

International Journal of Research in Pharmaceutical and Nano Sciences

Journal homepage: www.ijrpns.com



FORMULATION AND EVALUATION OF DOMPERIDONE FAST DISSOLVING TABLETS USING NATURAL SUPERDISINTEGRANTS

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ABSTRACT

In present study domperidone tablets were formulated by using natural superdisintegrant *lipidium sativum* seed powder and synthetic cross povidone with 10% concentration were prepared namely F-1 to F-5 formulation and these are characterized by hardness, thickness, weight variation, friability, wettability time and dissolution studies. Fast dissolving tablets can be prepared by direct compression method using natural and synthetic superdisintegrant. The values obtained from the evaluation studies indicate that all the parameters within the standard limits. *In vitro* disintegration studies showed that fast dissolving tablets from F-4(10% conc) showed the best disintegration time with in 23sec. *In vitro* dissolution studies showed that the formulation F-4 gave the maximum percentage drug release (100%) with in 6min. Hence as the concentration of the superdisintegrant increases drug release increases F-4 profile of *lipidium sativum* seed powder is almost equal to that of the synthetic superdisintegrant.

KEYWORDS

Fast dissolving tablets, Domperidone, Natural superdisintegrants (*lipidium sativum*), Cross povidone and *In vitro* studies.

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INTRODUCTION

Drug delivery systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. 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 manufacture¹. Patient compliance, high-precision dosing, and manufacturing efficiency make tablets the solid dosage form of choice².

The present work is to design and evaluate Domperidone fast dissolving tablets using the mucilage of *Lepidium sativum* seeds as natural super disintegrant. Dispersible tablet of Domperidone was prepared by direct compression using mannitol and lactose as directly compressible vehicles. The objective of present work is to provide an augmented superdisintegrant which has improved compatibility as compared to previously available superdisintegrants.

MATERIALS AND METHODS

MATERIALS

Domperidone was procured from **Aurobindo Pharma Ltd**, Hyderabad, Andhra Pradesh, India. *Lepidium sativum* seed mucilage was obtained from dried seeds of **Lepidium sativum** Linn. Lactose, Mannitol, Talc and Magnesium stearate were obtained from SD Fine chemicals, Mumbai. All the ingredients used were of analytical grade.

METHODS

Preparation of Domperidone fast dissolving tablets by direct compression method

Four formulations were developed by varying concentration of super disintegrating agents (2-4%). The drug was mixed with proper portion of superdisintegrant. Care should be taken to confirm the proper mixing of drug and superdisintegrant. Then other excipients were added. Then the mixture is passed through sieve (Sieve No.44). The mixture is blended with flavor, magnesium stearate and Talc³. Finally the blend is subjected for compression using Rotary tablet punching machine (Table No.1).

EVALUATION PARAMETERS^{4,5}

Pre-formulation Studies

Fourier Transform Infrared Spectroscopy

The fourier transform infra-red analysis was conducted for the structure characterization. FTIR spectra of the pure drug, polymers and formulations

were recorded by using BOMENMB SERIES FTIR instrument. Approximately 5mg of samples were mixed with 50mg of spectroscopic grade KBr, samples were scanned in the IR range from 500 to 3500 cm⁻¹, with a resolution of 4 cm⁻¹.

Pre-compression Studies

Angle of repose

The maximum angle possible between the surface of the pill of the granules and horizontal plane.

$$\tan \theta = h/r$$

Bulk density

The mass of the powder divided by the bulk volume.

$$P_b = M/ V_b$$

Tapped density

The ratio of total mass of the powder to the tapped volume of the powder.

$$P_t = M/ V_t$$

Compressibility Index

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

Hausner's ratio

Hausner's ratio = Tapped density / Bulk density.

Post-formulation studies

Hardness or Crushing strength Test

The force required to break the tablet is measured in kilograms. Hardness of the tablet was determined using the Monsanto hardness tester.

Thickness Test

The thickness of the tablet was determined using a Vernier calliper and the reading was recorded in millimeters.

Friability Test

The pre-weighed tablets were placed in the friabilator (EF-2, Electro lab, Mumbai) which was then operated for 100rpm, then dusted and reweighed. The Conventional compressed tablets that lose less than 0.5-1.0% of their weight are generally considered acceptable.

$$\text{Friability index} = \frac{I - F}{I} \times 100$$

Where,

I - Initial weight; F - Final weight.

Weight variation test

Weights of 20 individual tablets were noted and their mean weight also calculated. The percentage deviation was calculated by using the following formula,

Percentage deviation = $[X^*/ X] \times 100$

X - Actual weight of the tablet

X* - Average weight of the tablet

Estimation of Drug Content

Ten tablets of each formulation were weighed and powdered. The quantity of powder equivalent to 100 mg of drug was transferred into 250 ml volumetric flask, it was shaken with 150 of distilled water and volume was adjusted to 250ml with water. The solution was filtered, suitable dilutions were made and absorbance was recorded by using U.V. spectrophotometer (Labindia, Hyderabad) at 286nm. The experiment was repeated three times.

Calculation

The amount of Domperidone present in tablet can be calculated using the formula

$A_t/A_s \times S_w/100 \times 100$

Where, A_t = Absorbance of sample preparation

A_s = Absorbance of Standard preparation

S_w = weight at Domperidone working standard (mg).

In vitro disintegration time

Tablets were placed in six tubes of the basket. Then the assembly was suspended in water maintained at a temperature of $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$, 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.

In vitro dissolution

Freshly prepared dissolution fluid (0.1N Hcl) was placed in each dissolution vessels (900 ml) of dissolution test apparatus (USP, II paddle method). The tablets were placed in the dissolution medium. The temperature of the dissolution medium was maintained at $37 \pm 0.5^{\circ}\text{C}$ and the paddle was rotated at 50 rpm. 5 ml samples were withdrawn. The sample volume was immediately replaced with the same volume of fresh media as when a sample was taken. The samples withdrawn were filtered, diluted and estimated spectrophotometrically at 286 nm. Cumulative amount of the drug released at each interval was calculated by using standard graph of Domperidone.

RESULTS AND DISCUSSION

Pre-formulation Studies

Fourier Transform Infrared Spectroscopy

From the FTIR Studies results, it was concluded that there was no interference in the functional groups between drug and excipients.

Pre and Post compression studies

All the tablets are formulated by using Lepidium sativum as natural super disintegrant. They were evaluated by pre-compression (Table No.2) and post-compression parameters (Table No.3) and all the parameters final values are present in within the limits. The *in vitro* release studies (Table No.4 and Figure No.1) showed that the formulation F-4 gave the maximum percentage drug release (100%) with in 6min.

Table No.1: Formulation of Domperidone fast dissolving tablets

S.No	Ingredients	F1	F2	F3	F4	Cross povidone
1	Domperidone	10 mg	10mg	10mg	10mg	10mg
2	Lactose	161mg	156mg	151mg	146mg	146mg
3	Mannitol	10mg	10mg	10mg	10mg	10mg
4	Lipidium sativum Seed powder	5mg (2.5%)	10mg (5%)	15mg (7.5%)	20mg (10%)	20mg (10%) (cross povidone)
5	Talc	10mg	10mg	10mg	10mg	10mg
6	Magnesium Stearate	4mg	4mg	4mg	4mg	4mg
7	Flavor	q.s	q.s	q.s	q.s	q.s

Table No.2: Pre-compression studies of Domperidone fast dissolving tablets

S.No	Pre-compression Parameters	F1	F2	F3	F4	Cross povidine
1	Angle of repose	19.10	19.89	19.57	18.88	18.65
2	Bulk density (gm/ml)	0.670	0.651	0.64	0.631	0.625
3	Tapped density (gm/ml)	0.74	0.76	0.75	0.77	0.70
4	% Compressibility	14%	17%	13%	18%	11%
5	Hausner's ratio	1.17	1.24	1.15	1.23	1.13

Table No.3: Post-compression studies of Domperidone fast dissolving tablets

S.No	Post-compression Parameters	F1	F2	F3	F4	Cross povidine
1	Hardness (kg/cm ²)	3.9	3.8	3.9	3.8	3.7
2	Friability (%)	0.35	0.34	0.39	0.19	0.18
3	Thickness (mm)	2.8	2.9	2.9	3.0	3.1
4	<i>In vitro</i> disintegration time	1.05 min	45 sec	29 sec	23 sec	21 sec
5	Wetting time	58 sec	50 sec	43 sec	34 sec	30 sec

Table No.4: Comparative *in vitro* release studies of Domperidone Fast dissolving tablets

S.No	Time in mints	% of drug release				
		F1	F2	F3	F4	Cross povidine
1	1	15	31	43	56	61
2	2	29	43	54	72	74
3	3	35	55	67	85	87
4	4	42	65	78	91	93
5	5	57	77	85	95	98
6	6	64	83	92	100	100
7	7	78	95	100	--	--
8	8	84	100	--	--	--
9	9	93	--	--	--	--
10	10	100	--	--	--	--

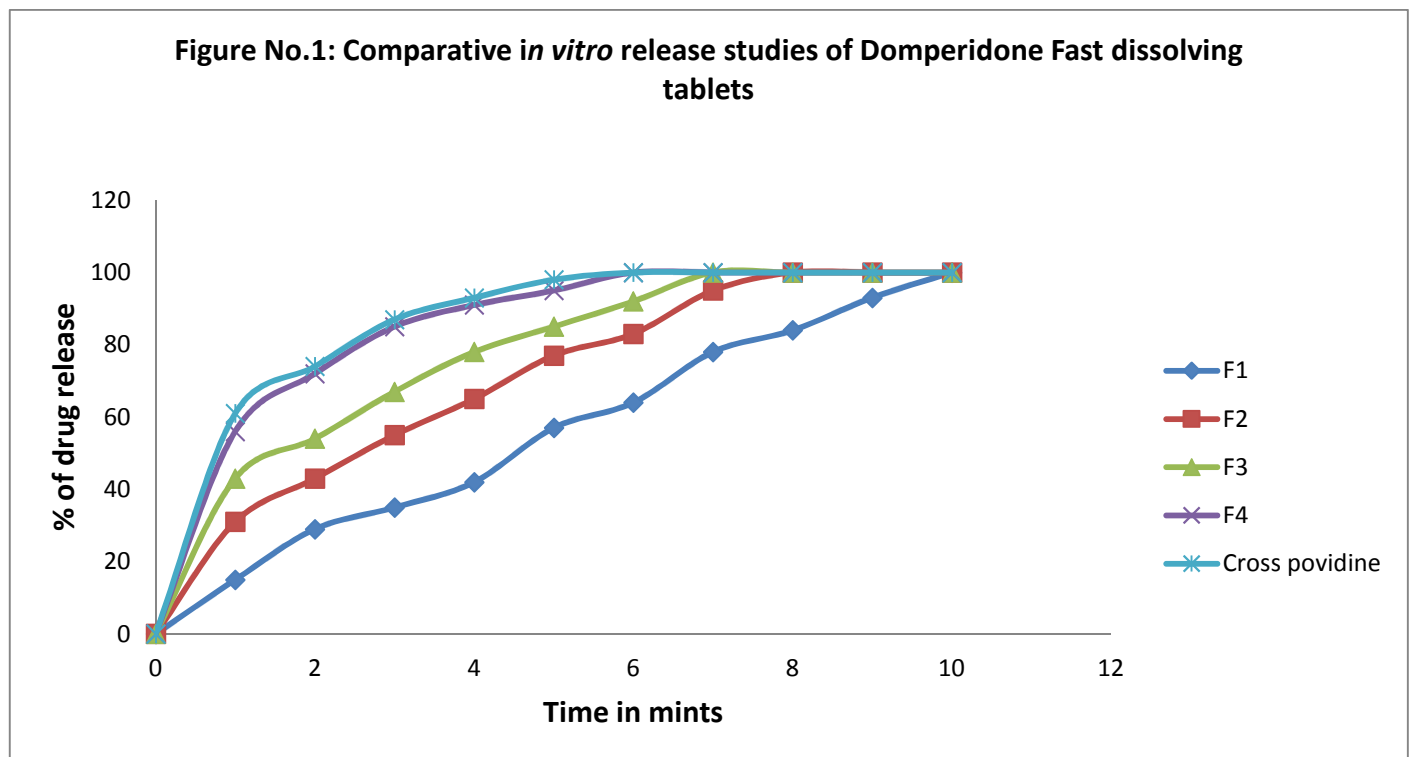


Figure No.1: Comparative *in vitro* release studies of Domperidone Fast dissolving tablets

CONCLUSION

From the above work was concluded that the pre-compression and post-compression studies values are present in within the limits. *In vitro* 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.

ACKNOWLEDGEMENT

The authors are sincerely thanks to A.M Reddy Memorial College of Pharmacy, Narasaraopet, Guntur, Andhra Pradesh, India for providing the facilities to complete this research work.

CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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Please cite this article in press as: Jhansi rani M. et al. Formulation and evaluation of domperidone fast dissolving tablets using natural superdisintegrants, *International Journal of Research in Pharmaceutical and Nano Sciences*, 2(2), 2013, 152-157.