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Preparation and Evaluation of Rapidly Dissolving Tablet of Telmisartan

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ABSTRACT

Objective: The aim of this work was to enhance the dissolution rate of telmisartan with the goal of developing fast disintegrating tablets (FDTs) with subsequent rapid dissolution for sublingual administration. **Methods:** Binary solid dispersion systems (SDS) were prepared by solvent evaporation technique for the drug with Gelucire 44/14 (formula A), polyethylene glycol 4000 (PEG4000) (formula B), Pluronic F68 (formula C), hydroxypropyl methylcellulose E5 (HPMC E5) (formula D), and finally by using sodium bicarbonate with the drug in (0.5: 1) ratio (formula E), and (1:1) ratio (formula F). These systems were evaluated for drug dissolution in addition to the physicochemical changes of the drug utilizing FTIR spectroscopy, thermal analysis, and X-ray diffraction. **Results:** The prepared formulations using sodium bicarbonate significantly enhanced the dissolution rate of the drug compared with those prepared using different types of polymers. The order of enhanced dissolution of the drug in the first 5 min Q_5 (%) was: formula E > F > D5, where the % drug dissolved was 88.94 ± 1.31, 84.77 ± 1.1 and 72.6 ± 0.81 (mean $\pm$ SD) for each formula, respectively. Formula E was selected for the formulation of the rapidly dissolving tablet of telmisartan since it showed enhanced dissolution of the drug, more palatable taste in the buccal cavity, relatively inexpensive material and ease of processing compared with a solid dispersion prepared using polymer. **Conclusion:** Sodium bicarbonate can be utilized in the preparation of telmisartan FDT with fast dissolution rate.

Keywords: Fast release tablets; Sodium bicarbonate; Solid dispersion; Sublingual tablet; Telmisartan

INTRODUCTION

Telmisartan is 2-(4-{[4-methyl-6-(1-methyl-1H-1, 3 benzodiazol-2-yl) -2-propyl-1H-1, 3-benzodiazol-1-yl methyl} phenyl) benzoic acid (**Figure 1**), approved as antihypertensive agent[1]. It exerts its action via competitive inhibition of the angiotensin-converting enzyme (ACE) with higher selectivity for (AT1) than (AT2) receptor. Telmisartan shows a long duration of action with the elimination half-life approaching 24 h. The pharmacokinetics pattern of telmisartan after oral administration follows nonlinear kinetics over the dose range 20-160 mg. Telmisartan is readily ionizable and subsequently, the solubility is pH dependent with maximum solubility observed at high and low pH, but in the range of *pH* 3-9, it is only poorly

soluble[2,3]. According to Biopharmaceutical Classification System (BCS), telmisartan is classified as class II drug, meaning that the drug is highly permeable but poorly soluble[4]. The poor solubility of telmisartan in biological fluids is one of its major problems which accounts for low bioavailability that reaches 42 % after oral administration. It also shows high first-pass metabolism, which further reduces the oral bioavailability [5]. Rapid dissolution in the oral cavity provides a chance for mucosal absorption of the drug and avoiding presystemic disposition. The development of rapidly disintegrating and dissolving oral tablets has gained interest recently. The main problem of such dosage form is the need for fast disintegration and rapid drug dissolution in small volumes of saliva. The Optimizing drug dissolution rate is thus the main

limiting factor in the formulation of these systems[6]. FDTs are intended for administration to patients who cannot swallow, such as the elderly patients, stroke victims, bedridden patients, patients affected by a renal failure, and patients who refuse to swallow, such as pediatric, geriatric, and psychiatric patients [7]. Numerous studies had been carried out in order to modify the dissolution kinetics of poorly soluble drugs to improve their bioavailability. A common method used to improve the dissolution rate of a poorly water-soluble drug is the formation of a solid dispersion (SD) with hydrophilic polymers. It has also been reported that the modulation of pH in dosage forms is a promising way to modify the release rate of several pH-dependent and ionizable drugs[4]. Accordingly, the aim of this work was to enhance the dissolution rate of telmisartan with the goal of formulating rapidly disintegrating oral tablets with subsequent fast dissolution. To achieve this objective, (SDS) of the drug was prepared using different types of polymers and sodium bicarbonate either alone or in combination to select the best formula which provides higher dissolution rate of telmisartan.
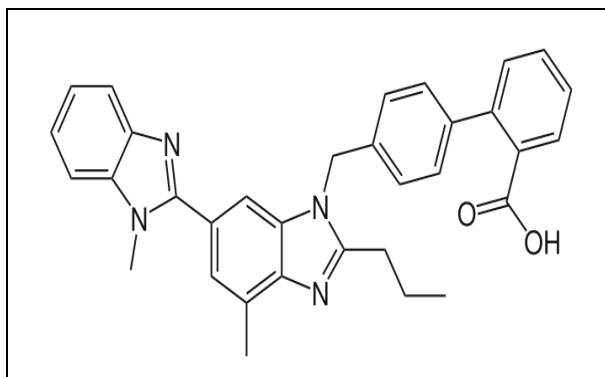
Figure 1. Chemical structure of Telmisartan.
(Adopted from Chivate et al., 2013)

MATERIALS AND METHODS

Materials

Telmisartan was supplied from Biopharm pharmaceutical industries 6th of October city, Cairo, Egypt. PluronicF68, Mannogem 2000USP/EP (Granular mannitol), AvicelPH102, croscarmellose sodium, crospovidone sodium, polyethylene glycol 4000(PEG4000), Hydroxypropyl methylcellulose (HPMC E5), Gelucire 44/14, magnesium stearate and aerosil were supplied from Sigma pharmaceutical industries, Quesna, Egypt. Methyl alcohol, dichloromethane, and all other materials were obtained from EL Nasr pharmaceutical chemicals Company, Cairo, Egypt.

Methods
Calibration curve

A Known amount of telmisartan (10 mg) was accurately weighed, dissolved in 1.0 M NaOH and the volume was adjusted to 100 ml in order to obtain a stock solution (100 µg/ml). Different aliquots of this solution were diluted with 1.0 M NaOH to produce solutions containing 5, 7, 8, 10, 12, 15, 18 µg/ml of telmisartan. The absorbance of these solutions was measured at 297 *nm* on UV-Visible spectrophotometer (Thermo Fisher Scientific, USA) against 1.0 M NaOH as a blank. The calibration curve was linear as shown in **Figure 2**.
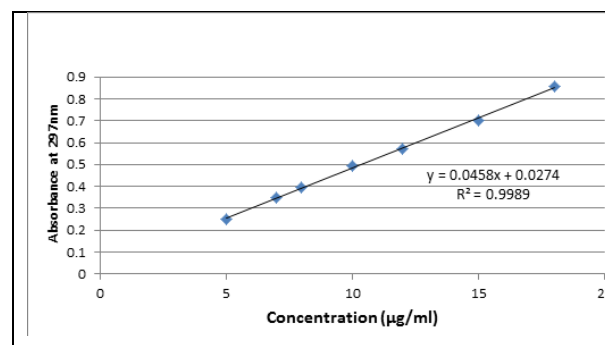
Figure 2. Calibration curve of Telmisartan in water at pH 7.5.

Preparation of solid dispersion systems (SDS)

Binary SDS of the drug with various polymers, sodium bicarbonate or combination of polymer and sodium bicarbonate were prepared by solvent evaporation technique according to the composition presented in **Table 1**. The drug and the polymers and/or sodium bicarbonate were dissolved in a mixture of dichloromethane with methanol (20:80). The organic solvent was removed by evaporation over a water bath at 50 °C with continuous stirring until complete evaporation. The residue was stored in desiccators at room temperature for 2 days until complete drying. The dry product was ground and sieved through a 300 µm sieve and stored in a tightly closed container.

Physical characterization of the prepared formulations
Determination of dissolution rate

The dissolution rate of telmisartan from different formulations was determined using the USP II dissolution apparatus (Coply, NG 42JY, Nottingham, UK). Telmisartan (40 mg) or equivalent formulations were exposed for 1.0 hr dissolution testing in phosphate buffer (pH 6.8). The dissolution medium (900 ml) was maintained at 37 ± 0.5 °C and the paddle speed was adjusted to 75 rpm. Samples were withdrawn from the dissolution medium at predetermined intervals

Table 1. The composition of the solid dispersion systems (SDS) and the amount of the drug dissolved in the first five min Q_5 (%)

Formulation	Telmisartan	Gelucire	PEG4000	Pluronic F68	HPMC E5	NaHCO$_3$	Aerosil	**Q5 (%) $\pm$ S.D
Control	1	0	0	0	0	0	0	6.41 $\pm$ 0.28
A1	1	1	0	0	0	0	0	8.37 $\pm$ 0.89
A2	1	2	0	0	0	0	0	14.79 $\pm$ 1.80
A3	1	3	0	0	0	0	0	13.05 $\pm$ 1.19
B1	1	0	1	0	0	0	0	7.83 $\pm$ 1.50
B2	1	0	2	0	0	0	0	9.01 $\pm$ 0.74
B3	1	0	3	0	0	0	0	13.81 $\pm$ 0.87
C1	1	0	0	1	0	0	0	27.05 $\pm$ 2.06
C2	1	0	0	2	0	0	0	24.6 $\pm$ 1.52
C3	1	0	0	3	0	0	0	24.92 $\pm$ 3.60
C4	1	0	0	2	0	2	0	33.03 $\pm$ 0.80
D1	1	0	0	0	1	0	0	13.90 $\pm$ 1.56
D2	1	0	0	0	2	0	0	22.72 $\pm$ 1.72
D3	1	0	0	0	3	0	0	21.69 $\pm$ 2.53
D4	1	0	0	0	2	2	0	45.33 $\pm$ 5.60
D5	1	0	0	0	2	2	1	*72.66 $\pm$ 0.81
E	1	0	0	0	0	0.5	0	*88.94 $\pm$ 1.31
F	1	0	0	0	0	1	0	*84.77 $\pm$ 1.10

statistically different (p-value < 0.01).
** Q_5 (%) values are expressed as mean $\pm$ SD. (n=3)*

(5, 10, 15, 30, 45 and 60 min) and then drug concentration was determined using UV-VIS spectrophotometer at 297 nm using dissolution medium as a blank. An equivalent amount of fresh medium was added to maintain a constant dissolution volume. The dissolution profiles were obtained as the plots of the cumulative amounts of drug dissolved as a function of time. These were used to calculate the dissolution parameters which included the amount of drug dissolved after 5 min (Q_5)[8].

Differential thermal analysis (DTA)

Thermograms of different samples (telmisartan, polymers and the prepared formulations) were recorded using DTA (PerkinElmer STA6000 module, Ohio, USA). Samples equivalent to 2.4 mg of the drug were loaded into aluminum pans and the lids were crimped using a Shimadzu crimper. The thermal behavior of each sample was investigated under nitrogen at a heating rate of 10 °C/min, covering temperature ranges of 25-400 °C.

Fourier-transform infrared spectroscopy (FTIR)

The FTIR was used to investigate any interaction between the drug and polymers[9]. This employed FTIR spectrophotometer (Bruker Tensor 27, Germany). FTIR spectra of Telmisartan, Sodium bicarbonate, HPMC E5, and their binary SDS were

recorded using FTIR spectrophotometer. Samples were mixed with potassium bromide (spectroscopic grade) and compressed into disks using hydraulic press before scanning from 4000 to 400 cm^{-1}.

Powder X ray diffraction (XRD)

The XRD patterns of the pure drug, pure sodium bicarbonate, pure HPMC and their formulations were collected using a X-ray diffractometer (GNR APD 2000 pro-X-ray diffractometer, Novara, Italy). Data collection was performed at ambient temperature, using 2θ scan axis with continuous scan mode. The scanning step size was adjusted to 0.03 and scan range of 3–65.

Preparation of fast disintegrating tablets (FDTs)

The formulation showed the best release pattern was used to prepare the *FDTs* which contained an amount equivalent to 40 mg of the drug per tablet. The composition of the prepared tablet formulation is depicted in **Table 2**. The drug or its equivalent formulation was mixed with the excipients for 10 min using the bottle method, before compression into tablets using 8 mm die and the tablet weight was adjusted to 220mg. This process employed single punch tablet machine (Royal Artist, Kapadia Industrial Estate, BLDG, Mumbai, India) and the compression force were adjusted to produce tablets having a hardness of 4-5 kg/inch^2.

Table 2. Master formula for preparation of 40mg telmisartan tablets

Ingredients	Formula of NaHCO₃ (mg/tablet)	Control tablet (mg/tablet)
Telmisartan	-	40
Drug-Sodium bicarbonate SDS	60	-
Mannitol (granular)	70	70
Avicel PH102	48	68
Croscarmellose sodium	10	10
Crospovidone	10	10
Magnesium stearate	2	2
Aerosil	20	20
Total weight	220	220
*Q_5 (%)	64.89% ± 0.91	5.40% ± 0.34

* Q_5 (%) values are expressed as mean ± SD. (n=3)

Evaluation of fast disintegrating tablets

Uniformity of weight

Twenty tablets were selected and weighed on digital weighing balance, and average weight was determined. Then individual tablets were weighed, and the individual weight was compared with an average weight. The allowed percentage deviation is 7.5 %. The tablets meet the USP test if no more than two tablets are outside the limit and no tablet differs by more than twice the limit[10] .

Tablet friability

Ten tablets were weighed and placed in the friabilator (Erweka - Apparatebau- G.M.B.H, Western Germany) and the equipment was rotated at 25 rpm for 4 min. The tablets were taken out, de-dusted, and reweighed. The friability was calculated as the percentage loss which should not exceed 1 % [6].

Drug content

To ensure uniform potency, a content uniformity test was applied by random selection of 30 tablets. At least 10 tablets of them were individually subjected to drug content determination. The tablets were considered acceptable if the content of each of at least 9 tablets was in the range of 85–115 % of the labeled amount of telmisartan. The tenth tablet should not contain < 75 % or > 125 % of the labeled content. If these conditions were not met, the remaining 20 tablets must be assayed individually and all of them should be within the limit [6].

Disintegration test

The test was carried out on six tablets using tablet disintegration tester (Copley Scientific, Model: NE4-COP, UK) using 900ml of phosphate buffer pH 6.8 as a disintegration media and the time taken for the complete disintegration of the tablet was recorded [6].

Wetting time

The wetting time of the tablets was monitored using the procedures developed previously[11]. A filter paper is placed in a petri dish containing 6 ml of distilled water. A small amount of allura red powder was placed on the surface of the tablet before placing the tablet on the wet filter paper. The time required for developing a red color on the surface of the tablet was recorded and taken as the wetting time.

Statistical analysis

The Student`s t-test was used for statistical analysis to probe the significance of the difference between different formulations.

RESULTS AND DISCUSSION

Solid state characterization of the prepared formulations

The drug content of the prepared formulations was in the acceptable range. The drug content values were in the range of 93.45-110. 4 % w/w, excluding any segregation of the drug during SD formation. The solid-state characterization involved DTA, FTIR, X-ray diffraction and dissolution studies.

Differential thermal analysis (DTA)

Figure 3 presents an example of the DTA traces of telmisartan, HPMC E5, sodium bicarbonate and binary SDS. The Pure drug produced a characteristic endothermic peak with aTm being recorded at 268.89 °C indicating that the pure unprocessed telmisartan present in the crystalline form. The recorded endothermic peak correlates with the specifications of the supplier which indicated that the melting point of the drug is in the range of 266.37-273.37 °C. The recorded thermal behavior is similar to that recorded by other investigators[12]. The pure HPMC E5 thermogram showed the melting point in the range of 313.71-373.93 °C (**Figure 3A**). This is similar to that recorded by other investigators[6,13] but it is important to note that the recorded thermograms of HPMC did not show the endothermic peak of the bound moisture indicating the dryness of the polymer. Preparation of SDS of the drug with increasing concentrations of HPMC E5 resulted in initial broadening

Table 3. The characteristic absorption bands of FTIR spectra of the pure drug and the prepared formulations

Absorption band	Pure drug	Solid dispersion of telmisartan with HPMC E5	Formula prepared using NaHCO₃
O-H hydrogen bond	3428 cm⁻¹	3443 cm⁻¹	3428 cm⁻¹
C-H aromatic	3060 cm⁻¹	3061 cm⁻¹	3060 cm⁻¹
C-H aliphatic	2961 cm⁻¹	2927 cm⁻¹	2966 cm⁻¹
C=O stretching	1384 cm⁻¹	1329 cm⁻¹	1329 cm⁻¹
C=C stretching	1600 cm⁻¹	1616 cm⁻¹	1557 cm⁻¹
C-N stretching	1696 cm⁻¹	1695 cm⁻¹	1693 cm⁻¹
C=N stretching	1459 cm⁻¹	1461cm⁻¹	1557 cm⁻¹

and decrease in the Tm of the main endothermic peak of the drug without complete disappearance even at the higher polymer ratio (**Figure 3B**). This change in the melting transition was accompanied by a gradual reduction in the enthalpy. This effect indicates a possible partial transformation of the drug from crystalline to amorphous form. Similar effects have been recorded after formulation of SDS of HPMC with other drugs[13]. For pure sodium bicarbonate, the thermogram showed endothermic peak starting at 85.72 °C and ending at 98.92 °C. This was attributed to the release of the adsorbed moisture from the sodium bicarbonate. Another broad peak was recorded in the range of 130.68-187.9 °C which corresponding to the melting and decomposition of sodium bicarbonate. The formulation prepared from the drug with sodium bicarbonate had resulted in complete disappearance of the endothermic peak of the drug in 1: 0.5 (drug: sodium bicarbonate) weight ratio (**Figure 3B**). This effect indicates the possible transformation of the drug from crystalline to amorphous form.

FTIR spectroscopy

Figure 4 shows the FTIR spectra of telmisartan, sodium bicarbonate, HPMC E5 and the prepared SDS formulations. The FTIR spectrum of pure telmisartan and the prepared SDS with HPMC E5 showed the characteristic peaks of the drug at the specified wave number (cm)⁻¹ corresponding to each functional group as indicated in **Table 3**. This is similar to that reported by other workers[14]. This revealed absence of interaction between the drug and HPMC E5. The FTIR spectrum of the prepared formulation of the drug with sodium bicarbonate showed alterations in the main absorption bands of pure drug reflecting a significant interaction between the drug and sodium bicarbonate. These alterations were manifested as a shift in the position of C-N stretching peak from 1669 cm⁻¹ in pure drug to 1693 cm⁻¹ in the prepared formulation. In addition, the position of a C=N

stretching peak was shifted from 1459 cm⁻¹ in pure drug to 1557 cm⁻¹ in the prepared formulation. This indicates hydrogen bond formation between sodium bicarbonate and a lone pair of an electron on the nitrogen atom, therefore, making a dipolar molecule and subsequently increased the solubility of the molecule.

X-ray Diffraction

Figure 5 shows the XRD pattern for pure telmisartan, pure HPMC E5, pure sodium bicarbonate and SDS. Characteristic peaks appeared in the XRD for telmisartan showed high-intensity peaks at 2θ values of 6.856, 14.253, 15.082, 19.065 and 22.35. This complies with the published data[15]. The XRD pattern of HPMC E5 did not show any distinct peak reflecting the amorphous nature of the polymer. This correlates with the published data on the polymer[16]. The XRD pattern of unprocessed sodium bicarbonate reflected its crystalline nature with the diffraction pattern showing distinct peaks. In case of SD of the drug with HPMC E5, sodium bicarbonate and aerosil respectively in a ratio (1: 2: 2: 1) the diffraction peaks disappeared suggesting the transformation of telmisartan from crystalline to amorphous form (Figure 5 (A)). The same was recorded in case of the formulation of the drug with sodium bicarbonate at the weight ratio of 1: 0.5 (**Figure 5B**) suggesting the transformation of the drug to the amorphous form. This result confirms the data obtained after thermal analysis of the same formulations.

Drug dissolution

Figure 6 shows the dissolution profile of the drug powder in a pure state or as binary SD with different polymers or with sodium bicarbonate. The dissolution parameters are presented in Table1. The dissolution profile of pure drug indicated slow dissolution with only 6.41 % ± 0.28 being released in the first 5 min This correlates with the published work of the same drug[17]. Preparation of the binary SD of the drug with Gelucire 44/14 or PEG4000 resulted in
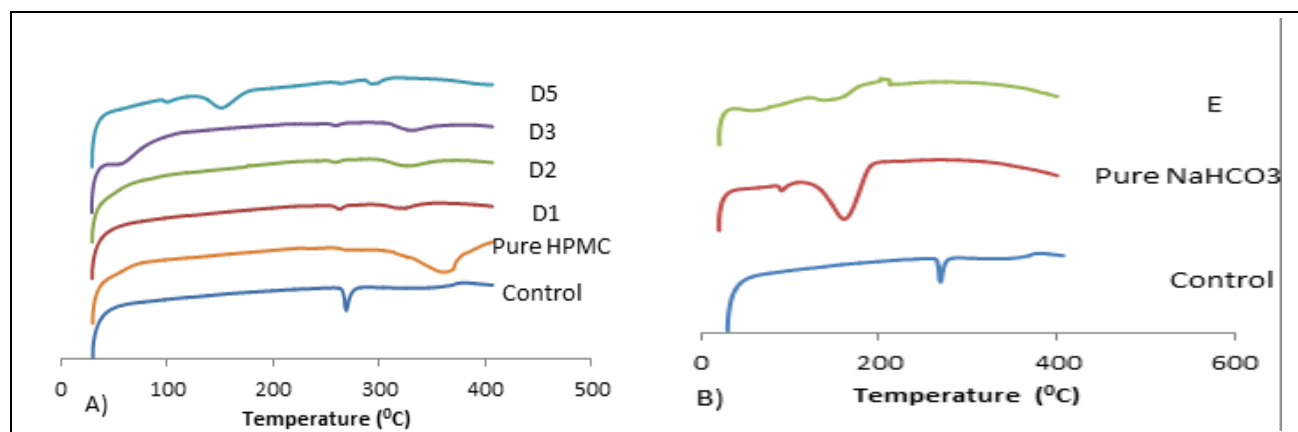
Figure 3. Panel A: Thermograms of unprocessed telmisartan (control), pure HPMC E5 and solid dispersions of telmisartan with increasing concentrations of HPMC E5 (D₁, D2, D3 andD₅). Panel B: Thermograms of telmisartan (control), pure sodium bicarbonate, and solid dispersion of telmisartan with sodium bicarbonate 1:0.5 (E) respectively. Formulation details are in Table 1.
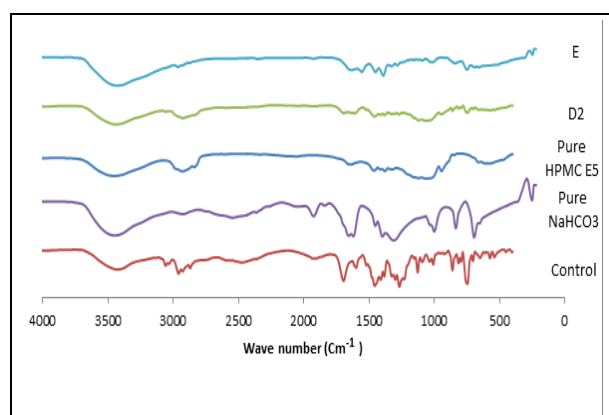
Figure 4: FTIR spectra of telmisartan (control), sodium bicarbonate, HPMC E5, and their solid dispersions. The traces from bottom to top are pure telmisartan (control), pure sodium bicarbonate, pure HPMC E5, drug-HPMC E5 solid dispersion (D2) and solid dispersion of telmisartan with sodium bicarbonate 1:0.5 (E) respectively.

a slight increase in the dissolution rate of the drug even at the highest polymer concentration (**Figure 6 A, B**) and **Table 1**). The binary SD of the drug with Pluronic F68 and HPMC E5 resulted in an increase in the dissolution rate compared to the pure unprocessed drug. Formulation of the binary SD of the drug with Pluronic F68 at a weight ratio of 1:1 (C1) resulted in a significant increase in drug dissolution compared with the unprocessed dug ($p < 0.05$) with 27.05% $\pm$ 2.06 of the dose being dissolved in the first 5 min. Increasing the polymer concentration (formula C2 and C3) resulted in a slight reduction in the dissolution rate of the drug

compared with formula C1, with the amount dissolved in the first 5 min being 24.6 $\pm$ 1.52 and 24.92 $\pm$ 3.6 for the formula C2 and C3 respectively (**Figure 6C**) and **Table 1**). In case of HPMC E5 the binary solid dispersions resulted in an increase in the dissolution rate in 1:1 drug: polymer, The weight ratio (D1). At this ratio, the formulation liberated 13.9% $\pm$ 1.56 of the drug in the first 5 min. There was a slight increase in the % dissolved of the drug upon increasing the polymer concentration to 2 in the formulation D2, but further increase in the polymer concentration slightly decreased the dissolution rate (**Figure 6D** and **Table 1**). The enhanced dissolution rate after solid dispersion formation of the drug with HPMC E5 can be attributed to crystalline structure modification and partial or complete amorphousization as revealed from the thermal analysis and X-Ray diffraction data. Similar explanation was used to describe the dissolution enhancement of other drugs after solid dispersion formation with the same polymer[6]. Sodium bicarbonate was added as a second excipient to solid dispersion showing a potential for enhanced drug dissolution. When sodium bicarbonate was added to a solid dispersion of the drug with Pluronic F68 in the ratio of (1: 2: 2) drug: excipient: sodium bicarbonate respectively (formula C4) the dissolution rate was increased to 33.025% $\pm$ 0.8 of the dose in the first 5 minutes. Incorporation of sodium bicarbonate with HPMC E5 in solid dispersion system (formula D4) significantly enhanced the dissolution rate of the drug with the % dissolved in the first 5 min reaching 45.3 % $\pm$ 5.6 in (**Figure 6E** and **Table 1**). The addition of aerosil to this formulation (formula D5) increased the % Q5 to reach 72.6.%. $\pm$ 0.81 in (**Figure 6F** and **Table1**) This increase in the dissolution rate can be
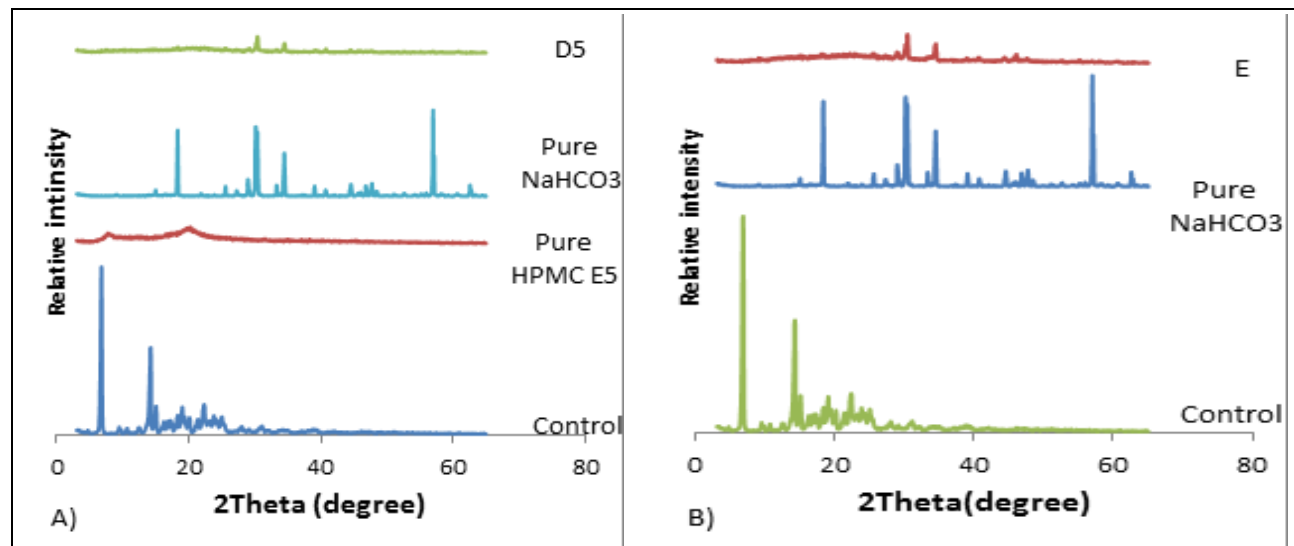
Figure 5. X-ray diffraction pattern of pure telmisartan (control), pure HPMC E5, pure sodium bicarbonate and their solid dispersions D5 (panel A) and E (panel B). Formulation details are in Table 1.

explained based on the adsorption of the prepared solid dispersion on the surface of aerosil which increases the surface area with a consequent increase in the dissolution rate of the drug. The presence of a drug in the amorphous state in this formulation can contribute further to the enhanced dissolution of the drug. Dissolution enhancement was recorded for drug adsorbed on the solid surfaces and the results were similarly explained[18].

When sodium bicarbonate was employed alone in the preparation of solid dispersion system instead of the polymer at the weight ratio of 1:1 and 1:0.5 drug: sodium bicarbonate (formula F and E) the dissolution rate was enhanced significantly. The recorded % Q_5 values were 88.94% $\pm$ 1.31 and 84.77 % $\pm$ 1.1 for both formula E and F respectively (**Figure 6F** and **Table 1**). This increase in the dissolution rate can be attributed to the nature of the drug which is readily ionizable and its solubility is pH dependent. Hence, the drug solubility increased upon the addition of sodium bicarbonate due to the increase in the pH of the diffusion layer. Another explanation for the enhanced dissolution rate was based on the results of powder X-ray diffractometry and thermal analysis, which indicated the transformation of the drug from crystalline to amorphous form.

The formula which produced the highest percentage of the drug dissolved in first 5 min $Q_{5 (\%)}$ was in the order: E > F > D5 where the % drug dissolved was 88.94 $\pm$ 1.31, 84.77 $\pm$ 1.1 and 72.6 $\pm$ 0.81 (mean $\pm$ SD) for each formula respectively. However, there was no statistical difference between formulae E and F (P > 0.05). Meanwhile, the statistical analysis showed highly significant difference between formulae E and D5 (p < 0.01).

Based on these results formula E which composed of telmisartan with sodium bicarbonate in a ratio (1: 0.5) was selected for the preparation of rapidly dissolving tablet of telmisartan. This selection was based on the enhanced dissolution rate, more palatable taste in the buccal cavity and relatively inexpensive material which is more economical for the pharmaceutical industry and easier in processing compared with the solid dispersions prepared using polymers.

Characterization of fast disintegrating tablets (FDTs)

The prepared tablets were found to be of uniform weight with the recorded deviation from the average weight being < 4.5 %. The recorded friability values were in the range of 0.85 %. This is acceptable based on the acceptance criteria of the USP (USP 2009). The drug content was in the range 93.45 % – 110.4 %. Dissolution profiles of the prepared tablets are shown in (**Figure 7**), which indicates that the percent drug release after 5 min (Q_5) in control tablet reached only 5.4 % $\pm$ 0.34 compared with 64.89% $\pm$ 0.91 (**Figure 7** and **Table 2**) in case of tablets sodium bicarbonate. The unpaired t-test for the effect of sodium bicarbonate on the % release of telmisartan for the test tablets compared with control indicated a highly significant effect of sodium bicarbonate (p < 0.01). Development of fast disintegrating tablets with subsequent rapid dissolution was employed to enhance dissolution rate of drugs including those which have dose of 100 mg[19]. The developed formulation can be considered promising for enhancing the dissolution rate of telmisartan.
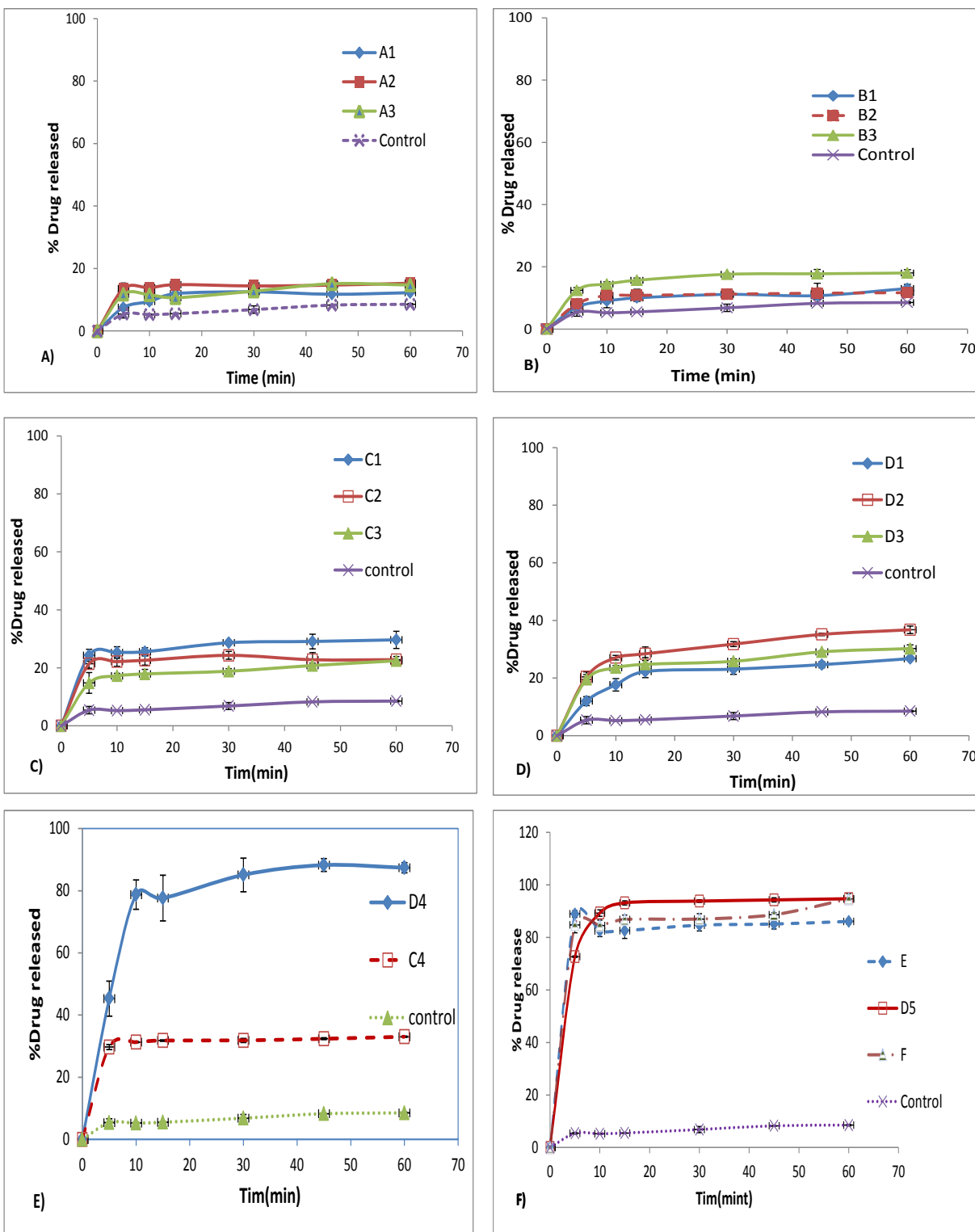
Figure 6. Dissolution profiles of telmisartan from its unprocessed powder and from solid dispersions with different additives. Formulation details are in Table1. Mean $\pm$ SD, n=3.
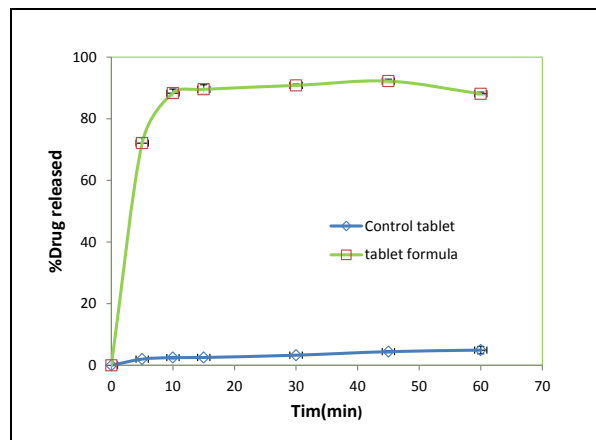
Figure 7. Dissolution profile of the selected fast dissolving tablet (FDT) compared with the control. Mean ± SD, n=3.

CONCLUSION

SD with a polymer or with sodium bicarbonate was able to enhance the dissolution rate of telmisartan depending on the presence of the pH modifying agent (sodium bicarbonate) and concentration of the polymer. The formula prepared using sodium bicarbonate with the drug in (0.5: 1) ratio was selected for preparation of rapidly disintegrating tablets with subsequent rapid dissolution. The selection of this formula was based on the highest percentage of the drug dissolved in first 5minQ_5 (%), low alkalinity, more palatable taste in the buccal cavity and inexpensive material which is more economical to the pharmaceutical industry.

Authors contributions

Both authors had equally contributed to the work in this research.

Conflict of Interest

The authors declare that they don't have any conflict of interest.

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