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Research Article

TO FORMULATE AND STUDY THE RELEASE KINETICS OF RIVAROXABAN TABLETS USING CO-PROCESSED EXCIPIENTS

KOLWALKAR S[1], KENY S[1]*, SAWAIKAR L[2], JADHAV A[2]

[1]Department of Pharmaceutics, PES's Rajaram and Tarabai Bandekar College of Pharmacy, Ponda, Goa, India, [2]Department of Pharmaceutical Chemistry, PES's Rajaram and Tarabai Bandekar College of Pharmacy, Ponda, Goa, India.
*Corresponding author: Swati Mayur Keny; Email: swatimayur33@gmail.com

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ABSTRACT

Objectives: The current study aimed at designing, developing, and characterizing orodispersible tablets of Rivaroxaban for treating the blood clots, minimizing the chances of stroke and systemic embolism.

Methods: The tablets were prepared by the direct compression method using co-processed excipients (Prosolv® Oro dispersible tablets [ODT] G2, Ludiflash®, Pearlitol). A co-processed excipient is a particle engineering technique where multiple excipients merge at a sub-particle level with the objective to attain functionality improvement as well as masking of the undesirable properties.

Results: Various parameters such as thickness, weight variation, hardness, friability, dispersion time, wetting time, disintegration time, content uniformity, and *in vitro* drug release were evaluated. Fourier-transform infrared spectroscopy analysis revealed no drug-excipient interactions. The presence of sharp peaks in the X-ray diffraction patterns of Rivaroxaban confirms its crystalline nature. Differential Scanning Calorimetry Thermogram of the physical mixture corresponds to the melting point of Rivaroxaban and β-cyclodextrin, suggesting no physical and chemical interaction between the active and the complexing agent. Among all the formulations, FM2 showed the most promising results in terms of disintegration time of 72 Seconds and *in vitro* drug release of 97 Percent (%) within 20 minutes.

Conclusion: The study concludes that the orodispersible tablets of Rivaroxaban complexed with β-cyclodextrin can potentially enhance drug bioavailability and achieve rapid drug intervention.

Keywords*:* Blood clot, Co-processed excipient, Ludiflash®, Orodispersible tablets, Pearlitol® 200 SD Mannitol, PROSOLV® ODT G2, Rivaroxaban, and Rivaroxaban: β-cyclodextrin complex.

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INTRODUCTION

Conventional dosage forms remain the most widely used and have a firm hold in all types of pharmaceutical preparations meant for oral use, even in the age of innovation and improvement in drug delivery for improved therapeutic outcomes. As the therapeutic efficacy of orally administered drugs is dependent on their physicochemical properties and biological interactions, novel approaches to drug delivery development, including nano-carriers, micelles, cyclodextrins, and lipid-based carriers, are currently being investigated to improve bioavailability and therapeutic activity. Oral medication conveyance remains the favored course for the consumption of a variety of medicaments [1]. Solid dosage forms are acceptable due to accurate dosage, effortless administration, self-medication, and most significantly, the compliance of patients.

The disadvantage of oral formulations, such as dysphasia, can be overcome by developing fast-dissolving oral formulations offering a rapid onset of action and reduced first-pass metabolism. Co-processed excipients are a combination of two or more compendia designed to physically modify their properties without a significant chemical change in the individual ingredient.

A co-processed excipient is a particle engineering technique where multiple excipients merge at a sub-particle level with an objective to attain functionality improvement as well as masking of the undesirable properties [2]. They offer several advantages, such as improved flow properties by controlled and optimized size, size distribution, improved compressibility, better dilution potential, and reduced lubricant sensitivity. However, it also improves the tablet hardness, thereby contributing to rapid disintegration and dispersion in the oral cavity.

Rivaroxaban is an oral, direct Factor Xa inhibitor. The onset of inhibition of Factor Xa activity with Rivaroxaban is rapid, and the inhibition is reversible. It is mainly used in treating blood clots. It is also used to lower the risk of stroke in people with atrial fibrillation, peripheral artery disease; chemically, it is 5-chloro-N-[(5S)-2-oxo-3-(4-(3-oxomorpholin-4-yl) phenyl]-1,3-oxazolidin-5-yl) methyl) thiophene-2-carboxamide. Following oral administration, Rivaroxaban is rapidly absorbed and reaches peak plasma concentration in 2–4 h, low molecular weight (435.882). The bioavailability of a 10 mg dose is >80% and its suitable elimination half-life ($t_{1/2}$=5–9 h) makes it a suitable candidate for administration by buccal route [3,4].

The present investigation aimed to formulate and evaluate an orodispersible tablet comprising the drug (Rivaroxaban) along with co-processed excipients (PROSOLV® Oro dispersible tablets [ODT] G2, Ludiflash®, Pearlitol). The designed tablets were evaluated for physical properties, drug excipient compatibility studies, disintegration time, dispersion time, wetting time, drug content, friability test, weight variation test, *in vitro* drug release. Solubility enhancement of the drug was done by the solid dispersion method. Thus, by formulating an orodispersible tablet of Rivaroxaban using co-processed excipients, rapid drug therapy intervention can be achieved.

METHODS

Materials

Rivaroxaban was obtained as a gift sample from Sanofi Healthcare Private Limited, Verna - Goa, PROSOLV® ODT G2 from Rettenmaier India Private Ltd, Thane, Mumbai. Pearlitol 200 from Signet Excipients Private Limited, Bandra, Mumbai, and Ludiflash from Sanofi Healthcare Private Limited, Verna - Goa, all chemicals used were of analytical grade.

Methods

Pre-formulation studies

Pre-formulation studies such as description, melting point, solubility, Infrared (IR) spectra, Ultraviolet (UV) spectroscopic studies, X-ray analysis, and differential scanning calorimetry studies, were performed on the procured drug samples and excipients to confirm their compatibility.

Characteristics of the drug

IR spectroscopy**:** Fourier transform (FT)-IR spectrum was obtained of the drug was obtained by preparing pellets of Drug: Potassium bromide(1:20) and employing Shimadzu IR Affinity-I CE, Japan. The samples were scanned in the IR range of 400–4000 cm^{-1}. IR spectrum was then interpreted for the characteristic functional group of the drug and for checking the compatibility of the drug with other excipients [5].

Standard calibration curve of Rivaroxaban in phosphate buffer (pH 6.8): Rivaroxaban (100) was accurately weighed into a 100 mL volumetric flask and volume made up with phosphate buffer to get a concentration of 1000 µg/mL [6]. A series of dilutions ranging from 1.0 mL, 1.5 mL, 2.0 mL, 2.5 mL, 3.0 mL, 3.5 mL, 4.0 mL, 4.5 mL, and 5.0 mL was pipetted out into a 10 mL volumetric flask. The volume was made up with phosphate buffer pH 6.8 to get a final concentration of 10 µg/mL–50 µg/mL as shown in Table 1.

The aliquots were scanned using a UV-visible spectrophotometer. The λ_{max} of Rivaroxaban was found to be 247 nm [7].

X-ray diffraction analysis (XRD) [8]: XRD patterns of the Rivaroxaban raw material and Rivaroxaban: β-Cyclodextrin complex were analyzed using a Rigaku SmartLab with Cu Kα radiation (wavelength of 1.54). The samples were then placed on a silicon plate at room temperature. Data collection was done with a standard scan of 15 min. The 2 theta scans were conducted between 5° and 80° with a step size of 0.0001°/2 theta. The analysis was carried out using a Rigaku SmartLab make instrument.

Differential scanning calorimetry (DSC) technique: The thermal property of the drug and excipients alone and in combination was studied using DSC (DSC-60 Shimadzu, TA-60 WS collection software [9].

Preparation of drug: β-cyclodextrin complex**:** The resultant powder was dried in the oven at 60°C before employing it to formulate the tablet [Table 2].

The static dissolution was performed, and the absorbance recorded showed that the solubility of pure drug Rivaroxaban was enhanced in case of 1:2 ratio, and this ratio was used to prepare a solid dispersion of the drug, which was later combined with co-processed excipient to fabricate the orodispersible tablet.

The resultant dry powder of Drug: β-Cyclodextrin complex was weighed [10-12].

Preparation of Rivaroxaban orodispersible tablets: Rivaroxaban Tablets were prepared by the direct compression method. The composition of each tablet is shown in Table 3. Measure the required quantity of Rivaroxaban, and incorporate the co-processed excipient in an appropriate amount. The blend was prepared by trituration, to which a minute quantity of glidant was added for lubrication. After proper mixing, the blended powder was collected and, using BB-Tooling, it was compressed into tablets [13,14].

Pre-compression evaluation of the powder: The prepared blend was evaluated for various parameters such as bulk density, tapped density, compressibility index, Hausner ratio, and angle ratio [15-17].

Post-compression tests for orodispersible tablets: Tablets were evaluated for organoleptic properties, hardness (5 tablets) using Monsanto hardness tester, weight variation (20 tablets), friability (20 tablets) using Roche friability tester, disintegration time (6 tablets) using DT apparatus, wetting time, *in vitro* dispersion time, drug content, and *in vitro* dissolution studies [18-20].

RESULTS AND DISCUSSION

Pre-formulation studies: Pre-formulation studies, such as description, melting point, solubility, IR spectra, UV spectroscopic studies, X-ray analysis, and DSC studies, were performed, and the XRD results are

Table 1: Calibration curve data of Rivaroxaban in phosphate buffer pH 6.8

Sr. no	Rivaroxaban	
	Concentration (µg/mL)	Absorbance (247 nm)
1	0	0
2	10	0.172
3	15	0.234
4	20	0.317
5	25	0.388
6	30	0.466
7	35	0.531
8	40	0.615
9	45	0.676
10	50	0.749

Table 2: Proportion of Rivaroxaban with β-cyclodextrin

Ratio	Rivaroxaban (mol wt=435.882 g/moL)	Beta cyclodextrin (mol wt=1134.98 g/moL)
1:1	100 mg	261 mg
1:2	100 mg	522 mg
1:3	100 mg	783 mg

Mol wt: Molecular weight of drug and complexing agent

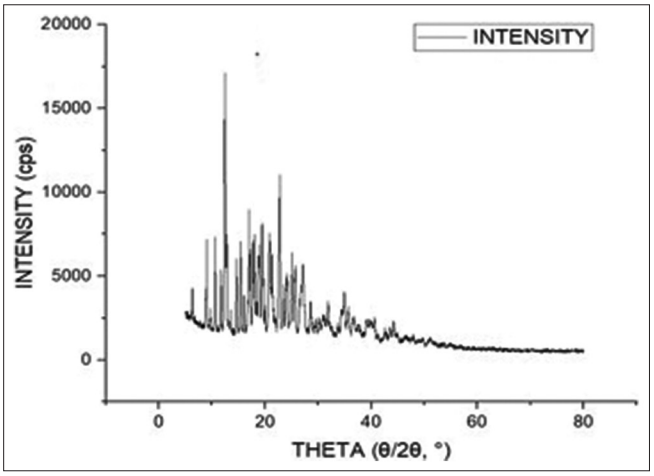

Fig. 1: X-ray powder diffraction data for rivaroxaban ($C_{19}H_{18}ClN_3O_5S$)

Table 3: Composition of ODT'S containing Rivaroxaban: β-cyclodextrin complex

Ingredients	FM1 (mg)	FM2 (mg)	FM3 (mg)	FM4 (mg)	FM5 (mg)	FM6 (mg)	FM7 (mg)	FM8 (mg)	FM9 (mg)
Rivaroxaban: β-cyclodextrin complex (1:2)	3100 mg of complex is equivalent to 10 mg of Rivaroxaban								
PROSOLV® ODT G2	80	85	75	-	-	-	-	-	-
Ludiflash®	-	-	-	70	75	80	-	-	-
PEARLITOL® 200 SD Mannitol	-	-	-	-	-	-	85	80	75
Kollidon® CL-SF	-	-	-	10	5	5	-	-	-
Talc	10	5	15	-	-	-	5	10	15
Sodium stearyl fumarate	-	-	-	10	10	5	-	-	-
Total	100	100	100	100	100	100	100	100	100

ODT: Oro dispersible tablets

Table 4: Composition of ODT'S containing Rivaroxaban: β-cyclodextrin complex

Ratio	Absorbance	Concentration (µg/mL)
Pure drug	1.959	13.4
1:1 ratio	0.924	66.71
1:2 ratio	0.131	72.14
1:3 ratio	0.881	59.51

ODT: Oro dispersible tablets

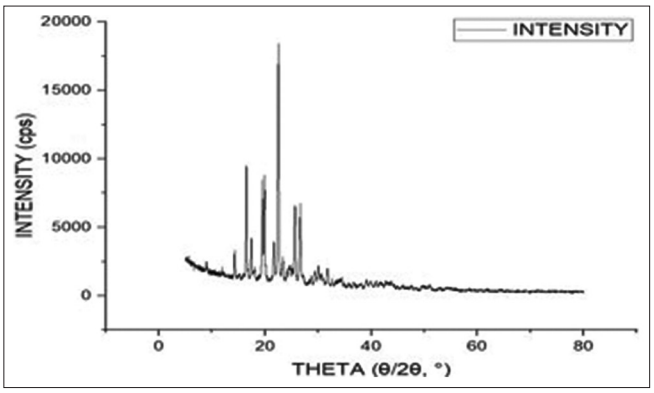

Fig. 2: X-ray powder diffraction data for β-Cyclodextrin ($C_{42}H_{70}O_{35}$)

reflected in Figs. 1-3 indicating no significant incompatibilities between the active and excipients.

IR spectroscopy: FT-IR spectrum was obtained of the drug by preparing pellets of Drug: Potassium bromide (1:20) and scanned in the IR range of 400–4000 cm^{-1}. The results reflected no incompatibility of the drug with other excipients.

Standard calibration curve of Rivaroxaban in phosphate buffer (pH 6.8): Rivaroxaban linear calibration curve was obtained in the concentration range of 10–50 µg mL^{-1} at λ_{max} 247 nm. It followed Beer's Lambert's law with a regression coefficient (R^2) value of 0.9992, as reflected in Fig. 4.

DSC technique: DSC Spectra of the pure drug and β-Cyclodextrin, along with the combination of drug and β-Cyclodextrin, were analyzed for identification using evaluated using DSC-60 Shimadzu, TA-60 WS collection software. The DSC analysis of Rivaroxaban and cyclodextrin showed melting endotherms at 230.93°C and 111.87°C, respectively. DSC thermogram of physical mixture corresponds to the melting point of Rivaroxaban and cyclodextrin, suggesting that there was no physical and chemical interaction observed, ruling out the possibility of drug and β-cyclodextrin interaction as depicted in Fig. 5 and evaluated using DSC-60 Shimadzu, TA-60 WS collection software.

Preparation of drug: β-cyclodextrin complex: Complex of Rivaroxaban and β-cyclodextrin was prepared based on the drug's molecular weight

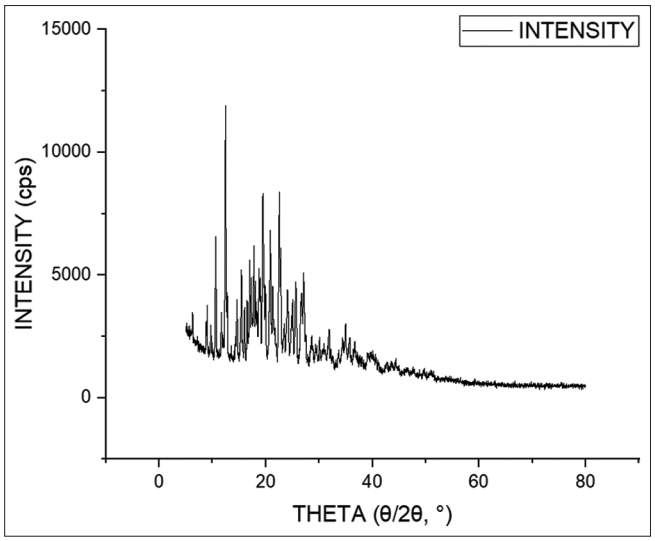

Fig. 3: X-ray powder diffraction data for Rivaroxaban: β-Cyclodextrin in 1:2 ratio

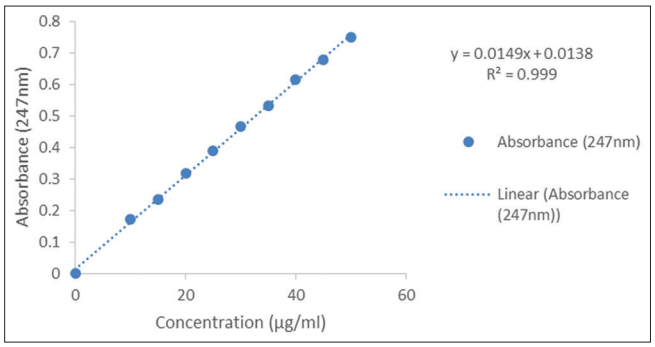

Fig. 4: Calibration curve of Rivaroxaban in phosphate buffer pH 6.8

by the solvent cast method in three different ratios such as 1:1, 1:2, 1: 3 The static dissolution was performed and absorbance recorded showed that the solubility was enhanced in case of 1:2 ratio based on % cumulative drug release, which was further used to prepare solid dispersion of drug as reflected in Table 4 and Fig. 6. The resultant dry powder of Drug: β-Cyclodextrin (1:2) complex was weighed and used further.

Preparation of Rivaroxaban orodispersible tablets: Rivaroxaban Tablets were prepared by the direct compression method employing BB tooling.

Pre-compression evaluation of the powder: The prepared blend was evaluated for various parameters such as bulk density, tapped density, compressibility index, Hausner ratio, angle ratio, and the results are shown in Table 5.

Table 5: Pre-compression test results of the FM-1–FM-9 of the Rivaroxaban tablet

Formulation code	Bulk density (g/mL)	Tapped density (g/mL)	Carr's index	Hausner's ratio	Angle of repose (°)
FM-1	0.496±0.012	0.539±0.014	7.79±0.247	1.08±0.005	28.16±0.214
FM-2	0.504±0.005	0.536±0.004	5.96±0.356	1.05±0.005	24.28±0.328
FM-3	0.502±0.008	0.548±0.009	8.21±0.112	1.08±0.002	26.36±0.452
FM-4	0.552±0.005	0.627±0.004	11.96±0.146	1.13±0.003	27.24±0.442
FM-5	0.530±0.008	0.616±0.024	13.96±0.112	1.16±0.002	28.57±0.364
FM-6	0.528±0.004	0.600±0.007	12.00±0.142	1.13±0.002	26.71±0.552
FM-7	0.467±0.012	0.520±0.010	10.19±0.184	1.11±0.001	25.64±0.547
FM-8	0.424±0.008	0.460±0.010	7.82±0.162	1.08±0.005	24.87±0.256
FM-9	0.468±0.012	0.508±0.013	7.87±0.378	1.11±0.001	26.18±0.638

All values are expressed as mean±standard, n=3

Table 6: Evaluated parameters post-compressed tablets of Rivaroxaban tablet

Formulation code	Diameter (mm)	Thickness (mm)	Hardness (Kg/cm^2)	Weight variation (mg)	% friability	Wetting time (s)
F1	8.72±0.005	2.41±0.0057	2.33±0.577	110.45	0.248	17.06±0.005
F2	8.71±0.005	2.43±0.0057	2.00±0.04	100.3	0.149	12.36±0.208
F3	8.69±0.01	2.41±0.0057	2.66±1.15	100.25	0.299	18.16±0.152
F4	8.72±0.015	2.38±0.0057	2.33±0.577	100.55	0.348	18.03±0.251
F5	8.71±0.01	2.40±0.0057	3.33±0.577	100.6	0.447	14.13±0.115
F6	8.69±0.0057	2.40±0.0057	2.00±0.04	100.45	0.398	16.43±0.251
F7	8.69±0.01	2.40±0.0057	2.33±0.577	100.55	0.646	14.23±0.305
F8	8.72±0.015	2.43±0.020	3.00±1.00	100.35	0.299	15.36±0.251
F9	8.72±0.011	2.44±0.0057	2.66±1.15	100.15	0.549	18.06±0.230

All values are expressed as mean±standard, n=3

Table 7: Disintegration time, drug content, *in vitro* dispersion time results of FM-1–FM-9

Formulation code	Disintegration time (s)	*In vitro* dispersion time (s)	Drug content (%)
FM-1	92.23±0.378	20.6±0.577	95.16±0.208
FM-2	72.26±0.230	15.3±0.577	98.26±0.321
FM-3	87.66±0.450	21.8±0.346	94.86±0.225
FM-4	79.16±0.152	22.1±0.360	91.92±0.353
FM-5	85.96±0.208	16.2±0.251	90.58±0.506
FM-6	90.06±0.416	19.3±0.416	90.28±0.165
FM-7	82.23±0.351	18.2±0.346	94.70±0.558
FM-8	78.26±0.115	17.3±0.404	92.80±0.620
FM-9	104.46±0.230	20.1±0.360	90.66±0.472

All values are expressed as mean±standard, n=3

Table 8: *In vitro* drug release studies of Rivaroxaban ODT using Prosolv® ODT G2

Time (min)	Percentage drug release		
	FM1	FM2	FM3
2	36.40±0.420	42.38±0.241	48.58±0.527
4	39.92±0.235	59.84±0.405	63.19±0.310
6	44.81±0.592	65.24±0.283	63.82±0.301
8	50.87±0.489	70.57±0.480	66.75±0.380
10	60.86±0.272	77.56±0.588	72.49±0.516
12	71.57±0.587	80.22±0.540	76.78±0.461
14	73.87±0.341	82.86±0.270	77.84±0.521
16	80.73±0.367	85.74±0.353	78.91±0.574
18	86.91±0.512	93.47±0.585	84.27±0.534
20	93.83±0.392	97.38±0.512	94.29±0.505

All values are expressed as mean±standard, n=3. ODT: Oro dispersible tablets

Post-compression test: The post-compression tests were performed on the formulated tablets, and the results are represented in Tables 6 and 7.

In vitro dissolution studies of Rivaroxaban ODTs: The *in vitro* drug release was determined by estimating the dissolution profile employing the USP II Paddle apparatus, 900 mL dissolution medium at 37±5°C. The test time period was 20 min, and the amount released of active drug was evaluated by UV Spectrophotometer at 247 nm, and the results are tabulated in Tables 8-10 for each co-processed excipient, respectively

Table 9: *In vitro* drug release studies of Rivaroxaban ODT using Ludiflash

Time (min)	Percentage drug release		
	FM4	FM5	FM6
2	22.71±0.457	32.63±0.529	21.54±0.468
4	23.98±0.396	41.72±0.512	32.85±0.356
6	29.56±0.526	42.95±0.205	46.72±0.415
8	40.97±0.351	45.38±0.431	54.73±0.414
10	42.88±0.203	51.65±0.562	56.66±0.588
12	48.75±0.591	53.82±0.540	64.79±0.558
14	62.37±0.542	66.87±0.525	72.71±0.556
16	70.85±0.572	73.95±0.390	76.92±0.381
18	85.04±0.583	84.97±0.572	86.70±0.453
20	92.45±0.595	91.29±0.359	90.42±0.565

All values are expressed as mean±standard, n=3. ODT: Oro dispersible tablets

Table 10: *In vitro* drug release studies of Rivaroxaban ODT using pearlitol (n=3)

Time (min)	Percentage drug release		
	FM7	FM8	FM9
2	29.75±0.435	34.46±0.418	28.28±0.419
4	36.86±0.505	43.91±0.542	37.47±0.548
6	42.35±0.494	50.85±0.589	46.03±0.522
8	46.77±0.571	55.77±0.480	53.82±0.371
10	55.64±0.450	62.78±0.275	58.75±0.578
12	58.19±0.584	73.31±0.580	69.55±0.411
14	68.47±0.540	81.78±0.320	75.96±0.276
16	73.56±0.595	84.81±0.451	82.74±0.591
18	87.86±0.384	86.65±0.550	88.66±0.448
20	91.86±0.417	94.26±0.459	92.71±0.390

All values are expressed as mean±standard, n=3. ODT: Oro dispersible tablets

Table 11: Drug release kinetics of Oro dispersible tablets of Rivaroxaban complexed with β-cyclodextrin

Formulation code	Zero order (r^2)	First order (r^2)	Higuchi (r^2)	Korsmeyer Peppas (r^2)	Hixon Crowell (r^2)	Best fitted model
FM-1	0.9354	0.9954	**0.9922**	0.8039	0.9827	Higuchi Model
FM-2	0.9252	0.9965	**0.9982**	0.8669	0.9913	
FM-3	0.9255	0.9875	**0.9809**	0.8185	0.9734	
FM-4	0.9339	0.9754	**0.9916**	0.8111	0.9638	
FM-5	0.9478	0.9893	**0.9882**	0.8105	0.9797	
FM-6	0.9317	0.9793	**0.9866**	0.8143	0.9677	
FM-7	0.9295	0.9774	**0.992**	0.8055	0.9648	
FM-8	0.9443	0.9862	**0.9904**	0.8225	0.9816	
FM-9	0.9217	0.9756	**0.9934**	0.8134	0.9664	

The bold value that is FM-2 exhibited the highest r^2 value for the Higuchi model (0.9982), indicating that the drug release primarily follows diffusion-controlled kinetics from the matrix.

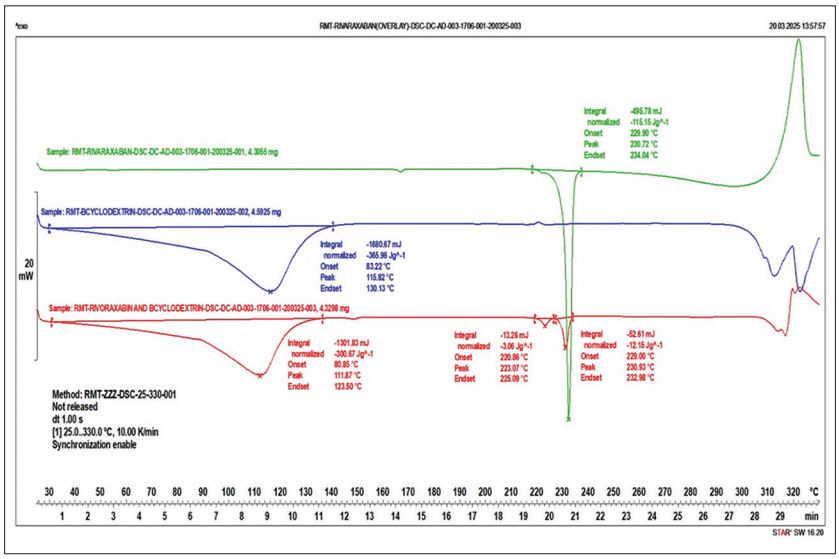

Fig. 5: Differential scanning calorimetry spectrum of a combination of Rivaroxaban, β-Cyclodextrin, and Rivaroxaban along with β-Cyclodextrin in 1:2 ratio

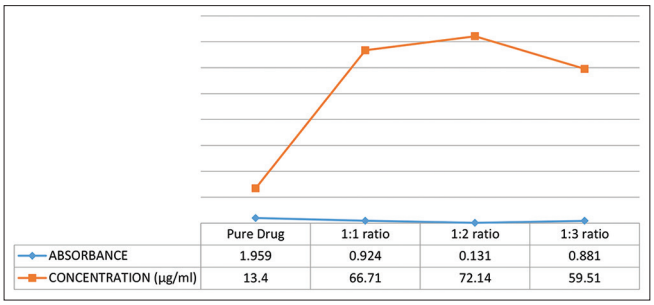

Fig. 6: Graph of absorbance versus concentration showing the drug release

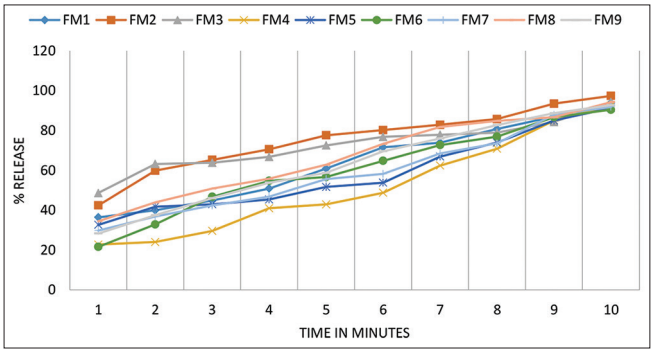

Fig. 7: *In vitro* drug release for FM1–FM9

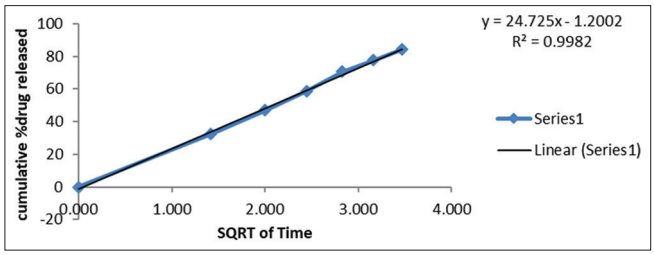

Fig. 8: Plot of the Higuchi model for FM-2 oro-dispersible tablets

and % release of all formulations is represented in Fig. 7, indicating FM2 to be the best in terms of maximum drug release.

RELEASE KINETICS

The drug release kinetics of various formulations of Rivaroxaban ODTs were analysed using mathematical models, including Zero-order, First-order, Higuchi, Korsmeyer-Peppas, and Hixson-Crowell equations. Among these, Formulation FM-2 demonstrated the most favourable release profile.

- FM-2 exhibited the highest R^2 value for the Higuchi model (0.9982), indicating that the drug release primarily follows diffusion-controlled kinetics from the matrix.
- A high correlation with the First-order model (R^2 = 0.9965) suggests that the release rate is also concentration-dependent, which is ideal for ensuring rapid onset of action in Orodispersible systems.

- Additionally, the Hixson-Crowell R^2 value (0.9913) supports the role of surface area reduction and tablet erosion in the release process [Table 11 and Fig. 8].

CONCLUSION

The disintegration time of formulations FM-1–FM-9 ranged from 72.26±0.230 s to 104.46±0.230 seconds.

FM2 exhibited the shortest disintegration time while FM9 the longest.

The designed orodispersible tablet FM2 (Rivaroxaban: β-cyclodextrin complex (1:2) along with PROSOLV® ODT G2 coprocessed excipient) proved to be the best amongst the nine formulations designed, ranging from FM1 to FM9.

FM1–FM3 corresponds to Rivaroxaban with PROSOLV® ODT G2 as coprocessed excipient, FM4–FM6 corresponds to Rivaroxaban with Ludiflash as coprocessed excipient and FM7–FM9 corresponds Rivaroxaban with PEARLITOL® 200 SD Mannitol as coprocessed excipient.

FM 2 prooved to be the best amongst all 9 formulations in terms of drug content, organoleptic parameters and in vitro drug release kinetics profile.

Hence, orodispersible tables with Rivaroxaban and co-processed excipients serve as a boost for the researchers and a boon to the patients in the future over the conventional tablets for immediate treatment of blood clots.

CONFLICT OF INTEREST

The authors declare no conflict of interest

AUTHOR CONTRIBUTIONS

Swati Mayur Keny, corresponding author for this publication, is a faculty member of PES's Rajaram and Tarabai Bandekar College of Pharmacy, Goa. All the above research work has been carried out on the same premises.

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