like Microcrystalline Cellulose (MCC), Aspartame, Magnesium stearate, and Talc, were obtained from S.D. Fine Chemicals Pvt Ltd, Mumbai.⁷

Analytical Method

The absorption maximum (λ_{max}) of Spironolactone was determined by scanning a standard solution from 200-400 nm in 0.1 N HCl.⁸ The λ_{max} was found to be 238 nm, A standard calibration curve was prepared using concentrations of 5, 10, 15, 20, and 25 $\mu\text{g/ml}$, and absorbance was measured at the determined 238 nm.⁹

Formulation of Tablets

Nine formulations (F1-F9) were prepared using the direct compression method. The drug and excipients were weighed, passed through a 40-mesh screen, and mixed. The blend was lubricated with Magnesium stearate and Talc. The final mixture was compressed into tablets with a target weight of 200 mg.¹⁰ The formulations varied in the type and concentration of super disintegrant used, as detailed in the table below.

Table 1: Formulation of Fast Dissolving Tablets

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Spironolactone	25	25	25	25	25	25	25	25	25
Cross Povidone	25	50	75	-	-	-	-	-	-
Croscarmellose sodium	-	-	-	25	50	75	-	-	-
Sodium starch glycolate	-	-	-	-	-	-	25	50	75
Aspartame	15	15	15	15	15	15	15	15	15
Magnesium stearate	12	12	12	12	12	12	12	12	12
Talc	10	10	10	10	10	10	10	10	10
Micro Crystalline Cellulose	113	88	63	113	88	6	113	88	63
Total weight (mg)	200	200	200	200	200	200	200	200	200

Evaluation of Powder Blend and Tablets

Pre-compression Evaluation

Prior to compression, the powder blends were analysed to ensure they possessed adequate flowability, a critical requirement for the direct compression method to prevent weight variation and ensure content uniformity.¹¹ The powder blends were evaluated for Angle of Repose, Bulk Density, Tapped Density, Carr's Index, and Hausner's Ratio to assess their flowability and compressibility.¹²

Angle of Repose: Determined by the funnel method. The blend was poured through a funnel to form a cone, and the angle was calculated.

Bulk and Tapped Density: Measured to calculate the compressibility indices.

Carr's Index and Hausner's Ratio: These parameters were calculated to predict the flow characteristics. A Carr's index below 15% and a Hausner's ratio below 1.25 were set as the acceptance criteria for "good" flow.

Post-compression Evaluation

Compressed tablets were tested for thickness, weight variation, hardness, friability, and drug content uniformity according to standard procedures.¹³

Weight Variation: 20 tablets were weighed individually, and the average weight was calculated to check for deviations.

Hardness and Friability: Hardness was measured using a Monsanto hardness tester (kg/cm²), and friability was assessed using a Roche friabilator (100 revolutions). The target was a friability loss of less than 1%.

Drug Content: Tablets were analyzed spectrophotometrically to ensure the drug load met label claims.

In-Vitro Disintegration Time: It is performed using a USP disintegration apparatus.

In-Vitro Dissolution Studies: It is conducted using USP Dissolution Apparatus II (Paddle method). The dissolution medium consisted of 900 ml of 0.1 N HCl (pH 1.2) maintained at 37±0.5°C. The study was carried out at 50 rpm. Aliquots were withdrawn at predetermined time intervals (5, 10, 15, 20, 30, and 45 minutes), filtered, and analyzed spectrophotometrically at 238 nm.¹⁴

Drug-Excipient Compatibility Study

FTIR spectroscopy was used to investigate any potential interactions between the drug and excipients. Spectra of the pure drug and the optimized formulation were recorded and compared.¹⁵

RESULTS AND DISCUSSION

Calibration curve of Spironolactone

The standard curve of Spironolactone was obtained and good correlation was obtained with R^2 value of 0.999.

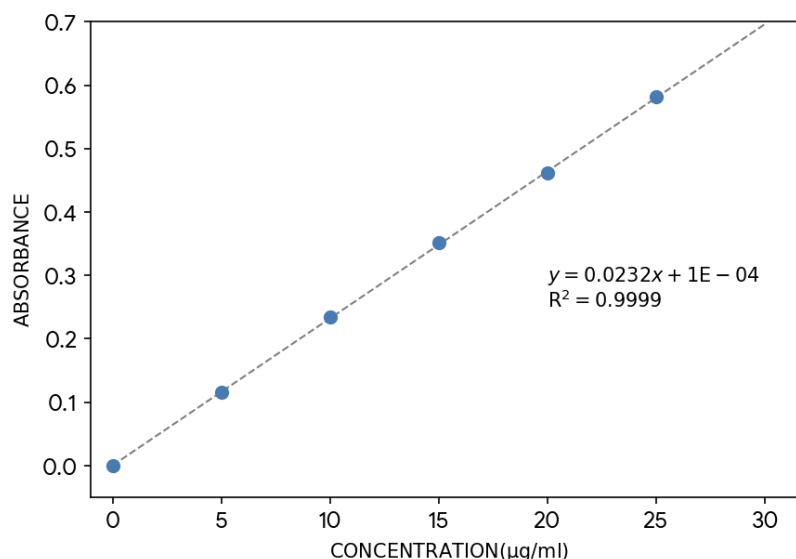


Figure 1: Standard graph of spironolactone

Characterization of precompression blend

The precompression blend Spironolactone were characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio. Angle of repose was less than 28°, Carr's index values were less than 11 for the precompression blend of all the batches indicating good to fair flowability and compressibility. Hausner's ratio was less than 1.25 for all batches indicating good flow properties.

Table 2: Physical properties of Precompression blend

Formulation code	Angle of repose (°)	Bulk density (gm/cm ³)	Tapped density (gm/cm ³)	Carr's index (%)	Hausner's ratio
F1	28.24 ± 1.13	0.545 ± 0.04	0.635 ± 0.01	14.17 ± 0.24	1.16 ± 0.026
F2	25.15 ± 1.15	0.531 ± 0.03	0.625 ± 0.02	15.04 ± 0.45	1.17 ± 0.029
F3	26.98 ± 1.32	0.524 ± 0.02	0.609 ± 0.01	13.95 ± 0.23	1.16 ± 0.055
F4	26.74 ± 1.13	0.534 ± 0.15	0.641 ± 0.02	16.69 ± 0.09	1.20 ± 0.034
F5	25.34 ± 0.89	0.522 ± 0.02	0.632 ± 0.01	17.40 ± 0.42	1.21 ± 0.045
F6	27.36 ± 1.15	0.543 ± 0.15	0.645 ± 0.02	15.81 ± 0.56	1.03 ± 0.061
F7	24.45 ± 0.52	0.513 ± 0.01	0.605 ± 0.03	15.20 ± 0.65	1.17 ± 0.033
F8	25.34 ± 0.37	0.521 ± 0.07	0.615 ± 0.01	15.28 ± 0.51	1.17 ± 0.0730
F9	26.20 ± 1.5	0.535 ± 0.02	0.635 ± 0.02	15.74 ± 0.04	1.18 ± 0.034

Evaluation of tablets

Physical evaluation of Spironolactone immediate release tablets

The results of the weight variation, hardness, thickness, friability, and drug content of tablets are given in table. All the tablets of different batches complied with the official requirement of weight variation as their weight variation passes the limit. The hardness of the tablets ranged from 2.83 ± 3.12 kg/cm² and the friability values were less than 0.561 % indicating that the tablets were compact and hard. The thickness of the tablets ranged from 2.43 to 2.56 cm. All the formulations satisfied the content of the drug as they contained 98-101% of Spironolactone and good uniformity in drug content was observed. Thus, all physical attributes of the prepared tablets were found to be practically within control limits.

Table 3: Physical evaluation of spironolactone

Formulation code	Average Weight (mg)	*Thickness (cm)	*Hardness (Kg/cm ²)	Friability (%)	*Content uniformity (%)
F1	148.12	2.47	2.83	0.54	98.34
F2	147.31	2.48	2.91	0.48	97.45
F3	151.08	2.44	2.86	0.63	99.83
F4	149.53	2.56	3.08	0.59	98.61
F5	146.73	2.53	3.12	0.47	99.86
F6	149.66	2.49	2.97	0.52	97.75
F7	150.83	2.43	2.88	0.41	99.92
F8	151.24	2.52	2.95	0.65	99.88
F9	149.33	2.48	3.06	0.57	98.52

In vitro release studies

The drug release rate from tablets was studied using the USP type dissolution test apparatus. The dissolution medium was 900 ml of 0.1N HCl (pH 1.2) at 50 rpm at a temperature of 37 ± 0.5 °C. Samples of 5 ml were collected at different time intervals up to 45 minutes and has analyzed after appropriate dilution by using UV spectrophotometer at 238 nm.

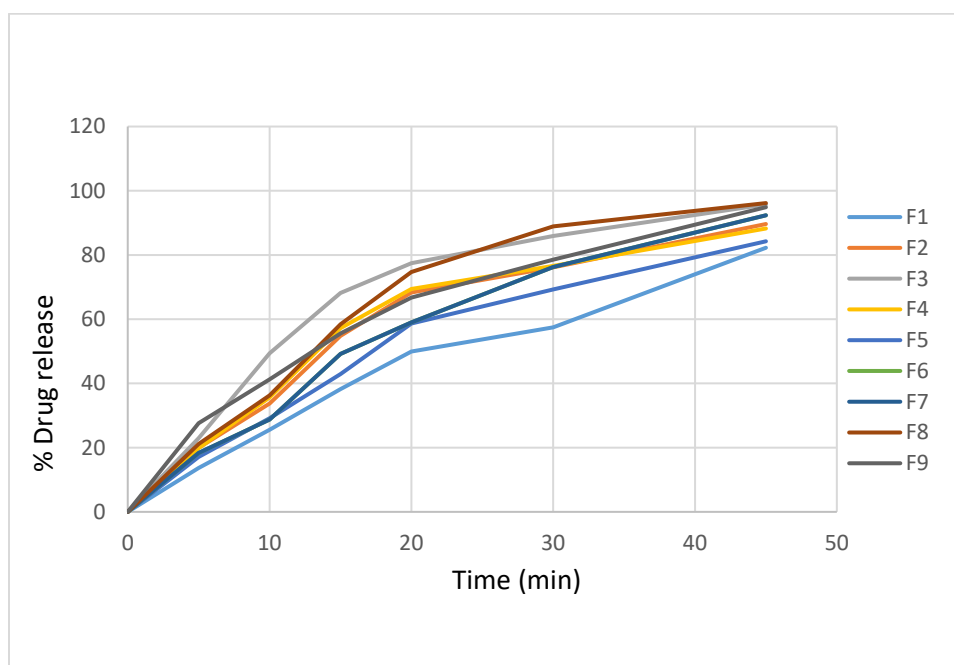


Figure 2: Comparison of the *in-vitro* drug release profile of formulation F1 to F9

Among all the formulations F7 formulation containing drug and Sodium starch glycolate showed good result that is 99.82 % in 45 minutes, at the concentration of 25 mg. Hence from all the formulations it is evident that F7 formulation is the better formulation

Drug-Excipient compatibility studies by FTIR studies

Spironolactone mixed with various proportions of excipients showed no colour change at the end of two months, providing no drug-excipient interaction.

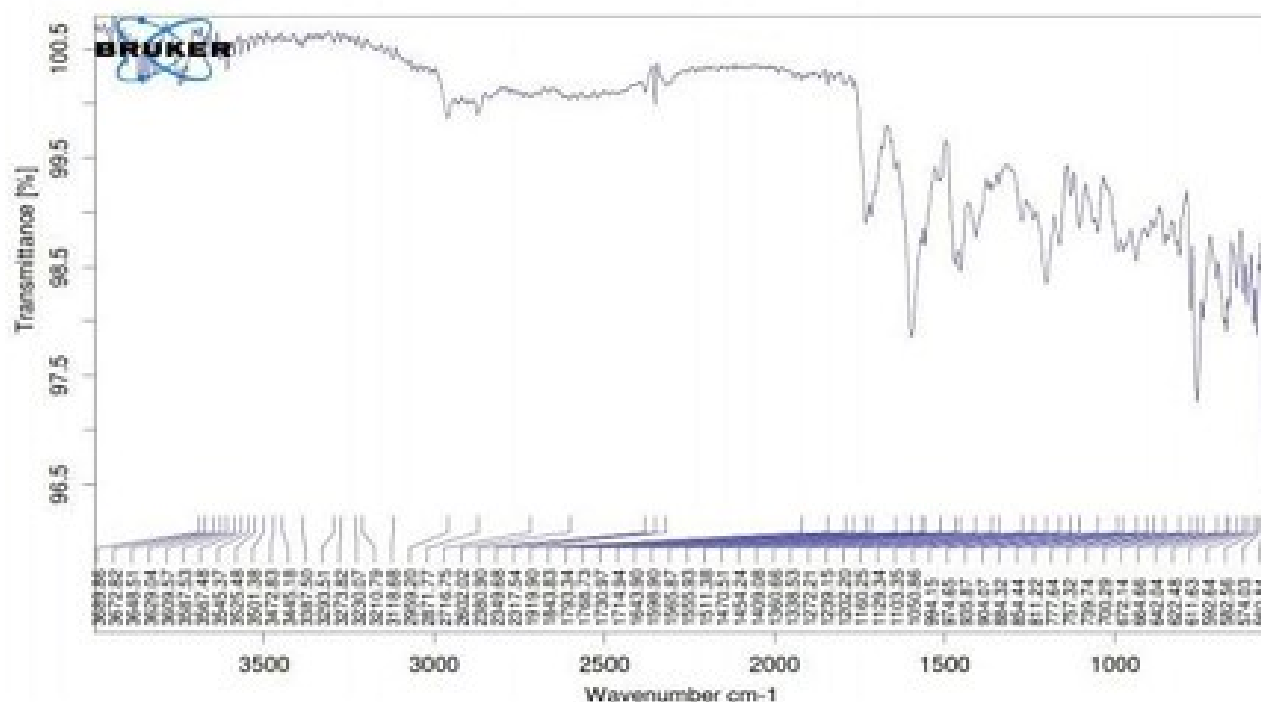


Figure 3: FTIR Spectrum of pure drug

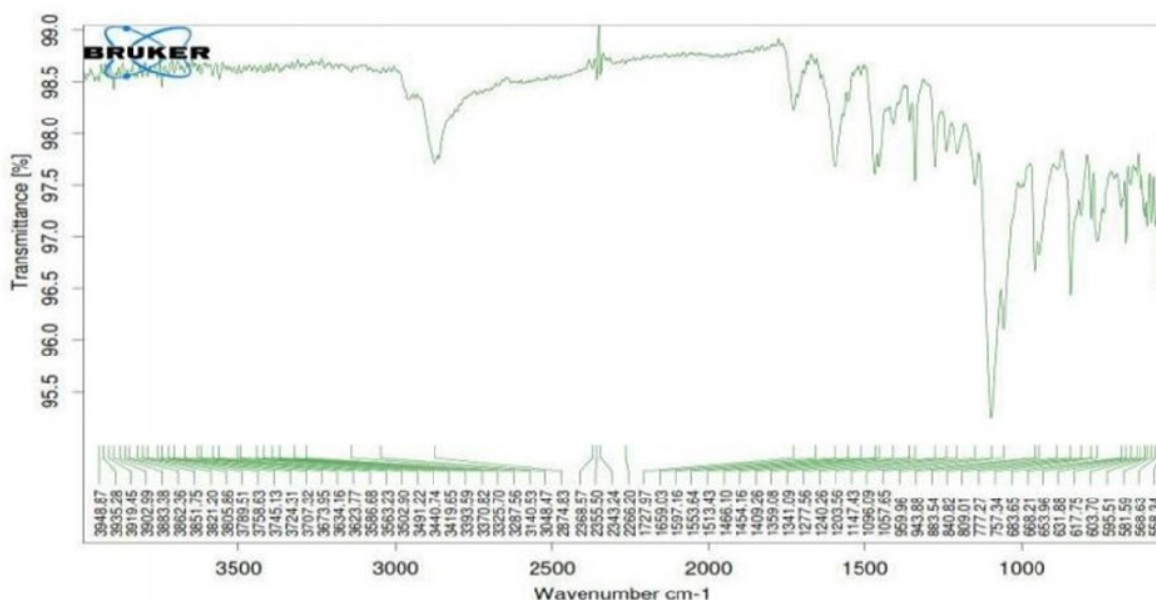


Figure 4: FTIR Spectrum of optimized formulation

Conclusion

The present study successfully focused on the formulation and evaluation of spironolactone immediate release tablets with the objective of developing a pharmaceutically acceptable dosage form exhibiting rapid drug release and satisfactory quality attributes. All the prepared formulations were evaluated for

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pre-compression parameters such as bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio, which indicated good flow properties suitable for direct compression.

The post-compression parameters, including tablet hardness, thickness, friability, weight variation, drug content uniformity, disintegration time, and in vitro dissolution studies, were found to be within the acceptable limits as per Indian Pharmacopoeia (IP) standards, confirming the suitability of the formulation process and excipients used.

The standout finding was the performance of Formulation F7, which achieved a drug release of 99.82%. This superior performance can likely be attributed to the specific mechanism of Cross Povidone (Crospovidone). Unlike SSG, which relies heavily on swelling, Cross Povidone acts through a combination of capillary action (wicking) and shape recovery. It rapidly absorbs water into the tablet pores, creating high hydrostatic pressure that breaks the tablet apart without forming a viscous gel barrier that might impede drug diffusion. The rapid disintegration observed in F7 directly correlates to the enhanced dissolution rate, effectively addressing the solubility issues inherent to spironolactone.

Among all the formulations developed, formulation F7 was considered the optimized formulation, as it showed superior performance in terms of rapid disintegration and enhanced drug release when compared to the other formulations. The optimized formulation demonstrated consistent tablet quality, uniform drug content, and immediate release characteristics, making it suitable for oral administration.

Overall, the study concludes that spironolactone immediate release tablets can be successfully formulated using appropriate excipients, and the optimized formulation (F7) has the potential to provide improved therapeutic efficacy and patient compliance. Further in vivo studies may be recommended to establish a correlation between in vitro performance and in vivo bioavailability.

The success of formulation F7 has significant practical implications for pharmaceutical manufacturing. By validating a direct compression formula, manufacturers can bypass the energy-intensive and time-consuming wet granulation process. This reduction in unit operations lowers the risk of batch-to-batch variability and reduces manufacturing costs. Furthermore, the high dissolution rate suggests that this formulation could offer bioequivalence to market leaders, potentially improving patient compliance by ensuring rapid therapeutic onset.

While the study is limited to in vitro data, the results provide a strong foundation for future in vivo studies and illustrate the potential for simplified, cost-effective manufacturing processes to produce high-quality

spironolactone tablets. The integration of these experimental findings with emerging computational formulation techniques could further accelerate the development of optimized therapies for hypertension and heart failure.

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