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AN INVESTIGATION INTO THE EFFECTS OF NATURAL SUPERDISINTEGRANTS IN THE FORMULATION AND EVALUATION OF CLOZAPINE ORODISPERSIBLE TABLETS

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ABSTRACT

The present study utilised the direct compression method to formulate orodispersible tablets of Clozapine using various natural superdisintegrants such as plantago Ovata mucilage and unripe banana powder at various concentrations (2 percent, 4 percent, 6 percent, and 8 percent) and a control formulation (without superdisintegrants). To increase the mouth feel, microcrystalline cellulose and mannitol were employed. The pre compression characteristics of the prepared formulations were determined, and all formulations were found to have satisfactory flow qualities. After compression, the tablets were examined for hardness, friability, homogeneity of drug content, wetting time, water absorption ratio, *in vitro* dispersion time, and dissolving studies. CLZ4 containing 8% plantago ovata mucilage had a faster *in vitro* dispersion time (9 seconds), disintegration time (13 seconds), wetting time (10 seconds), and drug release rate (99%) in 30 minutes. Stability analyses conducted on the promising formulations revealed no significant changes in drug content or in vitro dispersion time. There are no drug-excipient interactions, as determined by IR spectroscopy.

Keywords: Clozapine, Plantago Ovata mucilage, Unripe banana powder, Orodispersible tablets.

1. INTRODUCTION

Recently, scientists have looked into the effects of fast disintegrating agents such as cellulose derivatives, starches, and synthetic agents such as croscarmellose sodium (also known as Ac-di-sol), crospovidone, and sodium starch glycolate, on dissolution of the tablets. As an example, a variety of natural superdisintegrants like gum karaya and modified starch have been used in the formulation of fast dissolving tablets because they are cost-effective, environment friendly and widely available. Other natural superdisintegrants include isapghula seeds and *hibiscus rosa sinensis* and fenugreek seeds. The combined swelling and water absorption effects of the dose form help superdisintegrants disintegrate quickly. The swelling of superdisintegrants enhances the carrier's wetted surface area, which improves the formulation's wettability and dispersibility and, as a result, the disintegration and dissolution characteristics are improved as well. According to the critical concentration of the superdisintegrants, the best concentration for the superdisintegrants is chosen from the outset. Tablet disintegration time is inversely proportional to superdisintegrant concentration below this point, whereas above this point, disingration time remains constant or even increases [1-3].

Solids and liquids are both delivered via the oral route, which is the most popular. As far as solid dosage forms are concerned, they are the most preferred option due to the high degree of dose precision they provide, as well as their convenience of manufacture, administration and affordability. Tablets and capsules are the most used solid oral dose forms. It is difficult or painful to swallow solids, which is the principal disadvantage of the solid dosage form. It's not typical for people with mental health issues or those who aren't cooperative to be in these categories. Patients are more likely to take their medication if the tablet dissolves in their mouth instead of in water. Fast dissolving tablets are also known as orodispersible, rapid dissolving, fast disintegrating, quick dissolving tablets, and other similar terms. These terms are referred to as Orodispersible tablets in the United States Pharmacopeia (USP) [4-6].

US Pharmacopoeia defines orodispersible tablets as solid dosage forms containing therapeutic substances or active ingredients that dissolve swiftly under the tongue within a number of seconds. Tablets dissolve or disintegrate in the mouth without using water. Tablets must, therefore, improve disintegration time, dispersion time, drug release studies, bioavailability, and patient compliance, as well as mask the bitter taste of the drug and keep the drug stable under accelerated conditions, i.e. 40°C/75 % RH for up to six months, in accordance with ICH guidelines for drug stability [6-9].

Clozapine's uses include the treatment of schizophrenia, manic-depressive illness, and bipolar disorder. As well as being essentially insoluble in water and isopropyl alcohol, the substance has a half-life of 6 to 26 hours. Because the medicine has a longer half-life than immediate-release tablets, once-daily formulations in the form of orodispersible tablets are best. Psychic patients cannot be treated with immediate release pills. These are best suited for psychological patients, elderly, children, and those with limited access to water [10].

2. MATERIAL AND METHODS

Clozapine was procured from Dr.Reddy's Laboratory, Hyderabad, seeds of plantago ovata and Unripe bananas were collected locally and from herbal drug store and were authenticated before use, all other ingredients obtained from SD Fine Chemicals Pvt Ltd, Hyderabad.

2.1. Extraction Studies

2.1.1. Extraction of mucilage from seeds of Plantago ovate

It is made from the dried seeds of plantago ovata forskal, and is known as isapghula (Plantaginaceae). The seeds' epidermis includes mucilage, and this product contains some of that. It took 48 hours to immerse the seed of the African plantago ovata in distilled water. After that, the water was brought to a boil to allow the mucilage to be released completely into it. Filtering and isolating the marc required pressing the substance through muslin fabric. After that, the filtrate was treated with an equivalent volume of acetone in order to precipitate the mucilage. Using an oven set to less than 60°C, the separated mucilage was dried into a powder form [11].

2.1.2. Extraction of unripe Banana powder

Musaceae bananas that were not ripen were peeled and the flesh was cut. A preservative, methyl paraben, was used to preserve the sliced pulp after it was cleaned with distilled water. The pulp was crushed in a home blender and dried for 24 hours at 45°C in a convection oven. An airtight container filled with a desiccant was used to preserve the dry pulp after it had been ground in a mortar and sieved through sieve No.80 (177m) (silica gel packets).

2.2. Characterisation of the natural polymers

2.2.1. Organoleptic evaluation

The natural polymers were subjected to sensory evaluation in order to assess their macroscopic properties as well as their overall appearance. Taste, colour, odour, and texture were all evaluated.

2.2.2. Phytochemical Screening

A qualitative viewpoint on the chemical makeup of natural superdisintegrants was taken into consideration during this assessment. Phytochemicals have therapeutically significant effects that can be either useful or harmful. Research was conducted on powdered and mucilaginous samples of *rosa sinensis* and *ispaghula hibiscus* to find out if there were any carbohydrates, saponins, phenolics, proteins or other compounds of interest [12].

2.3. Physico chemical evaluation

2.3.1. Swelling Capacity

Swelling behaviour of natural polymers employed as superdisintegrants in water should be evaluated because it gives a clue to their disintegrating properties. A modified version of the Bowen and Vadino approach was used to measure the natural polymers' swelling capacity. Amount of powder in tapped volume (Vx) was calculated. The powder was then mixed with 85 ml of distilled water in a graduated cylinder, and the volume was increased to 100 ml by adding more water [13]. After allowing the suspension to stand for 24 hours, the sediment volume (Vy) was calculated.

Swelling capacity = Vy/Vx

2.3.2. Determination of pH

This analysis was carried out in order to estimate the acidity or basicity of aqueous dispersions of the natural polymers. The pH of a 1% aqueous dispersion was determined using an electronic pH metre [14].

2.3.3. Loss on drying

The purpose of this study was to determine the moisture content of natural polymers. Because water is required for microbial growth, the stability and shelf life of a naturally sourced powder are greatly influenced by the amount of moisture in it. A halogen moisture

analyzer was used to gauge the natural polymers' moisture content. The mass loss percentage was measured after heating 1 g of powder to 105°C for 5 minutes.

Loss on drying = (W_1-W_2/W_1) X 100

W_1 = initial weight of the powder, W_2 = final weight of the powder

2.3.4. Viscosity

One gram of powder was suspended in 75ml of distilled water for 4 hrs. distilled water was added up to 100 ml to produce concentration 1%. The mixture was homogenized by mechanical stirrer for 2 hrs and its viscosity was determined by using Brookfield viscometer, spindle SC4-18 at 5 rpm [15].

2.4. Drug - Excipients Compatibility studies by FTIR

For the drug material alone and the drug substance mixed with excipients, FTIR investigations were carried out. In a hot air oven at 60°C for two hours, one mg of the Clozapine was dried and uniformly combined with 99 mg of potassium bromide. The combination was compacted under high pressure to create a transparent pellet, which was then transferred to an IR spectrophotometer and scanned for % transmittance [16]. In all cases, the same technique was followed: Clozapine was mixed with excipients and scanned.

2.5. Development of Clozapine orodispersible tablets

Using a direct compression process, the clozapine orodispersible tablets were formulated for oral administration. In order to achieve uniformity and proper mixing of all the ingredients and separate collection in polyethylene bag, Clozapine was passed through the sieve # 60 separately. MCC, Mannitol, Menthol, Sodium saccharin, Plantago ovata mucilage, unripe Banana powder were all collected separately in the polyethylene bag. A mixture of talc and magnesium stearate was placed in a plastic bag after being sieved through sieve #40 and blended. With 10 mm round, flat punches and eight station rotating tablet compression machines [17], the entire powder blend could be compressed directly into tablets. Table 1 summarizes the formulation's ingredients.

Table 1: Composition of different formulations of Clozapine Orodispersible tablets

Ingredients (mg/tab)	CLZ_0	CLZ_1	CLZ_2	CLZ_3	CLZ_4	CLZ_5	CLZ_6	CLZ_7	CLZ_8
Clozapine	25	25	25	25	25	25	25	25	25
Poloxamer	25	25	50	75	100	25	50	75	100
Plantago ovata mucilage	-	05	10	15	20	--	-	-	-
Unripe banana powder	-	-	-	-	-	05	10	15	20
MCC	50	50	50	50	50	50	50	50	50
Mannitol	137.5	132.5	102.5	72.5	42.5	132.5	102.5	72.5	42.5
Menthol	5	5	5	5	5	5	5	5	5
Magnesium stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Talc	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Sodium saccharin	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Total tablet weight	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**

There were no superdisintegrants, microcrystalline cellulose, mannitol as diluting agents, sodium saccharin as a sweetener, or talc or Magnesium stearate in the formulation of the CLZ_0 experiment. It was also free of salt. Sodium saccharin was used as a sweetener, while talc was used as a glidant and magnesium stearate served as a lubricant in the CLZ_1 - CLZ_4 study. The superdisintegrants used in the study were Plantago ovata mucilage (2 percent, 4 percent, 6 percent, and 8 percent), microcrystalline cellulose, and mannitol.

Sodium saccharin, talc, and magnesium stearate were used as superdisintegrants in the CLZ_5-CLZ_8 clinical study, with varying quantities of unripe banana powder (2 percent, 4 percent, 6 percent, and 8 percent), microcrystalline cellulose and mannitol as diluents.

2.6. Preformulation Studies

In the logical development of a dosage form for a drug ingredient alone and in combination with excipients, the preformulation is the first stage to be completed. Prior to formulation, the aim is to acquire as much information as possible to help formulaters create the best possible drug delivery system. Bulk density (D_b) [18], Tapped density (D_t), Carr's index (%) [19], Hausner's ratio and Angle of repose (θ) were performed

2.7. Post Compression Studies

General appearance, general elegance, tablet identity and control of batch-to-batch uniformity and tablet-to-tablet uniformity are vital for consumer approval, as are all of these factors. The measurement of size, shape, colour, break lines, debossing, presence or absence of odour, taste, etc. is part of the overall appearance control. Tests for thickness [20], hardness [21], friability [22], weight variation and wetting time were also performed.

2.8. *In vitro* dispersion time

One tablet was placed in a beaker containing 10 ml of phosphate buffer at 37±2°C and the time required for complete dispersion was determined [23].

2.9. Water absorption ratio

In a 6ml petridish with water, a folded piece of tissue paper was inserted. The time it took for the tablet to completely moisten the paper was recorded. The tablet was dipped into water and weighed. Following equation was used to figure out the water absorption ratio, R:W. Standard deviation was calculated for three tablets from each formula.

$$R = 100(Wa-Wb)/Wb$$

Where,

Wb - weight of tablet before absorption,

Wa - weight of tablet after absorption

2.10. *In-vitro* disintegration time

The process of breakdown of a tablet in to smaller particles is called as disintegration. The *in-vitro* disintegration time of a tablet was determined using disintegration apparatus as per I.P specifications.

When determining the amount of a drug substance in a pharmaceutical product, assay is a critical aspect to consider. The UV technique is mostly used for assaying optimised test products. 100mg of medication is comparable to three weighted and crushed tablets deposited in a 100ml dissolving media [20]. A suitable dilution of the solution in the volumetric flask was performed after it had been filtered. A UV-visible spectrophotometer was used to measure the final solution's absorbance at 260 nm.

2.11. *In-Vitro* drug release studies

Using a paddle stirrer spinning at 50 revolutions per minute, the *in vitro* dissolution of Clozapine oral orodispersible tablets was examined in aUSP type-II dissolution equipment. The dissolution medium was a pH 7.4 phosphate buffer with a volume of 900 ml, throughout the experiment; the dissolving media was kept at a constant 37°C±0.5°C. Each experiment made use of a single tablet. In this study, predefined time intervals of dissolution medium (5ml) were used to collect samples for analysis of drug release by detecting absorbance at 260nm. A new batch of dissolving media was added to replace the volume that was removed at each interval [24]. The total amount of medicine released over time was computed and visualised using a graph.

2.12. Stability studies

According to ICH guidelines, the optimized formulation was kept for stability at accelerated conditions (40°C/75% RH) for studying quality of the drug product during its shelf-life. Tablets were withdrawn from stability chamber at 1st, 2nd, 3rd& 6th month and analyzed for assay, friability, disintegration, dissolution, dispersion time and related substances content.

2.13. Kinetic studies

The results of *in vitro* release profile obtained for all the formulations were plotted in modes of data treatment as follows[25]:

1. Zero - order kinetic model - Cumulative % drug released versus time.
2. First - order kinetic model - Log cumulative percent drug remaining versus time.
3. Higuchi model - Cumulative percent drug released versus square root of time.
4. Korsmeyer equation/Peppas model-Log cumulative percent drug released versus log time.

3. RESULTS AND DISCUSSION

3.1. Extraction Studies

Unripe Banana Powder and Plantago ovata mucilage were extracted and evaluated for organoleptic, physic chemical properties and phytochemical analysis for the presence of starch, saponins, phenols, proteins, tannins, lipids, flavonoids and reducing sugars. A pale-yellow powder was obtained from the dried pulp of unripe bananas of the genus *Musa*.

3.2. Characterisation of the natural polymers

3.2.1. Organoleptic evaluation

This powder was smooth to the touch with a faint-sweet and floury smell. Starch, a white smooth powder with no distinctive smell was obtained by centrifuging a suspension of Unripe Banana Powder. Plantago ovata mucilage contains fleecy pale-brown powder, soft and gritty to the touch with a distinctive herby smell.

3.2.2. Phytochemical Screening

The phytochemical analysis revealed that the unripe bananas powder contained presence of Starch, saponins, phenols, proteins, tannins, lipids, flavonoids and Monosaccharides. The Plantago ovata mucilage confirmed the presence of only saponins, shows in fig. 1.

3.3. Physico chemical evaluation

The physicochemical properties revealed that the both superdisintegrants swells in water, loss on drying was found 7.4% and 8.4%, swelling index was found to be 20.84 and 2.34, viscosity was found 9.33 and 2.42 cps and pH was found to be 5.8 and 5.3.

3.4. Drug-Excipients Compatibility studies by FTIR

Compatibility studies of drug alone and drug with physical mixture of excipients were performed using FT-IR spectrophotometer. The peaks obtained in the spectra of each sample of drug and excipient correlates with the peaks of drug spectrum. This indicates that the drug is compatible with the formulation components.

3.5. Preformulation Studies

The pre compression parameters of powder blend were performed for various formulations and the bulk density, tapped density, angle of repose, carr's index and Hausner's ratio values were found in the range of 0.49 to 0.54 g/cc, 0.56 to 0.61 g/cc, 24° to 31.05°, 7.14% to 15.51% and 1.05 to 1.18 respectively. All the formulations show good results and lies within the acceptable range which indicate good flow properties. The results of all the pre compression parameters are given in table 2.

Fig. 1: Phytochemical tests of UBP and POM

Table 2: Pre-compression parameters of clozapine powder blend CLZ_0 - CLZ_8

Formulation code	Bulk Density (g/cc)	Tapped density (g/cc)	Angle of repose (degree)	Carr's index (%)	Hausner's ratio
CLZ_0	0.54	0.61	31.05	11.47	1.12
CLZ_1	0.51	0.60	25.42	15	1.17
CLZ_2	0.51	0.59	24	13.55	1.15
CLZ_3	0.49	0.58	23.61	15.51	1.18
CLZ_4	0.51	0.58	27.24	12.06	1.13
CLZ_5	0.52	0.57	26.6	8.77	1.09
CLZ_6	0.53	0.56	25.9	5.35	1.05
CLZ_7	0.51	0.56	24.9	8.92	1.09
CLZ_8	0.52	0.56	25.15	7.14	1.07

3.6. Post Compression Studies

After compression of powder blend into tablets by direct compression method, the post compression parameters such as weight variation, thickness, hardness, friability, drug content uniformity were evaluated which were found in the range of 246.5 ±1.052 to 250.2

±1.686, 2.75±0.144 to 3.08±0.209 mm, 3.02±0.046 to 3.18±0.286 kg/cm^2, 0.46±0.09 to 0.53±0.02 %, 97.22±1.393 to 99.95± 0.836 respectively, which shows that all formulations were found to be stable and within the Indian pharmacopoeia specified limits and summarized in table 3.

3.7. The wetting time, water absorption ratio, disintegration time and *in vitro* dispersion time

The wetting time, water absorption ratio, disintegration time and *in vitro* dispersion time of all formulations (CLZ_1 _ CLZ_8) was found in the range of 10.69±0.49 to 62.33±1.58 sec, 59.56±1.78 to 98.97±1.09%, 13± 2.05 to 66±1.55 sec and 9.18±0.09 to 58.67±1.46 sec respectively. Among all the designed formulations, CLZ_4 containing 8%w/w of plantagovata mucilage shows better *in vitro* dispersion time 9.18±0.09 sec (fig. 2), wetting time 10.69±0.49 sec and water absorption ratio 98.97±1.09 %, when compared to unripe banana powder and results were summarized in table 4.

Table 3: Post Compression parameters of formulations CLZ_0 - CLZ_{16}

Formulation code	Weight Variation	Thickness	Hardness	Friability	Drug Content
CLZ_0	249.8±1.619	3.08±0.209	3.13±0.205	0.53±0.02	98.57±0.157
CLZ_1	249.8±1.032	2.98±0.154	3.15±0.246	0.48±0.02	99.22±0.393
CLZ_2	250.2±1.686	3.02±0.188	3.13±0.226	0.50±0.017	98.87±0.363
CLZ_3	250±1.414	3.03±0.188	3.12±0.249	0.49±0.015	99.95±0.836
CLZ_4	249.8±1.032	2.98±0.154	3.15±0.246	0.48±0.02	99.22±0.393
CLZ_5	246.5±1.052	2.75±0.144	3.02±0.046	0.49±0.92	97.22±1.393
CLZ_6	248.8±0.092	2.99±0.54	3.12±0.246	0.46±0.09	98.22±0.393
CLZ_7	246.8±0.062	2.83±0.184	3.11±0.106	0.49±0.09	98.22±0.320
CLZ_8	247.8±1.092	2.79±0.754	3.18±0.286	0.48±0.78	98.29±0.593

Table 4: Post compression parameters of formulations CLZ_0 - CLZ_8

Formulation Code	Wetting time (sec)	Water absorption ratio (%)	Disintegration time (sec)	In vitro dispersion time (sec)
CLZ_0	463.21±2.41	16.02±1.29	239±1.62	169.42±1.01
CLZ_1	46.09±1.05	81.35±0.27	51±1.22	44.88±0.63
CLZ_2	34.00±1.05	88.57±1.5	42±2.05	32.16±0.92
CLZ_3	19.86±0.30	92.77±0.65	24±1.12	16.28±0.75
CLZ_4	10.69±0.49	98.97±1.09	13±2.05	9.18±0.09
CLZ_5	62.33±1.58	59.56±1.78	66±1.55	58.67±1.46
CLZ_6	56.05±1.02	68.77±0.67	61±1.82	44.43±1.22
CLZ_7	38±0.38	79.41±1.41	45±2.05	33.11±0.05
CLZ_8	32.55±2.01	83.06±0.17	38±1.12	28.18±0.01

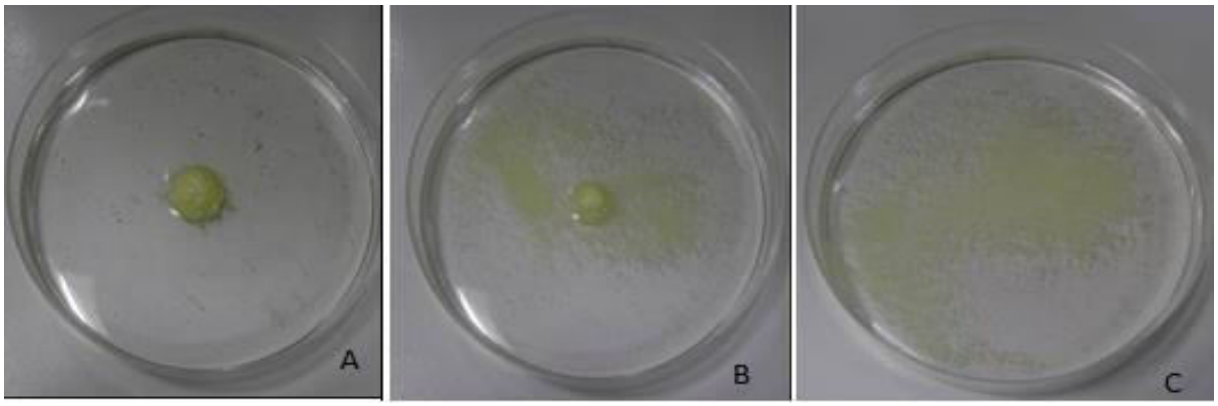

Fig. 2: *In vitro* dispersion time of CLZ_4 formulation

3.8. *In-Vitro* drug release studies

The *in vitro* drug release of pure drug clozapine control formulation (CLZ_0) was found 30.84±0.6%, formulations (CLZ_1 _ CLZ_4) containing plantago ovata mucilage as superdisintegrant release the drug 79.54 ±2.5%, 87.01±2.3%, 95.72±2.6%, 99.27±2.7% respectively, formulations (CLZ_5_ CLZ_8) containing unripe banana powder as superdisintegrant release the drug 79.54±2.5%, 87.01±2.3%, 95.72±2.6%, 99.27 ±2.7% respectively in 60 min. This data shows that among all the formulations, CLZ_4 containing 8%w/w of plantagovata mucilage shows better drug release characteristics (99.27±2.7%) at the end of 60 min and results were summarized in table 5 and in fig. 3.

3.9. Stability studies

Short-term stability studies conducted on formulation (CLZ_4) at 40°C/ 75% RH for 3 months. When comparing the final formulation to the initial formulation, no significant difference was observed were identified in the physical appearance, drug content, in vitro dispersion time, and dissolution during the stability testing. The results are given in Table 6.

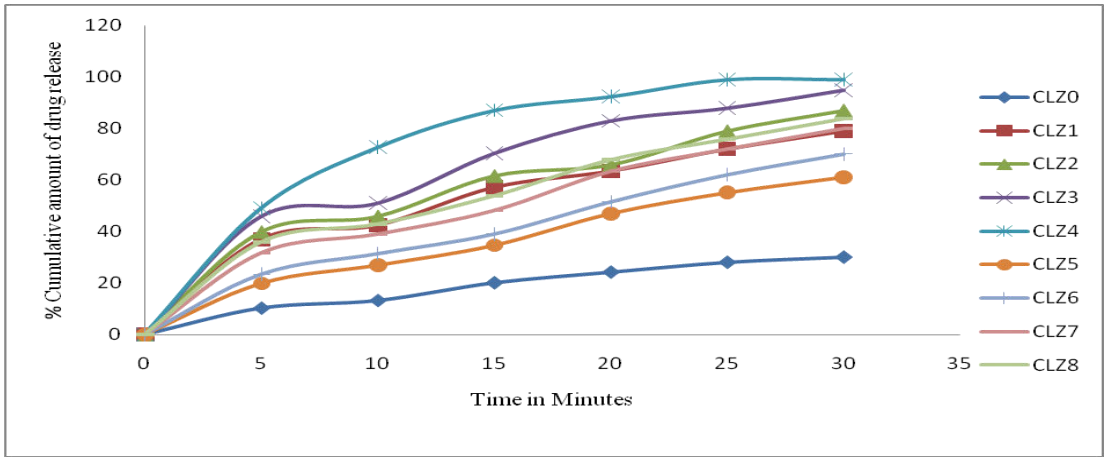

Fig. 3: Dissolution profile of Clozapine Orodispersible tablets

Table 5: Dissolution profile of Clozapine Orodispersible tablets

	Cumulative amount of drug release								
Time (Min)	CLZ_0	CLZ_1	CLZ_2	CLZ_3	CLZ_4	CLZ_5	CLZ_6	CLZ_7	CLZ_8
0	0	0	0	0	0	0	0	0	0
05	10.27±1.4	37.41±2.3	39.82±2.7	45.89±2.5	49.08±2.6	19.82±2.7	23.37±1.5	31.67±2.5	36.±1.8
10	13.21±0.5	42.46±1.7	45.89±1.6	51.04±1.4	72.67±2.6	26.89±1.6	31.37±2.3	39.00±1.3	43.±2.0
15	20.07±1.2	57.15±1.7	61.59±1.3	70.41±2.7	87.11±2.7	34.59±1.3	39.91±2.6	48.16±2.4	54 ± 2.5
20	24.19±1.4	63.47±2.6	65.91±2.5	83.02±1.5	92.38±2.6	46.91±2.5	51.47±2.4	63.34±2.5	68 ± 1.6
25	28.61±1.9	72.99±1.7	79.45±1.8	88.25±2.8	99.27±2.7	55.45±1.8	62.65±1.4	72.13±2.6	76 ± 1.2
30	30.84±0.6	79.54±2.5	87.01±2.3	95.72±2.6	99.83±2.3	61.01±2.3	70.24±2.4	80.95±2.7	84 ± 1.1

Table 6: kinetic studies of Clozapine Orodispersible tablets

Formulation code	Zero order (R^2 value)	First order (R^2 value)	Higuchi (R^2 value)	Peppas (R^2 value)	Hixon Crowell (R^2 value)
CLZ_0	0.9818	0.9864	0.9894	0.9918	0.9763
CLZ_1	0.9852	0.9806	0.9905	0.9881	0.9756
CLZ_2	0.9843	0.9488	0.9803	0.9465	0.9387
CLZ_3	0.9618	0.9469	0.9678	0.9800	0.9427
CLZ_4	0.9706	0.9783	0.9764	0.9664	0.9621
CLZ_5	0.9904	0.9854	0.9893	0.9791	0.9774
CLZ_6	0.9955	0.9762	0.9907	0.9956	0.9648
CLZ_7	0.9907	0.9657	0.9907	0.9849	0.9612
CLZ_8	0.9907	0.9718	0.9951	0.9864	0.9665

3.10. Kinetic studies

The *in vitro* drug release data of the fast dissolving tablets were evaluated kinetically by zero order, first order, Higuchi, peppas, Hixon crowell model. Statistical analysis of the data by the method of least squares gives correlation coefficient values in the range of 0.91 to -0.99 for most of the formulations, it was further confirmed by fitting data to the Korsmeyer-Peppas equation and the 'n' values for the all formulations obtained were in the range and results were summarized in table 7.

Table 7: Stability data for Optimized formulation Clozapine (CLZ_4)

Name of Test	Initial	1st month	2nd month	3rd month	6th month
Physical Changes	No changes	No changes	No changes	No changes	No changes
		Dissolution			
05 minutes	49.08±2.6	48.62±2.4	48.56±2.2	48.52±2.1	48.46±2.2
10 minutes	72.67±2.6	72.48±2.1	72.35±2.3	72.29±2.2	72.18±2.1
15 minutes	87.11±2.7	86.76±2.3	86.54±2.2	86.47±2.3	86.32±2.1
30 minutes	99.83±2.3	98.92±2.3	98.86±2.1	98.73±2.2	98.59±2.3
Assay (%)	99.22±0.39	98.57±0.43	98.22±0.26	98.18±0.32	98.11±0.63
Friability (%)	0.48±0.02	0.47±0.13	0.47±0.42	0.47±0.33	0.47±0.51
Disintegration (Sec)	13±2.05	13±2.21	13±2.11	13±2.10	13±2.09
Dispersion time (Sec)	9.18±0.09	9.29±0.16	9.35±0.09	9.47±0.11	9.56±0.43

4. CONCLUSION

In the oral route, which is the most often utilised mode of administration, both solids and liquids are delivered. Solid dosage forms are the most often used way of administration due to the high degree of dose precision they provide, as well as the convenience with which they can be manufactured, administered, and are reasonably priced. Solid dosage forms are also the least expensive type of administration. Among the most often used oral dose forms are tablets and capsules, which are solid oral dosage forms. Taking solids can be challenging, and they can be painful, which is the most significant disadvantage of the solid dosage form. Solids are also prohibitively expensive. It can be concluded from the current investigation that the natural superdisintegrant *Plantago ovata* mucilage (8 percent) outperformed unripe banana powder in terms of water absorption ratio, wetting time, in vitro dispersion time, and drug release characteristics. This work can be extended for site specific drug release of drugs having low solubility, poor absorption or degradation in upper gastrointestinal tract and short biological half-life.

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Conflict of interest

The authors have no relevant financial or non-financial interests to disclose.

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