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Original Article

Formulation and Evaluation of Ranolazine Fast Dissolving Tablets Using Various Superdisintegrants

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ABSTRACT

Background: This work is envisaged to understand the use of various superdisintegrants and their drug release effect in the formulation of Ranolazine fast-dissolving tablets (FDTs). **Materials and Methods:** The FDTs were formulated by using direct compression methods using different superdisintegrants like sodium starch glycolate, croscarmellose sodium and crospovidone. The superdisintegrant's effect at different concentrations was studied with help of precompression studies such as Hausner's ratio, compressibility index, differential scanning calorimetry (DSC) and post-compression studies like friability, disintegration and dissolution studies. **Results:** The effect of various superdisintegrants on desired drug release was studied and its concentrations were optimized. Based on the evaluation results of various trials, the effective concentration was found to be 15mg/tab of crospovidone. It has a disintegration time of 25 sec and a cumulative percentage drug release of 99.77±0.41. **Conclusion:** In this study, Ranolazine FDTs were developed and successfully optimized. The ideal superdisintegrant and its concentration were selected. Among the various superdisintegrants, crospovidone was more effective compared to other superdisintegrants. Hence, it is recommended to use crospovidone as an ideal superdisintegrant in the Ranolazine FDTs formulations.

Keywords: Crospovidone, Croscarmellose sodium, Sodium starch glycolate, Fast dissolving tablets (FDTs), Hausner's ratio, Ranolazine, Superdisintegrant.

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INTRODUCTION

In the novel world of medicine, newer dosage forms in newer routes of administration are gaining interest, but the conventional oral dosage form remains the most accepted and has high patient compliance. It is mainly due to their ease of use, cost-effective nature, and no pain during administration. Thus, the conventional oral route remains the most widely used route of drug administration especially tablets and capsules. Tablets have a wide range of advantage which includes release modifications, coatings and multiple layers that can be made on it. The dissolution rate of tablets can be altered with various mechanisms, one such method is the use of superdisintegrants for the development of fast-dissolving tablets.

FDTs are also known as fast dispersing, rapid melting, fast melting or rapid disintegrating tablets.[1] The fast-dissolving tablets are those which disintegrate within 3 min. FDTs also do not require water because when it is placed in the mouth, it rapidly disintegrates and the drug is released in mouth itself. The FDTs are most useful for patients like paediatric, geriatric, dysphagia and those who are frequent travellers and who cannot carry water with them.[2] FDTs has a wide range of application and can be used in formulating classes of drugs like anti-muscarinic, opioid analgesics, anthelmintic, antimalarial, antigout, antimigraine, NSAIDs, anti-arrhythmic and anti-angina, steroids, local anaesthetics, etc.[3] One such agent is ranolazine.

It comes under the class of drug antianginal. It is used in the treatment of severe cardiac pain in angina patients. It is usually taken orally. Ranolazine works by blocking the sodium inward in the heart muscles thereby reducing the intracellular calcium levels in the cardiac muscles.[4] Thus, the tension on the cardiac walls gets reduced, leading to less oxygen need for the muscle. The oral bioavailability of ranolazine is around 35% to 50% and

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Table 1: Formulation of Ranolazine FDTs.

Sl. No	Ingredients	Weight of ingredients used (mg)								
		FDTR1	FDTR2	FDTR3	FDTR4	FDTR5	FDTR6	FDTR7	FDTR8	FDTR9
1	Ranolazine	500	500	500	500	500	500	500	500	500
2	Aerosil	5	5	5	5	5	5	5	5	5
3	Sodium starch glycolate	5	10	15	-	-	-	-	-	-
4	Croscarmellose sodium	-	-	-	5	10	15	-	-	-
5	Crospovidone	-	-	-	-	-	-	5	10	15
6	Microcrystalline sodium	65	60	55	65	60	55	65	60	55
7	Aspartame	10	10	10	10	10	10	10	10	10
8	Magnesium stearate	5	5	5	5	5	5	5	5	5
9	Mannitol	10	10	10	10	10	10	10	10	10
Total		600	600	600	600	600	600	600	600	600

the Protein binding nature is nearly 62%. Usually, metabolism happens extensively in the hepatic (*CYP3A, CYP2D6*) and intestine regions. It has a half-life of about 7 hr. The drug gets its elimination in two routes: kidney (75%) and faeces (25%). Being an excellent drug of choice for a wide range of ailments, ranolazine is formulated in FDTs using various superdisintegrants.

Superdisintegrants are additives usually employed in the tablet dosage form which help in cleaving the physical forces inside the compressed tablet and thereby enhance the disintegration when gets contact with a fluid environment. Recently superdisintegrants are being explored due to their capability of the increasing rate of disintegration and it also improving a good feel in the mouth at a lower concentration than disintegrants.[5] This work is envisaged to understand the use of various superdisintegrants and their drug release effect in the formulation of Ranolazine fast dissolving tablets (FDTs).

MATERIALS AND METHODS

Ranolazine was procured from Sigma Aldrich Pvt. Ltd. Aerosil from Sisco Research Laboratories. Sodium starch glycolate, Croscarmellose sodium and Crospovidone were obtained from Sigma Aldrich Pvt. Ltd. Microcrystalline cellulose and Mannitol were purchased from Spectrum Reagents and Chemicals Pvt. Ltd., Aspartame and Magnesium stearate were obtained from Central drug house Pvt. Ltd.

Preformulation studies

The main aim of the preformulation work is to provide relevant data beneficial in formulating more stable and better bioavailable formulations.

Standard plot for Ranolazine

Suitable dilutions of ranolazine were prepared using pH 1.2, 6.8 and 7.4 buffers to obtain 10-50 µg/mL concentrations and absorbance was measured at 272nm.[6]

Drug-Excipient Compatibility Study Using Differential Scanning Colorimetry (DSC)

DSC study for Ranolazine, excipients and a mixture of Ranolazine with excipients were performed using "Shimadzu DSC-60". In this Ranolazine was mixed with the adjuvant involved in the preparation and DSC analysis of individual samples was studied. The study was done at the temperature ranging from 25 to 400°C, a heating rate of 10°C/min and the nitrogen flow rate was maintained at 30mL/min.[7,8] Then samples of weight 5 mg were taken in a pan made of aluminum sealed and the thermogram is recorded.

Formulation of Ranolazine FDTs

Ranolazine FDTs were developed by performing the direct compression method. Powder blends of Ranolazine, microcrystalline cellulose, aerosil, mannitol and various superdisintegrants in various concentrations were mixed for 20-25 min. Magnesium stearate and talc were added to the above mixture. The Powder mixture was made to undergo direct compression using a tablet punching machine.[9] The various formulation trials were formulated using different superdisintegrants and they were given in Table 1.

Evaluation of Ranolazine Fast dissolving tablets

Pre-compression parameters

For any drug, the pre-compression parameters have been studied in detail to know about the physical property (angle of repose, bulk density, tapped density, compressibility index /Carr's index, Hausner's ratio) of the drug.[10-14]

Post-Compression Parameters

For any tablet the post-compression parameters were mandatory and these parameters have to be performed to alter the pharmacokinetic property of the drug.

Shape and colour of tablets

The uncoated tablets are analyzed for shape and colour under a microscope.

Thickness

The individual tablet thickness is found using a vernier caliper which shows exact measurements and gives the variation between different tablets.[15]

Hardness test

The hardness of the tablet shows the capability of the tablet to resist mechanical strength while handling it. The hardness of the tablets was found using the Monsanto hardness tester. It was denoted in kg/cm^2. Randomly 3 tablets were taken from every formulation and the average and SD (standard deviation) were found.[16]

Weight variation test

Randomly from each formulation 20 tablets were picked weighed individually the mean and the standard deviation were evaluated.[17]

Friability test

Friabilator possesses a chamber made of plastic that is usually made to revolve at Revolutions per minute (RPM) of 25, during the revolution it drops those tablets from a distance of six inches during every revolution. The tablets were placed in the friabilator for a minimum of four minutes.[18] After the end of the process, processed tablets were dusted and reweighed, the weight of the tablet loss gives the friability and is expressed in percentage as

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{final weight}}{\text{Initial weight}} \text{ X } 100$$

The tablets whose weight loss was more than 1% weight were specified to be non-compliant.

Disintegration time

It is the time taken by the tablet to split into the small, specified size of granules under pre-set test parameters. The tablet disintegration time was found by the Indian Pharmacopeia specified disintegration test apparatus. One tablet is kept in each of the six tubes of the basket. Then the disc is added to all 6 tubes and the apparatus was made to run at 37±2°C using pH 6.8 (simulated saliva fluid) as immersion fluid. The apparatus assembly was made to raise and low for about 30 cycles per minute. The time taken by the apparatus to completely disintegrate the tablet without any palpable mass was recorded in seconds.

Drug Content

The content of ranolazine in the formulated tablet was measured by randomly picking 10 tablets from the batch and then powdered by using a mortar and pestle. Then the powder of weight equivalent to 5mg of ranolazine was dissolved in 6.8 pH phosphate buffer and then diluted up to 100mL using the same. The drug content of ranolazine tablets was estimated by taking 10 tablets which were crushed using a mortar and pestle. The weight of powder equivalent to 5 mg of the drug was dissolved in pH 6.8 phosphate buffer and diluted up to 100mL with the same. From this solution, 1 mL was further diluted to make up 10 mL using the phosphate buffer. Then the absorbance of this resulting solution was determined at 272nm spectro-photometrically.[18] The content of the drug in the tablet was found using the calibration curve.

In vitro dissolution study

In vitro dissolution study was performed using type-II dissolution apparatus which is made to revolve at 75 rpm. One tablet was positioned in each of 6 dissolution baskets having 900mL of phosphate buffer of pH 6.8 as a medium which was studied at 37°C ± 0.5°C previously.[19] After each time interval of 5, 15 and 30 min, a portion of the aliquot was withdrawn from midway of the zone between the top of the rotating blade and surface of the dissolution medium, not less than 1 cm from the sides of the vessel wall and filtered by using 0.45µm membrane filter. The samples collected at predestined time intervals were diluted to the needed volume with help of a medium. The samples were measured by UV-spectrometry at 272nm.[18,19] Then the percentage of drug release was measured using an equation from a standard calibration curve.

RESULTS

Pre-formulation studies

Standard plot for Ranolazine

Ranolazine standard calibration curve was carried out in different pH 1.2, pH 7.4 and pH 6.8 buffers at 272 nm.[18] The R^2 value gives

Table 2: Standard plot of Ranolazine.

Concentration (µg/mL)	Absorbance value		
0	0	0	0
10	0.055	0.060	0.051
20	0.110	0.121	0.102
30	0.166	0.182	0.153
40	0.220	0.242	0.204
50	0.275	0.301	0.256

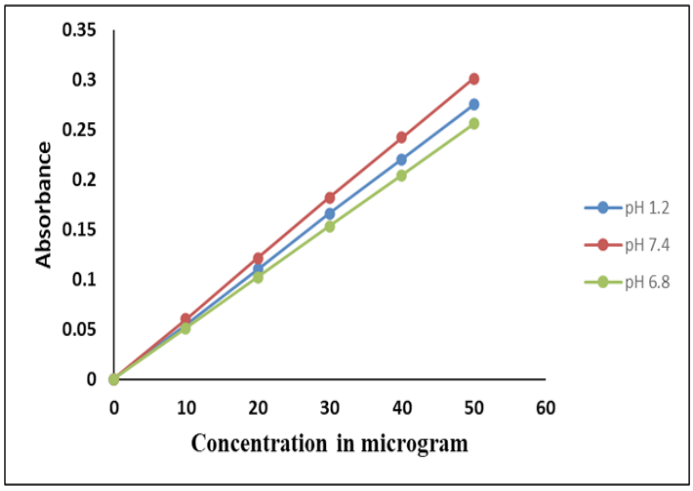

Figure 1: Standard plot for Ranolazine in pH1.2, 6.8 and 7.4 buffers.

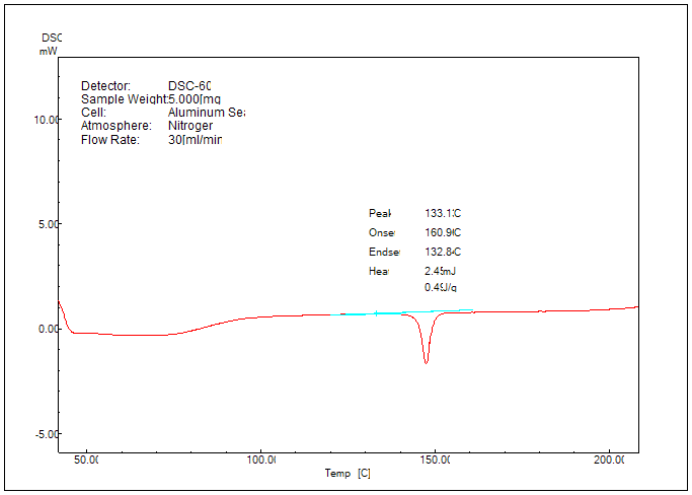

Figure 2: DSC Thermogram showing Ranolazine.

nearly 1 which shows linearity. The standard plot of Ranolazine was given in Table 2 and the standard graph in Figure 1.

Drug-excipients Compatibility Study by Differential Scanning Colorimetry (DSC)

The DSC of the raw drug Ranolazine and the blend of Ranolazine with excipients were given in Figures 2 and 3 respectively. Ranolazine thermogram indicates a sharp endothermic peak at 133.13°C (melting point). The drug excipient mixture also showed a similar thermal character of 134.13°C as the individual drug. These results also signify that the drug excipient mixture exhibits superimposition of the thermogram. DSC thermogram was very clear that no conclusive changes in the melting point endotherm of the drug ranolazine and excipients mixture. Hence, it was very significant that the drug excipient mixture does not possess any interaction between them.

Precompression parameters

Micrometric properties of ranolazine Fast dissolving tablets were summarized and given in Table 3. The micrometric study of ranolazine FDTs signifies that there was no conclusive change in all nine trials. The result was found to be within the acceptable range and passed the test.[19]

Post-compression parameters of Ranolazine FDTs

The physical evaluation and physicochemical evaluations were performed for the formulated Ranolazine FDT, and they were summarized in Table 4. Post-compression results of Ranolazine fast dissolving tablets showed there were no dominant differences in the thickness of the tablet, and weight variation in all the trials (FDTR1- FDTR9).

Superdisintegrants effect on in-vitro drug release of Ranolazine FDTs

Ranolazine fast dissolving tablets which were formulated using sodium starch glycolate as superdisintegrant showed drug release which was tabulated in Table 5 and the graph of cumulative drug release were given in Figure 4.

Ranolazine Fast dissolving tablets which were formulated using Croscarmellose sodium as superdisintegrant showed drug release which was tabulated in Table 6 and the graph of cumulative drug release was given in Figure 5.

Ranolazine Fast dissolving tablets which were formulated using crospovidone as superdisintegrant showed drug release which was tabulated in Table 7 and the graph of cumulative drug release were given in Figure 6.

Table 3: Results of the Micrometric properties of the granules.

TRIAL	Bulk density (g/cc)	Tapped density(g/cc)	Compressibility index (%)	Hausner's ratio	Angle of repose(°)
FDTR1	0.461	0.468	1.50	1.02	25.22
FDTR2	0.469	0.477	1.68	1.02	26.54
FDTR3	0.462	0.467	1.07	1.01	27.76
FDTR4	0.471	0.475	0.84	1.01	26.42
FDTR5	0.445	0.449	1.11	1.01	25.61
FDTR6	0.466	0.470	0.85	1.01	24.17
FDTR7	0.528	0.531	0.56	1.01	25.45
FDTR8	0.521	0.525	0.76	1.01	26.19
FDTR9	0.535	0.540	0.93	1.01	24.33

Table 4: Physical parameters of Ranolazine Fast dissolving tablets.

Trials	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Disintegration period (sec)
FDTR1	4.53±0.11	5.5±0.04	0.47±0.33	92
FDTR2	4.71±0.21	5.0±0.12	0.35±0.14	78
FDTR3	4.67±0.07	4.5±0.24	0.24±0.27	65
FDTR4	4.65±0.18	4.5±0.32	0.56±0.34	80
FDTR5	4.76±0.19	4.0±0.43	0.45±0.51	67
FDTR6	4.86±0.24	3.5±0.11	0.27±0.21	55
FDTR7	4.38±0.11	4.0±0.28	0.48±0.37	60
FDTR8	4.55±0.43	3.5±0.27	0.29±0.54	42
FDTR9	4.49±0.09	3.0±0.43	0.18±0.31	25

Table 5: Cumulative Percentage drug release of Ranolazine FDTs (FDRT1 - FDTR3).

Sl. No	Time in minutes	Cumulative percentage drug release		
		FDTR1	FDTR2	FDTR3
1.	0	0	0	0
2.	5	78.45±0.13	80.67±0.46	85.89±0.28
3.	15	87.92±0.24	90.73±0.27	94.86±0.32
4.	30	99.78±0.17	99.76±0.19	99.77±0.41

Table 6: Cumulative Percentage drug release of Ranolazine FDTs (FDRT4 – FDTR6).

Sl. No	Time in minutes	Cumulative percentage drug release		
		FDTR4	FDTR5	FDTR6
1.	0	0	0	0
2.	5	73.45±0.45	79.38±0.37	85.48±0.76
3.	15	87.29±0.12	90.82±0.25	92.82±0.64
4.	30	99.75±0.23	99.76±0.57	99.77±0.28

Table 7: Cumulative Percentage drug release of Ranolazine FDTs (FDRT7 – FDTR9).

Sl. No	Time in minutes	Cumulative percentage drug release		
		FDTR7	FDTR8	FDTR9
1.	0	0	0	0
2.	5	80.78±0.21	84.38±0.28	86.82±0.18
3.	15	89.65±0.18	92.72±0.43	99.78±0.25
4.	30	99.75±0.25	99.76±0.61	99.77±0.41

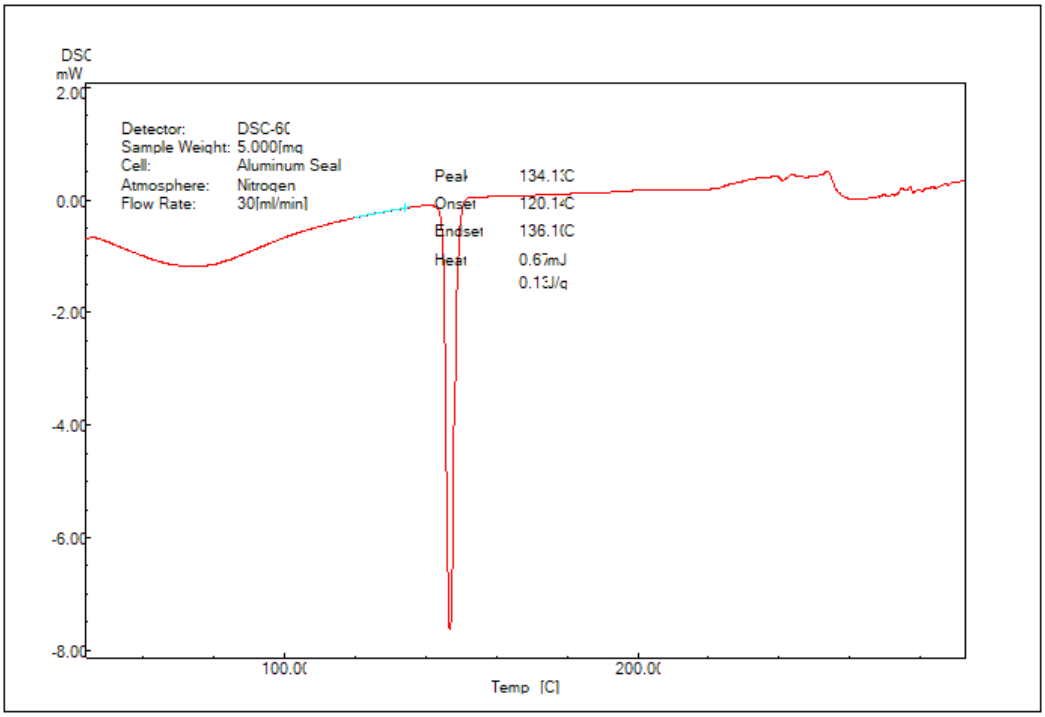

Figure 3: DSC thermogram showing Ranolazine FDTs blend.

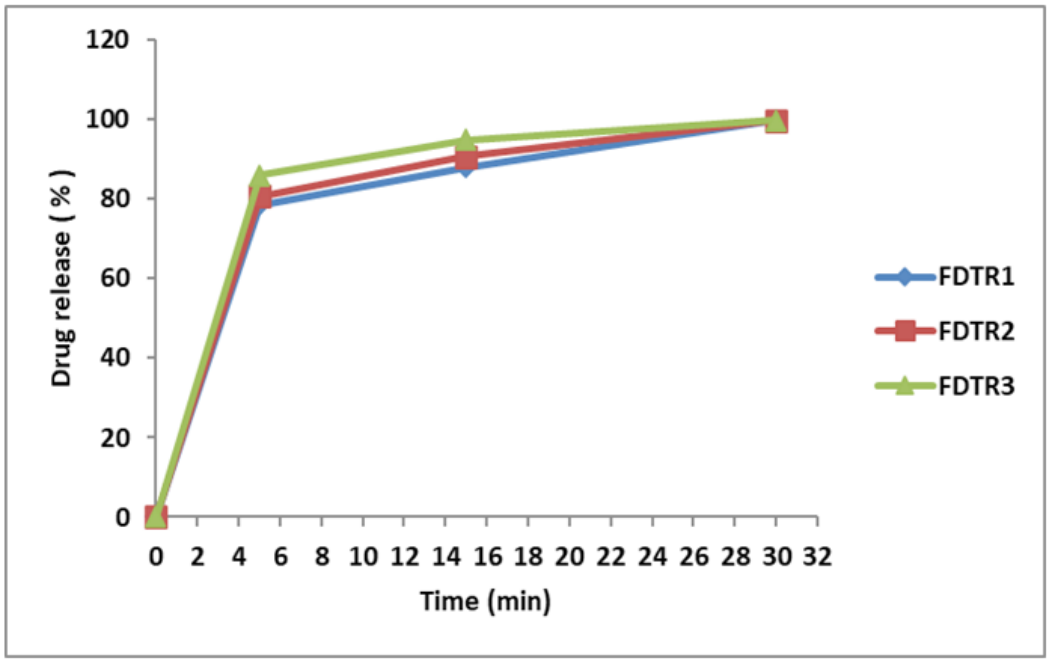

Figure 4: Percentage of Cumulative drug release of Ranolazine FDT (FDTR1-FDTR3).

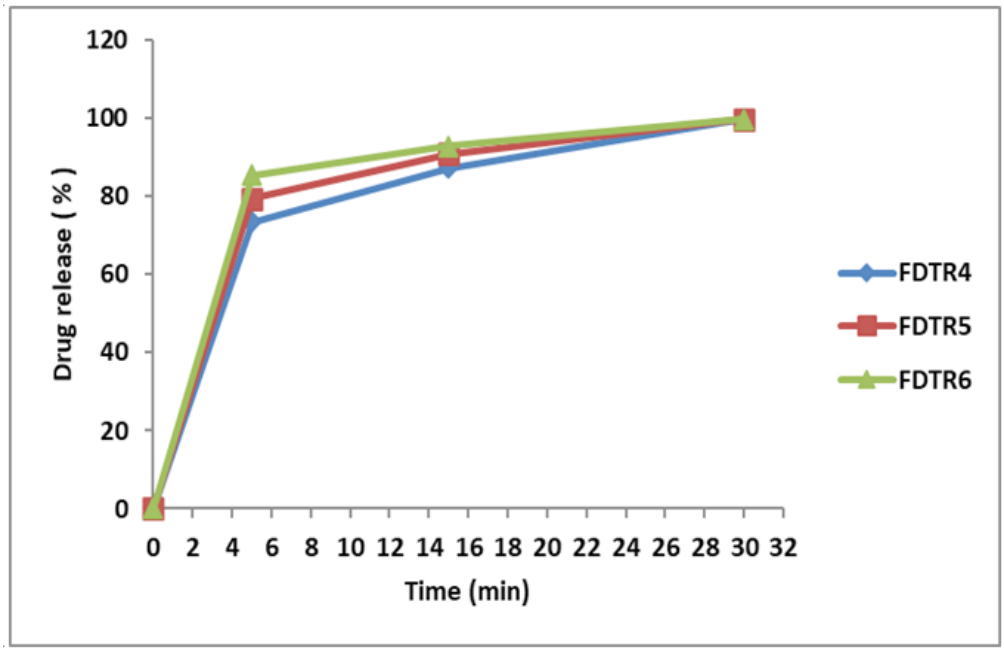

Figure 5: Percentage of Cumulative drug release of Ranolazine FDTs (FDTR4-FDTR6)

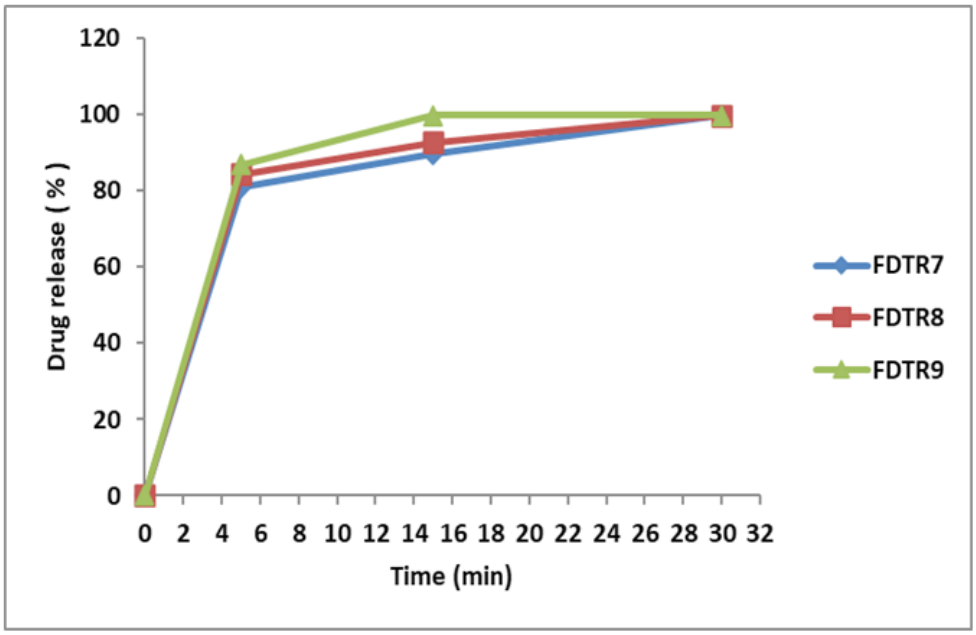

Figure 6: Percentage of Cumulative drug release of Ranolazine FDTs (FDTR7-FDTR9).

The dissolution medium 6.8 pH was taken to perform the *in vitro* drug release. Various concentrations of different superdisintegrants showed a predominant role in the *in vitro* release profile of the drug in the prepared ranolazine fast dissolving tablets.

DISCUSSION

FDTs main requirement is to make the faster dissolution of tablets; this can be made by selecting the superdisintegrant in optimized concentration. In this research work, the flow properties were excellent for the granules. As the flow property is directly linked to the hardness which in turn affects the dissolution, need to be studied. The thickness, weight variation tests for all trials were similar which indicated the prompt and systematic formulation process. But the hardness, disintegration time and friability values of all the trials were changed drastically. Hence the research gives guidance on the selection of superdisintegrant and its concentration for ranolazine FDTs. The formulations containing sodium starch glycolate and croscarmellose sodium showed more hardness and more disintegration time. For successful FDTs less hardness and less disintegration time are required. So the trials containing sodium starch glycolate and croscarmellose sodium

as superdisintegrants failed to pass the quality control tests. The *in vitro* release for the formulations having lesser concentrations of superdisintegrants showed a poor release pattern. The trial FDTR9 containing 15mg/tab concentration of crospovidone as superdisintegrant showed desired hardness (3.0kg/cm^2), disintegration time (25 sec) and release of 99.78±0.25% at the end of 15mts.

Thus, the formulation (FDTR9) having crospovidone as superdisintegrants at a concentration of 15mg/tab was found to be an optimized concentration and was marked as an optimized formulation. From evaluation results, it was found that the hardness of the tablet and *in vitro* drug release performance of the formulations were dependent on the superdisintegrants concentration and nature of superdisintegrants involved in the formulation. The superdisintegrants promote the disintegration of the tablet by their ability to absorb water in large amounts when they were exposed to an environment of an aqueous nature.[20,21]

CONCLUSION

The active pharmaceutical ingredient ranolazine was evaluated for its morphological, physical, and chemical characteristics. The results obtained were satisfactory and within the specified limits. Ranolazine was subjected to the pre-formulation study, and the results obtained with selected excipients showed good compatibility with the drug. Ranolazine FDTs were formulated by using different superdisintegrants and the suitable concentrations were optimized by various trials. The optimization procedures aided in the stabilization of the formula and the formulation of the ranolazine FDTs. The ranolazine FDTs were formulated by using the finalized formula and showed good results in the formulation of the stable solid dosage form. The dissolution profiles of the prepared ranolazine fast dissolving tablets were found to be good. The prepared ranolazine fast dissolving tablets disintegrate within a few seconds (25 sec) thus it was conclusive that the newly developed ranolazine FDTs can be suitable in the pain management of the patient with angina pectoris.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

FDTs: Fast Dissolving Tablets; **DSC:** Differential Scanning Calorimetry; **TD:** Tap Density; **BD:** Bulk Density; **NSAID:** Non-Steroidal Anti-Inflammatory Drugs; **nm:** nanometer; **mL:** milliliter; **min:** minute; **SD:** Standard Deviation; **rpm:** revolutions per minute.

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