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Formulation and Drug Release Study of Rivaroxaban Oral Disintegrating Tablets Using Various Super-Disintegrants

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Abstract: This study aims to improve Rivaroxaban's solubility, dissolution, and bioavailability. Orally disintegrating tablets (ODTs) made with super-disintegrants like crospovidone, sodium starch glycolate, and cross-carmellose sodium will do this. Tablet preparation used direct compression and formulation optimization with design expert software. After a thorough factorial design and evaluation of pre- and post-compression parameters, the F3 batch, which contained Rivaroxaban (7.97%), Crospovidone (3.59%), Croscarmellose sodium (5.18%), Sodium Starch Glycolate (5.18%), Lactose Anhydrous (31.08%), Mannitol (15.94%), MCC (27.89%), SSF (1.59%), and Talc (1.59%), was the best. The enhanced tablet formulation (F3) showed positive qualities, including 3.3 kg/cm² hardness, 23 seconds disintegration time, and 99% drug release after 30 minutes. The innovative Rivaroxaban orally disintegrating tablet (ODT) method disintegrated and dissolved faster than market forms. Rivaroxaban's physical and chemical properties were assessed before formulation. The medication was colorless, scentless, crystalline, and melted at 227°C-229°C, as described in published research. The pharmaceutical was found to be a BCS Class II drug with low water solubility and high solubility in acetate buffer pH 4.5 and 0.1 N Hydrochloric acid. Fourier-transform infrared spectroscopy (FTIR) confirmed no drug-polymer-excipient interactions. Every batch of tablets exhibited uniform thickness (3.5 mm to 3.8 mm) and diameter (10.31 mm to 10.36 mm), indicating good compression without adhering to shaping tools. All samples had a 3-5 kg cm-² hardness, indicating strong mechanical properties. The Roche friability method showed that all batches had good abrasion resistance, ranging from 0.1% to 0.5%. Variations in croscarmellose sodium and crospovidone on tablet disintegration time and hardness were examined using design expert software. The ANOVA showed important factors affecting these attributes. Data-driven polynomial equations predict tablet disintegration time and hardness. These models reveal formulation parameters that affect tablet performance. Thus, the improved F3 batch of rivaroxaban orally disintegrating tablets (ODTs) improves solubility, dissolving, and bioavailability. This may improve treatment outcomes.

Introduction

The introduction of oral anticoagulants in recent years has expanded the range of successful therapy for venous and arterial thromboembolic illness. This is in contrast to conventional vitamin K antagonists (Mueck, 2013). Rivaroxaban, an oral anticoagulant belonging to the oxazolidinone family, acts as a powerful and selective inhibitor of factor Xa, effectively preventing venous thromboembolism in people who have had total hip or knee replacement surgery (Eswarudu et al., 2020). The USA's Food and Drug Administration (FDA) initially approved this medication as an anticoagulant in 2011. Its

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purpose is to prevent blood clots linked to deep vein thrombosis, pulmonary embolism, and atrial fibrillation (Arif and Bilfaqi, 2013). Rivaroxaban acts as a competitive inhibitor of both free factor Xa and factor Xa that is attached to clots. Activated factor Xa is crucial in the coagulation cascade since it connects the intrinsic and extrinsic coagulation pathways and serves as a limiting factor in thrombin generation. Factor Xa is essential for the enzymatic conversion of prothrombin (factor II) into thrombin (factor IIa). Thrombin, a serine protease, is essential for the conversion of fibrinogen into fibrin, which forms the final structure of the clotting process. Highly specific factor Xa inhibitors are highly effective in halting the amplification of thrombin production due to the ability of a single molecule of factor Xa to generate more than 1000 molecules of thrombin. Rivaroxaban exerts a permanent impact (Gulseth et al., 2008).

Rivaroxaban is categorized as a BCS class II drug because of its limited solubility and significant permeability. Its weak solubility and insufficient bioavailability restrict Rivaroxaban's capacity to deliver medicine. In order to address this significant limitation, a rapid-release formulation of Rivaroxaban that has an immediate beginning of action within a shorter period of time and better bioavailability is required (Rao et al., 2022). Worldwide**,** oral administration remains the method with the highest patient compliance**.** Several researchers in the field of pharmaceutics have explored methods to reduce the frequency of doses or the size of dosage forms to improve patient compliance (McConville, 2017). The oral path is the most precious route because of its benefits, such as patient comfort, drug delivery convenience, and non-invasiveness. About 60% of existing small-molecule drug products are administered orally (Murkute, 2022). Tablets provide a handy method for administering drugs, and patients are more accustomed to using this type of medication. Orally administered drugs often result in higher patient compliance and greater efficacy in drug therapy compared to other methods of administration (Jesmeen and Uddin, 2011). A significant drawback of the solid oral dose form is the challenge of swallowing (dysphagia) and chewing for certain patients, particularly the elderly and children (Gholve, 2018).

Oral disintegrating tablets are a solid dosage form that disintegrates rapidly within less than 3 min when placed under the tongue, leaving an easily swallowable residue (Arora, 2013). These dosage forms contain super disintegrants, which facilitate quicker disintegration with lesser quantity than disintegrants. Oral disintegrating drug delivery is widely utilized to increase the bioavailability of several drugs (Verma, 2017) due to several advantages, including rapid dissolution, pregastric absorption, convenience and ease of administration, no need for water, etc. Oral disintegrating tablets are more favoured than conventional tablets (Rewar, 2014).

Considering all of these benefits of oral disintegrating tablets, the current study aims to develop oral disintegrating tablets for Rivaroxaban that have a better, immediate onset of action. Furthermore, pregastric absorption of drugs from the mouth, throat, and oesophagus as saliva goes down is accomplished with ODT, resulting in fast absorption or an increase in bioavailability.

Material and Methods

Material

Rivaroxaban was collected from Cipla, Mumbai, India. Crospovidone was collected from Glenmark, Nashik. MCC, Lactose anhydrous, and SSF were collected from Anshul Life Sciences, Mumbai, India. The investigation employed only analytical-grade, compressible compounds and solvents.

Methods

Preformulation study

Rivaroxaban's Physical Characterization

The analysis of color, odor and appearance was conducted manually, and the melting point of Rivaroxaban was evaluated using the usual approach documented in the literature.

Determination of melting point

The melting point of Rivaroxaban was determined using a digital melting point apparatus that has a temperature range of up to 350°C and a heating rate of 1-200°C per minute. The capillaries used for glass melting point measurements were filled with the temperature being studied, inserted into the holder, and the melting point equipment was activated. The experiment compared the melting point of Rivaroxaban with its conventional melting point, as documented in official compendia and literature.

Rivaroxaban's solubility analysis

The solubility of Rivaroxaban was assessed in 0.1 N HCl, Acetate buffer with a pH of 4.5, and water. A minute quantity of Rivaroxaban was introduced into a test tube containing a solvent and agitated manually for a brief duration. The solubility was ascertained via direct visual examination.

Rivaroxaban's Calibration Curve

The calibration curve for Rivaroxaban was established by measuring the absorbance of various concentrations (ranging from 5 to 25 ppm) in acetate buffer with a pH of

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4.5 (including 0.2% SDS) at a wavelength of 246 nm. The UV-visible spectrophotometric analysis was conducted with the Shimadzu UV-1800 spectrophotometer, with analysis performed using the UV probe program. The solvent solution utilized for both blank and sample preparation was an acetate buffer with a pH of 4.5. The analysis was conducted at a wavelength of 246 nm.

FTIR study

An FTIR analysis assessed the compatibility of Rivaroxaban with other substances. The FTIR technique was employed to acquire the infrared spectra of Rivaroxaban and other excipients. The spectra were acquired using the potassium bromide pellet method. A 1:1 ratio of pharmaceuticals was used to create a physical combination, which was subsequently filtered via sieve no #30. Drug and excipient samples were put in containers, sealed, and labeled. The desiccated samples were individually combined with potassium bromide at a ratio of 1:99, ground into a fine powder, and then inserted into the sample container to create compacted pellets. The pellets obtained were subjected to scanning within the frequency range of 400 to 4000 cm^{-2}. The spectral analysis was conducted within the usual absorbance range of the functional group. The reference is from Mallik et al. (2011).

Statistical design

To create a stable ODT 3^2 overall design, it was used for design planning using Design Expert software version 13, which gave satisfactory results in understanding the different independent variables of response, such as croscarmellose sodium (X1) and Crospovidone (X2) and dependent variables such as disintegration time (Y1) and hardness (Y2) (Dolas and Ware, 2023). Variables and three levels are presented in Table 1. Independent variables were used in three levels such as high (+1), medium (0) and low (-1). 9 formulation batches were prepared using these levels, and results were analyzed for disintegration and dissolution using the satisfactory model.

Table 1. Independent variable at three different levels

Batches	Coaded Level		Actual readings (mg)	
	X1	X2	X1	X2
F1	+1	+1	5	5
F2	-1	+1	0.5	5
F3	+1	0	5	3.5
F4	-1	0	0.5	3.5
F5	+1	-1	5	2
F6	-1	-1	0.5	2
F7	0	-1	2.75	2
F8	0	+1	2.75	5
F9	0	0	2.75	3.5

Formulation of Rivaroxaban

The orally disintegrating tablet (ODT) was formulated utilizing the direct compression technique as specified by the formula provided in Table 2. The direct compression method is the simplest approach for tablet production. The direct compression approach has recently been utilized due to the accessibility of enhanced excipients, particularly tablet disintegrants. Nine batches were made utilizing excipients, including cross-carmellose sodium, crospovidone, sodium starch glycolate, microcrystalline cellulose, anhydrous lactose, and mannitol. Each excipient was individually passed through a mesh with a size of 60 and collected. All of the participants were carefully ground in a mortar and pestle to obtain a consistent mixture. Lastly, use lubricant and talc, and proceed for a duration of 5 minutes. The medication and excipient combination were crushed using a 10 mm punch size on 8-station tablet compression equipment. Prior to tablet compression, the combination of all constituents was analyzed for precompression characteristics such as bulk density, tap density, compressibility index, angle of repose, and Hausner ratio.

Table 2. Composition of oral disintegrating tablets

Sr. No	Formula	Quantity							
		F1	F2	F3	F4	F5	F6	F7	F8
1	Rivaroxaben	20	20	20	20	20	20	20	20
2	Crospovidone	13	13	9	9	5	5	5	13
3	Croscarmellose Sodium	13	1	13	1	13	1	7	7
4	Sodium Starch Glycolate	13	13	13	13	13	13	13	13
5	lactose Anhydrous	75	86	78	90	82	93	88	80
6	Mannitol	40	40	40	40	40	40	40	40
7	MCC	70	70	70	70	70	70	70	70
8	SSF	4	4	4	4	4	4	4	4
9	Talc	4	4	4	4	4	4	4	4
Total Weight		250	250	250	250	250	250	250	250

Evaluation of ODT

Weight variation

Twenty randomly chosen tables were weighed in a single pan balance, both separately and collectively. The standard deviateon was computed, and the average weight was recorded. The tablets will pass the test if none of them exceed twice the percentage restriction and if no more than two tablets breach the limit. The IP specification permits a variation in weight of tablets weighing up to 250 mg by ± 7.5% (Bansal et al., 2013).

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Hardness

The tablets' hardness was assessed by randomly picking 10 tablets and measuring their durometer values. The average and standard deviation of the measurements were then determined.

Friability

The tablet was easily crumbled using a Roche friability test. The value is denoted as a percentage (%). 10 tablets were weighed (W initial) and then placed into the friability tester. The friability test was conducted at a rotational speed of 25 revolutions per minute for a duration of 4 minutes or until it reached 100 revolutions. The friability percentage was then determined by,

$F = (W\ initial – W\ final) \times 100/W\ initial$

% friability of tablets less than 1% is considered acceptable (Ramu et al., 2014).

Disintegration time

A medicine must initially be in a solution after oral administration to be absorbed from a solid dosage form, and the first crucial stage in this process is often tablet disintegration. Since the tablet must fully dissolve within three minutes to meet USP requirements, disintegration time was a crucial test in ODT technology. The USP disintegration equipment was used to measure the disintegration of tablets. Each tube was supplemented with six tablets, and the basket rack was immersed in a beaker containing 0.1 N HCl at a temperature of 37±2°C. The apparatus was operated until all residual matter was completely eliminated following the vertical movement of the basket assembly within the beaker. The duration required for all six tablets to completely pass through the 10-mesh screen was referred to as the disintegration time (Priya et al., 2009).

Dissolution time

The dissolution of Rivaroxaban orally disintegrating tablet (ODT) was tested using USP equipment type II at a speed of 75 revolutions per minute in a solution of acetate buffer with a pH of 4.5 and 0.2% SDS (900 ml). The temperature was kept constant at 37±0.5°C (Pharmacology, 2010). 10 ml samples were extracted at 5-minute intervals for a total of 30 minutes. These samples were then passed through Whatman filter paper and measured using a visible spectrophotometer set at 246 nm to determine the concentration of Rivaroxaban.

Results and Discussion

Preformulation study

A preformulation study was carried out to evaluate the physical and chemical properties of Rivaroxaban, with the goal of collecting necessary data for future research. The substance was characterized as a colorless, scentless, crystalline substance with a melting point that consistently matched the values reported in scientific literature, falling within the range of 227°C to 229°C. Rivaroxaban is classified as BCS Class II, indicating that it has poor solubility and high permeability (Reddy & Himavarsha, 2018). The solubility investigation confirmed that it is not soluble in water, therefore supporting its categorization as a BCS Class II molecule. The medication demonstrated high solubility in acetate buffer at pH 4.5 and 0.1 N Hydrochloric acid, but it remained insoluble in water. These findings are shown in Table 3, which provides an overview of Rivaroxaban's physicochemical qualities.

Table 3. Physiochemical properties of Rivaroxaban

Sr. No.	Parameter	Observation
1	Color	White
2	Odor	Odorless
3	Appearance	Crystalline
4	Melting Point	227^0C-229^0C
Solubility Analysis		
Sr. No.	**Solvent**	**Observation**
1	Acetate Buffer pH 4.5	Soluble
2	0.1 N HCl	Soluble
3	Water	Insoluble

Calibration Curve for Rivaroxaban

The highest absorption wavelength of Rivaroxaban is detected at 246 nm, as shown in Figure 1. The calibration curve for Rivaroxaban in Acetate buffer pH 4.5 (with 0.2% SLS) at a wavelength of 246 nm demonstrated both a linear relationship and consistent results. The correlation coefficient, which is 0.9933 as indicated in Table 4, demonstrates exceptional linearity within the 5-25 µg/ml concentration range. The data yields a regression equation of $y = 0.0103x + 0.0104$, as seen in Figure 2.

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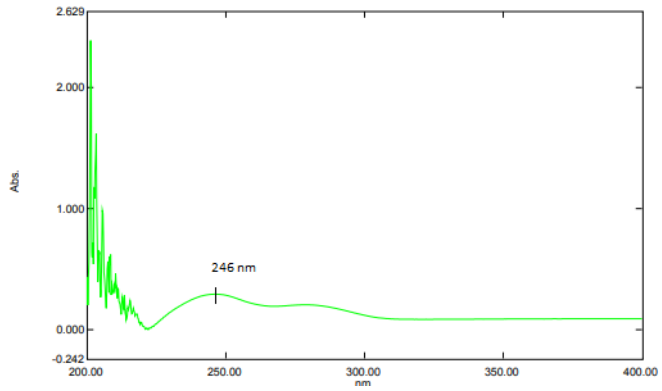


Figure 1. Maximum absorption wavelength of Rivaroxaban at 246 nm.

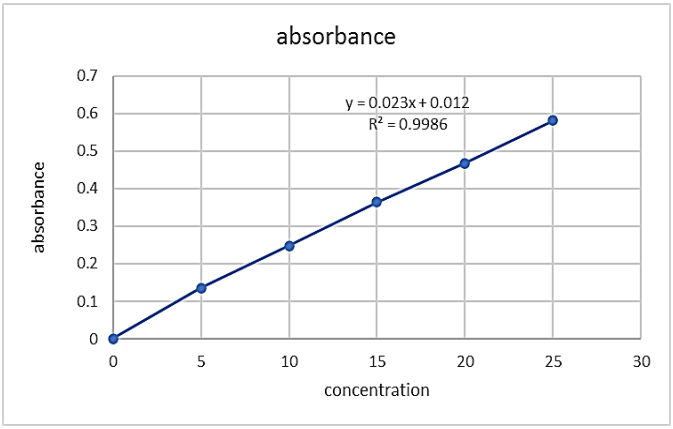
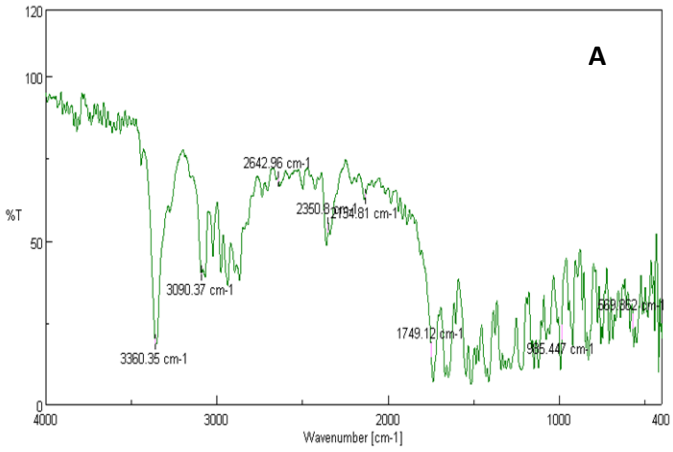


Figure 2. Calibration curve of Rivaroxaban

Drug excipient compatibility study

The Fourier Transform Infrared (FTIR) spectra of Rivaroxaban in its pure state (Figure 3(A)) and its physical combination (Figure 3(B)) were analyzed, indicating the absence of any interactions between the drug, polymer, and excipients. Rivaroxaban, in its pure form, displays distinct peaks at certain wavelengths: 3360.35 cm^{-1} (corresponding to N-H stretching in primary amines), 3090.37 cm^{-1} (representing C-H stretching in aromatic compounds), 1749.12 cm^{-1} (indicating C=O stretching in saturated esters) and 569.852 cm^{-1} (reflecting C-Cl stretching in alkyl and aryl halides).



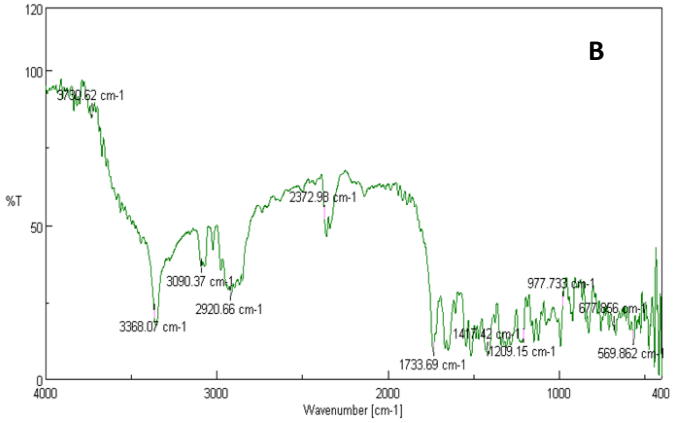


Figure 3. FTIR Spectra of Pure Drug(A) and Drug + Excipients (B).

Evaluation of formulated batches

Pre-compression parameters

Table 4 displays the assessment of the density and flow properties of the powder mix in all batches. This includes data such as bulk density, tap density, angle of repose, Carr's index, and Hausner's ratio. The lubricated mixture in all batches exhibited increased bulk density values, which resulted in improved compressibility and immediately influenced the Hausner's ratio (HR) and Carr's index (CI) of the lubricated blend, as shown in the research conducted by Akhtar and Dev (2017). In general, the granules exhibited desirable flow characteristics that are consistent with compression guidelines.

Post-compression parameters

All tablets from every batch were white, spherical, convex in form, and had flat top and bottom surfaces. Table 5 presents the measurements of thickness and diameter. The thickness measurements ranged from 3.5 mm to 3.8 mm, while the diameter measurements ranged from 10.31 to 10.36. The presence of homogeneity in the results suggests that the formulation was compressed successfully without adhering to the punch and dies. The hardness of all the batches ranged from 3 to 5 kg/cm^2. The hardness values for all batches and corresponding findings are presented in Table 5. All bears possess excellent mechanical strength and an adequate level of hardness. The purpose of conducting a friability test is to evaluate the tablet's resistance to abrasion during packing, handling, and transportation. The Roche friability test was employed to quantify it (Roy, 2016). The friability of all batches was observed to be within the range of 0.1 to 0.5%, which is less than 1%. The tablets from all manufactured batches exhibited weight variation within the permitted range as specified by the pharmacopoeia (< 7.5) (Table 5).

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Table 4. Flow properties of the lubricated blend.

Batches	Bulk Density (g/ml)	Tap Density (g/ml)	Car's Index (%)	Hausner's Ratio	Angle of repose
F1	0.476	0.555	14.2	1.166	30.46
F2	0.454	0.555	18.18	1.222	38.65
F3	0.454	0.526	13.63	1.157	32.82
F4	0.454	0.555	18.18	1.222	36.50
F5	0.500	0.666	25	1.333	38.65
F6	0.434	0.588	26.08	1.352	36.50
F7	0.444	0.555	20	1.252	37.56
F8	0.454	0.588	22.72	1.294	35.52
F9	0.444	0.555	20	1.252	36.50

Table 5. Post-compression parameters of the tablets.

Batches	Weight Variation	Hardness (Kg/cm^2)	Thickness (mm)	Diameter (mm)	Friability (%)
F1	248	4	3.8	10.32	0.3
F2	254	2.7	3.6	10.35	0.2
F3	251	3.3	3.5	10.31	0.1
F4	250	3.9	3.8	10.36	0.2
F5	245	2.1	3.8	10.35	0.3
F6	252	3.2	4.0	10.34	0.1
F7	253	4.2	3.6	10.32	0.5
F8	247	5	3.5	10.36	0.1
F9	253	5.6	3.6	10.35	0.2

Disintegration time

Table 6 presents the disintegration time findings for all batches, indicating that the disintegration time for each batch was less than 2 minutes. The disintegration time exhibited an inverse connection with the concentration of the disintegrant and a positive correlation with the concentration of the binder.

Table 6. Disintegration time of formulated batches.

Batches	Disintegration time(s)
F1	26
F2	76
F3	23
F4	79
F5	39
F6	68
F7	99
F8	87
F9	101

Optimization of oral disintegrating tablet

In order to examine the impact of independent factors on replies, the study utilized Design Expert software version 13. The layout design for nine batches of Rivaroxaban oral disintegrating tablets is presented in Table 7.

Table 7. Layout of the actual design of DOE.

Run	Factor 1 A:Croscarmellose	Factor 2 B:Crospovidone	Response 1 Disintegration time (s)	Response 2 Hardness (Kg/cm^2)
1	5	5	26	4
2	0.5	5	76	2.7
3	5	3.5	23	3.3
4	0.5	3.5	79	3.6
5	5	2	39	2
6	0.5	2	68	3.2
7	2.75	2	99	4.2
8	2.75	5	87	5
9	2.75	3.5	101	5.6

Statistical analysis for disintegration time

The disintegration time of a drug is significantly influenced by the proportion of croscarmellose sodium and crospovidone in its formulation. Altering the amount of these two substances can either increase or reduce the disintegration time of the drug, depending on their concentration. Croscarmellose sodium significantly affects disintegration time more than crospovidone, as seen by its relatively low p-value. Upon inputting the data into the design expert program, a fit summary was generated, which subsequently recommended the 'quadratic versus 2F1 model'. An analysis of variance (ANOVA) was conducted to determine the statistically significant components and those that were not. Table 8 displays the ANOVA findings for disintegration time. The model's F-value is 26.61, indicating its significance. The probability of noise being the cause of a significant F-value is only 1.09%. Model terms are considered significant when their p-values are below 0.0500. Both A and A^2 are important model variables in this scenario. Values beyond 0.1000 suggest that the model terms lack

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significance. The equation, expressed in terms of coded factors, enables the prediction of the reaction for certain amounts of each element. The equation representing the relationship between disintegration time and the variables A and B is as follows:

Disintegration time = 96.89 – 22.50*A -2.83*B.

Table 8. ANOVA table for the disintegration of DOE.

Source	Sum of Squares	df	Mean Square	F-value	p-value
Model	7045.36	5	1409.07	26.61	0.0109
A-Croscarmellose	3037.50	1	3037.50	57.36	0.0048
B-Crospovidone	48.17	1	48.17	0.9096	0.4106
AB	110.25	1	110.25	2.08	0.2447
A^2	3842.72	1	3842.72	72.57	0.0034
B^2	6.72	1	6.72	0.1269	0.7452
Residual	158.86	3	52.95		
Cor Total	7204.22	8			

Statistical analysis of hardness

The disintegration time of a drug is greatly affected by the ratio of croscarmellose sodium and crospovidone in its formulation. Modifying the quantity of these two chemicals can either augment or diminish the duration of medication breakdown, contingent upon their concentration. The disintegration time is strongly influenced by croscarmellose sodium to a greater extent than crospovidone, as indicated by its comparatively low p-value. After entering the data into the design expert tool, a fit report was produced, which then suggested the 'quadratic vs 2F1 model'. A statistical study called analysis of variance (ANOVA) was performed to identify the components that had significant statistical effects and those that did not. The ANOVA data for disintegration time are presented in Table 8. The F-value of the model is 26.61, which signifies its relevance. The likelihood of noise being the underlying factor behind a substantial F-value is just 1.09%. Model terms are deemed statistically significant when their p-values are less than 0.0500. Both A and A^2 are significant model variables in this situation. Values over 0.1000 indicate that the model terms are not statistically significant. The equation, formulated using coded factors, allows for the anticipation of the reaction for specific quantities of each constituent. The equation that expresses the correlation between disintegration time and the variables A and B is as follows: The disintegration time may be calculated using the formula:

Hardness = 5.37 – 0.0333*A + 0.3833*B

Table 9. ANOVA table for the hardness of DOE.

Source	Sum of Squares	df	Mean Square	F-value	p-value
Model	9.78	5	1.96	35.73	0.0071
A-Croscarmellose	0.0067	1	0.0067	0.1218	0.7501
B-Crospovidone	0.8817	1	0.8817	16.11	0.0278
AB	1.56	1	1.56	28.55	0.0128
A^2	6.48	1	6.48	118.42	0.0017
B^2	0.8450	1	0.8450	15.44	0.0293
Residual	0.1642	3	0.0547		
Cor Total	9.94	8			

In–vitro drug release

The in vitro assessment of all prepared batches was conducted for a duration of 30 minutes using acetate buffer at pH 4.5 as the dissolving medium, supplemented with 0.2% SDS. The percentage of cumulative drug release (% CDR) was then measured. The findings are depicted in Figure 4. A comparative analysis was performed to assess the dissolving profile of the optimized batch F3 in comparison to the commercially available formulation Xarelto. This analysis was carried out using an acetate buffer with a pH of 4.5 and containing 0.2% SDS. The results are presented in Figure 5. The dissolution profile data indicate that the formed oral disintegrating tablet of Rivaroxaban exhibits superior disintegration and absorption of the medication compared to the marketed formulation.

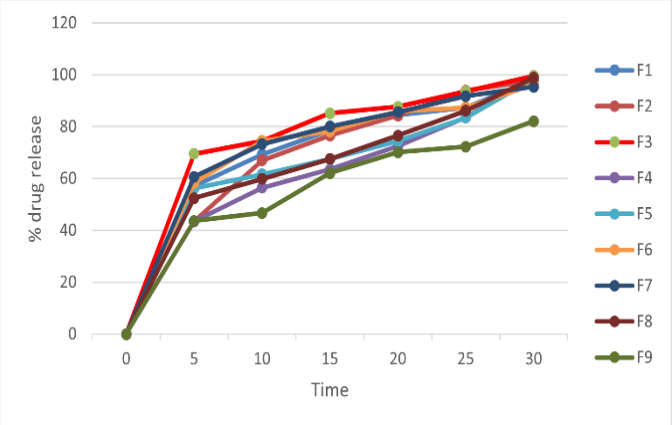

Figure 4. The comparative dissolution profile of all formulated batches.

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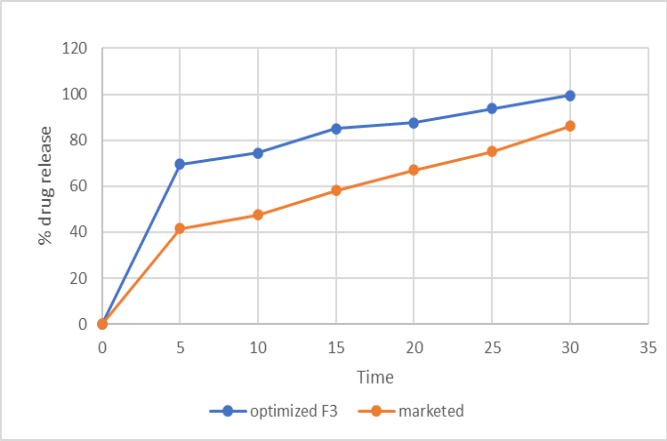

Figure 5. Comparative study of dissolution profile of F3 batch and marketed formulation.

Conclusion

The study successfully achieved its main objective of enhancing Rivaroxaban's solubility, dissolution rate, and bioavailability. The tablet formulation was improved by including super-disintegrants, such as crospovidone, sodium starch glycolate, and cross-carmellose sodium, into the orally disintegrating tablets (ODTs). They utilized design expert software and adopted a direct compression strategy for this objective. The F3 batch was determined to be the most optimum formulation, exhibiting exceptional characteristics including a hardness of 3.3 kg/cm², a disintegration time (DT) of 23 seconds, and a total drug release exceeding 99% within a 30-minute period. Comparative evaluations found that the orally disintegrating tablets (ODTs) of Rivaroxaban, which were created, had superior rates of disintegration and dissolution when compared to existing commercial formulations. The formulation investigation provided crucial data on Rivaroxaban's physical and chemical properties, confirming its classification as a BCS Class II drug due to its low solubility in water but high solubility in acetate buffer pH 4.5 and 0.1 N Hydrochloric acid. FTIR study indicated an absence of interactions between the drug, polymer, and excipients. The tablets from all batches exhibited consistent thickness and diameter, indicating satisfactory compression without any stickiness. The tablet compositions' mechanical strength, abrasion resistance, and uniformity were validated by hardness, friability, and weight variation tests. The study utilised design expert software to examine the impact of varying amounts of croscarmellose sodium and crospovidone on the disintegration time and tablet hardness. The ANOVA analysis identified crucial elements that influence these characteristics, and the resultant polynomial equations established predictive models for tablet performance. The optimized F3 batch of rivaroxaban tablets, designed to dissolve in the mouth, offers a dependable and effective solution for rapid disintegration. Additionally, these tablets exhibit improved solubility, dissolving, and bioavailability. The findings of this study offer valuable insights for developing sophisticated dose forms that can enhance the efficacy of medicines.

Conflict of interest

There is no conflict of interest to disclose.

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