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Effect of natural polymer on release pattern of domperidone immediate release tablets using *fenugreek* seeds mucilage in comparison with synthetic superdisintegrants

Saripilli Rajeswari*[1], Pottipireddy Aruna[1], Kudamala Sravya[2]

[1]Maharajah's College of Pharmacy, Phool Baugh, Vizianagaram - 535002, AP, India.

[2]Dept. of Pharmaceutical Technology, Andhra University, Visakhapatnam–530003, AP, India.

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ABSTRACT: Background: The domperidone immediate-release tablets (IRT) are an effective anti-emetic medicine used to relieve nausea and vomiting caused by delayed gastric emptying. **Aim:** The aim of the present research work was to formulate IRTs of domperidone by direct compression method and to evaluate *fenugreek* seeds mucilage as a natural superdisintegrating agent. **Method:** The IRTs were prepared by using *fenugreek* seed mucilage powder, crospovidone, croscarmellose sodium, and sodium starch glycolate as superdisintegrants (2, 4, and 6 % w/w) and microcrystalline cellulose (22, 24, and 26 % w/w) as a directly compressible vehicle. All the prepared tablets were evaluated for hardness, friability, drug content uniformity, weight variation, disintegrating time, wetting time, and *in vitro* drug release studies. **Results:** Domperidone obeys Beer's law in the concentration range based on *in vitro* drug release studies (> 90 % within 30 min), the two formulations were tested for short-term stability (At storage condition of 40 °C/75 % RH for 3 months) and drug excipient interaction (IR spectroscopy). From all the prepared formulations, the formulation FR8 prepared with 6 % w/w *fenugreek* seeds mucilage and 24 % w/w of MCC was optimized as the best formulation (> 90 % within 30 min) compared to conventional commercial tablets formulation (> 75 % within 30 min). There is no significance on drug content and *in vitro* drug release ($p < 0.05$) (Accelerated stability studies). The evaluation data of all the prepared fast-dissolving tablet formulations were within the limits of the Pharmacopoeia standard. **Conclusion:** From the obtained data, *fenugreek* seed mucilage powder can be used as a suitable natural disintegrant in the formulation of IRTs with low concentrations as synthetic superdisintegrants.

Corresponding author
Dr. S. Rajeswari
Maharajah's College of Pharmacy,
Phool Baugh, Vizianagaram – 535002,
Vizianagaram, India.
Tel: +91-9652105582
E-mail ID: rajeswarimalli@gmail.com

Keywords: Domperidone, *fenugreek* seeds mucilage, croscarmellose sodium, crospovidone, sodium starch glycolate.

INTRODUCTION:

An oral route is the most common and applicable route of administration of drugs due to various advantages including ease of administration, avoidance of pain, versatility, and most importantly patient compliance. As solid formulations do not require any sterile conditions, they are less expensive [1]. Immediate release tablets were introduced as an alternative to conventional oral dosage forms that are useful in patients leading to

ineffective therapy [2,3]. Many drugs given orally are poor in bioavailability because of the pH of the stomach, the presence of enzymes, and extensive first-pass metabolism. Recent development in novel drug delivery system aims to enhance the safety and efficacy of drug molecules by formulating a convenient dosage form for administration [4]. Hence, the immediate release dosage form disintegrates rapidly and releases the drug within a short period of time. The basic approach used in the development of immediate-release tablets is the use of superdisintegrants like cross-linked crospovidone, croscarmellose sodium, and sodium starch glycolate. Domperidone (DOM) is 5-Chloro- l-[1-[3-(2,3-dihydro-2-oxo-1H-benzimidazol-1-yl)propyl]-4-piperidinyl]-1,3-dihydro-2H-benzimidazole-2-one is a peripherally selective dopamine D_2 receptor antagonist, which acts as a gastrointestinal emptying adjunct and peristaltic stimulant. DOM is structurally related to the butyrophenones which do not cross the blood-brain barrier and mainly act on the chemotriger zone, located within the postrema zone [5]. The purpose of the present research work was to develop and characterize immediate release tablets of DOM using natural superdisintegrant *fenugreek* seeds mucilage (FSM) [6] in comparison with various synthetic superdisintegrants such as crospovidone (CP), croscarmellose sodium (CCS), and sodium starch glycolate (SSG). These immediate release tablets release the medicament within a short duration of time which may result in the quick onset of the pharmacological action and increased bioavailability of the drug.

MATERIALS AND METHODS:

Domperidone was obtained as a gift sample from Aurobindo Labs, Hyderabad, India. Crospovidone, Croscarmellose sodium, and Sodium starch glycolate were purchased from Yarrow Chem Product, Mumbai, India. Microcrystalline cellulose was purchased from Chemica-biochemica reagents, Mumbai, India. *Fenugreek* seeds purchased from Local market, Vizianagaram, Andhra Pradesh, India. All the materials were of pharma grade.

Extraction of *fenugreek* seeds mucilage:

The seeds were powdered and passed through sieve #60. Then 100 g of the powder was soaked in a sufficient quantity of distilled water for 5 h, boiled for 2 h, and then kept aside for 1 h for a complete release of mucilage into the water. Then the contents were squeezed through an 8-fold muslin cloth to remove the marc from the solution. To the filtrate added 3 volumes of ethanol to precipitate the *fenugreek* mucilage. Then the precipitated mucilage was filtered and dried at room temperature. Dried *fenugreek* mucilage was collected, grounded, passed through sieve # 80, and stored at room temperature in a desiccator as shown in Fig 1 [7-9].

Fig 1. Figure shows (a) *Fenugreek* seeds, b) Soaked *fenugreek* powder for 5 h and boiled for 2 h, c) Precipitated *fenugreek* seed mucilage after adding ethanol, d) Extracted *fenugreek* seed mucilage after filtration, and e) Dried and grounded *fenugreek* mucilage powder after passing through sieve No. # 60 mesh.

Preparation of domperidone immediate-release tablets:

Each tablet containing 10 mg domperidone was prepared by using the direct compression method with 50 tablets for the batch. The compositions of various formulations of the tablets with their formulation codes were given in (Table 1). All the materials were passed through a sieve 80 # and mixed. The blend was compressed into tablets using 8 mm flat round punches on 12-station tablet compression machines (Rimex MINI press, Karnavathi engineering Pvt. Ltd. Gujarat, India) [10-12].

Evaluation of pre-compression parameters:

Pre-compression parameters such as angle of repose, bulk density and tap density, Carr‘s index, and Hausner‘s ratio were determined [13-15].

Angle of repose:

It was determined by the falling funnel method. The powder was allowed to flow through the funnel fixed to a stand at a definite height. The angle of repose (θ) was

Table 1. Formulation of domperidone immediate release tablets.

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Domperidone	10	10	10	10	10	10	10	10	10	10	10	10
Crospovidone	2	4	6	-	-	-	-	-	-	-	-	-
Croscarmellose sodium	-	-	-	2	4	6	-	-	-	-	-	-
Sodium starch glycolate	-	-	-	-	-	-	2	4	6	-	-	-
Fenugreek seed mucilage	-	-	-	-	-	-	-	-	-	2	4	6
Microcrystalline cellulose	23	21	19	23	21	19	23	21	19	23	21	19
Magnesium stearate	5	5	5	5	5	5	5	5	5	5	5	5
Mannitol	10	10	10	10	10	10	10	10	10	10	10	10
Total weight	50	50	50	50	50	50	50	50	50	50	50	50

calculated by measuring the height (h) and radius r of the heap of granules, using the following equation.

$\theta = Tan^{-1}(h/r)$ ……..(1)

***Bulk density*:**

The bulk density and tapped density were determined by pouring the blend into a graduated cylinder of density apparatus. The bulk density apparatus was allowed to tap for a fixed time to obtain tapped volume (V_f). The bulk volume (V_0) and the weight of powder (M) were determined. The bulk density (ρ_o) and tapped density (ρ_t) can be calculated using the formula given in the equation.

Bulk density = M/V_0 ……(2)

Tapped density = M/V_f ……(3)

***Carr's index (CI)*:**

The flow ability of powder can be evaluated by comparing the bulk density and tapped density of powder and the rate at which it is packed down. Carr's index is calculated by using the following equation.

$CI\ (\%) = [(\rho_t - \rho_o)/\rho_t] \times 100$ …….(4)

***Hausner's ratio*:**

An indirect index of powder flow and calculated by using the equation.

Hausner's ratio = ρ_t/ρ_o ……(5)

***Compatibility studies*:**

The compatibility studies were performed using IR spectrophotometer, DSC, XRD, and SEM.

Evaluation of post-compression parameters:

Post-compression parameters such as weight variation, thickness, hardness, friability, water absorption ratio, wetting time, disintegration test, *in vitro* dispersion time, content uniformity, and *in vitro* dissolution study were determined.

***Weight variation test*:**

Randomly 20 tablets were taken from each batch and their weight was determined individually and collectively on a digital weighing balance. The average weight of the tablet was determined by the collective weights [16].

Thickness:

Randomly 10 tablets from each formulation were taken, and their thickness was measured using a Vernier caliper, and the reading was recorded millimeters [17].

Hardness test:

Three tablets were randomly picked from each formulation batch and the mean and standard values were calculated [17]. The hardness of the tablet was determined using the Monsanto hardness tester and expressed in kg/cm^2.

Friability test:

A sample of whole tablets corresponding to about 6.5 g was weighed and the initial weight was recorded (W_o) and placed in a Roche friabilator and rotated at the speed of 25 rpm for 100 revolutions [16]. Then tablets were removed from the friabilator, dusted off the fines, and again weighed and the final weight was recorded (W_f). Percentage friability was calculated by using the formula given in equation 6.

Friability (%) = $[(W_o - W_f)/ W_o] \times 100$ ….(6)

Disintegration test:

The disintegration time was performed using a USP disintegration test apparatus with 0.1 N HCl medium at 37 ± 0.5 ˚C. A tablet was placed in each of six tubes of apparatus, and one disc was added to each tube. The time was recorded when all the fragments of the disintegrating tablet (6 tablets) passed through the screen of the baskets [16].

Content uniformity test:

The drug content was determined by taking 10 dosage units at random and powdering. The blend equivalent to 10 mg of DOM was weighed and dissolved in 100 ml of 0.1 N HCl buffer, stirred for 15 min, and filtered. Absorbance was measured at 285 nm using a UV-Visible double beam spectrophotometer (UV- 1700 Shimadzu) [18].

In vitro dissolution studies:

In vitro dissolution studies of DOM were performed in USP XXIII dissolution testing apparatus II (paddle type). The dissolution test was performed using 900 ml of 0.1 N HCl (pH-1.2), at 37±0.5 ˚C at 50 rpm speed. A sample of 5 ml solution was withdrawn from the dissolution apparatus at 5, 10, 15, 30, 45, and 60 min respectively, and replaced with 5 ml of fresh dissolution medium. The samples were filtered and measured spectrophotometrically at 285 nm. All the dissolution tests were carried out in triplicates. The cumulative percentage of drug release was calculated using an equation obtained from a standard curve [19, 20].

Statistical analysis:

All the values are expressed as mean ± standard deviation (S.D). The t-test was used to study the significant difference between the control and test at 0.05 % of the level of significance. All the values are represented in three determinants. The value less than 0.05 were taken as no significant difference.

RESULTS:

In the present investigation, immediate-release tablets of DOM were prepared by using natural superdisintegrants (FSM powder). For comparison, tablets were also prepared by synthetic superdisintegrants (CP, CCS, and SSG). Initially, the FSM powder was extracted from 100g of *fenugreek* seed powder around 65 g of FSM powder was obtained.

Identification of pure drug:

Physical characterization studies stated that DOM is a white crystalline powder with a bitter taste. The melting point of DOM was found to be in the range of 251.8 °C when tested using the capillary method in the melting point apparatus in triplicate. All the studies were conducted in aqueous media (0.1 N HCl buffer). Identification of the drug was done from absorption maxima, IR, and DCS studies. Absorption maxima of 285.02 nm confirmed that the drug was pure DOM, shown in Fig 2 as was previously mentioned in associated literature [17].

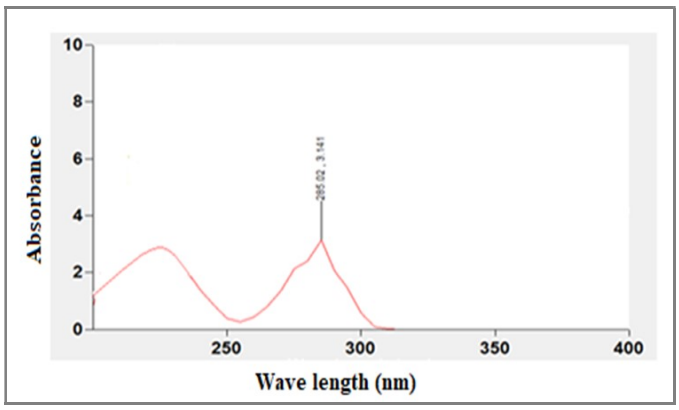

Fig 2. Represents the λ_{max} of domperidone pure drug.

Fourier transform infrared spectroscopy:

The FTIR analysis of the pure drug DOM, optimized formulation F8 and F12 were shown in Fig 3. The IR spectrum of the pure drug showed a characteristic stretching peak at 3350 cm^{-1}, aromatic C-H stretch at 3000 cm^{-1}, symmetric -C-H stretching at 2900 cm^{-1}, indicating N-H and stretching at 1700 cm^{-1} indicates C=O, -C=C- stretch denoting the presence of alkyl halide at 700 cm^{-1} indicating the drug was pure. The FTIR spectra of optimized formulation F12 containing 6 % *fenugreek* seed mucilage powder showed O-H stretching at 3424.3 cm^{-1}, C-H stretching vibration at 2918.7 cm^{-1}, and C-O stretching vibration at 1102 cm^{-1}. The FTIR spectra of mannitol stretch nearly at 3400 cm^{-1} indicating OH, 3000 cm^{-1} indicates COOH group, and 1450 cm^{-1} indicates benzene. The FTIR spectra of SSG showed characteristic stretch nearly at 3200 cm^{-1} indicates C-H, stretch nearly at 1300 cm^{-1} indicates -COOH group, and at 1600 cm^{-1} indicates -C=C. All the stretches were also found in the formulation without any changes in the peaks indicating that there is no interaction between drug and polymers.

Differential Scanning Calorimetric Studies (DSC):

The DSC thermograph of pure DOM, optimized formulations F8 and F12 as shown in Fig 4. The DSC thermograph of domperidone showed a sharp endothermic peak at 251.8 °C due to the melting point of the drug. The optimized formulation FD8 with 4 % SSG showed a sharp endothermic peak at 204.8 °C. The optimized formulation FD12 with 6 % *fenugreek* seed mucilage powder showed a sharp endothermic peak at 169.24 °C. This indicates the crystallinity nature of the drug converted to an amorphous state.

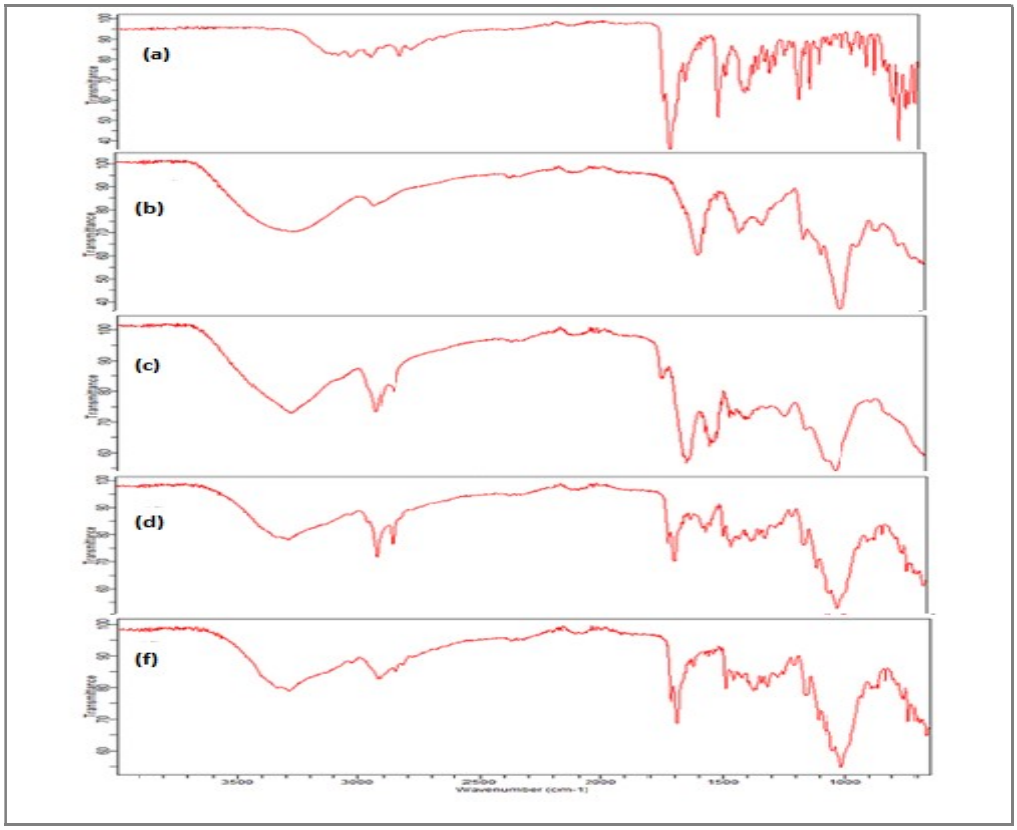

Fig 3. FTIR Spectrum of a) Domperidone pure drug b) SSG, c) *Fenugreek* seed mucilage powder, d) Optimized formulation F8 containing 4% of SSG e) F12 containing 6% of FSM powder.

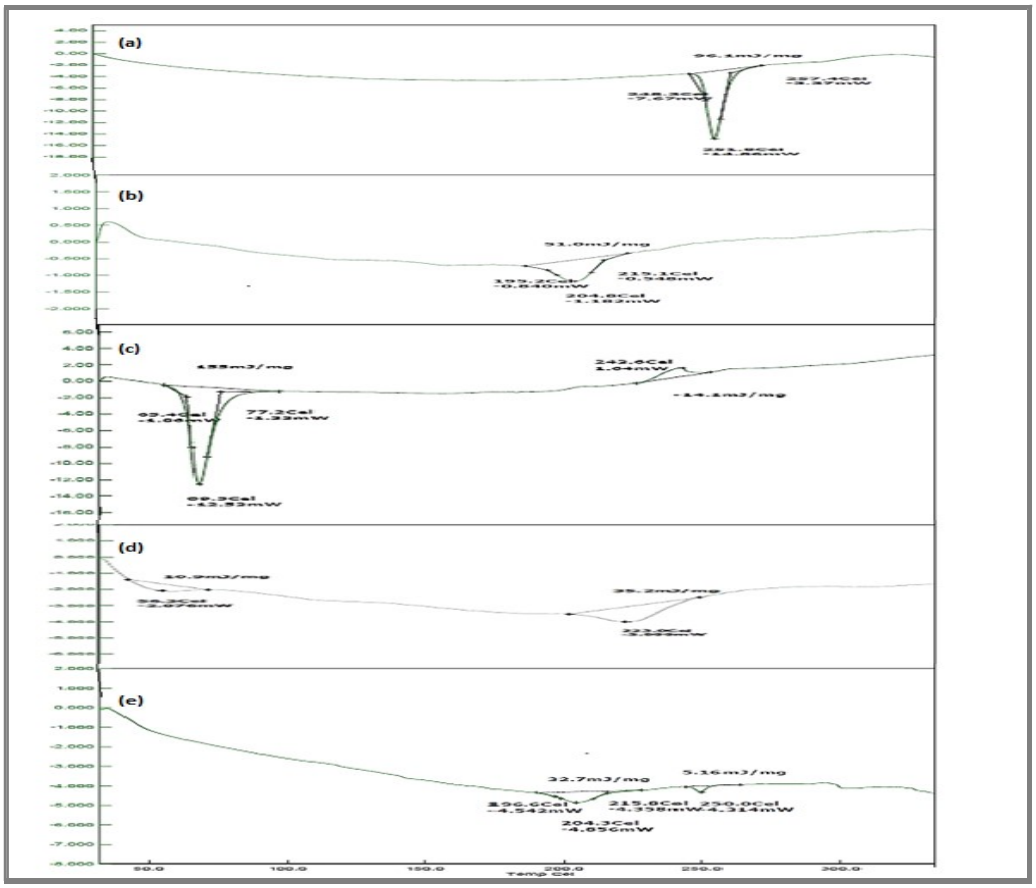

Fig 4. DSC thermogram of a) Domperidone pure drug b) SSG, c) *Fenugreek* seed mucilage powder, d) Optimized formulation F8 containing 4% of SSG e) F12 containing 6% of FSM powder.

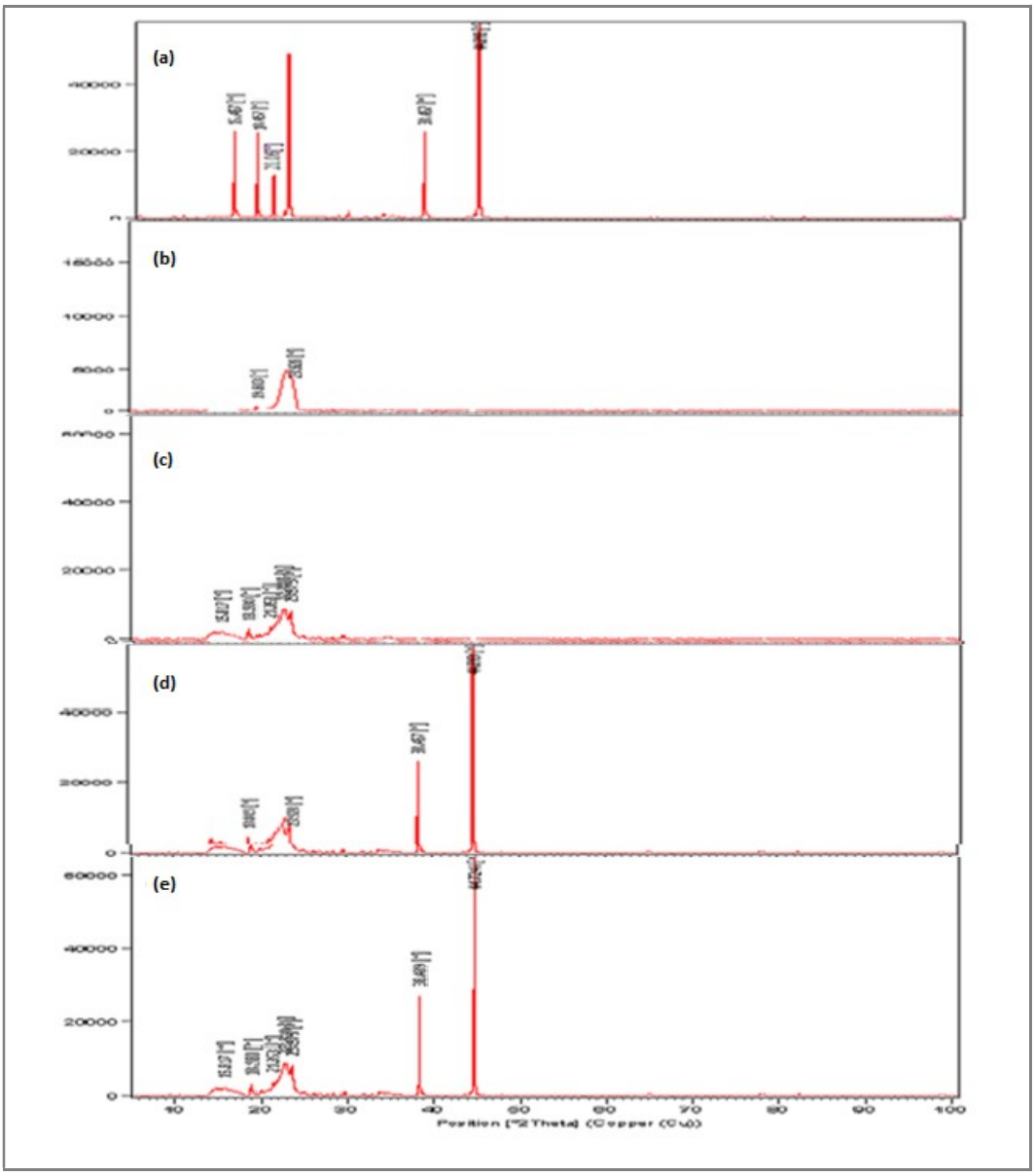

Fig 5. XRD studies of a) Domperidone pure drug b) SSG, c) *Fenugreek* seed mucilage powder, d) Optimized formulation F8 containing 4% of SSG e) F12 containing 6% of FSM powder.

XRD studies:

The XRD pattern of DOM, optimized formulations F8 with 4% SSG and F12 with 6 % *fenugreek* seed mucilage powder are shown in Fig 5. The XRD pattern of domperidone exhibited sharp and intense peaks at 2θ equivalent to 16.45, 18.45, 21.06, 22, 38.45, and 44.69 ° which reflects the crystalline nature of the pure drug.

Evaluation of pre-compression studies:

Flow characteristics of the material being compressed were evaluated and the results are shown in Table 2. As the angle of repose values was within the range of 20.05 to 22.19° for F1 to F12 formulations respectively, they indicated excellent to good flow properties. The compressibility index values of all the formulations were within the range of 10.74 to 14.88 % respectively, with a good compressibility index as all the values, are within 15 % results in good to excellent flow properties and describe the frictional and cohesive interactions of the polymers in the formulation. Hausner's ratio of all the formulations was in the range of 1.12 to 1.19 which indicated good flow characteristics for the prepared lubricated blends, as all the values are <1.25 indicating the polymers with low interparticle friction.

Evaluation of Post-compression parameters:

***Tableting characteristics of the domperidone*:**

All the prepared tablets were evaluated for the post-compression parameters and the results are given in Table 3 and Table 4. All the prepared DOM immediate-release tablets are greater than 50 mg (0.050 g) and are well within the range of 5 % and hence qualify for test

Table 2. Pre-compression properties of prepared formulations.

Formulation code	Angle of repose (°)	Bulk density (g/cm^3)	Tapped density (g/cm^3)	Carr's Index (%)	Hausner's ratio
F1	21.15±0.14	0.274±0.03	0.321±0.02	14.64	1.17
F2	22.19±0.11	0.268±0.01	0.306±0.01	12.41	1.14
F3	21.05±0.13	0.263±0.02	0.303±0.01	13.20	1.15
F4	21.58±0.10	0.270±0.02	0.317±0.02	14.82	1.17
F5	21.98±0.12	0.364±0.04	0.408±0.01	10.78	1.12
F6	20.05±0.18	0.364±0.03	0.417±0.01	12.70	1.14
F7	21.86±0.12	0.298±0.02	0.334±0.02	10.74	1.16
F8	21.15±0.10	0.276±0.04	0.328±0.01	14.88	1.18
F9	21.59±0.10	0.271±0.02	0.315±0.02	14.83	1.16
F10	20.76±0.12	0.283±0.01	0.334±0.02	11.78	1.17
F11	21.68±0.12	0.291±0.03	0.315±0.01	12.62	1.19
F12	20.85±0.12	0.278±0.01	0.321±0.02	11.49	1.14

Each data represent mean ± Standard deviation (n = 3).

Table 3. Physicochemical properties of the domperidone.

Formulation code	Weight variation (kg/cm^2)[a]	Thickness (mm)[b]	Hardness (kg/cm^2)[b]	Friability (%)[c]	Disintegration Time (S)[d]	Drug content (%)[e]
F1	50.08±0.11	1.63±0.14	3-4	0.39	108±1.61	99.89±0.14
F2	50.07±0.12	1.71±0.16	3-4	0.42	95±1.24	99.71±0.40
F3	50.17±0.13	1.62±0.18	3-4	0.38	91±1.22	98.91±0.68
F4	51.97±0.11	1.71±0.24	3-4	0.45	122±1.44	100.57±0.12
F5	50.83±0.14	1.68±0.23	3-4	0.37	110±1.35	99.68±0.43
F6	51.01±0.12	1.72±0.15	3-4	0.35	88±1.32	100.12±0.15
F7	50.95±0.13	1.70±0.18	3-4	0.42	107±1.06	99.19±0.48
F8	50.21±0.11	1.68±0.22	3-4	0.40	89±1.03	101.23±0.11
F9	51.01±0.14	1.67±0.15	3-4	0.35	86±1.32	100.15±0.13
F10	50.85±0.13	1.71±0.18	3-4	0.42	118±1.44	99.18±0.46
F11	50.61±0.12	1.69±0.22	3-4	0.41	104±1.31	100.23±0.12
F12	51.11±0.14	1.63±0.15	3-4	0.36	90±1.32	100.18±0.13

Where a: mean±% deviation. (n=20); b: n=5; c: n≈6.5g of total weight, d: n=3, e: n=10.

Table 4. Release kinetics data of the domperidone optimized formulations F8 and F12.

Formulation Code	Zero order (r)	First order (r)	Higuchi (r)	Korsmeyer-Peppas (r)	Hixson-Crowell (r)	Korsmeyer-Peppas (n)	Mechanism of release
F8	0.568	0.987	0.886	0.998	0.817	0.046	Fickian
F12	0.675	0.973	0.696	0.979	0.712	0.052	Fickian

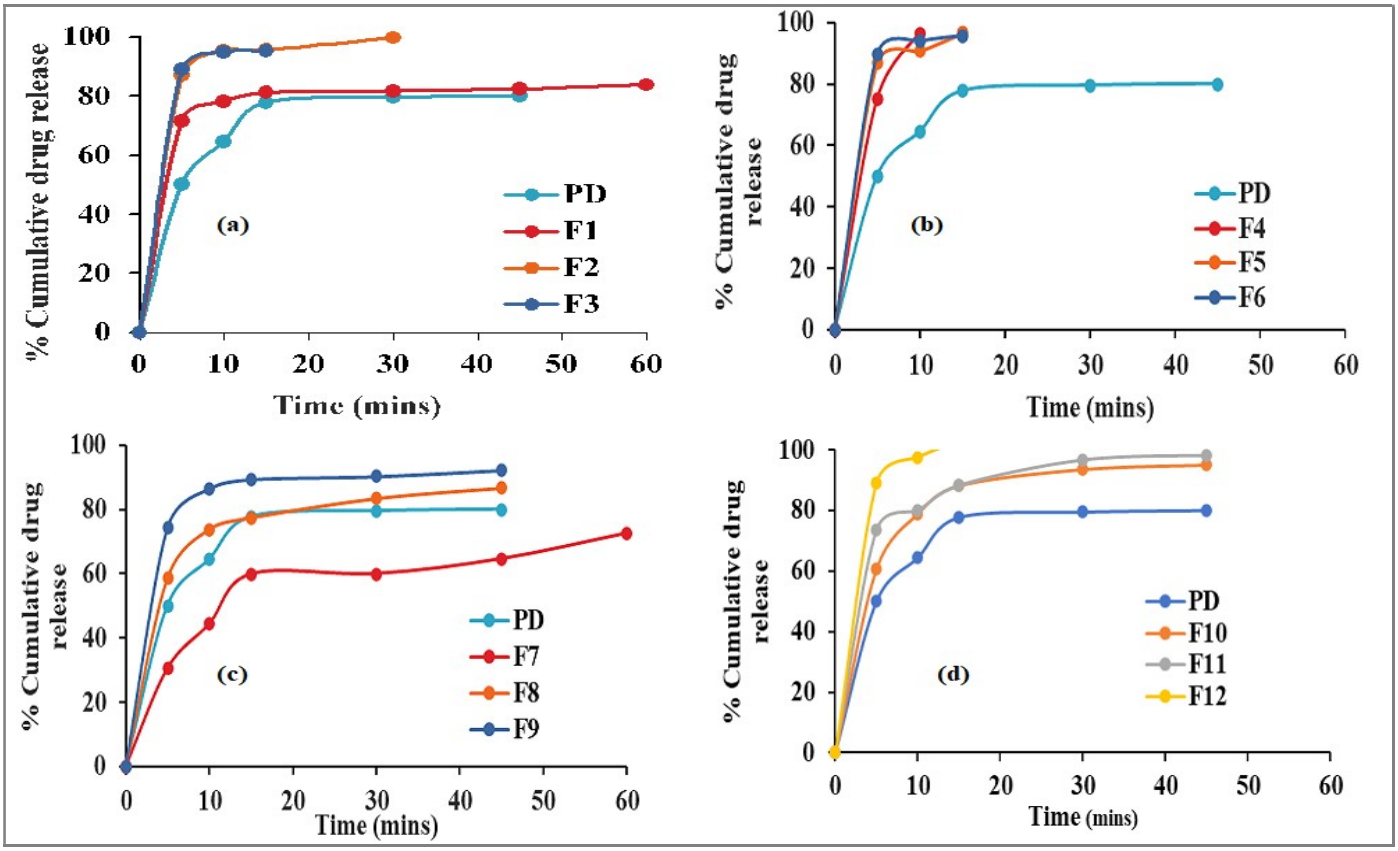

Fig 6. *In vitro* cumulative % drug release profiles of domperidone pure drug with a) FI to F3 (SSG), b) F4 to F6 (CCS), c) F7 to F9 (CP) and d) F10 to F12 (*Fenugreek* seed mucilage powder).

for uniformity of weight. The thickness of all the formulations was in the range of 1.62 to 1.74 mm. The hardness for all the formulations was in the range of 3 to 4 kg/cm^2. For all the batches the percentage of weight loss in the friability test was found to be less than 0.5 %. The disintegration time of all the formulations was in the range of 80 to 122 s. The assay of all the prepared DOM formulations was found to be in the range of 98.91 to 101.23 %. Thus, DOM prepared with the selected superdisintegrants was considered as good quality fulfilling the official requirements of tablets.

***In vitro* dissolution studies:**

The *in vitro* dissolution studies of immediate release tablets were conducted in 0.1 N HCl for 1 h and the drug release profiles were shown in Fig 6. The drug release from F1 to F3 composed of CP 2, 4, and 6 % were found to be 79.54, 81.66, and 99.63 % in 30 min. The drug release from F4 to F6 composed of CCS 2, 4, and 6 % were found to be 72.6, 86.63, and 92.23 % in 60 min. The drug release form formulations F7 to F9 were composed of SSG 2, 4, and 6 % was found to be 90.61, 99.86, and 95.73 in 15 min. The drug release form formulations F10 to F12 which were composed of FSM powder 2, 4, and 6 % were found to be 88.17, 96.53, and 102.72 in 15 min. From the above, it can be concluded that as the concentration of FSM powder is increased the release rate of the drug is also increased. Formulations F8 prepared with 4 % of SSG and F12 prepared with FSM powder with 6 % showed more than 98 % of drug release within 1 h. Among these two optimized formulations, F12 showed 102.72 % drug release, and F8 showed 99.66 % drug release in 1 h, but using natural superdisintegrant is better tolerated. Hence formulation F12 is selected as the best formulation among all the other formulations. The various kinetic models were applied to *in vitro* drug release profiles of DOM in order to evaluate the mechanism of drug release. The different kinetic models evaluated were zero order, first order, Higuchi, and Hixson-Crowell. All the formulations followed First order release with the Fickian mechanism of drug release, due to the dominant erosion pattern with burst drug release and the results are given in Table 8. This pattern may be due to the use of superdisintegrants both synthetic and natural.

Comparative studies:

The DOM pure drug, optimized formulations F8 with 4 % SSG and F12 with 6 % FSM powder was compared with the marketed product. The drug release was found

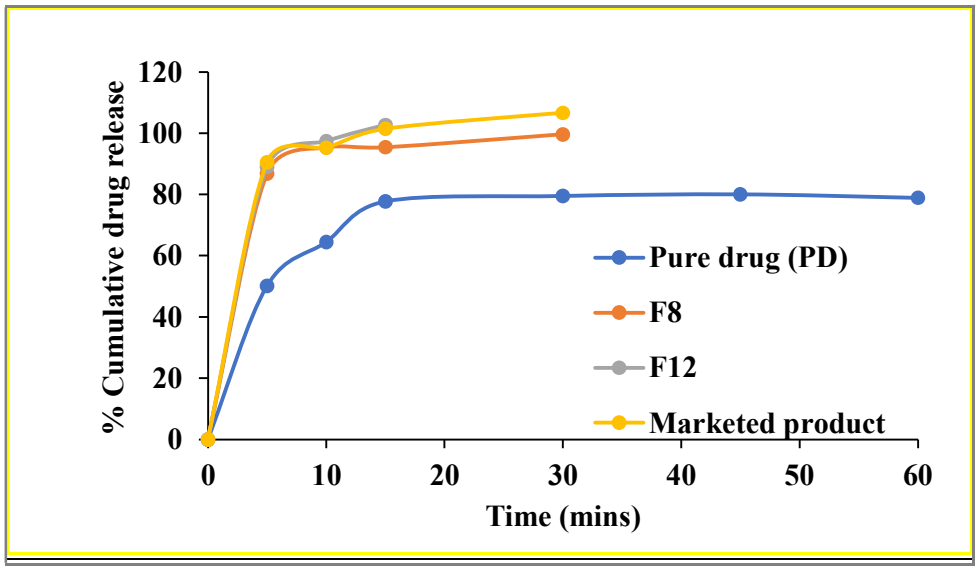

Fig 7. *In vitro* cumulative % drug release profile of domperidone pure drug, optimized formulations F8, F12, and marketed product (Domstal).

to be 80.53 % for the marketed product in 5 min, whereas 86.8 and 89.02 % for F8 and F12 formulations, as shown in Fig 7. Hence, the *in vitro* drug release for the prepared formulations was found to be better than the marketed product.

DISCUSSION:

The main objective of the present study was to develop an immediate-release tablet of domperidone for exploring FSM as the potential disintegrating agent. The FSM immediate-release tablets of domperidone were successfully developed by direct compression technique [21]. The results of thickness showed that the tablets maintained uniform dimensions during manufacturing [22]. The weight variation test results were found to be within acceptable limits. As per the IP specifications for tablets 80 mg or less, ±10 % is acceptable. These differences may be attributed to the deviation in the particle size of powders [23]. The results of the hardness test revealed that the tablets had sufficient crush strength during transportation. Friability results of the friability study demonstrated that the developed formulations could withstand mechanical shock during transportation. The results of drug content indicative of the powder mixtures employed were free-flowing, subsequently, the die cavity was uniformly filled during compression; hence uniform weight tablets were obtained. The disintegration time is the most important parameter for the development of successful IR. The faster onset of action of the tablet can be seen in the IR dosage form from the stomach which gives local drug absorption. Therefore, the disintegration time for all the formulations F1 to F12 was found to be 122 s; it might be due to the breakdown of the inter particulate bonds, which were forged during the compaction of the tablet. Therefore, formulation F8 and F12 with disintegration time were less than 90 s. To achieve the goal of immediate release, the tablets can disintegrate in less than 90 s to release the drug immediately. Domperidone IR tablets are prepared with synthetic superdisintegrants and natural disintegrants; they might cause a burst release of the tablet core when they come in contact with gastric fluid. The burst release of tablets by disintegrants causes the tablet to break into granules that were surrounded by the gastric fluid increasing the surface area of the particle and thereby leading to increased drug release from the tablet. From the *in vitro* drug dissolution study data, it was confirmed that the FSM powder (F10 – F12) has revealed disintegration characteristics. Finally, it was unambiguous that the natural macromolecules can be prominently potential for the development of an immediate release drug delivery system. Various mathematical models are available, among which that Korsmeyer-Peppas model is the major one used to fit the kinetics of drug release from the tablets. The formulation from F8 and F12 showed non-Fickian and erosion drug releases. Based on the *in vitro* drug release results, the cost-effectiveness of FSM compared to SSG; F12 has been selected as the final formulation. FTIR data demonstrated that FSM could be a good disintegrating agent by forming a hydrogen bond between hydroxyl and carboxyl groups. DSC study results exhibited that the developed formulation was converted into an amorphous form and the absence of

drug excipient interactions. The XRD of formulations F12 discovered the straight line and the absence of characteristic peaks indicates the amorphous nature.

CONCLUSION:

The present study was carried out to the development of immediate-release tablets of DOM by using various superdisintegrants at different ratios in comparison with a natural disintegrant. The formulations prepared with 4 % w/w concentration of SSG F8 for immediate release tablets and 6 % w/w FSM powder F12 were found to be more suitable than the formulation prepared with other synthetic superdisintegrants and gave maximum drug release (%) within 5 min. It was found that the release rate was influenced by the nature of the superdisintegrant and the concentration of the disintegrant employed in the preparation of the tablets. Formulation F12 drug release of FSM powder is slightly greater than that of the synthetic superdisintegrant. Hence, the FSM powder is a suitable candidate for its application as a natural disintegrant in the preparation of immediate-release tablets.

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