RESEARCH ARTICLE

Formulation Development and Evaluation of Ticagrelor Oral Dispersible Tablets by Using Co-processed Superdisintegrants

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Received: 18th January, 2023; Revised: 11th March, 2024; Accepted: 13th May, 2024; Available Online: 25th June, 2024

ABSTRACT

Ticagrelor is a contemporary anti-platelet drug that inhibits the aggregation of platelets by blocking the adenosine phosphate (ADP) receptors of the subtype P2Y12; generally utilized in patients who have a previous history of myocardial infarction or with acute coronary syndrome to prevent occurring of myocardial infarction, cardiovascular death and stroke in future. This study focuses on the development of formulation development & assessment of an oral dispersible tablet of ticagrelor, a Biopharmaceutical Classification System (BCS) class 4 drug, by using the co-processed superdisintegrants to enhance drug dissolution and bioavailability. Wet granules with different concentrations of co-processed superdisintegrants developed the tablets. This study includes seven formulations that were formulated using the different selected excipients. The various batches were assessed for physical characteristics, disintegration, dissolution studies, hardness and friability. *In-vitro* dissolution investigations were conducted for formulations. S1 to S7 at time points 5, 15 and 30 minutes. According to the results of the formulation S7 was discovered to be the optimum formulation, as shown 102.89% drug release at 5 minutes and a disintegration time of 16 seconds. Thus, it appears that S7 is the most suitable formulation of ticagrelor oral dispersible tablet in order for enhanced bioavailability.

Keywords: Oral dispersible tablet, Co-processed superdisintegrants, Ticagrelor, Drug delivery, Solubility enhancement, Dissolution.

International Journal of Drug Delivery Technology (2024); DOI: 10.25258/ijddt.14.2.45

How to cite this article: Dhobale G, Chavan S, Dhobale S, Tare H. Formulation Development and Evaluation of Ticagrelor Oral Dispersible Tablets by Using Co-processed Superdisintegrants. International Journal of Drug Delivery Technology. 2024;14(2):907-912.

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

The pharmaceutical industry currently uses oral drug delivery as the most popular drug delivery method.[1] Oral solid dosage forms are currently the most popular in oral drug delivery because they have a high patient compliance rate, are inexpensive to produce, and are a highly convenient approach.[2] Tablets and capsules are most often administered orally. However, swallowing conventional tablets by an oral route of administration can be challenging for both children and elderly patients, which results in low patient compliance. Innovative drug delivery systems called as "Dispersible Tablets" have been produced by scientists to address this shortcoming.[3]

New oral dispersible tablets (ODT) technologies meet the needs of patients and pharmaceutical companies in a variety of ways, from improved life-cycle management to comfortable dosing for dysphasic patients in psychiatry, pediatrics, and the elderly.[4] Because they improve patient compliance, oral dispersible tablets ODTs have drawn a significant amount of focus in the last 30 years as a preferred option for conventional tablets and capsules. Their unique benefits, like their ability to be administered anytime, anywhere, make them appropriate for both pediatric and geriatric patients. Additionally, patients who are bedridden, mentally ill, or do not have easy access to water can benefit from them. Due to their advantages over other dosage forms, such as patient compliance, these oral medications are currently quite popular.[5,6]

Dispersible tablets provide a benefit to those with swallowing difficulties. Dysphasia, or trouble swallowing, has been documented to affect people of all ages. However, it is more common in the pediatric and geriatric populations, as well as in individuals who are institutionalized and have difficulties from nausea, vomiting, and motion sickness.[7,8] DTs with a pleasing flavor and taste help a wider range of people tolerate bitter medications. ODTs should have some desirable qualities

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that distinguish them from standard dose forms. Essential requirements for various dosage formulations include: these dosage forms have a number of important and desired qualities, such as not requiring water for oral administration, dissolving or dispersing quickly in saliva, tasting well. Leaving minimal to no residue in the mouth after administration. It should be lightweight, portable, and inexpensive to produce. It should also be compatible with flavor masking and able to be made in a straightforward, customary method.[9,10]

Ticagrelor is a highly effective anti-platelet agent that has shown its potency in the management of cardiovascular diseases, especially in acute coronary syndrome. The formulation of ticagrelor in ODT is very challenging due to its poor water solubility and tendency to undergo degradation under certain conditions. To overcome these challenges in formulation, an emerging promising approach, "co-processed superdisintegrants," is utilized.[11] It involves the combination of various advantages of multiple disintegrants which generally enhances the tablet disintegration and dissolution rate[12].

This study aims to develop formulation development and evaluation of oral dispersible tablets of ticagrelor utilizing the co-processed superdisintegrants.[13] Using a comprehensive strategy, numerous formulation parameters such as excipient selection, compression techniques, and processing condition optimization will be studied in order to produce tablets with the optimum disintegration time, dissolution profile, and stability.[14,15]

The investigation results and findings from this research could help to develop a novel formulation strategy for ticagrelor, enhancing its patient acceptability and therapeutic efficacy. It will also contribute to the formulation development of oral dispersible dosage forms of other weakly water-soluble medicines., Resolving unfulfilled patient & medical professional goals in the efficient management of cardiovascular diseases.[16,17]

Drug Profile

Ticagrelor (Figure 1) serves as a platelet aggregate formation inhibitor to prevent thrombotic complications like strokes and cardiac arrest.

Structure

Pharmacological class: Antithrombotic drug
Molecular weight: 522.57 g/mol
Physical state: Solid
Color: White crystalline powder
Melting point: 140 to 142°C.
Bioavailability: 36%.

Solubility

Soluble in methanol, ethanol, DMSO, and dimethylformamide. It fails to exhibit pH-dependent solubility in aqueous buffers.
Water solubility: 0.016 mg/mL

Dose: For one year, dose 60 to 180 mg twice day orally.
BCS Class: Ticagrelor is classified as class IV compound (low solubility, low permeability).
Pharmacodynamics: P2Y12 receptor blocker

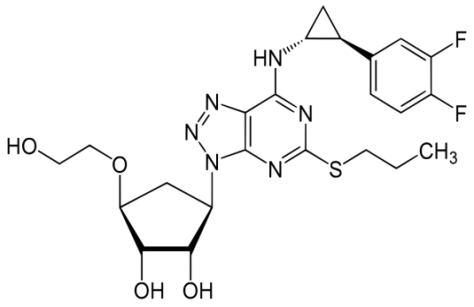

Figure 1: Chemical structure of ticagrelor

Absorption of drug: Bioavailability is 36%, with a peak plasma time of 1.5 hours for tablets.
Drug distribution: Ticagrelor has a stable state volume of distribution of 88L.

Metabolism

Ticagrelor metabolism & formation of the active metabolite are primarily regulated by CYP3A, which interacts with other CYP3A substrates in a variety of ways, including inhibition. Ticagrelor and its active metabolite function as mild inhibitors of P-glycoprotein.

Excretion

(58% in feces, 26% in urine). Ticagrelor's mean $t_{1/2}$ is around 7 hours, whereas the active metabolites is around 9 hours.[18]

MATERIALS AND METHODS

Ticagrelor, lactose monohydrate, sodium starch glycollate, PVPK, crosspovidone, magnesium stearate, sodium saccharine, orange flavor all the excipients and drug were obtained from the Kopran Ltd., Savroli.

Preparation of Co-processed Superdisintegrants

Chloroform, a volatile solvent, was used in the solvent evaporation procedure to create the co-processed superdisintegrants. Table 1 shows the different ratios of cross-povidone and sodium starch glycolate mixed with 10 to 15 mL of chloroform. After the chloroform had evaporated, the solution was vigorously mixed. Then, sieve number 60 was used to granulate the wet coherent mass. After being heated to 60°C for 30 minutes, the wet granules were removed from the oven. Before being sealed in a container for later use, the dried granules were once again passed through sieve #60 to remove any lumps.[19]

Evaluation of Ticagrelor

- Ticagrelor's organoleptic characteristics, including color, odor, and taste, were investigated.
- Melting point determination: Ticagrelor's melting point was established using the capillary method. The medication was introduced into a one-sided closed capillary and then placed in the melting point apparatus. The point in time when the medicine went from solid to liquid was noted.
- Aqueous solubility: Solubility of ticagrelor was determined over the pH range of 1.2 to 6.8.

Preparation of Ticagrelor Oral Dispersible Tablets

Each formulation contains 90 mg of pure API. Lactose monohydrate is added as diluent, PVPK is added as a binder and, magnesium stearate as lubricant sodium saccharine is used as a sweetening agent and as a flavoring agent. The weighed quantity of API and lactose was passed through 60#. The above-shifted material was mixed in RMG (Rapid mixing granulator) at slow (30 RPM) for 10 minutes. The weighed quantity of PVPK-30 was added in 160 mL of water and agitated till a binder solution was formed and then it was added in the dry mix in RMG for 1-minute and mixed for 3 minutes at medium speed and dried using the rapid dryer. The Dried granules were prepared and passed through sieve 20#. Then, magnesium stearate was added in blend and mixed using the lab blender for about 10 minutes at 20 rpm. The dried blend the compressed in tablets by using tablet compression machine (Cadmach).[20]

Pre-Compression Evaluation Parameters

Various pre-compression characteristics, such as the blend's angle of repose (Θ), bulk density (Dv), tapered density (Dt), compressibility index (CI), and Hausner ratio (H), were evaluated before the compression procedure. A tapping density tester (Elctrolab) was used to determine the bulk and angle of repose, while the funnel method was used to calculate the angle of repose.[21]

Post-Compression Evaluation Parameters

Wetting time, drug content, hardness, thickness, disintegration time, water absorption ratio, and weight variation test were among the many criteria used to assess the compressed tablets.[22]

Assay of ticagrelor by HPLC method

Chromatographic conditions
Column: Luna A18, 15 cm
Mobile phase: Acetonitrile:Potassium dihydrogen orthophosphate (0.01M) buffer (50:50), pH adjusted to 3
Injection volume: 20 µL
Wavelength: 255 nm
Temperature: 40°C

Sample preparation

Ticagrelor tablets (90 mg) were dissolved in methanol, sonicated, and diluted to 25 mL with the mobile phase. Resulting concentration: 0.144 mg/mL.

Standard preparation

Ticagrelor standard (90 mg) was dissolved in methanol, sonicated, and diluted to 25 mL with the mobile phase. Resulting concentration: 0.144 mg/mL.

Injection procedure

Each solution, the standard and the sample, was added to the chromatograph in a separate 20 µL volume. We measured peak regions and collected chromatograms.

Calculation

$(L/D) \times C \times (r_u/r_s)$ where, L (labeled amount, in ml), of in every tablet. D (Ticagrelor conc. Ml/mL) Cconc. of USP Ticagrelor in standard preparation, calculated on an anhydrous basis). The peak area responses from the standards and the sample preparation are represented by ru and rs, respectively.[23]

***In-vitro* Drug Release**

Ticagrelor orodispersible tablets' *in-vitro* dissolution experiments were carried out utilizing a dissolution tester (Elecrolab). The dissolution media tween 80 was utilized in a volume of 900 mL, with a temperature of 37 ± 0.5°C (75 rpm). Each dissolve apparatus jar contained one tablet. 5 mL of sample was removed from each jar every 15 minutes for up to 1-hour. Then, the volume of the dissolving medium was maintained at 900 mL by replacing the same volume of tween 80 in each jar. Following filtering, the spectrophotometric measurement of ticagrelor released from ODTs was taken at 299 nm, with tween 80 used as a blank, to determine the amount of the compound.[24,25]

Stability Study

Stability studies were conducted on a selected batch using ICH guidelines to evaluate drug content and formulation stability. One batch of manufactured tablets was wrapped in aluminum blisters and stored at 40 ± 20°C and 75 ± 5% RH. During stability investigations, samples were collected at one, two, and three-month intervals to assess the appearance, hardness, drug content, and percentage of dissolution.[26,27]

RESULT AND DISCUSSION

Evaluation of Ticagrelor

Organoleptic characteristics

The organoleptic characteristics of ticagrelor are presented in Table 2.

Ticagrelor was discovered to be a white to off-white powder with no distinct odor or flavor. Ticagrelor exhibited identical color, taste, and odor.

Melting point: 138–141°C.

Hygroscopicity: Non-hygroscopic

Solubility Study

The aqueous solubility of ticagrelor is higher and constant across the physiological pH range due to the hydrophilic nature of the molecule (Table 3).

Composition of Formulation of ODTs of Ticagrelor

In the above formulations, S1 and S2 contain 7 mg of crosspovidone and sodium starch glycollate, respectively. In S3, S4, S5, S6 and S7 formulations, 7 mg of A1,A2,A3,A4 and A5 co-processed superdisintegrants were present (Table 4).

Pre-Compression evaluation Parameters

The micrometric investigation was undertaken for all of the formulations, and the findings were reported. Formulations with co-processed superdisintegrants had reduced angle of repose values (25.18–26.45), indicating that all formulations had acceptable flow characteristics. The compressibility index (14.184–20.65) indicated that all formulations had good

Table 1: Composition of co-processed superdisintegrants of sodium starch glycollate and crosspovidone

Mixture nos	*A1*	*A2*	*A3*	*A4*	*A5*
Crosspoovidone	1	1	2	1	3
Sodium starch glycollate	1	2	1	3	1

Table 2: Organoleptic characteristics of ticagrelor (API)

Tests	*Observation*
Color	White
Odor	No odor
Taste	Tasteless

Table 3: Solubility analysis of API

Solvent	*Solubility (mg/mL)*	*Dose: solu bility ratio*
In 0.1N HCL + 0.2% Tween 80	0.477	377.36
0.01N HCL + 0.2% Tween 80	0.496	362.90
Water+0.2% Tween 80	0.801	224.72
In (4.5 pH) acetate Buffer+0.2% Tween 80	0.393	458.01
In (6.8 pH) Phosphate buffer+0.2% Tween 80	0.389	462.73

Table 4: Formulation design

API and Excipients	*Formulation (mg/tab)*						
	S1	*S2*	*S3*	*S4*	*S5*	*S6*	*S7*
Ticagrelor	90	90	90	90	90	90	90
Sodium starch glycollate	7	-	-	-	-	-	-
Crosspovidone	-	7	-	-	-	-	-
Co-processed superdisintegrant	-	-	7	7	7	7	7
PVPK-30	3	3	3	3	3	3	3
Magnesium stearate	6	6	6	6	6	6	6
Sodium saccharine	3	3	3	3	3	3	3
Orange flavor	2	2	2	2	2	2	2
Lactose monohydrate	189	189	189	189	189	189	189

compressibility and flow qualities. Haunser ratios indicate that powders have a low inter-particle friction ratio of less than 1.25. As a result, all formulations exhibit reduced particulate friction (Haunser ratio <1.25) (Table 5).

Post-compression Evaluation Parameters

Since the mixtures of all methods have good flowing properties, the compressed tablets have constant weight. The tablets' hardness was found between 2.65 to 3.49 kg/cm^2. The thickness of all pills is approximately 3.34 mm. Friability was found to be less than 1% across all formulations, indicating that tablets have a high mechanical strength. The drug content was determined to be between 97.88 and 101.48%, which was below pharmacopeial norms. The water absorption

Table 5: Pre-compression evaluation parameters

Formulation code	*Bulk density (gm/mL)*	*Tapped density (gm/mL)*	*Compressibility index*	*Hausner's ratio*	*Angle of repose (Θ)*
S1	0.363	0.438	15.98	1.20	27.57
S2	0.333	0.433	23.09	1.30	28.72
S3	0.390	0.458	14.84	1.17	25.94
S4	0.409	0.460	11.08	1.12	25.18
S5	0.345	0.426	19.01	1.23	26.89
S6	0.340	0.415	18.07	1.22	26.24
S7	0.406	0.478	15.06	1.17	26.45

Table 6: Post-compression parameters

Formulation code	*S1*	*S2*	*S3*	*S4*	*S5*	*S6*	*S7*
Weight variation (mg)	298.56	298.45	297.4	301.56	299.45	298.89	300.78
Thickness (mm)	3.42	3.34	3.36	3.32	3.23	3.34	3.24
Hardness (kgcm^2)	2.65	2.56	3.28	2.98	3.16	3.39	3.50
%Friability	0.68	0.70	0.60	0.64	0.62	0.68	0.75
% Drug content	97.88	102.10	97.99	98.89	97.68	100.10	101.48
Water absorption ratio	62.97	67.66	74.49	76.28	83.56	86.19	92.45
Disinte gration time (s)	55.32	43.56	36.92	27.96	26.00	19.78	16.34

Table 7 : *In-vitro* dissolution study

Time (minutes)	*Percentage drug release*						
	Formulation						
	S1	*S2*	*S3*	*S4*	*S5*	*S6*	*S7*
5	82.47	84.04	86.92	89.58	92.30	98.58	102.89
15	90.27	88.61	91.46	94.81	96.83	100.81	103.65
30	94.67	95.98	97.89	98.8	100.39	102.21	104.33

ratio was determined to be between 62.97 and 92.45%. All formulations (S7) that contained sodium starch glycollate: Crosspovidone (3:1) had the highest water absorption ratio (92.45%). Formulations with co-processed superdisintegrants have a short disintegration time. Formulation (S7) with sodium starch glycollate: Crosspovidone (3:1) had the shortest disintegration time (16.34s). Table 6 shows the findings of the post-compression evaluation.

In-vitro Dissolution Study

The best formulations are S3, S4, S5, S6, and S7, with drug release rates of 97.89, 98.80, 100.39, 102.21 and 104.33% at 30 minutes, respectively (Table 7).

Stability Study

At 25°C and 60% relative humidity, and 40°C and 75% relative humidity, a stability study was conducted over three months. Experiments on S7's stability showed that its color, look,

Table 8: Stability study

Stability period	*25°C/60% RH*				*45°C/75 %RH*			
	%Weight	*%Friability*	*%Drug content*	*Dissolution profile*	*%Weight*	*%Friability*	*%Drug content*	*Dissolution profile*
Initial	0	0.62	101.48	104.33	0	0.62	101.48	104.33
End of first month.	0.22	0.66	100.98	103.9	0.27	0.66	101.34	102.20
End of Second month	0.66	0.72	99.87	102.46	0.71	0.74	101.22	100.34
End of Third month	0.98	0.79	98.54	99.94	1.03	0.83	101.02	98.89

friability, and wetting time did not vary much over time.[28] (Table 8).

CONCLUSION

Ticagrelor ODTs provide a significant benefit over regular tablets since they dissolve and disperse quickly in saliva, eliminating the need for water. Ticagrelor is particularly useful in the treatment of acute coronary syndrome and cardiac angina since it improves patient convenience and compliance. In this investigation, multiple batches of ODTs were generated utilizing different concentrations of superdisintegrants and co-processed superdisintegrants using wet granulation techniques. Among the seven formulas examined, S7 showed the most promise. It disintegrated faster than earlier batches, taking 16 seconds. Furthermore, the drug assay findings verified compliance within acceptable ranges. *In-vitro* dissolution experiments demonstrated that S7 produced 100.89% drug release in 5 minutes, demonstrating its effectiveness. These findings highlight the potential of formulation S7 as a preferred choice for ticagrelor ODT production, offering rapid drug release and optimal patient adherence.

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