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Original Article

OPTIMIZATION OF STARCH GLYCOLATE AS NOVEL SUPERDISINTEGRANT IN THE FORMULATION OF GLIPIZIDE FAST DISSOLVING TABLETS THROUGH 2^3FACTORIAL DESIGN

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ABSTRACT

Objective: To synthesize, characterize and evaluate starch glycolate as a superdisintegrant in the formulation of Glipizide fast dissolving tablets by employing 2^3 factorial designs.

Methods: Starch glycolate was prepared and its physical and micromeritic properties were performed to evaluate it. The fast dissolving tablet of Glipizide was prepared by employing starch crotonate as a superdisintegrant in different proportions in each case by direct compression method using 2^3 factorial design for the evaluation of tablet parameters like disintegration and dissolution efficiency in 5 min.

Results: The starch glycolate prepared was found to be fine, free-flowing and amorphous. Starch glycolate exhibited good swelling in water with a swelling index (10%). The study of starch glycolate was shown by fourier transform infrared spectra (FTIR). The drug content (100±5%), hardness (3.5–4 kg/sq. cm), and friability (<0.15%) was been effective with regard to all the formulated fast dissolving tablets employing starch glycolate. The disintegration time of all the formulated tablets was found to be in the range of 13±0.015 to 180±0.014 sec. The optimized formulation F8 had the least disintegration time i.e., 13±0.015 sec. The wetting time of the tablets was found to be in the range of 8±0.015 to 95±0.013 sec. The *In vitro* wetting time was less (i.e., 8±0.015s) in optimized formulation F8. The water absorption ratio of the formulated tablets was found to be in the range of 75±0.012 to 150±0.014%. The percent drug dissolved in the optimized formulation F8 was found to be 99.95% in 5 min.

Conclusion: Starch glycolate was an efficient superdisintegrant for fast-dissolving tablets. The disintegration and dissolution efficiency of the fast dissolving tablets of glipizide was good and depended on the concentration of superdisintegrant employed i.e., starch glycolate, sodium starch glycolate, crospovidone. The formulated fast dissolving tablets of glipizide exhibited good dissolution efficiency in 5 min which can be used for the fast therapeutic action of glipizide.

Keywords: Optimized, Superdisintegrant, Fast dissolving, Optimization, Starch glycolate

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INTRODUCTION

Fast dissolving tablets emerge as one of the popular and widely accepted dosage forms, especially for pediatric patients because of incomplete development of the muscular and nervous system and a case of geriatric patients suffering from Parkinson's disorder or hand tremors. Few solid dosage forms like capsules and tablets are present days facing the problems like difficulty in swallowing (dysphagia), resulting in many incidences of non-compliance and making the therapy ineffective [1]. Oral dosage form and oral route are the most preferred route of administration for various drugs that had limitations like first-pass metabolism, psychiatric patients, bedridden and uncooperative patients [2]. FDTs are disintegrating or dissolve quickly in the saliva without a need of water. Fast dissolving tablets are designed to dissolve in saliva remarkably faster, within a few secs (less than 60 secs), and those are real fast-dissolving tablets [3]. FDTs formulations contain super disintegrants to enhance the disintegration rate of a tablet in the buccal cavity [4]. FDTs have advantages such as easy portability and manufacturing, accurate dosing, good chemical and physical stability and an ideal alternative for geriatric and paediatric patients [5]. FDTs have disintegrated quickly, absorb faster so, *in vitro* drug release time improves and this property of drugs (dosage form) enhanced bioavailability [6]. FDT formulations have the advantage of both conventional tablet formulation and liquid dosage form [7]. There are several technologies that are conventional or patented based on spray drying, cotton candy process, sublimation, melt granulation, direct compression freezes drying/lyophilisation, phase transition process, mass extrusion, etc. have been developed for manufacturing of FDTs [8]. This review contains brief information about FDTs including definition, advantages, needs or requirements of FDTs, salient features of FDTs, limitations, challenges in developing FDT [9], etc.

Glipizide; a second-generation sulfonylurea, act by stimulating the release of insulin from the pancreas, reducing blood glucose level in humans [10]. The present investigation deals with a systematic formulation approach for optimization of glipizide fast dissolving tablets employing starch glycolate, sodium starch glycolate, and crospovidone sodium as superdisintegrants. A 2^3 factorial design was applied to investigate the main and interaction effects of the three formulation variables i.e., starch glycolate (A), sodium starch glycolate (B), crospovidone (C) in each case to find the formula with less disintegration time and more dissolution efficiency 5 min and to permit arbitrary selection of tablets with immediate release of drug within 5 min. The result of formulation, optimization and evaluation of Glipizide fast dissolving tablets are described in this article.

MATERIALS AND METHODS

Materials

Starch glycolate (prepared in the laboratory), Sodium hydroxide, mannitol (Finar chemicals Ltd, Ahmedabad), Glipizide, Potato starch, Sodium Starch Glycolate, Crospovidone (Yarrow chem. Products, Mumbai), Distilled water. Microcrystalline cellulose (Qualigens fine chemicals, Mumbai), Talc and Magnesium Stearate (Molychem, Mumbai).

Methods

Preparation of starch glycolate (a novel superdisintegrant)

Initially, 10 parts of potash starch were slurried in 10 parts of distilled water and 10 parts of starch glycolate were dissolved in distilled water. Both are stirred continuously for 30 min. adjust the pH to 3.5 by using 10M NaOH and stirred for 16 h at 25 °C. After 16 h it was filtered and washed with distilled water. The

product was kept in the oven at 60 °C for 2 h. The product obtained was ground and sieved [11].

Characterization of starch glycolate

The starch glycolate prepared was evaluated for the following

Solubility

Solubility of starch glycolate was tested in water, aqueous buffer of pH 1,2,3,3, and 5.393 and organic solvents such as alcohol, dichloromethane, chloroform, acetone and petroleum ether [12].

pH

The pH of 1% w/v slurry was measured [12].

Melting point

Melting point was determined by using the melting point apparatus [12].

Viscosity

Viscosity of 1% dispersion in water was measured using Ostwald Viscometer [12].

Swelling index

Starch glycolate (200 mg) was added to 10 ml of water and light liquid paraffin taken in two Different graduated test tubes and mixed. The dispersion in the tubes was allowed to stand for 12 h. The volumes of the sediment in the tubes were recorded [12]. The swelling index of the material was calculated as follows.

$$S.I\ (\%) = \frac{\text{Volume of sediment in water} - \text{volume of sediment in light liquid paraffin}}{\text{Volume of sediment in light liquid paraffin}} \times 100$$

Test for gelling property

The gelling property (gelatinization) of the starch and starch glycolate prepared was evaluated by heating a 7% w/v dispersion of each in water at 100 °C for 30 min [12].

Particle size

Particle size analysis was done by sieving using standard sieves [12].

Density

Density (g/cc) was determined by the liquid displacement method using benzene as a liquid [12].

Bulk density

Bulk density (g/cc) was determined by the three-tap method in a graduated cylinder [12].

Angle of repose

Angle of repose was measured by the fixed funnel method [12].

Compressibility index

Compressibility index (CI) was determined by measuring the initial volume (V_0) and final volume (V) after hundred tapings of a sample of starch lactate in a measuring cylinder [12]. CI was calculated using the equation.

$$\text{Compressibility index (CI)} = \frac{V_0 - V}{V} \times 100$$

Where, V_0= initial volume of powder, V= final volume of powder

Fourier transform infrared (FTIR) spectroscopy

FTIR spectra of starch glycolate were recorded on samples prepared in Potassium Bromide (KBr) disks using a BRUKER FT–IR, (Tokyo, Japan). Samples were prepared in (KBr) disks by means of a hydrostatic press at 6-8 tons pressure [12]. The scanning range was 500 to 3000 cm^{-1}.

X-ray diffraction

Diffraction pattern of starch glycolate was recorded with an x-ray diffractometer (analytical spectra's Pvt. Ltd., Singapore). X-ray diffraction was performed at room temperature (30 °C) with a diffractometer; target, Cu(λ1.53 A), filter, Ni; voltage, 35 kV; current 30mA; time constant 10 mm/s; scanning rate 2 °/min; measured from 10-35 ° at full scale 200 [12].

Ester test

To 1 mg of Starch glycolate, 2m of ethanol and 1 ml of 0.1 ml NaOH were added. To this, a phenolphthalein indicator was added [12]. The colour change was observed.

Preparation of glipizide fast dissolving tablets

The tablets were prepared by direct compression method. The composition of different formulations of glipizide fast dissolving tablets was shown in table no 1. For uniformity in particle size, each ingredient was passed through # 80 mesh-sized screen before mixing. Starch glycolate, sodium starch glycolate, crospovidone, mannitol and microcrystalline cellulose were accurately weighed and mixed using mortar and pestle and then added to glipizide. Finally, talc and magnesium stearate were added to the powder mixture [13]. Finally, the mixed blend was compressed by using an eight-station rotator Karnavathi machinery Pvt, ltd., Ahmedabad, India.

Evaluation of glipizide fast dissolving tablets

Hardness

The tablet hardness, which is the force that requires breaking in a diametric compression force. The hardness tester used in the study was the Monsanto hardness tester, which applies force to the tablet diametrically with the help of an inbuilt spring and expressed in kg/cm^2 [14].

Table 1: Formulae of glipizide fast dissolving tablets employing starch glycolate prepared by direct compression method

Ingredients	F1	F2	F3	F4	F5	F5	F7	F8
Glipizide	5	5	5	5	5	5	5	5
Starch glycolate	---	10	---	10	---	10	---	10
Sodium starch glycolate	---	---	10	10	---	---	10	10
Crospovidone	---	---	---	---	10	10	10	10
Mannitol	87	77	77	57	77	57	57	57
Micro crystalline cellulose	100	100	100	100	100	100	100	100
Talc	4	4	4	4	4	4	4	4
Magnesium stearate	4	4	4	4	4	4	4	4
Total	200	200	200	200	200	200	200	200

Uniformity of weight

Weight variation test was done with 20 tablets. It is the individual variation of tablets weighed from the average weight of 20 tablets [14].

Average weight of the tablet	% Deviation
80 mg or less	±10
More than 80 mg or less than 125 mg	±7.5
125 mg or less	±5

Friability

The friability of tablets was measured using a Roche friabilator. Tablets were rotated at 25 rpm for 4 min or up to 100 revolutions. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated [14].

$$F = \frac{W\,(initial) - W\,(final)}{W\,(initial)} X100$$

Drug content uniformity

For content uniformity, ten tablets were weighed and powdered a quantity of powder equivalent to 10 mg of Glipizide was extracted into 7.4 phosphate buffer and filtered. The Glipizide content was determined by measuring the absorbance spectrophotometrically at 254 nm after appropriate dilution with 7.4 phosphate buffer. The drug content was calculated as an average of three determinations [14].

Wetting time

The wetting time of tablets was measured using a very simple procedure five circular tissue papers of 10 cm diameter were placed in a petri dish with a 10 cm diameter. Ten ml of water containing a water-soluble dye (Amaranth) was added to the petri dish. A tablet was carefully placed on the tissue paper. Time required for water to reach the upper surface of the tablet was noted as wetting time [14].

Water absorption ratio

A piece of tissue paper folded twice in a small petri dish containing 5 ml of water. A tablet was put in the tissue paper allowed to completely wet. The wetted tablet was then weighed [14]. Water absorption ration R was determined using the following equation.

$$R = 100\ (W_a - W_b)/W_b$$

Where,

W_a = weight of tablet after water absorption.

W_b = weight of tablet before water absorption.

***In–vitro* disintegration time**

Disintegration time for FDTs was determined using USP disintegration apparatus using pH 7.4 phosphate buffer. The volume of the medium was 900 ml and the temperature was 37±0.2 ℃. The time in second taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured [14].

***In–vitro* dissolution rate studies**

The in vitro dissolution rate studies of glipizide Fast Dissolving Tablets were performed using 8 stage dissolution test apparatus (Electrolab TDT-08L) fitted with paddles (50 rpm) at 37±0.5 ℃, using 7.4 phosphate buffer (900 ml) as a dissolution media. At the predetermined time intervals, 5 ml samples were withdrawn, filtered through 0.45µ membrane filter, diluted and assayed at 275 nm using a shimadzu UV/Visible double beam Spectrophotometer. Cumulative percentage release was calculated using standard absorbance from the calibration curve. All the dissolution experiments were conducted in triplicate (n = 3) [14].

Drug–excipients compatibility studies

The compatibility of Starch glycolate with the selected drug (Glipizide) was evaluated in DSC and FTIR.

Differential scanning calorimetry (DSC)

DSC thermograms of Glipizide and their mixtures (1: 1) with starch glycolate were recorded on Perkin Elmer Thermal Analyzer Samples (2-5 mg) were sealed into aluminum pans and scanned at a heating rate of 10 °C min^{-1} over a temperature range 30–350 °C [15].

Infrared spectroscopy

FTIR spectra of Glipizide and their mixtures (1: 1) with starch glycolate were recorded on a Perkin Elmer, IR Spectrophotometer model: Spectrum RXI, using KBr disc as reference [15].

RESULTS AND DISCUSSION

The starch glycolate prepared was found to be a fine, free-flowing amorphous powder. The physical and micromeritic properties of the starch glycolate are summarized in table 2. It was insoluble in aqueous solvents and insoluble in organic solvents tested (methanol, petroleum ether, dichloromethane, and chloroform) the pH of 0.1% aqueous dispersion was 3.83

Starch glycolate exhibited good swelling in water. The swelling index was 10% all micrometric properties indicated good flow and compressibility needed for solid dosage from manufacturing. The density of starch glycolate was found to be 0.76 g/cc. The FTIR spectrum of starch and starch glycolate was shown in fig. 1, 2. The presence of peaks absorption at 1727.18 cm-1 characteristic peaks of ester, so from FTIR studies it was concluded that starch glycolate (ester) was formed when starch was allowed to react with formic acid. The X-ray diffraction pattern (fig. 3) of starch glycolate showed characteristic peaks, which indicates that the structure was slightly crystalline. The disappearance of the pink color in the ester test confirmed the presence of ester, i.e., starch glycolate.

As the starch glycolate was slightly crystalline and it had got all the characteristics of superdisintegrants it was concluded that starch glycolate can be used as novel superdisintegrants in the formulation of fast dissolving tablets.

Table 2: Physical and micromeritic properties of the starch glycolate prepared

Parameters	Observation
Solubility	Insoluble in all aqueous and organic solvents tested
pH (1% w/v aqueous dispersion)	3.8±0.1
Melting Point	Charred at 190-210 °C
Viscosity (1%w/v aqueous dispersion)	1.00873±0.0001cps
Swelling index	10±0.5%
Gelling property	No gelling and the swollen particles of starch glycolate separated from the water. Whereas in the case of starch, it was gelatinized and formed gel.
Particle Size	6.02±0.2 (80 mesh)
Density	1.053±0.0006 g/cc
Bulk Density	0.76±0.05 g/cc
Angle of Repose	33.02°±0.045°
Compressibility Index	16.27±0.02 %

n=3±SD (Standard deviation)

Drug excipient compatibility studies

The compatibility of starch glycolate with the selected drug (Glipizide) was evaluated by DSC and FTIR studies. The DSC thermograms of glipizide and glipizide–starch glycolate are shown in fig. 4 and 5. The DSC thermograms of Glipizide and GL–SG exhibited exothermic peaks at 212.94 °C and 208.16 °C respectively. These melting peaks of GL and GL–SG correspond to

the melting points of glipizide (200-203 °C). The peaks observed in the DSC thermograms of glipizide and GL–SG mixtures correspond to the melting points of the respective drug indicating no interactions between the selected drug and Starch glycolate polymer. The DSC study, thus, indicated no interaction between starch glycolate and selected drug.

The FTIR spectra of GL and GL–SG are shown in fig. 6 and 7. The characteristic FTIR bands of GL at 2932.23 cm^{-1} (aromatic C-H), and GL-SG at 2933.45 cm^{-1}(aromatic C-H) and GL at 1329.53(SO_2NH) and GL-SG at 1328.71(SO_2NH) were all observed in the FTIR spectra of both GL and GL–SG. These FTIR spectra observations also indicated no interaction between Starch glycolate and the drug selected.

Thus the results of DSC and FTIR indicated no interaction between the selected drug and starch glycolate, the new superdisintegrant. Hence, starch glycolate could be used as a superdisintegrant in the design of fast dissolving tablets of the selected drug.

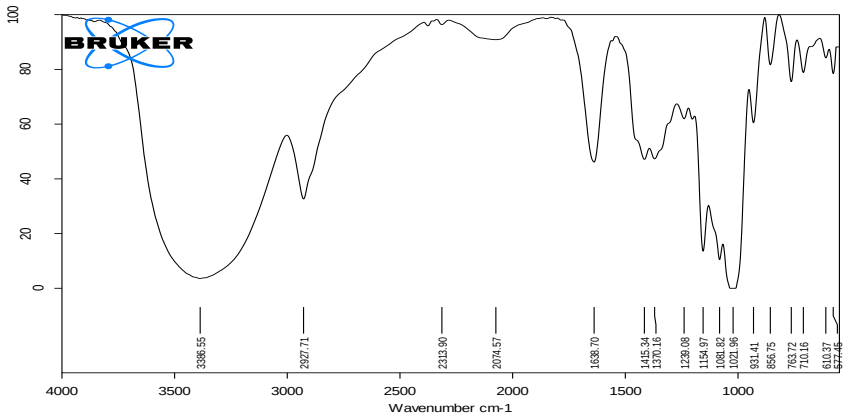

Fig. 1: FTIR spectra of potato starch

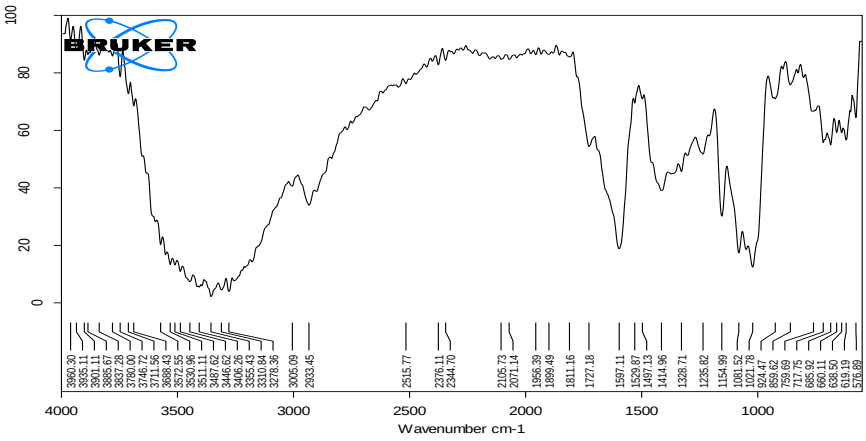

Fig. 2: FTIR spectra of starch glycolate

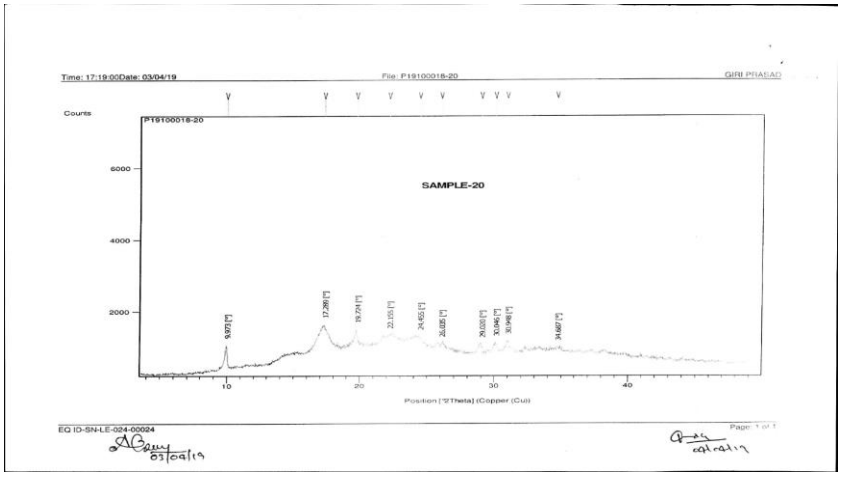

Fig. 3: X-ray diffraction pattern of starch glycolate

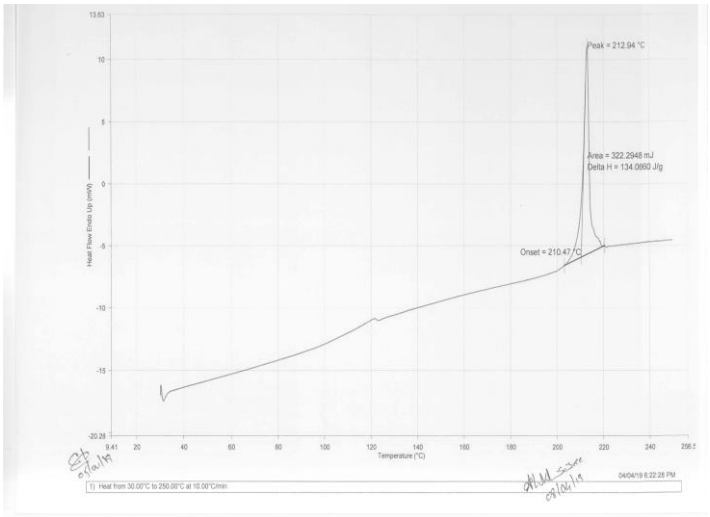

Fig. 4: DSC Thermo gram of glipizide pure drug

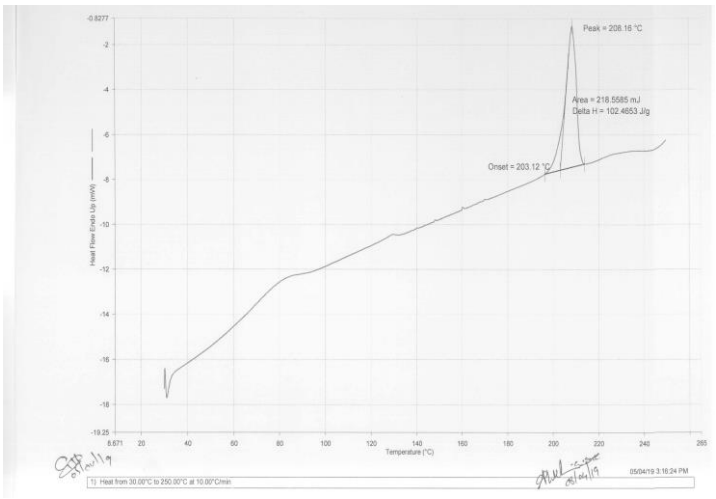

Fig. 5: DSC thermogram of glipizide with starch glycolate

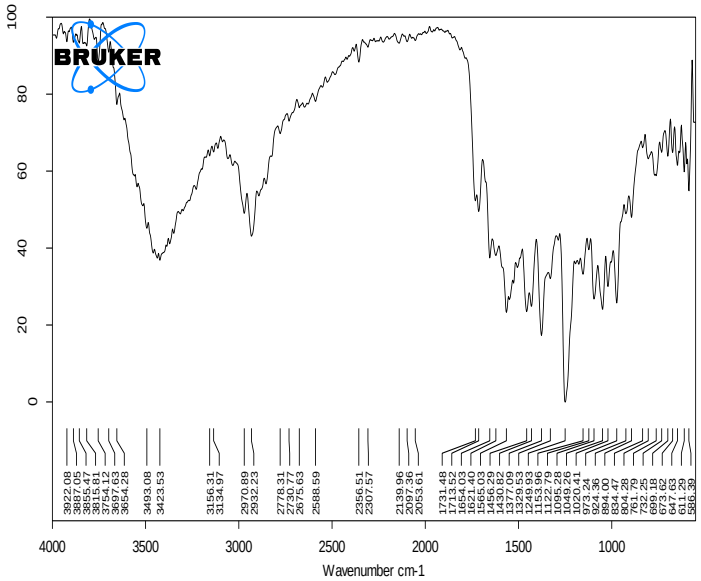

Fig. 6: FTIR spectra of glipizide pure drug

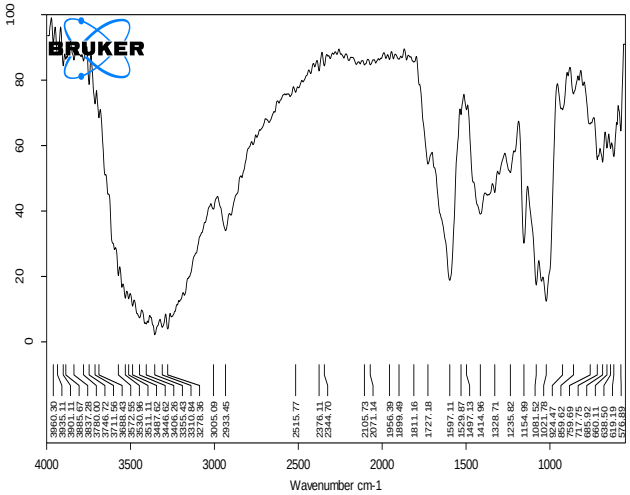

Fig. 7: FTIR spectra of glipizide with starch glycolate

Evaluation of tablets

Fast dissolving tablets each containing 100 mg of glipizide could be prepared by employing starch glycolate and other known superdisintegrants, sodium starch glycolate and crospovidone by direct compression method.

Hardness

Hardness of the tablet was in the range of 3.5–4 kg/sq. cm. it indicates good strength with a capability to resist physical and pre-functionary stress conditions during handling. The hardness was much less in comparison to tablets having the hardness in the range of 5.1±0.11 to 6.4±0.11, prepared by Asmaa A. Bayoumi [16].

Friability

Weight loss on the friability test was less than 0.15 % in all cases which is less in comparison to the tablets having 0.42% friability, prepared by Amrita Sony and *et al.* [17].

Drug content

All the fast dissolving tablets prepared contained glipizide within 100±5% of the labeled claim which is more when compared to the tablets having drug content 97.05 to 99.13, prepared by S Jaya and *et al.* [18].

Wetting time and water absorption ratio

The result of wetting time and water absorption ratio was found to be within the prescribed limits and satisfy the criteria of the dissolving tablets (fig. 8). The wetting time was less in F_8 i. e 8±0.015 secs which consists of a combination of 5 % starch glycolate, 5 % sodium starch glycolate and 5 % crospovidone. It is less when compared to the tablets having a wetting time of 17.75±1.67 secs, prepared by Rasha Khalid Dhahir and *et al.* [19].

The water absorption ratio of the formulation F8 was observed to more i. e 125±0.015 % which is relatively more when compared to the tablets having water absorption ratio in the range of 73.2 to 94.38%, prepared by Bandaru Nagajyothi and *et al.* [20].

***In vitro* disintegration time**

The disintegration time of all the formulated tablets was found to be in the range of 13±0. 03 to 124±0.03 secs as indicated in the table 3. The disintegration time was relatively less when compared to the tablets with a disintegration time of 20±10 secs, prepared by Mangesh M Kumare and *et al.* [21].

***In vitro* dissolution rate studies**

The drug dissolution from the glipizide fast dissolving tablets employing starch glycolate and other known superdisintegrants were in table 4. and fig. 9, 10. The dissolution parameters of the formulation from (F1–F8) which were made by direct compression method were shown in the table 5. In all these cases the PD_5 (percent dissolved in 5 min) was more i. e 99.95±0.03% in F8 which consists at 5 % Starch glycolate, 5 % Sodium starch glycolate and 5 % crospovidone. The percent drug release is much more when compared to the tablets having the release of 96. 94±0.47% for 30 min, prepared by Krishna Mohan Chinnala and *et. al.* [22]. The same was in the case of DE_5 % (dissolution efficiency in 5 min). The PD_5 and DE_5 % revels that starch glycolate was effective at 5% starch glycolate, 5% sodium starch glycolate, and 5 % crospovidone when the formulations were made by direct compression using these superdisintegrants. The number of folds increases in DE_5% was given to table 5. From the results, it was concluded that starch glycolate (new superdisintegrant) could be used as superdisintegrant in the formulation of fast dissolving tablets of glipizide.

Fast dissolving tablets formulated employing starch glycolate (5%), sodium starch glycolate (5%) and crospovidone (5%) as superdisintegrants exhibited in disintegration and dissolution efficiency in 5 min. Formulation 8 gave a release of 99% in 5 min fulfilling the official specification, based on disintegration time and dissolution efficiency in 5 min. Formulation 8 is considered as a good fast dissolving tablet formulation of glipizide.

Table 3: Physical properties: hardness, friability drug content of glipizide fast dissolving tablets prepared by direct compression method

Formulation	Hardness (kg/cm²) n±SD	Friability (%) n±SD	Drug content mg/tab) n±SD	Disintegration time (sec) n±SD	Wetting time (sec) n±SD	Water absorption ratio (%) n±SD
F1	3.9±0.01	0.12±0.013	5±0.013	180±0.014	95±0.013	75±0.015
F2	3.5±0.03	0.13±0.015	5±0.012	110±0.013	93±0.012	100±0.014
F3	4.0±0.01	0.14±0.012	5±0.014	34±0.015	90±0.014	100±0.013
F4	3.8±0.04	0.12±0.014	5±0.015	59±0.013	55±0.015	75±0.012
F5	3.7±0.03	0.14±0.012	5±0.011	14±0.018	42±0.012	150±0.014
F5	3.9±0.01	0.15±0.012	5±0.015	24±0.012	7±0.018	100±0.011
F7	3.7±0.02	0.14±0.014	5±0.017	13±0.014	5±0.017	100±0.017
F8	4.0±0.04	0.12±0.013	5±0.013	13±0.015	8±0.015	125±0.015

n=3±SD (Standard deviation)

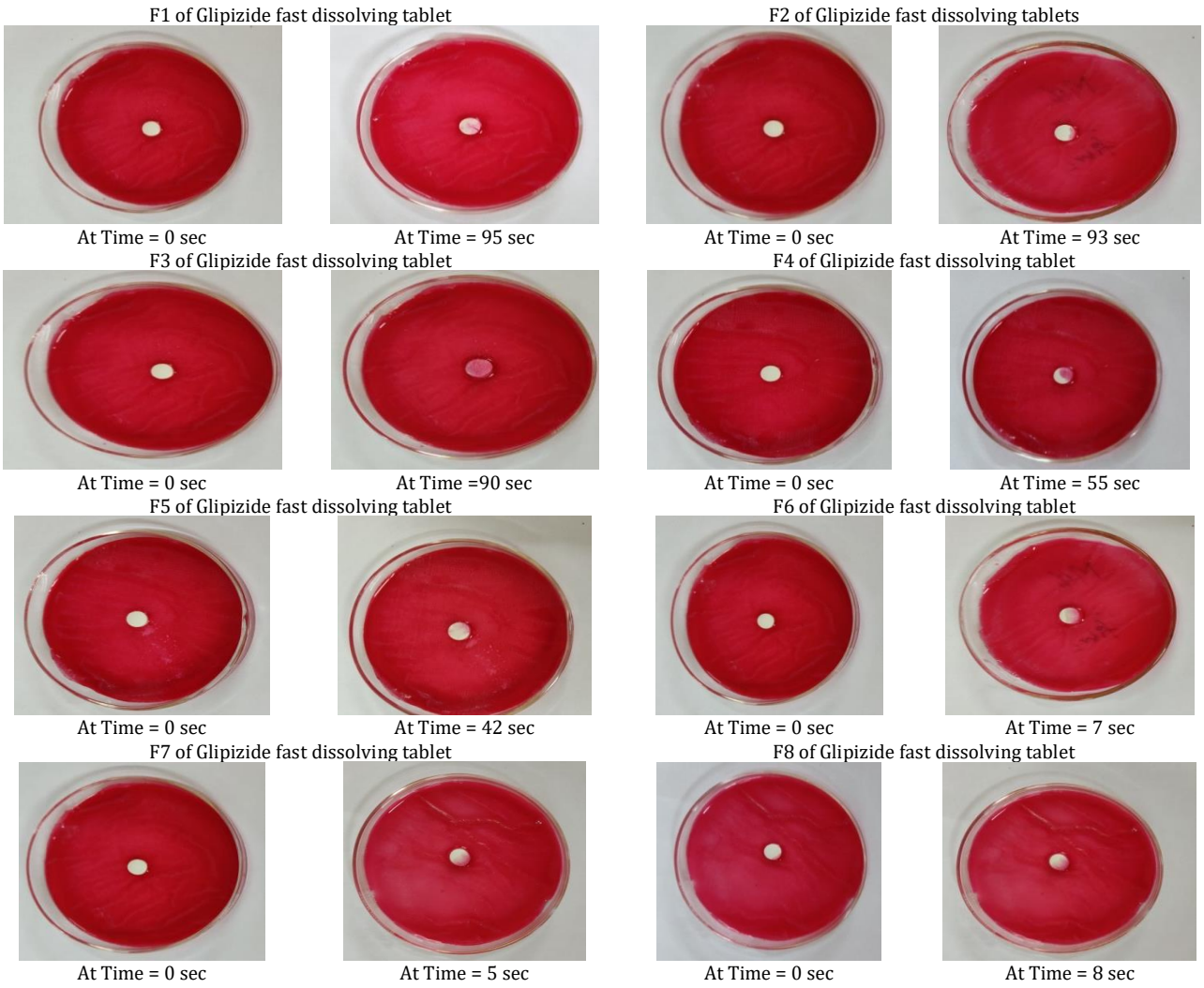

Fig. 8: Glipizide fast dissolving tablets prepared employing starch glycolate

Table 4: Dissolution data of glipizide fast dissolving tablets employing starch glycolate

Time (min)	F1	F2	F3	F4	F5	F5	F7	F8
5	78.97±0.02	95.75±0.05	99.87±0.05	99.58±0.08	95.33±0.05	99.53±0.04	99.31±0.04	99.95±0.03
10	79.58±0.04	101.02±0.03	---	---	99.71±0.04	---	---	---
15	80.39±0.03	---	---	---	---	---	---	---
30	81.10±0.01	---	---	---	---	---	---	---
45	82.52±0.02	---	---	---	---	---	---	---
50	95.75±0.05	---	---	---	---	---	---	---

n=3±SD (Standard deviation)

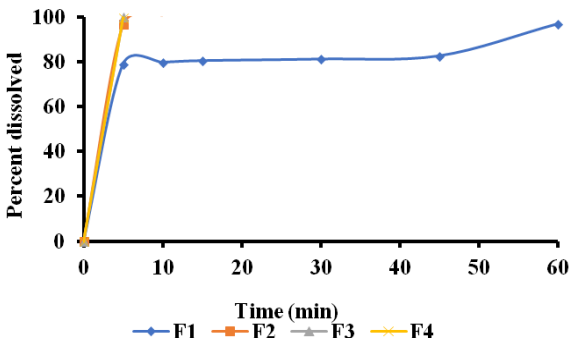

Fig. 9: Dissolution profiles of glipizide fast dissolving tablets prepared employing starch glycolate (F1-F4)

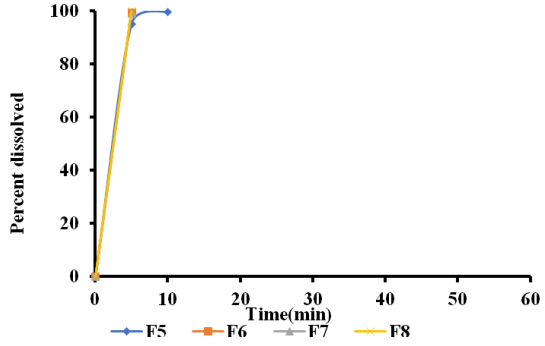

Fig. 10: Dissolution profiles of glipizide fast dissolving tablets prepared employing starch glycolate (F5-F8)

Table 5: Dissolution parameters of glipizide fast dissolving tablets formulated employing starch glycolate and other known superdisintegrants prepared by direct compression

Time (min)	F1	F2	F3	F4	F5	F5	F7	F8
PD_5	78.97±0.02	95.75±0.05	99.87±0.05	99.58±0.08	95.33±0.05	99.53±0.04	99.31±0.04	99.95±0.03
DE_5 %	72.8±0.01	92.6±0.03	96.1±0.05	96.1±0.05	91.4±0.04	95.8±0.05	96.1±0.05	96.3±0.02
No of folds increase in DE_5 %	----	1.27	1.32	1.32	1.25	1.31	1.32	1.32

n= 3±SD (Standard deviation), PD_5-Percent dissolved in 5 min, $DE_{5\%}$-Dissolution efficiency in 5 min

CONCLUSION

From the results obtained the following conclusions are drawn, all the fast dissolving tablets formulated employing starch glycolate were of good quality with regard to drug content, hardness and friability and fulfilled the official (IP/USP) requirements of compressed tablets with regard to the above mentioned physical properties.

With glipizide, drug release from the fast dissolving tablets formulated employing starch glycolate (5%) by direct compression was fast and within 5 min. Overall, starch glycolate was found to be a superdisintegrant that can be used along with sodium starch glycolate and crospovidone, and hence it could be used in the formulation of fast dissolving tablets to provide immediate release of the contained drug within 5 min. Hence, starch glycolate was recommended as a novel superdisintegrant in fast dissolving tablets for obtaining an immediate release of the poorly soluble drugs.

ABBREVIATION

M–Molar, NaOH–Sodium Hydroxide, °C-Degree Centigrade, #-Number, pH-Potential of hydrogen, ml-milliliter, g–grams, S. I-Swelling Index, W/V–Weight/Volume, FTIR-fourier transform infrared spectra

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AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICT OF INTERESTS

Declared none

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