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Formulation and Evaluation of Orally Disintegrating Tablets: Comparison of Natural and Synthetic Superdisintegrants

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ABSTRACT

Orally disintegrating tablets (ODTs) are gaining popularity over conventional tablets due to their convenience in administration and suitability for patients having dysphagia (difficulty in swallowing). In the present study, an attempt was made to compare the disintegration efficiency of mucilage isolated from natural source, Plantago ovata with widely used synthetic superdisintegrant, sodium starch glycolate (SSG) in the formulation of ODTs. Both the superdisintegrants were used at different concentration levels to assess their efficiency. ODTs were prepared by direct compression method using mannitol as directly compressible vehicle. Tablets were evaluated for various physical parameters such as weight variation, thickness, hardness, friability, wetting time, water absorption ratio, drug content, in vitro disintegration time and dissolution studies. Swelling index was also measured for comparing the swelling property of SSG with mucilage of Plantago ovata. The present study revealed that mucilage of Plantago ovata proved to be more effective for their disintegrating property than the most commonly used synthetic superdisintegrant, SSG.

Keywords: Orally disintegrating tablets, Direct compression, Sodium starch glycolate, *Plantago ovata* mucilage powder.

INTRODUCTION

Despite of tremendous advancements in drug delivery, the oral route remains the preferred route for administration of various therapeutic agents because of accurate dosage, low cost therapy, self medication, non invasive method, ease of administration etc. leading to high level of patient compliance [1,2]. However, traditional tablets and capsules administered with a glass of water

may be inconvenient or impractical for geriatric patients because of changes in various physiological and neurological conditions associated with aging including difficulty in swallowing, hand tremors, deterioration in their eyesight, hearing, memory, risk of choking in addition to change in taste and smell [3]. Due to decline in swallowing ability with age, many elderly patients generally complain that it is difficult for them to take some currently available conventional dosage forms such as tablets, capsules or powders. Pediatric patients may also suffer from ingestion problems as a result of underdeveloped muscular and nervous control. Moreover, patients traveling with little or no access to water, limit utility of orally administered conventional tablets or capsules [4].

Therefore, to cater the escalating needs of such patients, recent advancements in technology have developed viable dosage alternatives known as orally disintegrating tablets. These are solid unit dosage forms/entities containing medicinal substances which disintegrate or dissolve rapidly in oral cavity, usually within a few seconds, requiring no additional water to facilitate swallowing [5]. These dosage forms are better alternative for oral medication in improving the quality of life and patient compliance. ODTs are also known as orodispersible tablets, mouth dissolving tablets, rapimelts, melt-in-mouth tablets, rapid dissolving and fast disintegrating tablets. Many substances such as Ac-Di-Sol (croscarmellose sodium), crospovidone, sodium starch glycolate etc. have been used in the formulation of ODTs. Various natural substances which can also be used for their disintegrating properties includes gum karaya, modified starch, agar, different mucilages isolated from *Mimosa pudica, Ocimum basilicum, Ocimum americannum, Plantago ovata, Lepidium sativum* etc. in the formulation of ODTs. Substances of natural origin are preferred over synthetic and semisynthetic ones because they are comparatively cheaper, abundantly available, nonirritating and nontoxic in nature [6].

Metoclopramide hydrochloride is an antiemetic agent having central antidopaminergic action on chemoreceptor zone (CTZ). At high concentrations, the drug can block $5HT_3$ receptors present on inhibitory interneurones in nucleus tractus solitarius/CTZ. The drug has a short biological half life and usually administered in a dose of 10-15 mg, 4 times in 24 hours to maintain effective concentration throughout the day [7]. Hence, the objective of present investigation was to develop ODTs of selected model drug metoclopramide hydrochloride using SSG as well as mucilage isolated from seeds of *Plantago ovata* and to compare disintegrating property of both.
Plantago ovata is a 10-45 cm tall, stemless or short stemmed annual herb. Leaves are borne alternately on the stem. Seeds of *Plantago ovata* are dull, pinkish grey-brown, long to elliptical. They are odorless, and taste is bland but mucilaginous. Seed epidermis is made up of polyhedral cells whose walls are thickened by a secondary deposit which is the source of mucilage. The mucilage of *Plantago ovata* is colloidal in nature and its composition varies with the conditions of preparations. It is mainly composed of xylose, arabinose and galactouronic acid. However, galactose and rhamnose have also been reported. It is a natural substance having disintegrating and gel formation properties. It can also be used as binding, suspending and thickening agent [8,9].

MATERIALS AND METHODS

Materials: Metoclopramide hydrochloride and Microcrystalline cellulose (MCC) were obtained as a gift sample from Ind Swift Pvt. Ltd., Chandigarh, India. SSG was generous gift sample from

Wockhardt Research Centre, Aurangabad, India. Directly compressible vehicle mannitol (Qualigens Fine Chemicals, Mumbai, India) and magnesium stearate (Loba Chemie, Mumbai, India) were also used. *Plantago ovata* seeds were procured from the local market. All other chemicals used were of analytical grade.

Methodology:

Isolation of mucilage

Seeds of *Plantago ovata* were soaked in distilled water for 48 h and then boiled for few minutes so that mucilage was completely released into water. The material collected was squeezed through muslin cloth for filtering and separating out the marc. Subsequently, an equal volume of acetone was added to the filtrate so as to precipitate the mucilage. The separated mucilage was dried (in an oven at temperature less than 60º C), powdered, sieved (#80) and stored in a desiccator until further use [10,11].

Standard calibration curve

Solutions ranging from 5-50 µg/mL were prepared in distilled water. Absorbance was measured for each solution at λ_{max} 309 nm using double beam UV visible spectrophotometer (Systronics, model-2202, Ahmedabad) [7,12,13].

Formulation development

Direct compression technique was adopted for the preparation of ODTs because it is the easiest and convenient tableting technique. Also, it is considered as the suitable method to prepare ODTs using various excipients [14]. Various constituents of all the formulations containing metoclopramide hydrochloride ODTs are shown in table 1. Batch of 50 tablets was prepared for all the designed formulations. All the ingredients were passed through # 60 mesh separately [15]. Then, the ingredients were weighed accurately and mixed thoroughly in a poly bag for about 5 minutes to achieve complete mixing. The obtained blend was lubricated with magnesium stearate along with the addition of talc and mixed for another 2 minutes, and the resultant mixture was directly compressed into tablets using mini rotary tableting machine (Fluid Pack Machinery, Ahmedabad, India) with punches of 7.4 mm. Before tablet preparation, the mixture blend was also subjected for precompression parameters like angle of repose, compressibility index, bulk density, tapped density and Hausner's ratio.

Table 1. Formulation of metoclopramide hydrochloride ODTs using various superdisintegrants

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8
Metoclopramide hydrochloride	10	10	10	10	10	10	10	10
SSG	3.75	7.5	11.25	15	-	-	-	-
Mucilage powder	-	-	-	-	3.75	7.5	11.25	15
Mannitol	116.45	112.70	108.95	105.20	116.45	112.70	108.95	105.20
Microcrystalline cellulose	15	15	15	15	15	15	15	15
Magnesium stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Talc	3	3	3	3	3	3	3	3
Sodium saccharin	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3

Evaluation of the Blend

Flow properties of powder mixture

Good flow properties are important prerequisite for the successful manufacture of tablet dosage

forms. Data generated on flow properties can be of great concern in the design and development of formulations. Obtained records can provide significant guidance on the selection of proper excipients for further utilization. Certain natural and derived properties must be evaluated to assess the flowability of blend which in turn affects the critical parameters like uniformity of weight in dosage form and weight variation in final formulation. The natural properties include bulk density and tapped density while compressibility index and Hausner's ratio are derived from these properties.

Flow properties of blend (before compression) were characterized in terms of angle of repose, Carr's index and Hausner's ratio. For determination of angle of repose (θ), the blend was poured through the walls of a funnel, which was fixed at a position such that its lower tip was at a height of exactly 2.0 cm above hard surface. The blend was poured till the time when apex of the pile touched the lower tip of the funnel. The $\tan^{-1}$ of the (height of the pile / radius of its base) provided the angle of repose. Bulk density, tapped density, Hausner's ratio (HR) and Carr's index (CI) were calculated using tap density apparatus. The cylinder was raised and dropped under its own weight by a fixed drop height of 3 mm ± 10 % at a nominal rate of 250 drops per minute using tap density apparatus (Electrolab, USP, ETD-1020, Mumbai) [5,7].

Evaluation of Tablets

Weight variation

Twenty tablets were selected at a random from each formulation and average weight was determined. Then individual tablets were weighed using digital electronic balance and the individual weight was compared with the average weight. The mean ± SD (standard deviation) values were calculated. The weight variation test would be a satisfactory method of assessing the drug content uniformity [3].

Thickness

Three tablets were selected randomly from each formulation and their thickness was measured with Vernier caliper [3]. The mean ± SD values were also calculated.

Hardness

Hardness of tablets was measured using Pfizer type hardness tester. Three tablets were selected from each formulation randomly and their hardness was measured. The mean ± SD of hardness values were calculated. The resistance of the tablet to abrasion, chipping or breakage under conditions of storage, transformation and handling before usage depends on its hardness [16].

Friability

Friability of the tablets was determined using Roche friabilator. This device subjects a number of tablets to the combined effect of abrasions and shocks in a plastic chamber revolving at 25 rpm and dropping the tablets at distance of six inches with each revolution. Preweighed sample of tablets was placed in the friabilator, and were subjected to 100 revolutions [7,17]. Tablets were then de-dusted, reweighed and percentage loss was calculated. Friability is obtained by the following formula:

$$\text{Friability} = \frac{\text{Initial weight-Final weight}}{\text{Initial weight}} \times 100$$

Wetting time

Wetting time of dosage form is related to the contact angle. It needs to be assessed for an insight into the disintegration properties of the tablets; a lower wetting time implies a quicker disintegration of the tablet. For this purpose, a piece of tissue paper folded twice was placed in a small petridish containing 6 mL of water. Tablet was kept on the paper and the time for complete wetting was measured [18,19]. The mean ± SD values were calculated accordingly.

Water absorption ratio

The weight of tablet prior to placement in the petri dish was noted (w_b) utilizing a digital balance. The wetted tablet was removed and reweighed (w_a). Water absorption ratio, R, was then determined according to the following equation.

$$R = 100\times (w_a - w_b) / w_b$$

where w_b and w_a were tablet weights before and after water absorption, respectively [3,5]. The mean ± SD values were calculated.

***In vitro* disintegration test**

Disintegration time is very important for ODTs which is desired to be less than 60 seconds. This rapid disintegration assists swallowing of the tablet and also plays a role in drug absorption in buccal cavity, thus promoting bioavailability. *In vitro* disintegration time was determined using disintegration test apparatus (Electrolab, USP model ED-2L, Mumbai) without disk for six tablets. The disintegration medium was 900 mL of distilled water kept at 37 ± 0.5ºC and stirred at a rate of 30±2 cycles/min. The time was measured in seconds for complete disintegration of the tablet with no palpable mass remaining in the apparatus [14]. The test was carried out in triplicate.

Drug content uniformity

Powdered one tablet selected randomly from each batch and mixed it in 50 mL of 0.1 M hydrochloric acid. The obtained solution was heated at 70º C for 15 min, cooled and diluted to 100.0 mL with water and filtered. To 20 mL of this solution, 15 mL of 1.25 M sodium hydroxide was added and extracted with three quantities, each of 30 mL of chloroform. Each extract was dried with anhydrous sodium sulphate and filtered. The combined extract was diluted to 100 mL with chloroform and mixed. The absorbance of resulting solution was measured and concentration of metoclopramide hydrochloride was calculated [13]. The mean ± SD values were also determined.

Swelling index

Swelling index is the volume in milliliters occupied by 1 gram of superdisintegrant, including any adhering mucilage, after it has swollen in an aqueous liquid for 4 h. Swelling index of *Plantago ovata* and sodium starch glycolate were carried out by using British Pharmacopoeia method [20,21]. Three tests were carried out at the same time. Swelling index was calculated by the means of three tests.

In vitro dissolution studies

In vitro drug release was determined using USP dissolution apparatus type II (paddle type) at 50 rpm maintained at 37± 0.5º C in 900 mL of distilled water as dissolution medium. Percent drug release was calculated by taking an aliquot of 10 mL at different pre-determined time interval, filtered through Whatmann filter paper and was assayed at 309 nm for metoclopramide hydrochloride using double beam UV spectrophotometer. An equal volume of fresh dissolution medium was replaced to maintain the original volume [5,12]. The dissolution studies were carried out in triplicate for each formulation batch.

Mechanism of Drug Release

Mathematical modeling of drug release profile

The cumulative amount of metoclopramide hydrochloride release from formulated ODTs at different time intervals were fitted to zero order kinetics, first order kinetics, Higuchi model and Korsmeyer–Peppas model to characterize mechanism of drug release [22-27].

RESULTS AND DISCUSSION

Powder mixture of all the formulations were evaluated for various precompression parameters like bulk density, tapped density, Carr's index and Hausner's ratio using tap density apparatus. Bulk density was found in the range of 0.437-0.498 g/cm^3 and tapped density between 0.571-0.670 g/cm^3 as shown in table 2. Compressibility index was found to lie in the range of 22.50-25.67% with fair to good flow properties. Flow properties of powder can be judged from the angle of repose. The angle of repose <30º indicates free flowing material and >40º with poor flow properties. The angle of repose were found in the range of 25.1º-30.1º as given in table 2 showing that the blend was free flowing and can be used for direct compression. Hausner's ratio is related to interparticle friction. Powders with low interparticle friction have ratio of approximately 1.2, whereas more cohesive, less free flowing powders have ratio >1.6. Hausner's ratio for all the formulations (F1-F8) was between 1.29-1.35 indicating low interparticle friction. No formulas showed Hausner's ratio >1.6.

Table 2. Precompression parameters of various formulations

Formulation	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Hausner's Ratio	Compressibility Index (%)	Angle of repose (θ)
F1	0.438	0.573	1.31	23.53	29.5
F2	0.440	0.575	1.31	23.48	30.1
F3	0.437	0.571	1.31	23.46	29.2
F4	0.438	0.573	1.31	23.53	26.6
F5	0.498	0.670	1.35	25.67	28.0
F6	0.475	0.635	1.34	25.20	28.0
F7	0.477	0.627	1.31	23.90	26.6
F8	0.472	0.609	1.29	22.50	25.1

Eight formulations were prepared using different concentration of superdisintegrants under similar conditions to avoid processing variables. Obtained tablet of all formulations were of uniform weight due to uniform die fill, with acceptable variations as per I.P 1996 specifications. Drug content was found to be between 96.33-98.32% as represented in table 3 which is within acceptable limits. Hardness was found to be in the range of 2.9-3.5 kg/cm^2 in all the formulations

indicating good mechanical strength with an ability to withstand physical and mechanical stress conditions while handling. The percentage friability was ranged from 0.38-0.74% for all the formulations which is within limit i.e. less than 1.0 % except for F8 which inferred that mucilage powder has strong binding capacity at 2.5-7.5 % concentration, beyond this concentration the binding efficiency decreases.

Table 3. Evaluation parameters of metoclopramide hydrochloride ODTs

Parameters	F1	F2	F3	F4	F5	F6	F7	F8
Weight variation (mg) n = 20	150.4±1.31	150.6±1.33	150.4±2.11	151.0±1.81	150.9±1.10	150.8±1.13	149.9±1.26	149.8 ±1.37
Hardness (kg/cm^2)	3.15 ± 0.06	3.06±0.06	3.1 ± 0.1	2.9 ± 0.06	3.5 ± 0.10	3.33±0.11	3.0 ± 0.10	3.0± 0.00
Friability (%)	0.38	0.39	0.59	0.74	0.59	0.65	0.70	1.3
Uniformity of content (%)	96.33± 0.51	98.21± 0.73	98.07± 0.84	98.32 ± 0.84	98.173 ± 0.70	96.97± 1.18	97.58 ± 1.59	97.2 ± 1.48
Thickness (mm)	3.1± 0.00	3.03±0.05	2.93 ± 0.05	3.1 ± 0.03	2.9 ± 0.00	3.1± 0.05	3.03 ± 0.05	3.0 ± 0.00
Water absorption ratio	32.19 ± 0.39	56.26± 0.30	58.76 ± 0.06	69.94 ± 0.35	57.86 ±0.32	105.3± 0.94	115.9 ± 0.99	142.5 ± 0.96
Wetting time (s)	369± 4.36	318.3 ± 2.52	230.3 ± 1.53	119 ± 3.60	209.3 ± 4.93	169.7± 2.51	83.0 ± 1.00	50.0 ± 1.00
In vitro disintegration time (s)	308 ±2.00	283 ± 2.00	210.7 ± 1.16	82.7 ± 0.57	204 ± 3.00	124.3 ± 2.08	54.3± 0.58	32 ± 0.00
In vitro drug release (%)	85.13 ± 0.68	91.55 ±1.03	92.70 ± 1.97	93.07 ± 1.96	93.46 ± 0.69	95.33 ± 1.04	98.36 ±1.55	99.49 ± 1.28

Data are expressed as mean ± S.D. (n = 3)

In vitro disintegration time of various formulations was calculated using disintegration test apparatus. After observing the disintegration time, it was concluded that as the concentration of the superdisintegrant increases, the disintegration time decreases in all formulations and it has been shown in Figure 1 by plotting a bar graph between disintegration time and various superdisintegrants.

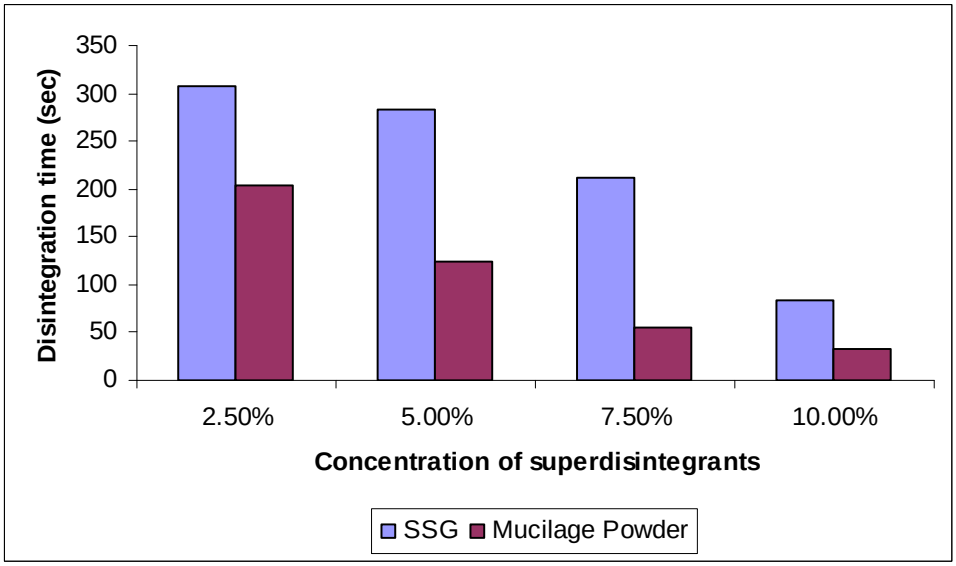

Figure 1: Disintegration time of ODTs containing different concentration of superdisintegrants

Wetting time was used as parameter to correlate with disintegration time. Wetting is related to the inner structure of the tablets and hydrophilicity of the excipients. SSG swells rapidly and enormously with gelling. This may be due to the fact that SSG is disintegrated by swelling mechanism leading to longer wetting time. It was observed that formulations F5-F8 containing

mucilage powder took lesser time for wetting of the tablets as compared to the formulations containing SSG. This might be due to rapid penetration of water into the pores of tablet. Disintegration time was found to be in between 32 to 308 seconds for all the formulations and wetting time was found in between 50 to 369 seconds for all formulations represented in table 3. This showed good correlation between disintegration time and wetting time and it was revealed that lesser the wetting time shorter would be the disintegration time. A correlation between disintegration time and wetting time has been shown in figure 2. Wetting time results are in consistent with disintegration test results.

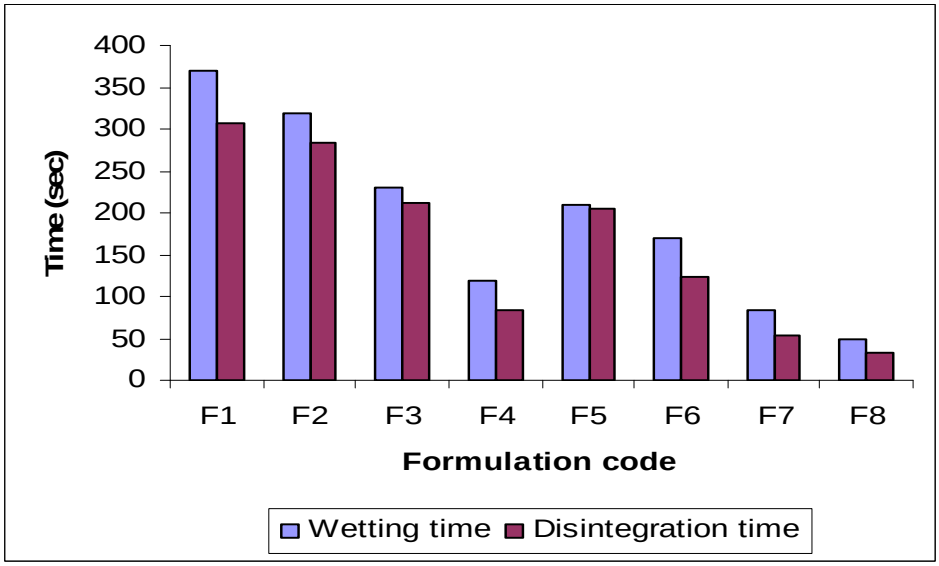

Figure 2: Correlation between disintegration time and wetting time

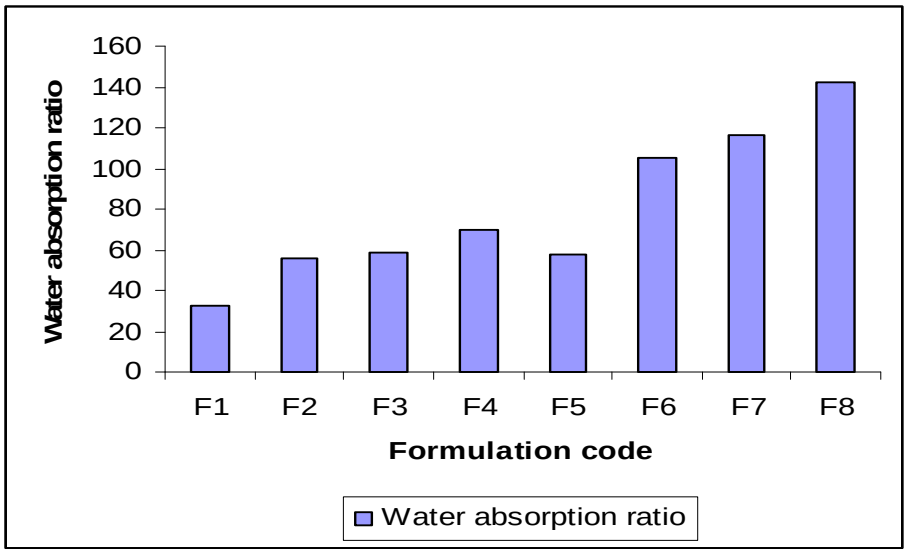

Figure 3: Water absorption ratio of different metoclopramide hydrochloride ODTs

Water absorption ratio is an important criteria for understanding the capacity of disintegrants to swell in presence of little amount of water. Water absorption ratio of all formulations was calculated according to procedure and formula as described. It was within the range of 32.19-142.5%. Water absorption ratio of mucilage powder was higher as compared to that of SSG. It was observed that water absorption ratio increased with an increase in superdisintegrants concentration ranging from 2.5-10.0% which have been represented in figure 3.

Swelling index of both disintegrants has been given in table 4. Because of higher swelling index, formulations containing *Plantago ovata* mucilage powder disintegrated quickly and completely as compared to formulations containing SSG. This rapid disintegration of ODTs with mucilage powder was due to the penetration of saliva into the pores of tablets which leads to swelling of superdisintegrants so as to create enough hydrodynamic pressure for quick and complete disintegration of the tablets. Since SSG swells with more gelling than mucilage powder, so despite of having higher water absorption ratio, its disintegration time got extended.

Table 4. Swelling index for various ingredients

S. No.	Name of ingredient	Swelling index (% v/v)
1	*Plantago ovata* mucilage powder	94 ± 2.5
2	Sodium starch glycolate	59 ± 1.75

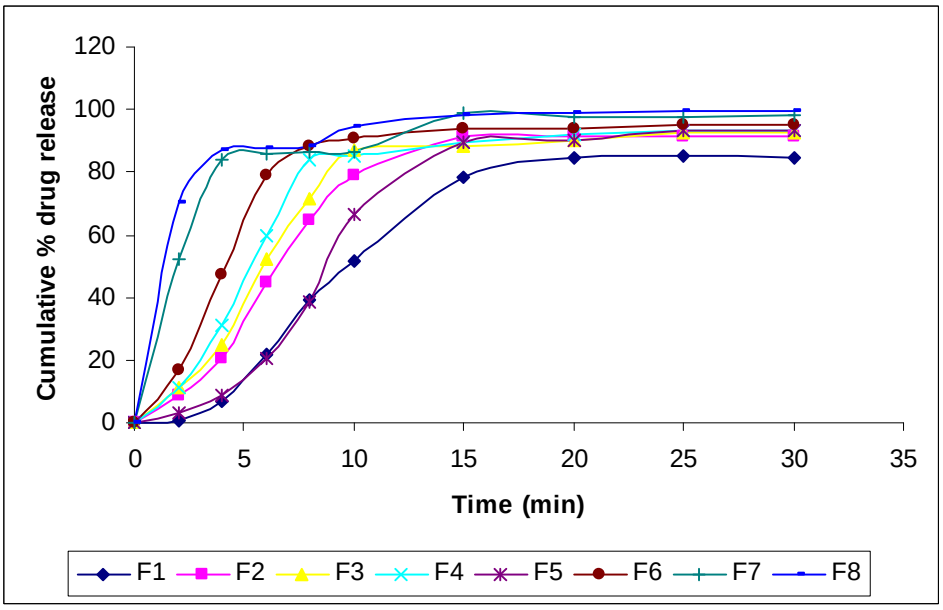

Figure 4: Dissolution profile of various formulations containing SSG and mucilage powder

In vitro drug release studies of all the formulations were carried out in triplicate. It is evident that disintegration has effect on the dissolution characteristics and an increase in superdisintegrant concentration resulted in increasing order of cumulative percentage drug released in the first 4 minutes. This may be due to the increase in concentration of superdisintegrant resulted in rapid disintegration of tablets and the particles were exposed to dissolution medium at comparatively faster rate. The percent drug released at various intervals from 2-30 minutes was calculated using

equation obtained from calibration curve. F1, F2, F3 and F4 formulations with SSG were found to release 6.92%, 20.82%, 24.59% and 31.31% of drug respectively in the first four minutes. Likewise, formulations F5-F8 released 8.81%, 47.05%, 84.05% and 87.23% of drug respectively at the end of 4 minutes. The plot between cumulative percentage drug release vs. time as shown in figure 4 revealed that the formulations F7 and F8 were found to release more than 95% of drug at the end of 15 minutes while the formulations F3 and F4 with SSG having same concentration to F7 and F8 were found to release less than 90% drug at the end of 15 minutes.

Drug release rate from the formulation with mucilage powder was found to be fast as compared to the formulations containing SSG. Rapid increase in the dissolution of drug with increase in mucilage powder may be attributed to swelling of mucilage powder which leads to penetration of water into the pores of tablets and generation of hydrodynamic pressure for quick and complete disintegration of tablet. However, in case of tablets prepared with SSG, disintegration takes place by rapid uptake of water followed by quick and enormous swelling into smaller particles but dissolution occurs more slowly due to formation of a viscous gel layer by SSG.

Release data of all the formulations were fitted into four different mathematical models namely zero order, first order, Higuchi model and Korsmeyer-Peppas (power law) model to characterize the mechanism of drug release. The release rate constants (K_0, K_1, K_H) as obtained from regressed plots of different kinetic models such as zero order, first order, Higuchi and the release exponent value (n) for power law of all the formulations are given in table 5 along with correlation coefficients (R^2). Considering the correlation coefficient (R^2) values, the drug release from most of the formulated orally disintegrating tablets were found to follow first order model rather than other models. Correlation coefficient (R^2) value obtained in zero order, first order, Higuchi and Peppas release kinetic of formulation F4 were 0.639, 0.786, 0.722 and 0.771 respectively. In this formulation, *in vitro* drug release was best explained by first order because best linearity was found in first order equation plot as indicated by their highest correlation coefficient value as compared with other models. On considering the R^2 value for F5, the drug release was best explained by Korsmeyer-Peppas model as the plot showed the highest linearity (R^2 = 0.909), but a close relationship was also noted with first order kinetics (R^2 = 0.907). The value of release exponent (n) obtained from Korsmeyer-Peppas model gives an indication of the drug release mechanism. The release exponent "n" value for the different formulation ranged from 0.12-1.59.

Table 5. Fit of different kinetic models for release of drug from ODTs

Formulation code	Zero order		First order		Higuchi model		Korsmeyer-Peppas model	
	K_0	R^2	K_1	R^2	K_H	R^2	n	R^2
F1	3.324	0.862	0.0792	0.898	24.06	0.921	1.59	0.865
F2	3.123	0.736	0.0935	0.812	21.39	0.819	0.86	0.810
F3	2.986	0.691	0.0912	0.821	19.93	0.775	0.75	0.820
F4	2.863	0.639	0.0888	0.786	18.68	0.722	0.71	0.771
F5	3.627	0.837	0.1130	0.907	26.19	0.892	1.30	0.909
F6	2.611	0.552	0.0912	0.726	15.79	0.632	0.54	0.705
F7	2.033	0.447	0.1158	0.780	8.617	0.669	0.19	0.744
F8	1.832	0.377	0.1510	0.950	6.112	0.773	0.12	0.866

Formulations F2, F3, F4 and F6 showed the diffusional exponent; "n" in between 0.5 and 1.0 which indicates the anomalous transport kinetics or non-fickian diffusion that means the drug was released by the combined mechanism of pure diffusion controlled and swelling controlled drug release. Formulations F1 and F5 having "n" value greater than 1 was found to follow supercase II transport. The remaining formulations (F7-F8) having "n" value less than 0.5 were beyond the limits of Korsmeyer-Peppas model. Release kinetics plays a pivotal role in formulation development because if the kinetics of drug release is known, one can also advance for the establishment of *in vitro-in vivo* (IVIVC) correlation.

CONCLUSION

In the present investigational study, it was concluded that mucilage powder isolated from *Plantago ovata* showed better disintegrating efficiency than the most commonly used synthetic superdisintegrant, SSG in the formulation of ODTs. As natural ingredients are cheap, easily available, biocompatible, biodegradable, easy to manufacture etc., they can be utilized as suitable superdisintegrant in place of currently available synthetic superdisintegrating agents. Advanced research with a variety of natural superdisintegrants and new preparation methods can lead to the fabrication of more promising dosage form with novel performance and characteristics. Moreover, experimentation can be further extended for *in vivo* studies in animal models and human volunteers.

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