Evaluating the Role of *Celosia argentea* Powder and Fenugreek Seed Mucilage as Natural Super-Disintegrating Agents in Gliclazide Fast Disintegrating Tablets

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ABSTRACT

Objective: The objective was to formulate gliclazide (GLZ) fast disintegrating tablets (FDTs) by using fenugreek seed mucilage and *Celosia argentea* powder as natural disintegrating agents as well as sodium starch glycolate as a synthetic disintegrating agent.

Experimental: An attempt was made to extract the fenugreek seed mucilage and prepare the *C. argentea* powder and evaluated both for various physicochemical characterizations. FDTs of GLZ were formulated by direct compression method using different concentrations (3-7% w/w) of fenugreek seed mucilage and *C. argentea* powder and compared with synthetic disintegrating agent sodium starch glycolate. The formulated tablets were evaluated for various physical tests like weight variation, friability, hardness, etc. and the complied results fall with the limits.

Results: Among all the formulations, F9 containing 7% *C. argentea* powder produced the least disintegrating time of 19 sec resulting in a higher drug release rate of 98.13% at the end of 60 min. *C. argentea* powder as a natural disintegrant showed better disintegrating property than the most widely used synthetic disintegrant sodium starch glycolate in the formulations of FDTs.

Conclusion: The study concluded that *C. argentea* powder will act as a good disintegrating agent and it may be believed to exhibit promising additive anti-diabetic activity with GLZ.

Key Words: Gliclazide, Tablet, *Celosia argentea*, Fenugreek seed mucilage, Natural, Super-disintegrant

INTRODUCTION

The bioavailability of the drug is dependent on *in vivo* disintegration, dissolution, and various physiological factors¹. Tablet disintegration has received considerable attention as an essential step in obtaining fast drug release². The emphasis on the availability of drugs highlights the importance of the relatively rapid disintegration of a tablet as a criterion for ensuring uninhibited drug dissolution behavior³. "Disintegrants are agents added to tablet and some encapsulated formulations to promote the breakup of the tablet and [capsule "slugs"] into smaller fragments in an aqueous environment thereby increasing the available surface area and promoting a more rapid release of the drug substance"⁴. Superdisintegrants are generally used at a low level in the solid dosage form, typically 1- 10 % by weight relative to the total weight

of the dosage unit⁵. Diverse categories of superdisintegrants such as synthetic, semi-synthetic, natural, and co-processed blends, etc. have been employed to develop effective immediate-release tablets and to overcome the limitations of conventional tablet dosage form⁶.

Superdisintegrants is used as excipients in the tablet formulation as it has to meet certain criteria other than its swelling properties. The requirement placed on the tablet disintegrant should be clearly defined⁷. A group of superdisintegrants including croscarmellose sodium (ac-di-sol) sodium starch glycolate (Primojel and Explotab) and crospovidone (Polyplasdone XL) alleviate most of these problems⁸. The use of the superdisintegrants in a fast dispersible tablet is possible as a tablet shows optimum physical properties. Some super-disintegrating agents are natural in origin and are preferred

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over synthetic substances because they are comparatively cheaper, abundantly available, non-irritating, and nontoxic in nature⁹. The natural materials like gums and mucilage's have been extensively used in the field of drug delivery for their easy availability, cost-effectiveness, eco-friendliness, emollient, non-irritant nature, non-toxicity, capable of a multitude of chemical modifications, potentially degradable, and compatible due to natural origin¹⁰. There are several gums and mucilages are available which have superdisintegrating activity such as *Plantago ovata* seed mucilage (isphagula), *Lepidium sativum* mucilage, gum karaya, fenugreek seed mucilage, locust bean gum, *Cassia fistula* gum, and guar gum¹¹.

The major objective was to develop a fast disintegrating tablet (FDTs) is accomplished by using suitable excipients and superdisintegrants to achieve fast disintegration within a short period of time. FDTs tablet was developed that is safe, efficacious and to get the comparable dissolution profile. The task of developing the FDTs tablet of gliclazide (GLZ) by using superdisintegrants was needed because of its low aqueous solubility and low bioavailability. The research work was aimed to design and characterization of fast disintegrating GLZ-based anti-diabetic tablet using the natural disintegrating agent; fenugreek seed mucilage (**Batch: FS1-FS3**) and *Celosia argentea* (**Batch: FM4-FM6**) as well as a synthetic disintegrating agent; sodium starch glycolate (**Batch: FC7-FC9**), which results in a stable dosage form.

MATERIALS AND METHODS

Materials

GLZ was obtained as a generous gift from Zim Laboratories Ltd., Nagpur. The fenugreek seeds were purchased from the local market and *C. argentea* flower was obtained from a local farm. Sodium starch glycolate and microcrystalline cellulose were procured from Loba Chem Ltd., Mumbai. All other reagents and solvents employed in this study were of analytical grade and purchased from HiMedia Ltd., Mumbai.

Methods

Extraction of fenugreek seed mucilage

The seeds were powdered using a grinder and 50 g of the powder was extracted with n-hexane to remove lipophilic compounds using a soxhlet apparatus. To remove pigments and to deactivate enzyme, the defatted powder was boiled in ethanol for 20 min. This treated powder was then soaked in 5 litres water and the pH was adjusted to 3.5 using 0.5 M hydrochloric acid. The mixture was stirred by a mechanical stirrer for 12 h and then filtered through filtration paper. The filtrate was centrifuged (5000 g) and the supernatant was concentrated in vacuum to 50% of its initial volume. The resulting solution was mixed with the same volume of 96%

ethanol and stored in a refrigerator for 4 hr. The precipitated mucilage was separated by centrifugation (5000 g). The collected mucilage was re-suspended in distilled water, agitated for 20 min, and re-precipitated one more time to eliminate chloride ions and other impurities. Finally, the residue was washed with diethyl ether and acetone and dried overnight at 45°C, resulting in an off-white powder.

Preparation of *C. argentea* powder

The dried *C. argentea* flowers were collected and dried in sunlight. The size reduction was done in the grinder and sieved through mesh #80 and stored in a desiccator.

Phytochemical screening

The phytochemical investigation was done for the presence of glycoside, alkaloid, cellulose, mucilage, steroid, protein, reducing sugar, and tannin, according to Kamble et al., 2017¹².

Physicochemical characterization of natural disintegrants

Swelling ratio

The swelling ratio is the volume in ml occupied by 1 g of the drug; including any adhering mucilage after it has been swollen in an aqueous liquid for 4 hr. One gram of powder was taken in a 25 mL ground glass stoppered cylinder graduated over a height of 120 to 130 mm in 0.5 divisions. To this 25 mL of water was added and this was shaken vigorously every 10 m for 1 hr and then allowed to stand for 24 hr¹³. The volume occupied by the disintegrating agent including adhering mucilage was measured. The swelling ratio was calculated from the mean of three determinations.

$$\text{Swelling ratio} = V_2 - V_1 / V_1$$

where, V_1 = initial volume of material before hydration; V_2 = volume of hydrated material.

Loss on drying

Loss on drying was carried out by using a hot air oven at 105°C for 2 hr¹⁴.

$$\% \text{ Loss on drying} = [(W_1 - W_2) / W_1] \times 100$$

Characterization of Drug and Excipients

Pre-formulation study on GLZ

The GLZ was subjected to various pre-formulation studies like solubility, description, and pH.

Fourier Transform Infrared (FTIR) Spectroscopy

This study has been done to check whether there is any compatibility related problems are associated with drug and the excipients used for the formulation of fast disintegrating tab-

lets. The drug and excipients must be compatible with one another to produce a product that is stable, efficacious, attractive, and easy to administer and safe. If the excipients are new and not been used in formulations containing the active substance, the compatibility studies are of paramount importance. FTIR can be used to investigate and predict any physicochemical interactions between components in a formulation and can therefore be applied to the selection of suitable chemically compatible excipients. The study was conducted with an intention to check the compatibility of disintegrants fenugreek seed mucilage, sodium starch glycolate, and *C. argentea* powder with GLZ. Also, it helps to check the suitability of disintegrants for the preparation of fast disintegrating tablets. FTIR spectra were studied using a Shimadzu FTIR (Shimadzu IR Affinity-1, Japan) spectrophotometer by KBr disks in the spectral range of 4000 cm^{-1} to 500 cm^{-1} ¹⁵.

Differential Scanning Calorimetry (DSC)

The thermal behavior of pure drug and polymer were studied using a differential scanning calorimeter (Mettler Toledo®)

at a heating rate of $10^{\circ}\text{C}/\text{min}$. The measurements were performed at a heating range of $30\text{--}400^{\circ}\text{C}$ under nitrogen atmospheres¹⁶.

Formulation of fast disintegrating Tablets (FDTs)

The drug and all excipients were weighed accurately in separate polybags. The active pharmaceutical ingredient (API), fenugreek seed mucilage, *C. argentea*, sodium starch glycolate, microcrystalline cellulose, mannitol were sifted through sieve no. #40. The above-sifted material was transferred and mixed carefully. Magnesium stearate, talc, and aerosil were sifted through sieve no. #80 and the lubricating material *i.e.* magnesium stearate was transferred into the above blend materials and mixed for the duration of 5 minutes (**Table 1**). The lubricating material of the above blend was compressed in a 10 station compression machine using 8 mm concave punch.

Table 1: Composition of different formulations of gliclazide FDTs

Ingredients	Batch (in mg)								
	FS1	FS2	FS3	FM4	FM5	FM6	FC7	FC8	FC9
Gliclazide	80	80	80	80	80	80	80	80	80
Sodium starch glycolate	06	10	14	-	-	-	-	-	-
Fenugreek seed mucilage	-	-	-	06	10	14	-	-	-
<i>Celosia argentea</i>	-	-	-	-	-	-	06	10	14
Microcrystalline cellulose	65	61	57	65	61	57	65	61	57
Mannitol	45	45	45	45	45	45	45	45	45
Magnesium Stearate	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33
Talc	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33
Aerosil	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33

Pre-compression parameter of the powder blend

The lubricated blend was analyzed for bulk density, tapped density, Hausner ratio, and compressibility index according to the method described by Mahajan et al., 2017¹⁷.

Bulk Density

It refers to the packing of particles. Bulk density was used to determine the amount of drug that occupies the volume in g/ml. The bulk density of the ingredients was evaluated using a graduated cylinder. It is the ratio of the total mass of powder to the bulk volume of powder. It was measured by pouring

the weighed quantity of powder into a graduated measuring cylinder and the volume was noted. It was expressed in g/ml and is calculated by using the following formula.

$$\text{Bulk density} = \frac{\text{Mass of the powder (W)}}{\text{Untapped volume (V0) g / ml}}$$

Tapped density

It is the ratio of the total mass of powder to the tapped volume of powder. The tapped volume was measured by tapping the powder 10, 500, and 1250 taps in tap density apparatus (Electro Lab USP II) according to USP. The blend was subjected for 500 taps; % volume variation was calculated

and subjected for additional 1250 taps, and the % variation was calculated.

$$\text{Tapped density } (\tilde{\rho}_t) = \frac{\text{Mass of the powder (w)}}{\text{Tapped volume of the powder (Vf)}}$$

Compressibility index (Carr's index)

The compressibility index is an important measure that can be obtained from the bulk and tapped densities. In theory, the less the compressible material, the more flowable it is. A material having values of less than 20% is defined as the free-flowing material. The relationship between % compressibility indexes with flowability can be given by:

$$\text{Compressibility index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

Hausner's ratio

It indicates the flow properties of the granules and is measured by the ratio of tapped density to the bulk density.

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Angle of repose

The angle of repose is an indication of the friction forces existing between granule particles. It is the maximum angle possible between the surface of the pile of granules and the horizontal plane. The angle of repose was determined by passing the fixed quantity of powder from the funnel at constant height till the top of the pile made by the powder touches the funnel. The flowability of the granules was determined by calculating the angle of repose by fixed height method:

$$\theta = \tan^{-1} (h / r)$$

where, θ = angle of repose; h = height of pile; r = average radius of powder cone.

Post-compression parameter of fast disintegrating tablet

Tablets are evaluated as per pharmacopoeial specification and according to the method given by Mahajan et al., 2017a¹⁸.

Weight of tablet

Twenty tablets randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets were calculated. The batch passed the test for weight variation if not more than two of the individual tablet weight deviates from the average weight by more than the percentage shown in officials and none deviate by more than twice the percentage shown in the tablet.

Tablet dimensions

The thickness of the tablets was measured using a Vernier caliper. It was determined by checking ten tablets from each formulation. It is expressed in mm.

Hardness

Hardness indicates the ability of a tablet to withstand mechanical shock while handling. For each formulation, the hardness of the tablet was determined by using Monsanto hardness tester. It is expressed in N. Ten tablets were selected and hardness was measured.

Friability

For tablets with an average weight of 650 mg or less take a sample of whole tablets corresponding to about 6.5 mg and for the tablet with an average weight of more than 650 mg take a sample of 10 whole tablets. The tablets carefully dedusted and the required number of tablets was weighed accurately. Place the tablet in the Roche friabilator. The friabilator was operated at 25 rpm for 4 min then removes any loose dust from them and weighs them accurately. A maximum loss of weight not greater than 1.0 % is acceptable for the tablet. The percent friability was calculated by using the following equation.

$$\% F = (W_0 - W / W_0) \times 100$$

Where, % F = friability in percentage; W = Weight of tablet after revolution; W_0 = Initial weight of tablet.

Disintegration time

The *in vitro* disintegration time of each tablet formulation was determined by using a beaker at $37^\circ\text{C} \pm 2^\circ\text{C}$ in 900 mL disintegration media. 6 tablets of each formulation were taken and placed in a glass beaker. The time taken for complete disintegration was noted.

Wetting time and water absorption ratio

Double folded tissue paper was placed in a petridish and 6 mL of water was added to the petridish. A tablet was carefully placed on the surface of the tissue paper in the petridish at a temperature of 25°C . The time required for water to reach the upper surface of the tablets and to completely wet them was noted as the wetting time. These measurements were carried out in replicates of six. Wetting time was recorded using a stopwatch. The wetted tablet was then weighted and the water absorption ratio (R) was determined by using the equation:

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

where, W_a = weight of tablet after water absorption; W_b = weight of tablet before absorption.

Drug content

Standard solution

100 mg of pure GLZ was dissolved in little quantity of pH 6.8 phosphate buffer solution in a volumetric flask and then the volume was made to 100 mL mark with buffer solution and sonicated for 10 min. The above solution produced 1 mg/mL solution of GLZ which was further diluted with methanol to produce a series of concentrations ranging between 5-25 µg/mL. The absorbance was measured using spectrophotometer at 226 nm against buffer solution as blank¹⁹. The standard calibration curve was plotted.

Sample solution

20 tablets from each batch were randomly selected, weighed accurately, and then finely powdered in a mortar. To a powder equivalent to 80 mg of GLZ, about 50 mL of 6.8 pH solution was added and dissolved with the aid of the shaker for 24 hrs. A sufficient quantity of buffer solution was added to produce 100 mL in a volumetric flask, mixed well, and filtered using a membrane filter. 1 mL of the above filtrate was further diluted to 10 mL using buffer solution and mixed well. The absorbance of the resulting solution (10 µg/mL) was measured at the 226 nm using a blank in the reference cell²⁰. The total content of the drug in the solution was calculated with the help of a standard graph.

Dissolution study

In vitro dissolution study was carried out for optimized formulation of GLZ in 0.1 N HCl and pH 6.8 phosphate buffer was analyzed spectrophotometrically at 226 nm. The API has pH-dependent solubility in nature; its solubility is inversely proportional to the pH. It has good solubility in strong acidic conditions. During the multimedia dissolution of the given discriminating dissolution media, we had performed dissolution with various dissolution media. The dissolution was performed in pH 6.8 phosphate buffer and 0.1 N HCl²¹.

Stability study

The optimized batches were packed in aluminum foil and performed the stability study at 40°C temperature/ 75% Relative Humidity (RH). The stability samples were evaluated initially, after one month, and finally after three months²².

RESULT AND DISCUSSION

The drug powders were subjected to preformulation studies. The preformulation characteristics are within the pharmacopoeia specification. The preformulation studies were carried out and the results were found to be satisfactory.

Preliminary Phytochemical test

The phytochemical studies of fenugreek seed mucilage indicated the presence of carbohydrate, protein, and mucilage

whereas other components such as cellulose, flavonoids, alkaloids, tannins, and reducing sugar. *C. argentea* powder showed the appearance of carbohydrate, protein, and cellulose while mucilage, flavonoids, alkaloids, tannins, and reducing sugar were absent (Table 2).

Table 2: Preliminary phytochemical screening

Parameter	Fenugreek seed mucilage	<i>Celosia argentea</i> powder
Carbohydrate	+ve	+ve
Protein	+ve	+ve
Cellulose	-ve	+ve
Mucilage	+ve	-ve
Flavonoids	-ve	-ve
Alkaloids	-ve	-ve
Tannins	-ve	-ve
Reducing sugar	-ve	-ve

Physicochemical parameters of natural disintegrants

Both the natural disintegrants share similar characteristics in terms of % yield (~30), pH (~5.8), swelling ratio (~7), ash value (~0.88), acid-soluble ash (~0.3), water-soluble ash (~0.37), % LOD (~0.46), and taste (tasteless) which indicated their imperative properties suitable for pharmaceutical applications (Table 3).

Table 3: Physicochemical parameters of natural disintegrants

Parameter	Fenugreek seed mucilage	<i>Celosia argentea</i> powder
Colour	Off white-cream yellow color	Brownish green
Odour	No characteristic odor	Pleasant
Taste	Tasteless	Tasteless
% yield	31.66	26.42
pH (1%)	5.6	5.9
Ash value (%)	0.85	0.92
Water soluble ash (%)	0.35	0.39
Acid insoluble ash (%)	0.25	0.37
% LOD	0.47	0.45
Swelling ratio (ml)		
HCl	7	7.2
Water	5.5	5.7
pH 6.8 buffer	6.7	6.9

Compatibility studies

FTIR spectra were recorded for GLZ, *C. argentea* powder, fenugreek seed mucilage, sodium starch glycolate, and physical mixture. All the above characteristics peaks of the drug appeared in the spectra of the physical mixture at the same wave number indicating no modification or interaction between the drug and the excipients (**Figure 1**). The drug and excipients compatibility was carried out by the FTIR method and physical observation showed there was no interaction between them.

Figure 1: Drug-excipients interaction studies: (A) gliclazide; (B) *Celosia argentea* powder; (C) fenugreek seed mucilage; (D) sodium starch glycolate; and (E) physical mixture (gliclazide + *Celosia argentea* + fenugreek seed mucilage).

Differential Scanning Calorimetry

The DSC thermograms were recorded for GLZ, *C. argentea* powder, fenugreek seed mucilage, sodium starch glycolate, and their physical mixtures. The DSC heating and cooling curves were recorded as a plot of enthalpy vs. temperature in (°C). The thermal analysis of the drug and disintegrants was confirmed by differential scanning calorimetry at a scanning rate of 10°C/min. GLZ showed sharp melting endothermic peak at 187.52°C, *C. argentea* powder at 151.08°C, fenugreek seed mucilage at 217.12°C, sodium starch glycolate at 130.05°C whereas the thermogram of physical mixture shows a respective endothermic peak at 167.30 °C for *C. argentea* powder, 166.69-209.70°C for fenugreek seed mucilage, 171.91°C for sodium starch glycolate (**Figure 2**), respectively. DSC studies had proven the interaction between the drug and disintegrants where the melting point was found to be reduced because of physicochemical interaction and embedding of the drug into disintegrants network. The study indicated that there was no significant interaction between the drug and the excipients.

Figure 2: DSC thermogram studies: (A) gliclazide; (B) *Celosia argentea* powder; (C) fenugreek seed mucilage; (D) sodium starch glycolate; and (E) physical mixture (gliclazide + *Celosia argentea* + fenugreek seed mucilage).

Pre-Compression parameters

In the above table characteristic of the powder blend of FS3, FM6, and FC9 is given. The blend ready for compression was evaluated for bulk density, tapped density, compressibility index, and Hausner's ratio. It was found that the blend had a compressibility index from 5.63% to 5.90% and Hausner's ratio from 1.05 to 1.06, which indicate that blend ready for compression. From the values of the Compressibility index and Hausner's ratio, it was observed that a blend of the above formulation has excellent flow properties and compressibility index (**Table 4**).

Table 4: Evaluation of lubricated blend

Batch no.	Bulk density (g/ml)	Tapped density (g/ml)	Car's index (%)	Hausner ratio	Angle of repose (°)
FS3	0.464±0.007	0.493±0.008	5.88±0.01	1.06±0.01	32.02±0.02
FM6	0.478±0.006	0.508±0.008	5.90±0.01	1.06±0.02	34.23±0.03
FC9	0.452±0.007	0.479±0.009	5.63±0.01	1.05±0.01	30.11±0.02

Post-Compression parameters

Total of nine FDT formulations were prepared using different concentrations of fenugreek seed mucilage, *C. argentea* powder, and sodium starch glycolate. The various formulation of GLZ was prepared by using a direct compression method because of the good flow property of API. The tablets were formulated by using excipients such as microcrystalline cellulose, mannitol, talc, aerosol, and magnesium stearate. The optimized three batches out of all nine batches on the basis of hardness, friability, disintegration time, weight variation, thickness, and drug content were screened. The thickness of the tablets was found to be in the range of 3±0.04 mm. The results showed that the thickness of all formulates tablets are

found to be uniform. The hardness of the all tablet formulation was found to be in range (2-3 N) which indicated that all the tablets have adequate mechanical strength. The accepted percentage deviation of $\pm 7.5\%$ for less than 324 mg weight tablets was taken in to account for all the produced formulations. The weight of tablets found within limits. In the friability test, the maximum weight loss should be no more than 1%. The result revealed that the tablets passed the friability test.

The percent of drug content in all batches was in the range of 97.56%-99.18%. The wetting time of all batches of tablets (FS3 to FC9) was found to be 13-18 seconds. Out of all the formulations, the batch FC9 containing *C. argentea* powder showed the least wetting time of 19 seconds which results in a high absorption ratio ($97.02 \pm 0.01\%$) which was responsible for low disintegration time. The disintegration time varies according to the concentration of polymers. The drug content of different batches was found between 97.56-99.18% indicating uniformity in drug content within tablets. FC9 showed a higher dissolution rate of 98.13% at the end of 60 min (Table 5). The formulation of a fast disintegrating tablet was done by direct compression method by using natural disintegrating agents (fenugreek seed mucilage, *C. argentea* powder) and synthetic disintegrants (sodium starch glycolate) which shows less disintegration time and higher drug release profile.

Table 5: Physical parameter of fast disintegrating tablet

Parameters	FS ₃	FM6	FC ₉
Weight (mg) *	Pass	Pass	Pass
Thickness (mm) *	2.98 ± 0.03	3 ± 0.04	3 ± 0.04
Hardness (N) *	3 ± 0.02	2.5 ± 0.02	2.5 ± 0.02
Disintegration time (sec)	26 ± 0.04	21 ± 0.04	19 ± 0.01
Friability (%)	0.56 ± 0.004	0.66 ± 0.002	0.62 ± 0.004
Wetting time (sec) *	18 ± 0.04	15 ± 0.01	13 ± 0.01
Water absorption ratio (%) *	96.65 ± 0.04	96.89 ± 0.04	97.02 ± 0.01
Drug content (%) *	97.56 ± 0.03	98.49 ± 0.01	99.18 ± 0.02
% drug release (%) *	97.45 ± 0.01	97.96 ± 0.01	98.13 ± 0.02

Multimedia Dissolution Data of Fast Disintegrating Tablet:

The multimedia dissolution was carried out by using different dissolution media over a period of 60 min using the USP type II (paddle) dissolution apparatus at 50 rpm under 0.1 N HCl and pH 6.8 phosphate buffer. From the result, it was observed that FDTs in 0.1 N HCl media showed improved dissolution rate with a formulation containing *C. argentea* powder (Table 6). The % drug release of fast disintegrating tablets in 0.1 N HCl was found to be greater than pH 6.8 phosphate buffer dissolution media (Figure 3).

Table 6: Multimedia dissolution study of the fast disintegrating tablet

Media	6.8 phosphate buffer			0.1 N HCl		
	FS ₃	FM6	FC ₉	FS ₃	FM6	FC ₉
Time point (min)	% cumulative drug release					
10	34.24 ± 0.01	34.72 ± 0.01	37.80 ± 0.01	41.06 ± 0.01	47.51 ± 0.01	47.74 ± 0.01
20	46.75 ± 0.01	46.51 ± 0.01	47.72 ± 0.01	51.29 ± 0.01	56.06 ± 0.01	56.30 ± 0.01
30	59.84 ± 0.01	59.84 ± 0.01	60.09 ± 0.01	62.47 ± 0.01	64.39 ± 0.01	64.63 ± 0.01
40	68.21 ± 0.01	71.28 ± 0.01	71.76 ± 0.01	71.54 ± 0.01	74.63 ± 0.01	86.23 ± 0.01
50	80.57 ± 0.01	86.27 ± 0.01	86.51 ± 0.01	83.68 ± 0.01	81.31 ± 0.01	94.40 ± 0.01
60	97.45 ± 0.01	97.96 ± 0.01	98.13 ± 0.02	98.42 ± 0.02	98.64 ± 0.02	99.66 ± 0.02

Figure 3: Release characteristics of various natural disintegrant containing formulations.

Stability studies

The optimized batches were packed in aluminum foil and performed stability study at 40°C / 75% RH for three months. The stability samples were evaluated initially and after one and three months which showed no change in physical appearance, assay, and drug release which indicate the tablet was stable.

CONCLUSION

Fast disintegrating tablet prepared by direct compression. The natural disintegrants (*C. argentea* powder) showed bet-

ter results than synthetic disintegrants (sodium starch glycolate). From the above result, it can be concluded that batch FC9 showed better results than batch FS3 and FM6, and also shows less disintegration time improvement in dissolution rate by using superdisintegrants that means improving dissolution ultimately improvement in bioavailability. Hence, the anti-diabetic drug GLZ can be successfully formulated as a fast disintegrating tablet with natural disintegrants like *C. argentea* and fenugreek seed mucilage.

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Conflict of interest

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