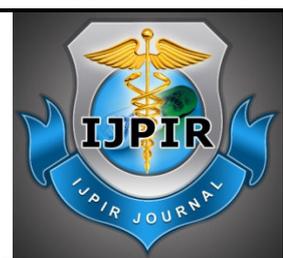


## Research Article



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### Formulation and assessment of domperidone fast dissolving tablets using natural superdisintegrants

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#### ABSTRACT

Current research is focused on development and optimization of fast dissolving tablets of Domperidone by applying  $3^2$  factorial designs. Direct compression method was used. Two factors as independent variables (X1-amount of  $\beta$ -cyclodextrin and X2-amount of *Lepidium Sativum* mucilage) were taken with three levels (+1,0,-1). The levels of two factors were selected on the basis of preliminary experiments conducted and their effect on three dependent variables (disintegration time, wetting time and in vitro drug release) was estimated. All the active blends were evaluated for precompression parameters (angle of repose, bulk density, carr's index, hausner's ratio) and formulated tablets were evaluated for post compression parameters (hardness, friability, weight variation, wetting time, disintegration time, water absorption ratio) and In vitro drug release studies. The software Design Expert (8.0.7.1) was used for generating experimental design, modeling the response surface and calculating the statistical evaluation. The optimized batch was further evaluated for SEM and accelerated stability studies. Tablet parametric tests of formulations (F1-F9) were observed within prescribed limits. DT was observed in the range from  $15 \pm 2$  to  $42 \pm 4$  sec and WT from  $19 \pm 2$  to  $44 \pm 3$  sec for formulation batches (F1-F9). Batch F6 was observed as promising batch with DT values of 15 sec and in vitro drug release (94%) in 15 min. No remarkable changes were observed in batch F6 (physicochemical properties and in vitro release profile) when kept for 3 months at  $40^\circ\text{C}$  and 75% RH conditions. This indicates good stability of the formulation even after stressed conditions. Polynomial mathematical models, generated for various response variables using multiple regression analysis were found to be statistically significant ( $p < 0.05$ ). Conclusion: An optimized combination of *Lepidium Sativum* mucilage with  $\beta$ -cyclodextrin leads to successful development of fast dissolving tablets of Domperidone.

**Keywords:**  $\beta$ -cyclodextrin, direct compression, *Lepidium Sativum* mucilage, factorial design superdisintegrant

#### INTRODUCTION

Drug delivery systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities<sup>1</sup>. Oral administration is the most popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly, patient compliance. Also solid oral delivery systems do not require sterile conditions and are therefore, less expensive to manufacture. Patient compliance, high-precision dosing, and manufacturing efficiency make tablets the solid dosage form of choice<sup>2</sup>.

Many patients have problem swallowing tablets and hard gelatin capsules and therefore do not take medicinal drugs as prescribed. It is predicted that 50% of the population is suffering from this problem, which leads to a high incidence of noncompliance and useless therapy. The demand for solid dosage forms that may be dissolved and suspended in water, chewed, or unexpectedly dissolved within the mouth is specially strong inside the paediatric and geriatric markets, with further application to different patients who opt for the benefit of a conveniently administered dosage form<sup>3</sup>. In some instances consisting of motion sickness, unexpected episodes of allergic attacks or coughing and unavailability

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of water, swallowing conventional tablets can be difficult. especially the problem is skilled by way of paediatric and geriatric sufferers. Such problems can be resolved by speedy Dissolving pill, because of the growth inside the common human lifestyles span and the decline, with age, in swallowing ability, oral tablet administration to patients is a full-size trouble and has end up the item of public attention. The problem can be resolved by way of the creation of swiftly dispersing or dissolving oral forms, which do not require water to aid swallowing.

**Candrasura:** Candrashura consists of dried seeds of **Lepidium sativum** Linn. (Fam. Cruciferae) a small erect, annual herb, about 15-45 cm high, cultivated throughout India.

**a) Macroscopic:** Seeds, small, oval-shaped, pointed and triangular at one end, smooth, approximately 2-3mm long, 1-1.5 mm wide, reddish brown, a furrow present on each surfaces extending up to two thirds downward, a mild wing like extension present on each the edges of seed, when soaked in water seed coat swells and receives covered with a transparent, colourless mucilage, taste, mucilaginous.

**b) Microscopic:** Powder-Cream-yellow with a number of reddish-brown fragments of seed coats, under microscope shows pieces of seed coat, some showing red colouring matter and others with uniformly thick walls, endosperm oily.

**Constituents** - Alkaloids, essential oil, fixed oil and mucilage.

### Methodology for Extraction of Mucilage

The seeds of *Lepidium sativum* contain the mucilage around the outer layer. The primary problem in isolation of mucilage is that it swells but does not separate from the seeds. Due to this, general methods of separation of mucilage are not relevant to separate the seed mucilage and subsequently, distinctive approaches had been tried for the separation of mucilage<sup>4</sup>.

**Method A:** In first method (method A) the seeds (100 g) have been boiled with distilled water (1 litre) for 15 minute and the mass was filtered thru Buckner funnel without filter paper. The retained residues were boiled with distilled water (0.5 litres) for 15 minute and the combined liquid was passed through eight folds of muslin cloth. The mucilage was precipitated from the filtrate with the aid of including ethanol. The precipitated mucilage becomes dried in an oven at 45°C till it became absolutely dried. The powder was passed via 80 # mesh sieve and weighed to calculate the yield.

**Method B:** In the second method (method B) the seeds (100 g) were soaked for 12 hour in distilled water (1litre) after which added to a blender to separate mucilage from seeds. After blending for 15 minute the mass changed into passed thru eight folds of muslin cloth. The mucilage changed into precipitated from the filtrate by way of adding 1 litre of acetone. The powder become passed through 80 # mesh sieve and weighed to calculate the yield after drying at 45°C for 6 h.

**Method C:** In third method (method C) the seeds (100 g) were soaked for 12 hour in distilled water (1litre) and crushed in blender for 15 minute. The dispersion was boiled for 30 minute and the mass was surpassed became passed through eight folds of muslin cloth. The mucilage was precipitated from the filtrate through adding acetone. The

powder was passed through 80 # mesh sieve and weighed to calculate the yield after drying at 45°C for 6 hour.

## CHARACTERIZATION OF MUCILAGE

**1. Chemical characterization of *Lepidium sativum* mucilage:** The presence of mucilage in extracted material was confirmed using Molisch's test and by treatment with ruthenium red.

**2. Plantago ovata seed mucilage:** <sup>5</sup> Psyllium or Ispaghula is the common name used for several members of the plant genus *Plantago* whose seeds are used commercially for the production of mucilage. Mucilage of *plantago ovata* has various characteristics like binding, disintegrating and sustaining properties.

**3. Gum karaya:** <sup>5</sup> Gum Karaya is a vegetable gum produced as an exudate by trees of the genus 'Sterculia'. Chemically, gum karaya is an acid polysaccharide composed of the sugars galactose, rhamnose and galacturonic acid. The excessive viscosity nature of gum limits its uses as binder and disintegrant inside the improvement of conventional dosage form. Karaya gum has been investigated for its potential as a tablet disintegrant. The consequences showed that changed gum karaya produce speedy disintegration of tablets. The optimized formulation confirmed acceptable physical characteristics. The optimized batch produced entire drug release within 6 minutes. The incorporation of clove oil provided extra residences which includes symptomatic relief from nausea and vomiting, proper mouth sense and taste masking. Kinetic evaluation showed that drug release from optimized formula was effectively described through first order release kinetics. Gum karaya may be used as an alternative superdisintegrants to normally available synthetic and semi-artificial superdisintegrants due to their low fee, biocompatibility as well as easily availability.

**4. Fenugreek seed mucilage:** <sup>5</sup> *Trigonella foenum graceum*, commonly known as Fenugreek, is an herbaceous plant of the leguminous family. Fenugreek seeds include a high percent of mucilage (an herbal gummy substance present inside the coatings of many seeds). Although it does not dissolve in water, mucilage forms a viscous tacky mass when exposed to fluids. Like different mucilage-containing substances, fenugreek seeds swell up and become slick while they are uncovered to fluids. Mucilage extracted from fenugreek seeds had been subjected to toxicity studies; it showed that extracted mucilage is without toxicity.

**5. Mango peel pectin:** <sup>5</sup> Mango peels which constitutes 20–25% of the mango processing waste was located to be a good supply for the extraction of pectin of top quality, suitable for the instruction of film and acceptable jelly. Pectin is complex hetro polysaccharides that are a hydrophilic colloid. Rishabha Malviya et al investigated that mango peel pectin stand as an excellent candidate as superdisintegrant although, no longer as stronger as artificial superdisintegrant but due to its excellent solubility and higher swelling index, it may be used in the formula of fast dispersible tablets.

**6. Agar and treated agar:** <sup>5</sup> Agar is the dried gelatinous substance acquired from *Gelidium amansii* (Gelidaceae) and numerous different species of red algae like, *Gracilaria* (Gracilariaceae) and *Pterocadia* (Gelidaceae). Agar is yellowish gray or white to almost colorless, odourless with mucilaginous taste and is available inside the form of strips,

sheet flakes or coarse powder. Agar includes polysaccharides as agarose and agarpectin. Agarose is responsible for gel strength and Agarpectin is liable for the viscosity of agar solutions. excessive gel strength of agar makes it an ability candidate as a disintegrant. The treated agar mucilage is ready through dissolving five-10 gm powder in 100ml of distilled water. Agitation becomes executed constantly by using a stirrer for someday to swell the contents. The swollen contents were dried on a tray for three days at room temperature. The dried powders had been grinded by way of mortar and pestle. Then grinded powder was passed via sieve no.100.

**7. Guar gum:** <sup>5</sup> Guar gum is especially which include the high molecular weight (about 50,000-8,000,000) polysaccharides composed of galactomannans and is obtained from the endosperm of the seed of the guar plant, *Cyamopsis tetragonaloba* (L) Taub. (Syn. *Cyamopsis psoraloides*). it's far used as thickener, stabilizer and emulsifier, and permitted in most areas of the world (e.g. eu, u.s.a., Japan, and Australia). it is obviously happening gum (marketed under the trade name jaguar). it's far free flowing, completely soluble, neutral polymer composed of sugar units and is authorized for use in food. It isn't sensitive to pH, moisture contents or solubility of the tablet matrix. It isn't always pure white and sometimes varies in colour from

off-white to tan tends to discolour with time in alkaline tablets.

**8. Gellan gum:** <sup>5</sup> Gellan gum is a water-soluble polysaccharide produced by *Pseudomonas elodea*, a bacterium. Gellan gum is an anionic, high molecular weight, deacetylated exocellular polysaccharide gum produced as a fermentation product by a pure culture of *Pseudomonas elodea*, with a tetrasaccharide repeating unit of one  $\alpha$ -L-rhamnose, one  $\beta$ -D-glucuronic acid and two  $\beta$ -D-glucose residues.

**9. Soy polysaccharide:** <sup>5</sup> It is a natural superdisintegrant that does not contain any starch or sugar so can be used in nutritional products.

**10. Chitin and chitosan:** <sup>5</sup> Chitin ( $\beta$ -(1 $\rightarrow$ 4)-N-acetyl-D-glucosamine) is a natural polysaccharide obtained from crab and shrimp shells. It possesses amino group covalently linked to acetyl group as compared to free amino group in chitosan. Chitosan is produced commercially by deacetylation of chitin, which is the structural element in the exoskeleton of crustaceans (such as crabs and shrimp) and cell walls of fungi. Chitosan is the best known natural polysaccharide used for its versatile applications in pharmaceutical industry.

## II. Synthetic disintegrants

Tablet 1: List of synthetic superdisintegrant

Example	Super-Disintegrants	Mechanism Of Action	Special Comment
Crosslinked cellulose	Crosscarmellose <sup>®</sup> Ac-Di-Sol <sup>®</sup> Primellose <sup>®</sup> Vivasol <sup>®</sup>	Swells 4-8 folds in <10 seconds. Swelling and wicking both.	Swelling is in two dimensions. -Direct compression or granulation -Starch free
Crosslinked PVP	Crosspovidone Kollidon Polyplasdone	Swells 7-12 folds in <30 seconds Swells very little and returns to original size after compression but act by capillary action	Swells in three dimensions and high level serve as sustain release matrix Water insoluble and spongy in nature so get porous tablet
Crosslinked starch	Sodium Starch Glycolate	Swells 7-12 folds in <30 seconds	Swells in three dimensions and high level serve as sustain release matrix
Crosslinked alginic acid	Alginic acid NF Satialgine	Rapid swelling in aqueous medium or wicking action	Promote disintegration in both dry or wet granulation

## MATERIALS AND METHODS

### Methods of Evaluation<sup>7</sup>

#### Pre formulation parameters Evaluation

##### 1. Angle of repose

The frictional force in a loose powder can be measured by angle of repose  $\theta$ . It is defined as, the maximum angle possible between the surface of the pile of the granules and the horizontal plane. The angle of repose was determined by the funnel method suggested by Newman. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and the angle of repose was calculated using the following formula.

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

Where,  $\theta$  = Angle of repose,  $h$  = Height of the cone,  $r$  = Radius of the cone base.

**Tablet 2: Flow properties and corresponding Angle of repose**

Flow property	Angle of Repose (Degrees)
Excellent	25 – 30
Good	31 – 35
Fair (aid not needed)	36 – 40
Passable (may hang up)	41 – 45
Poor (must agitate, Vibrate)	46 – 55
Very poor	56 – 65
Very, Very poor	> 66

**2. Bulk density:** Bulk density  $P_b$  is defined as the mass of the powder divided by the bulk volume and is expressed as  $\text{gm}/\text{cm}^3$ . Apparent bulk density ( $P_b$ ) was determined by pouring blend into a graduated cylinder. The bulk volume ( $V_b$ ) and weight of the powder ( $M$ ) was determined. The bulk density was calculated by using the following formula.(8)

$$P_b = M / V_b$$

Where,  $P_b$  = Bulk Density,  $M$  = Weight of sample in gm,  $V_b$  = Final volume of blend in  $\text{cm}^3$ .

**3. Tapped density:** It is the ratio of total mass of the powder to the tapped volume of the powder. The volume was measured by tapping the powder for 500 times. Then the tapping was done for 750 times and the tapped volume was noted. The tapped density was calculated by using the following formula.

$$P_t = M / V_t$$

Where,  $P_t$  = Tapped Density,  $M$  = Weight of sample in gm,  $V_t$  = Final volume of blend in  $\text{cm}^3$ .

**Compressibility index = 100 \* Tapped density / Bulk density**

**Hausner's ratio = Tapped density / Bulk density**

**Table 3: Scale of flow ability**

Compressibility index (%)	Flow character	Hausner's ratio
1 – 10	Excellent	1.00 – 1.11
11 – 15	Good	1.12 – 1.18
16 – 20	Fair	1.19 – 1.25
21 – 25	Passable	1.26 – 1.34
26 – 31	Poor	1.35 – 1.45
32 – 37	Very poor	1.46 – 1.59
> 38	Very, Very poor	> 1.60

**4. Compressibility Index and Hausner's ratio:** In recent years, the compressibility index and the closely related Hausner's ratio have become the simple, fast, and popular methods of predicting powder flow characteristics. The compressibility index has been proposed as an indirect measure of bulk density, size, shape, surface area, moisture content and cohesiveness of materials because all of these can influence the observed compressibility index<sup>9</sup>. The compressibility index and the Hausner's ratio are determined by measuring both the bulk volume and tapped volume of a powder.

**Basic methods for the determination of compressibility index and Hausner's ratio:** The compressibility index and the Hausner's ratio may be calculated using measured values of bulk density and tapped density as follows:

## Compressed Tablets Evaluation

**1. Thickness:** The thickness of the tablets was determined by using Vernier callipers. Five tablets from each formulation were used and average values were calculated.

**2. Hardness test:** Hardness (diametral crushing strength) is a force required to break a tablet across the diameter. The hardness of a tablet is an indication of its strength. The tablet should be stable to mechanical stress during handling and transportation. The permissible limit for hardness is 3 – 5 kg/cm<sup>3</sup>. The hardness was tested using Monsanto tester. “Hardness factor”, the average of the five determinations was determined and reported<sup>10</sup>

**3. Friability test:** Roche friabilator was used to measure the friability of the tablets. It was rotated at a rate of 25 rpm. Five tablets were weighed collectively and placed in a chamber of the friabilator. In the friabilator, the tablets were exposed to rolling, resulting from free fall of tablets within

the chamber of the friabilator. After 100 rotations (4 minutes), the tablets were taken out from the friabilator and intact tablets were again weighed collectively. Permitted friability limit is 1.0%. The percent friability was determined using the following formula<sup>11</sup>.

$$(W_1 - W_2)/W_1 * 100$$

Where,  $W_1$  = weight of the tablets before test,  $W_2$  = weight of the tablets after test.

**4. Uniformity of weight (Weight variation test):** 20 tablets were weighed individually. Average weight was calculated from the total weight of the tablets. The individual weights were compared with the average weight<sup>12</sup>. The percentage difference in the weight variation should be within the permissible limits (7.5%). The percent deviation was calculated using the following formula.

$$\% \text{ weight variation} = \frac{\text{Individual weight} - \text{Average weight}}{\text{Average weight}} * 100$$

**Table 4: Weight variation specification as per IP**

Average weight of tablet	% Weight variation
80 mg or less	± 10
More than 80 mg but less than 250 mg	± 7.5
250 mg or more	± 5

**5. Content uniformity:** 10 tablets are accurately weighed and powdered. Tablets powder equivalent to 20 mg of medicament was taken in the test tube and extracted with methanol. The methanolic extract collected into 50ml volumetric flask and volume made upto 50ml with purified buffer. The solution was subsequently diluted and assayed for drug content.

**6. Wetting time:** Wetting time is closely related to the inner structure of the tablets and to the hydrophilicity of the excipient. According to the following equation proposed by Washburn E.W (1921), the water penetration rate into the powder bed is proportional to the pore radius and is affected by the hydrophilicity of the powders.

$$dl/dt = r \gamma \cos\theta / (4\eta l)$$

Where  $l$  = length of penetration,  $r$  = capillary radius,  $\gamma$  = surface tension,  $\eta$  = liquid viscosity,  $t$  = time, and  $\theta$  = contact angle.

It is obvious that pores size becomes smaller and wetting time increases with an increase in compression force or a decrease in porosity. A linear relationship exists between wetting time and disintegration time. Thus wetting is the important step for disintegration process to take place.

A piece of tissue paper folded double was placed in a Petri plate (internal diameter is 6.5 cm) containing 6ml of water. The tablet was placed on the paper and the time for complete wetting of the tablet was measured in seconds. The method was slightly modified by maintaining water at 37°C. Wetting time corresponds to the time taken for the tablet to disintegrate when kept motionless on the tongue<sup>13</sup>.

**7. Disintegration time (min):** Tablets were placed in six tubes of the basket. Then the assembly was suspended in water maintained at a temperature of 37°C ± 2°C, and then the apparatus was switched on. Simultaneously, start the stopwatch results were noted. Stopwatch was stopped when

the last tablet gets disintegrated. The tablets pass the test, if all tablets have disintegrated in the specified time (NMT 20 min), if 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. Not less than 16 of the total of 18 tablets tested should be disintegrated completely.

## 8. Dissolution studies:

**Preparation of Dissolution medium:** 8.5ml of Hydrochloric acid was taken in a 1000ml volumetric flask and made upto 1000ml with distilled water.

### Dissolution parameters:

Medium: 900ml of 0.1M Hydrochloric acid; Apparatus: USP type II (Paddle); RPM: 50; Time: 45min; Temperature: 37°C ± 0.5°C; Sampling intervals: 1 minute; Sampling volume : 5 ml

A sample (5ml) of the solution was withdrawn from the apparatus every 1min.for 10min, and samples were replaced with fresh dissolution medium. The samples were filtered through Watmann filter paper. Measure the absorbance of the filtrate, diluted with the dissolution medium if necessary, at 286nm using UV-Spectrophotometer and using the dissolution medium as blank<sup>14</sup>.

## RESULTS AND DISCUSSION

### Estimation of Domperidone

**Preparation of stock solution:** 25mg of Domperidone was weighed accurately and transfer to 25ml volumetric flask and made upto the volume with 0.1NHCl. From this stock - I, 10ml is transfer to 100ml volumetric flask and made upto the volume by using buffer. This is the stock - II solution. From the stock - II various concentrations of 2, 4, 6, 8, 10µg/ml were prepared.

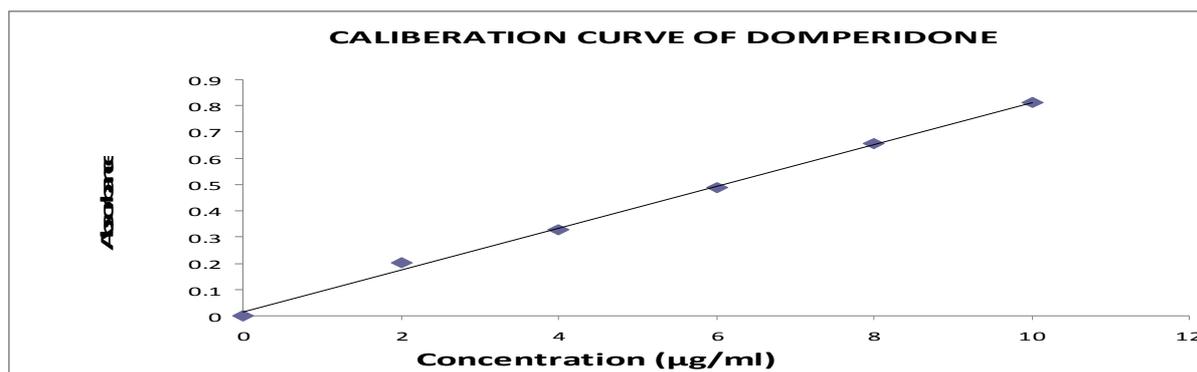
**Preparation of 0.1N HCl buffer:** 8.5ml of HCl was taken in 1000ml volumetric flask and it is made upto 1000ml with distilled water.

**Standard calibration curve of Domperidone:** The absorbance of serial dilutions of 2, 4, 6, 8, 10 $\mu$ g/ml were

measured at 286nm by using U.V. Spectrophotometer. A graph of concentration vs absorbance was plotted.

**Table 5: List of standard absorbance values.**

S.NO	Concentration ( $\mu$ g/ml)	Absorbance
1	0	0
2	2	0.2012
3	4	0.3275
4	6	0.4865
5	8	0.6565
6	10	0.8125



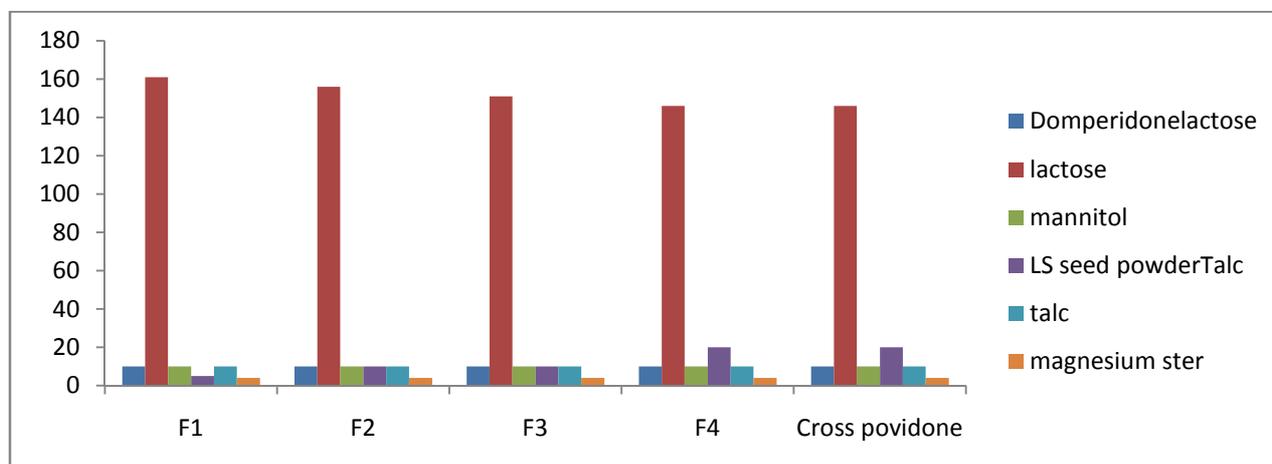
**Fig 1: calibration curve of Domperidone**

### Development of Formulation

Fast dissolving tablets of Domperidone was prepared by using the different concentrations of Lepidium sativum mucilage and the formulations are mentioned in the table 6.

**Table 6: Composition of Formulations**

MATERIALS	F1	F2	F3	F4	cross povidone
Domperidone	10 mg	10 mg	10 mg	10 mg	10 mg
Lactose	161 mg	156 mg	151 mg	146 mg	146 mg
Mannitol	10 mg	10 mg	10 mg	10 mg	10 mg
Lepidium sativum seed powder	5mg (2.5%)	10 mg (5%)	15 mg (7.5%)	20 mg (10%)	20 mg (10%) (cross povidone)
Talc	10 mg	10 mg	10 mg	10 mg	10 mg
Magnesium stearate	4 mg	4 mg	4 mg	4 mg	4 mg



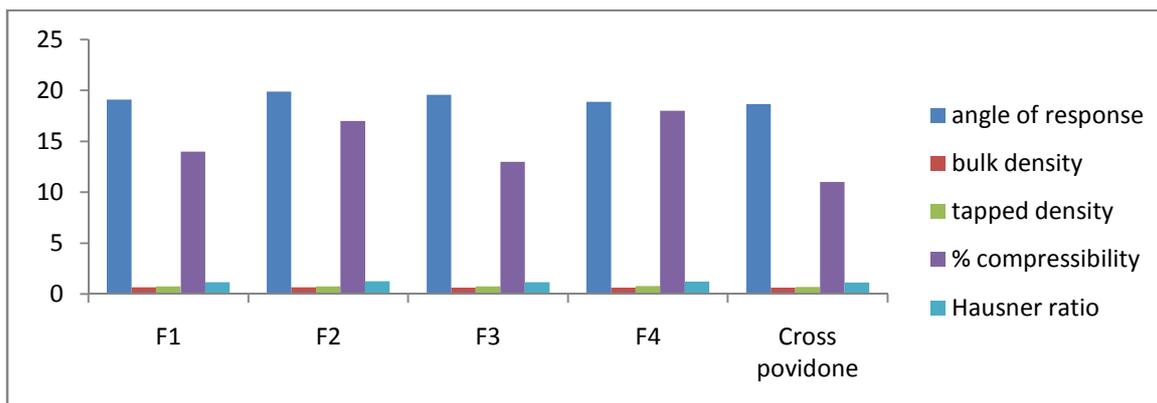
**Fig 2: Development of formulation**

## Evaluation for Blend

Different blend parameters are performed as per the standard procedures and the results are mentioned in the table and graphs.

**Table 7: Evaluation parameters for blend**

TESTS	F1	F2	F3	F4	Cross povidone
Angle of repose	19.10	19.89	19.57	18.88	18.65
Bulk density(gm/ml)	0.670	0.651	0.64	0.631	0.625
Tapped density (gm/ml)	0.74	0.76	0.75	0.77	0.70
% Compressibility	14%	17%	13%	18%	11%
Hausner ratio	1.17	1.24	1.15	1.23	1.13



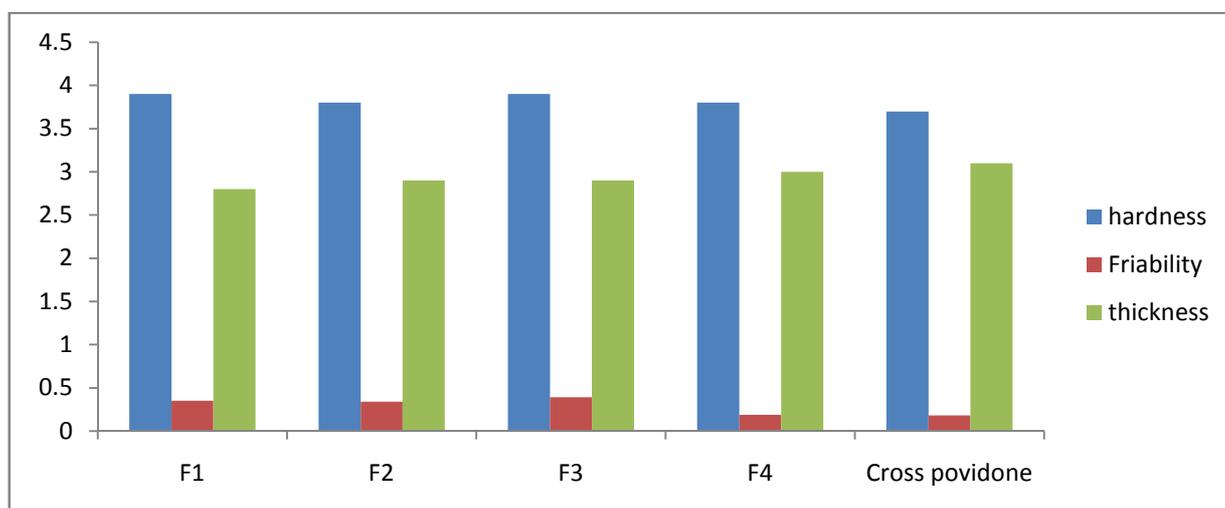
**Fig 3: Evaluation parameters for blend**

## Evaluation of Tablet

The prepared tablets were tested for the compressed tablet parameters and the results were mentioned in the table 8.

**Table 8: evaluation parameters for tablets**

TESTS	F1	F2	F3	F4	Cross povidone
Hardness (kg/cm <sup>2</sup> )	3.9	3.8	3.9	3.8	3.7
Friability (%)	0.35	0.34	0.39	0.19	0.18
Thickness (mm)	2.8	2.9	2.9	3.0	3.1
Invitro disintegration time	1.05 min	45 sec	29 sec	23 sec	21 sec
Wetting time	58 sec	50 sec	43 sec	34 sec	30 sec



**Fig 4: evaluation parameters for tablets**

### In vitro disintegration tests

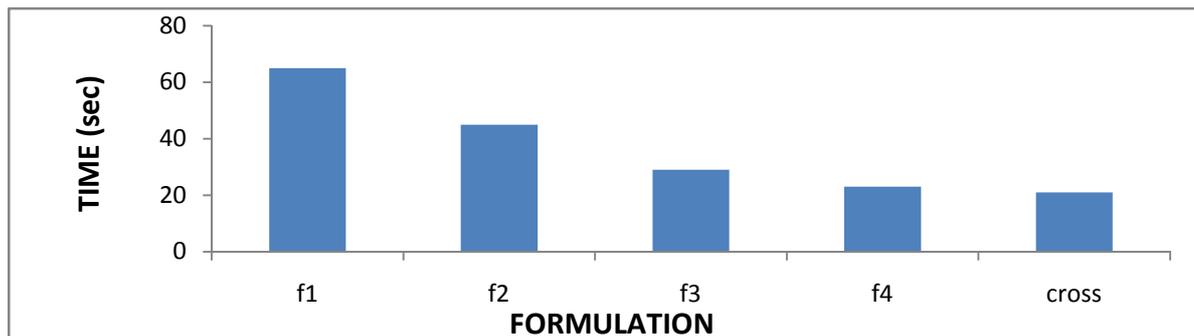


Fig 5: invitro disintegration tests

### Wetting Time

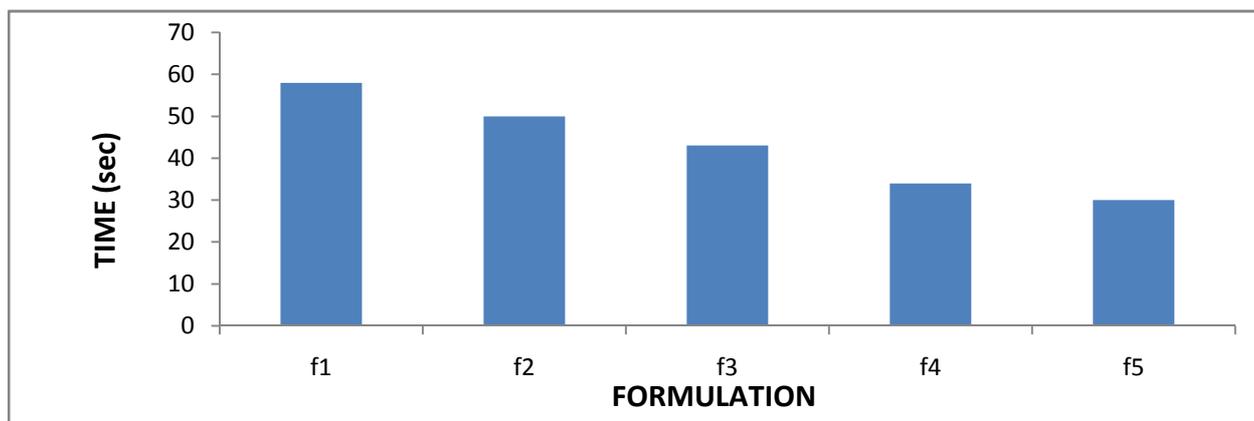


Fig 6: Wetting Time

**Drug Release Profiles of Domperidone Fast Dissolving Tablets:** Dissolution studies of different formulations prepared were performed and the drug release profiles for different formulations were mentioned in the following table 9.

**Table 9: List of Domperidone drug release profiles**

TIME	F1	F2	F3	F4	Cross povidone
1min	15%	31%	43%	56%	61%
2min	29%	43%	54%	72%	74%
3min	35%	55%	67%	85%	87%
4min	42%	65%	78%	91%	93%
5min	57%	77%	85%	95%	98%
6min	64%	83%	92%	100%	100%
7min	78%	95%	100%	--	--
8min	84%	100%	--	--	--
9min	93%	--	--	--	--
10min	100%	--	--	--	--

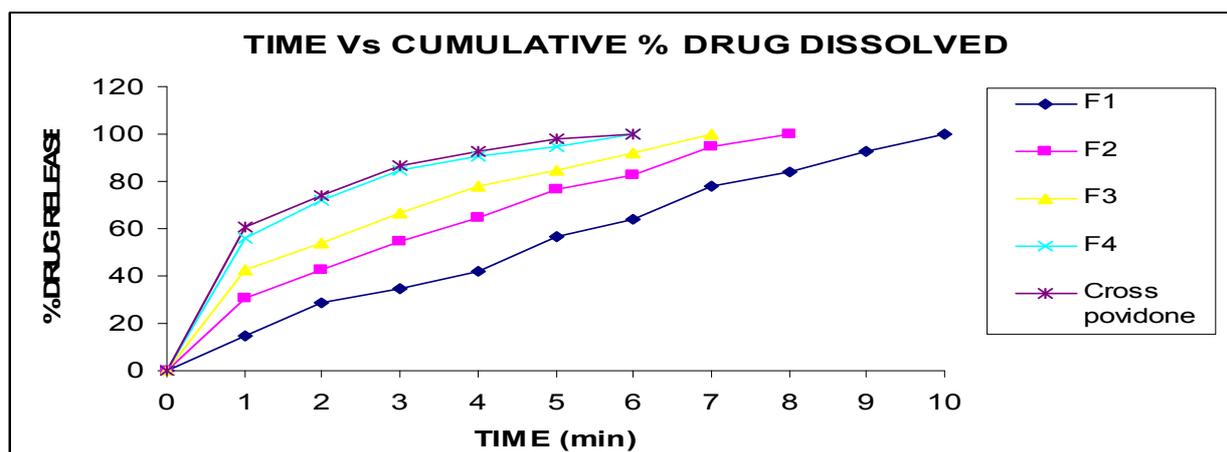


Fig 7: List of Domperidone drug release profiles

Fast dissolving tablets each containing 10mg of Domperidone could be prepared by employing different proportions of *Lepidium sativum* seed powder of (2.5%, 5%, 7.5% & 10%) and synthetic super disintegrant like cross povidone (10%) in the formulation by direct compression method.

The hardness of tablet was in the range of 3 – 5 kg/cm<sup>2</sup>. Weight loss in friability test was less than 0.6% in all cases. All the fast dissolving tablets contain Domperidone with in 100±5% of the label claim.

All the tablets were found to disintegrating with in 3min as such the prepared tablets were of good quality with regard to drug content, hardness and friability. All the tablets formulated employing super disintegrants were disintegrating with in 3min and they are suitable for fast release.

Domperidone release profiles of fast dissolving tablets are given in table: 9. Domperidone release from the prepared tablets was fast and completed within 10min depended on the concentration of super disintegrant. As super disintegrant concentration increases release rate increases. Thus drug release from the fast dissolving tablets employing superdisintegrants could be improved varying proportions of superdisintegrant. Fast dissolving tablets formulated employing 10% *Lepidium sativum* seed powder gave 100% release with in 6min. there is slight difference between

profiles of natural and synthetic superdisintegrants, so *Lepidium sativum* seed powder is an effective natural superdisintegrant.

## CONCLUSION

In present study Domperidone tablets were formulated by using natural superdisintegrant *Lepidium sativum* seed powder and synthetic cross povidone with 10% concentration were prepared namely F1 to F5 and are characterised by Hardness, Wettability, Friability, Disintegration time and Dissolution studies. Fast dissolving tablets can be prepared by direct compression method using natural superdisintegrant. The values obtained from the evaluation studies indicate that all the parameters within the standard limits. Invitro studies showed that fast dissolving tablets from F4 (10% concentration) showed the best disintegration time within 23sec. Invitro dissolution studies showed that the formulation F4 gave the maximum percentage drug release (100%) within 6min. Hence as the concentration of the super disintegrant increases drug release increases. F4 profile of *Lepidium sativum* seed powder is almost equal to that of the synthetic superdisintegrant.

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