



FORMULATION AND EVALUATION OF RIVAROXABAN SOLID DISPERSION FOR IMPROVED ORAL DRUG DELIVERY

V. Ranjith*, S. K. Senthil Kumar, K. Saravanan, R. Sathiya, A. Sharma, N. Sivaraj, D. Sivasankari

Department of Pharmaceutics, Arunai College of Pharmacy, Tiruvannamalai, Tamil Nadu, India.

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ARTICLE INFO	ABSTRACT
Keywords: Rivaroxaban Solid dispersion Soluplus Polyvinylpyrrolidone (PVP) Solubility enhancement Direct compression Superdisintegrants Dissolution	Rivaroxaban is an oral direct factor Xa inhibitor used in the prevention and treatment of Deep Vein Thrombosis (DVT). Its poor aqueous solubility can limit dissolution and oral drug delivery. The present study aimed to enhance the solubility and dissolution of rivaroxaban by preparing solid dispersions using Soluplus and polyvinylpyrrolidone (PVP), followed by development of tablets containing the selected solid dispersion. Four solid-dispersion formulations (SD1-SD4) containing rivaroxaban with different concentrations of Soluplus and PVP were prepared by a solvent evaporation method using ethanol. The prepared dispersions were evaluated for solubility, and SD4 containing 15 mg rivaroxaban, 30 mg Soluplus and 30 mg PVP showed the highest drug solubility, with 3.342 mg dissolved in 20 mL and approximately 17-fold enhancement compared with the pure drug (0.192 mg/20 mL). SD4 was selected for tablet formulation. Four tablet formulations (F1-F4) were prepared by direct compression using croscopovidone, croscarmellose sodium and sodium starch glycolate as superdisintegrants. The granule blends showed acceptable flow characteristics. All tablet formulations complied with the reported weight-variation and friability requirements and disintegrated within 30 min. At 60 min, the in-vitro drug release was 89.13%, 92.50%, 84.16% and 98.13% for F1, F2, F3 and F4, respectively. F4 showed the highest drug release. The findings indicate that solid dispersion using Soluplus and PVP improved rivaroxaban solubility, while incorporation of superdisintegrants supported rapid drug release from the tablet formulation.

* Corresponding author

Mr. V. Ranjith, M. Pharm., Assistant Professor, Department of Pharmaceutics, Arunai College of Pharmacy, Tiruvannamalai, Tamil Nadu, India.

E-mail: ranjithvelul@gmail.com, Tel.: +91 9894281879

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1. Introduction

Deep vein thrombosis (DVT) is a thrombotic disorder in which a clot forms in a deep vein, most commonly in the legs. DVT is an important component of venous thromboembolism and may be complicated by pulmonary embolism. The development of DVT is associated with factors including venous stasis, vascular injury and altered coagulation. The clinical importance of DVT and the need for effective anticoagulant therapy provide a rationale for the development of reliable oral anticoagulant dosage forms.

Rivaroxaban is an oral anticoagulant that selectively inhibits factor Xa. By inhibiting factor Xa, rivaroxaban reduces thrombin generation and thereby decreases fibrin clot formation. It is used in the prevention and treatment of DVT and pulmonary embolism and for reduction of thromboembolic risk in non-valvular atrial fibrillation. In the present study source, rivaroxaban is characterized as a BCS class II drug with low aqueous solubility and high permeability, making dissolution and solubility enhancement important formulation objectives.

Poor aqueous solubility is a common formulation challenge because dissolution can become a limiting step for oral absorption. Solid dispersion is an established approach in which a poorly water-soluble drug is dispersed in a hydrophilic carrier. The technique can improve wettability, reduce effective particle size and promote conversion or

2. Materials and Methods

Drug and formulation materials

Rivaroxaban was used as an active pharmaceutical ingredient. Soluplus and PVP were used as hydrophilic polymers for solid-dispersion preparation. Microcrystalline cellulose, mannitol, croscopovidone, croscarmellose sodium, sodium starch glycolate, Aerosil, magnesium stearate, talc, saccharin sodium and vanilla flavour were used in tablet development.

Preformulation studies

The dissertation described determination of melting point by the capillary-tube method, drug-excipient compatibility by FT-IR using the KBr pellet

Table.1 Four solid-dispersion formulation of different ratio.

Formulation	Rivaroxaban (mg)	Soluplus (mg)	PVP (mg)
SD1	15	15	15
SD2	15	15	30
SD3	15	30	15
SD4	15	30	30

Solubility study

The pure drug and prepared solid dispersions were added to 20 ml distilled water until saturated solutions were obtained. The samples were sonicated for 20 min, filtered using Whatman filter paper and analyzed by UV spectroscopy at 247 nm.

Tablet formulation

The selected solid dispersion was used to prepare four tablet formulations by direct compression. The formulation blends contained rivaroxaban equivalent to 15 mg, croscopovidone, croscarmellose sodium, mannitol, sodium starch glycolate, microcrystalline cellulose, PVP, Aerosil,

Table.2 Formulation of granules by using selected solid dispersion formulation.

Ingredients (mg)	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)
Rivaroxaban equivalent to 15 mg	60	60	60	60
Croscopovidone	5	10	5	10
Croscarmellose sodium	5	5	10	10
Mannitol	64	59	59	54
Sodium starch glycolate	5	5	5	5

stabilization of the drug in a less crystalline or amorphous state. Earlier literature has described solid dispersions as a strategy for improving the dissolution and oral performance of poorly soluble drugs, while amorphous systems can provide a solubility advantage when appropriately stabilized. [1–4, 10, 13, 14]

Previous studies specifically involving rivaroxaban have reported improved biopharmaceutical performance using polymeric amorphous solid dispersions, including systems containing Soluplus, and have emphasized the importance of drug-polymer interactions and physical stability. [5–7, 10] Studies using other formulation approaches, including spray-dried polymeric dispersions and hot-melt extrusion, have also reported improved rivaroxaban solubility or dissolution. [3–5] Soluplus is an amphiphilic polymer that has been investigated as an absorption/dissolution enhancer for poorly soluble drugs, while PVP is a hydrophilic polymer commonly used in pharmaceutical formulations. [15]

Therefore, the present work was designed to formulate rivaroxaban solid dispersions using Soluplus and PVP, identify the formulation providing the greatest solubility enhancement, and use the selected dispersion for tablet development. The study further evaluated powder flow properties and post-compression characteristics, including weight variation, friability, hardness, disintegration and in-vitro dissolution.

method, and determination of the ultraviolet maximum and standard curve. Rivaroxaban was scanned over 200–400 nm and the analytical wavelength used for the standard curve and solubility measurements was 247 nm. The standard-curve study covered 2, 4, 6, 8, 10 µg/mL in phosphate buffer pH 6.8.

Preparation of rivaroxaban solid dispersions

Four solid-dispersion formulations were prepared using different concentrations of Soluplus and PVP. Rivaroxaban and the polymers were dissolved in 20 ml ethanol, and the prepared solution was placed in a desiccator until the solvent was removed and a residue was obtained. The residue was collected and evaluated for solubility. Four Solid-dispersion formulations of different ratio were shown in the table below table 1.

magnesium stearate, talc, saccharin sodium and vanilla flavour. Each formulation had a total tablet weight of 200 mg. The tablets were compressed using a rotary tablet compression machine with an 8.50-mm punch size. The four different formulations were mentioned below table 2.

Evaluation of powder blends and tablets

The powder blends were evaluated for angle of repose, bulk density, tapped density, Carr's compressibility index and Hausner's ratio. Tablets were evaluated for weight variation, friability, hardness, disintegration time and in-vitro drug release.

Ingredients (mg)	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)
Microcrystalline cellulose	51	51	51	51
PVP	4	4	4	4
Aerosil	1	1	1	1
Magnesium stearate	1	1	1	1
Talc	1	1	1	1
Saccharin sodium	1	1	1	1
Vanilla flavour	2	2	2	2
Total weight	200	200	200	200

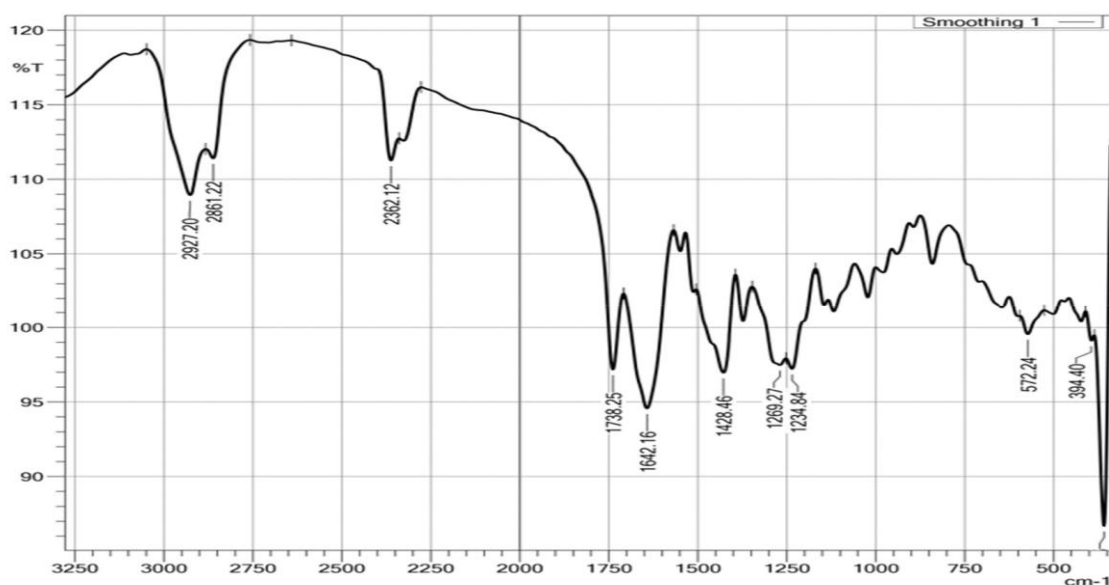
3. Results and Discussion

Melting Point

Rivaroxaban API melting point was found to be **234°C**.

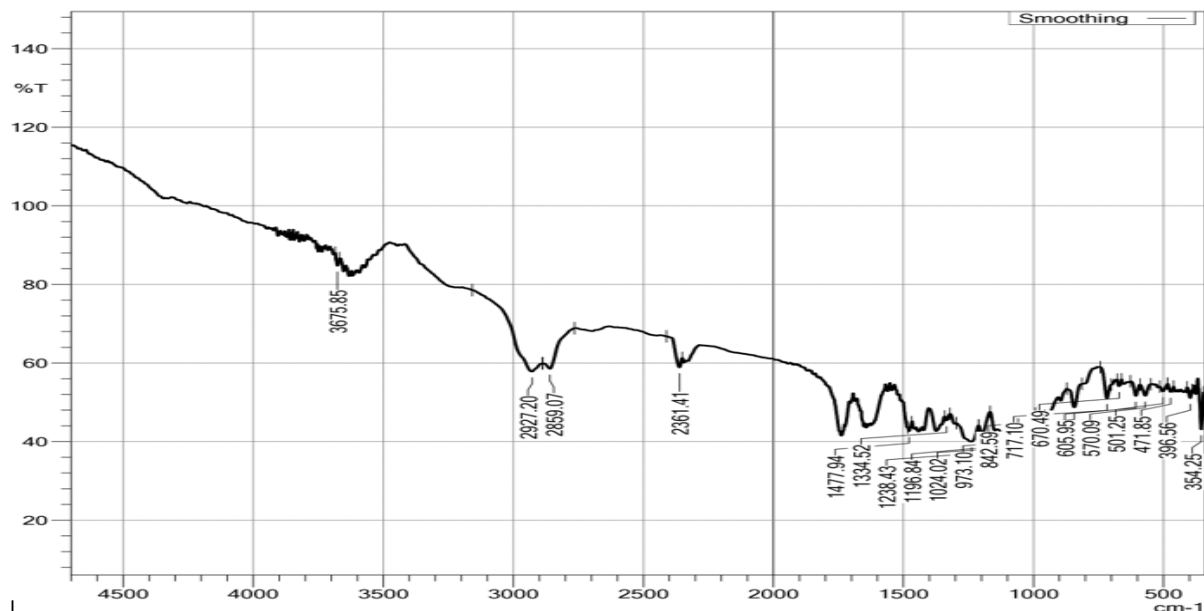
FT-IR Study

A) Rivaroxaban FT-IR



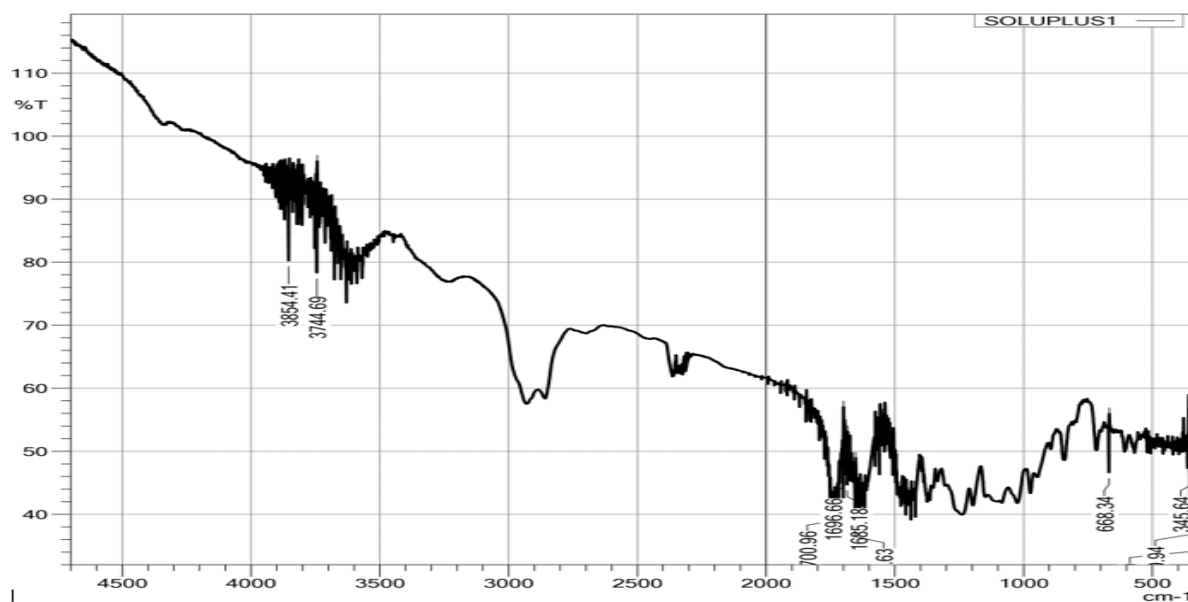
The Rivaroxaban FT-IR Shows the following Peak Values: 3353.15 wavenumber shows N-H Stretching, 1669.51 wavenumber shows C=O stretching, 1428.46 wavenumber shows CH₂ scissoring, 1145.92 wavenumber shows C-O-O stretching.

B) PVP FT-IR



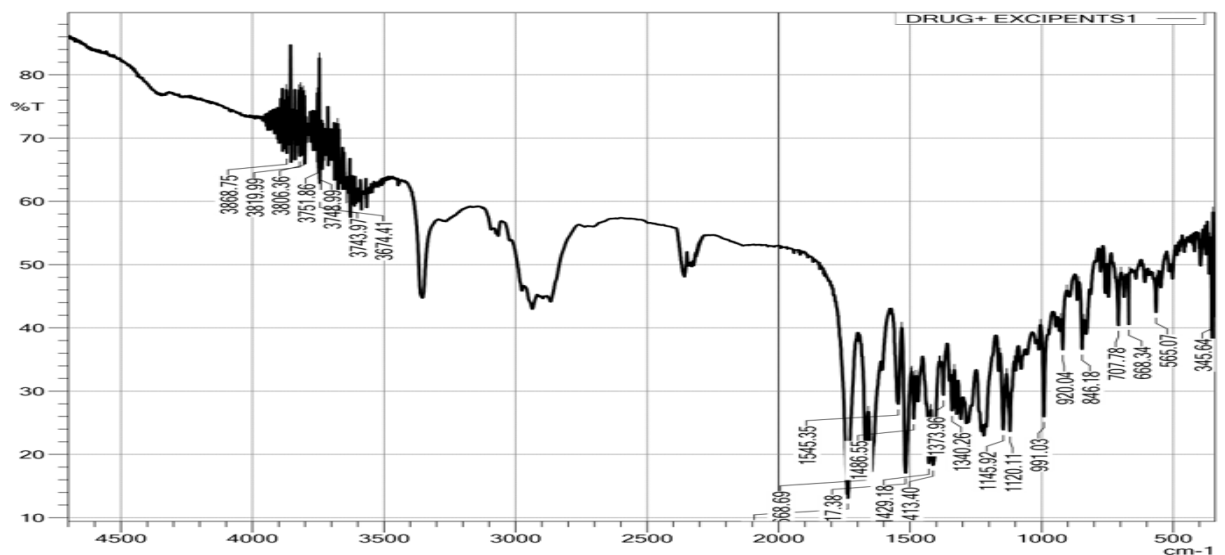
The PVP FT-IR Shows the following Peak Values: 1477.94 wavenumber show CH₂ bending, 2927.20 wavenumber shows C-H stretching, 1238.93 wavenumber show C-N stretching.

C) Soluplus FT-IR



The Soluplus FT-IR Shows the following Peak Values: 3744.69 wavenumber shows O-H stretching, 1700.96 wavenumber shows C=O stretching, 1685.18 wavenumber shows C=O stretching.

D) Drug & Excipients



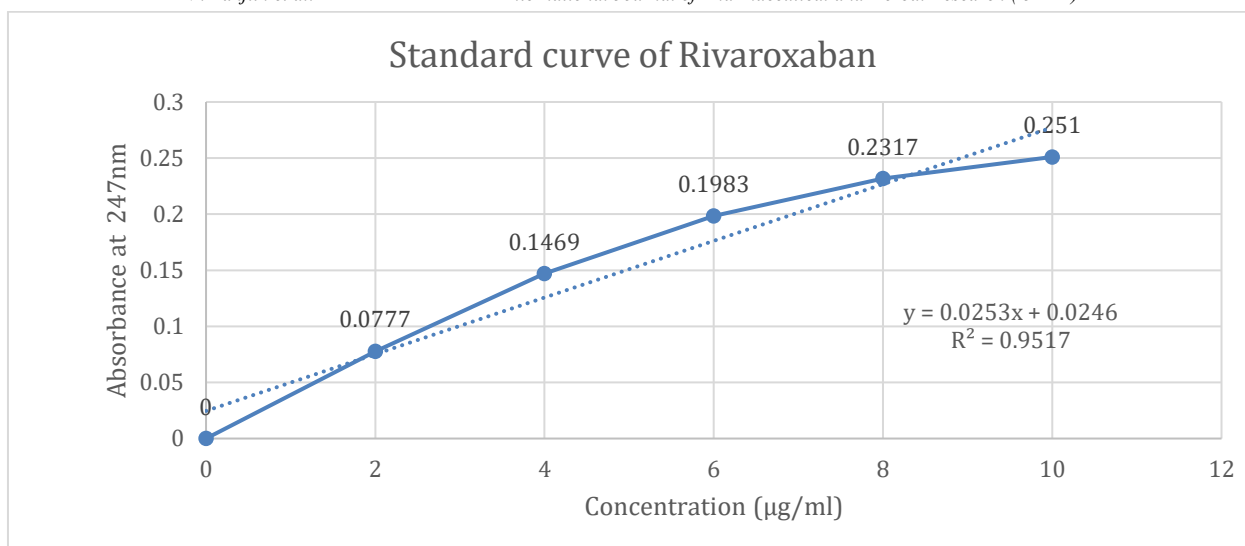
The Drug & Excipients FT-IR Shows the following Peak Values: 3743.97 wavenumber shows N-H stretching, 3674.41 wavenumber shows O-H stretching, 1668.69 wavenumber shows Amide C=O stretching, 1340.26 wavenumber shows C-O stretching, 1145.92 wavenumber shows C-N stretching, 707.78 wavenumber shows C-Cl stretching.

Analytical characteristics

The calibration curve of rivaroxaban in phosphate buffer pH 6.8 was measured at 247 nm. The reported correlation coefficient was 0.9517 for the 2, 4, 6, 8, 10 µg/mL concentration range, indicating the reported linear response over the investigated range. The concentration & absorbance at 247nm are mentioned in table 3

Table.3 Calibration curve of Rivaroxaban at 247nm.

Concentration (µg/mL)	Absorbance
0	0
2	0.0777
4	0.1469
6	0.1983
8	0.2317
10	0.251



Solubility enhancement

All solid-dispersion formulations showed greater drug solubility than the pure drug. SD4 produced the highest value, 3.342 mg/20 mL, compared with 0.192 mg/20 mL for the API, corresponding to approximately 17-

fold enhancement. SD4 was therefore selected for tablet preparation. The dissertation attributes the improvement to the amphiphilic nature of Soluplus, the hydrophilic nature of PVP and reduction in crystalline character associated with solid-dispersion processing. The solubility of API & Solid dispersion are shown below table 4.

Table.4 solubility study for API & solid dispersion.

Sample	Drug dissolved in 20 mL
API	0.192 mg
SD1	0.204 mg
SD2	0.898 mg
SD3	1.294 mg
SD4	3.342 mg

Preformulation Evaluation

The reported bulk density, tapped density, angle of repose, Carr's index and Hausner ratio values indicated acceptable flow characteristics of the prepared blends and supported their suitability for direct compression. The Preformulation evaluations are mentioned below table 5.

Post-formulation evaluation

The reported tablet evaluation showed that weight variation was within the stated pharmacopoeia limit. Friability values were below 1%, hardness values were within the reported acceptable range, and all four

formulations disintegrated within 30 min. The post-formulation evaluation are mentioned below table 6.

In-vitro drug release

At 60 min, the reported drug release was 89.13%, 92.50%, 84.16% and 98.13% for F1, F2, F3 and F4, respectively. F4 showed the highest release. The dissertation relates this performance to the combined action of croscopovidone, croscarmellose sodium and sodium starch glycolate, which promote water uptake through wicking and swelling, together with hydrophilic excipients that improve wetting and penetration of the dissolution medium. The In-vitro drug release was mentioned below table 7.

Table. 5 Preformulation evaluation.

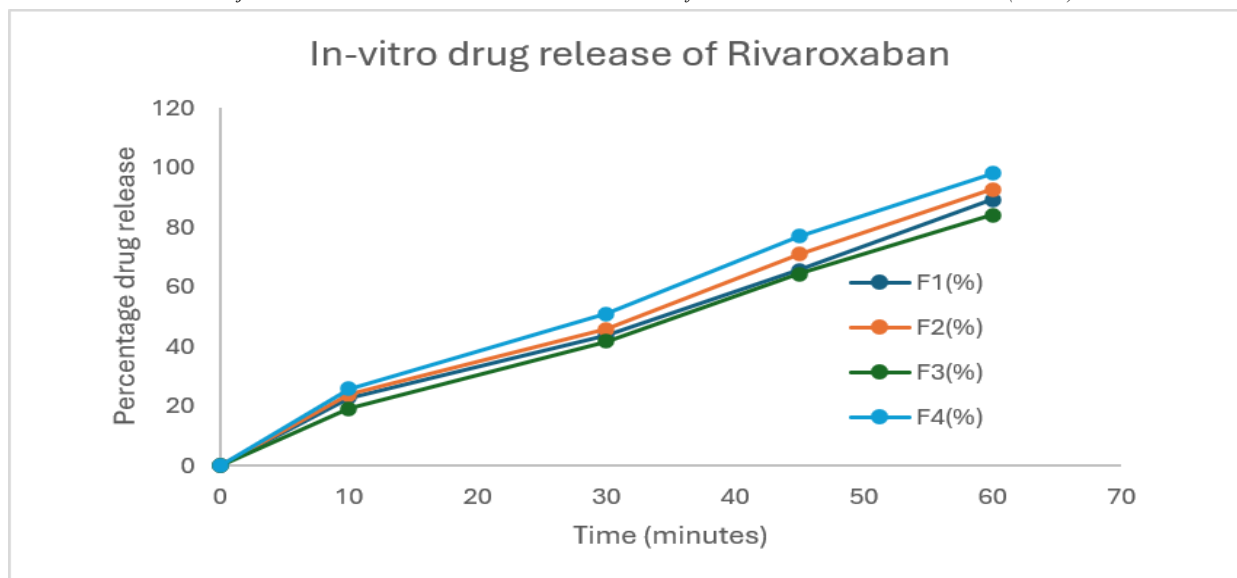
Formulation	Bulk density (mg/mL)	Tapped density (mg/mL)	Angle of repose	Carr's index	Hausner ratio
F1	0.56	0.724	28.4°	22.65%	1.2
F2	0.579	0.695	27.6°	16.69%	1.2
F3	0.56	0.724	25.6°	22.65%	1.2
F4	0.579	0.695	26.5°	17.12%	1.2

Table.6 post formulation evaluation.

Formulation	Weight variation	Friability (%)	Hardness (kg/cm ²)	Disintegration
F1	80-250 ± 7.5	0.56	4.1	Within 30 mins
F2	80-250 ± 7.5	0.52	4.4	
F3	80-250 ± 7.5	0.5	4.3	
F4	80-250 ± 7.5	0.53	4.7	

Table.7 In-vitro drug release of Rivaroxaban.

Time (min)	F1 (%)	F2 (%)	F3 (%)	F4 (%)
10	22.85	23.81	19.06	25.87
30	43.61	45.75	41.85	50.96
45	65.61	71.0	64.26	76.93
60	89.13	92.5	84.16	98.13



4. Conclusion

The present study developed rivaroxaban solid dispersions using Soluplus and PVP to address the poor aqueous solubility of the drug. Among the four dispersions, SD4 produced the highest solubility, approximately 17-fold greater than the pure API under the reported test conditions and was selected for tablet development. The resulting tablet formulations showed acceptable reported precompression and post-compression characteristics. F4 provided the highest in-vitro drug release, reaching 98.13% at 60 min. Within the scope of the experimental data presented in the dissertation, the study supports Soluplus & PVP solid dispersion as a useful formulation approach for improving rivaroxaban solubility and the use of Superdisintegrants to promote rapid tablet drug release.

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