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FAST DISSOLVING DOMPERIDONE TABLET

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ABSTRACT

The purpose of this Project work is to prepare fast dissolving tablets of Domperidone by wet granulation. In the present study, Sodium Starch Glycolate, was taken as super disintegrant and starch paste as a binder for Preparation of fast dissolving Domperidone Tablet. Here the Domperidone (anti-emetic) is taken as the model drug for the study and wet granulation as a method for preparation of the Fast Dissolving Tablet. The disintegrant incorporated during the wet granulation process as extra granular incorporation. Here the concentration of Superdisintegrants and concentration of starch paste were taken as independent variables. The effect of Disintegration time and friability were investigated as dependent parameters. The optimized batch obtained from the study was compared with the marketed products.[1] Oral medication conveyance is the most prominent defeat. It is outstanding since quite a while for its generally utilized course of organization among all the failure that has been investigated for the precise conveyance of medication arranged different measurements from the pharmaceutical items. Dysphagia is a typical issue which needs to look in all times of gatherings in worry to strong dose shapes. The patient needs to improve consistency to take care of the problem of Dysphagia. The Rapidly dissolving tablets have risen as an option in contrast to regular oral medication use.[2]

KEYWORDS: Domperidone, Wet Granulation, Sodium Starch Glycolate, Disintegration Time.

FDT: Fast Dissolving Tablet
DOM: Domperidone
SSG: Sodium Starch Glycolate
D.T.: Disintegration Time
RH: Relative Humidity
MDT: Mean Dissolution Time
IP: Indian Pharmacopoeia

INTRODUCTION

Oral route of drug administration have wide acceptance among all dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance.[3] The reasons that the oral route achieved such popularity may be in part attributed to its ease of administration as well as the traditional belief that by oral administration the drug is as well absorbed as the food stuffs that are ingested daily. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablets when water is not available in the case of motion sickness and sudden episodes of coughing during the common cold, allergic conditions and bronchitis.[4] To overcome from this particular situation we can use Fast dissolving tablet or Rapidly disintegrating tablet. In recent years, scientists have focused their attention on the formulation of quickly disintegrating tablets. The task of developing rapidly disintegrating tablets is accomplished by using a suitable diluents and superdisintegrant. The domperidone is selected as the model drug which comes under anti-emetic class. Domperidone is optimized suits for preparation of FDT as it has longer half life and in case of vomiting it required quick release. Sodium starch glycolate was chosen because of its high swelling capacity. Moreover, the disintegrant efficiency of sodium starch glycolate is unimpaired by the presence of hydrophobic excipient such as lubricants. Sodium starch glycolate exhibits good flow (angle of repose <36°). The bulk density of sodium starch glycolate is 0.756 g/cm3.[5]

AIM AND OBJECTIVE

Aim

The aim of this Project work was to develop the rapidly disintegrating tablets of Domperidone. Rapidly disintegrating tablets were formulated to give quick onset

of action by rapidly disintegrating after administration and achieve better patient compliance.

Objective

- The main objective of the rapidly disintegrating tablets is to enhance absorption and bioavailability of the drug.
- Preparation of Fast dissolving tablet batches by Wet Granulation method
- The prepared rapidly disintegrating tablets are subjected to study the following properties..

Pre-compression parameters

Micromeritic properties – Bulk density, Tapped density, Angle of repose

Post-compression parameters

Shape and colour
Hardness test
Friability test
Weight variation test [6]

Rational for selection of Drug

Need

- Vomiting is the common problem for all the age groups.
- Paediatric, geriatric, bedridden patients suffers from dysphagia, which Results in high evidence of ineffective therapy.
- During traveling, the water availability chances may be less and also Vomiting occurs in some people.
- Few drugs like Domperidone, Promethazine HCl, Metoclopromide etc. acts As antiemetic / anti-motionsickness with promising results.
- Domperidone, an antiemetic and prokinetic is one of the effectively used in Vomiting / motion sickness, having less side effects, with half life of 7.5 Hours. Considering the above points, the present study was aimed to develop Rapidly disintegrating tablets. This helps in Improved clinical effects through pregastric absorption, leading to an increase in Bioavailability of the drug and quick onset of pharmacological action can take Place.[6]

OBJECTIVES

The main objective of the rapidly disintegrating tablets is to enhance Absorption and bioavailability of the drug.

MATERIALS AND METHODS

1) Materials

Ingredients	Category
Domperidone	Active Pharmaceutical Ingredient
Sodium starch glycolate(S.S.G.)	Super Disintegrant
Lactose	Dilluent
Starch (Paste)	Binder
Magnesium Stearate	Lubricant
Talc	Glident

- Preparation of standard calibration curve for Domperidone
- Preparation of rapidly disintegrating tablets of Domperidone by Wet Granulation method

Pharmacokinetics

The systemic bioavailability is only about 15% in fasting subjects given in a dose by mouth, although this is increased when Domperidone is given after food. Domperidone is more than 90% bound to plasma protein, and has a terminal elimination half-life of about 7.5 hours. It is chiefly cleared from the blood by extensive metabolism. About 30% of an oral dose is excreted in urine within 24 hours, almost entirely as metabolites; the remainder of a dose is excreted in faeces over several days about 10% as unchanged drug. It does not readily cross the blood-brain barrier.[7-9]

Mechanism of action

Dopamine (acting through D2 receptors) is an inhibitory transmitter in g.i.t. – normally acts to delay gastric emptying when food is present in stomach. It also appears to cause gastric dilatation and LES relaxation attending nausea and Vomiting. Its prokinetic action is not blocked by atropine and is based only on D2 receptor blockade in upper g.i.t. It does act on CTZ, which is responsible for its antiemetic property. Other manifestations of D2 blockade are antagonism of apomorphine induced vomiting. CTZ like extrapyramidal effects are rare.[7-9]

Side effects

Dry mouth, loose stools, headache, rashes, galactorrhoea, cardiac arrhythmias have developed on rapid i.v. injection.

Uses

- Used as antiemetics for short term treatment of nausea and vomiting.
- Used associated with cancer therapy, nausea and vomiting or associated with levodopa or bromocriptine therapy for Parkinsonism.
- Used for prokinetic actions in disorders of gastrointestinal motility.[7-9]

2) Equipments

Apparatus	Use
Rotary automatic tablet Punching machine	Compress granules to tablet
Dissolution apparatus	Dissolution profile
Disintegration apparatus	Disintegration study
Digital Weighing balance	Weighing of ingredients

- The Materials are Domperidone as API and other excipients like SSG(Sodium Starch glycolate), Starch(Paste), Magnesium stearate, Lactose, Talc are provided from our Institute, Sigma Institute of Pharmacy, Bakrol, Vadodara.
- Dissolution Apparatus (Type 2), Disintegration Apparatus, U.V. spectrophotometer, Friabilator, Rotary automatic Tablet punching machine were used in the Project work at the lab of Sigma Institute of Pharmacy, Bakrol, Vadodara.
- Domperidone is mainly Used as anti-emetic drug serve by an Inhibition of the dopaminergic receptor.
- Other excipients like SSG as Super-disintigrant , Lactose as Dilluent, Starch Paste as binder then Magnesium stearate and Talc used as lubricant and Glident.
- We used Wet Granulation method for Preparation of Fast dissolving Domperidone Tablet.

Preparation of Fast dissolving Domperidone Tablet

There are Different Fast dissolving tablet Formulations were Prepared by Wet Granulation method. All Powders were passed through 80 mesh sieve. Required Quantity of Drug and Excipients mixed thoroughly in which SSG was added in 40-60 % Ratio where the 40% SSG was added in powder mixture before granulation and 60% SSG was added after granulation Process. Then Talc and Magnesium stearate were added as Glident and lubricant respectively. The weighted quantity of blend was compressed using Rotary tablet punching machine. Each Tablet of contain 10 mg DOM and each Tablet total weight was 300 mg.[26]

Procedure

- Collect all ingredients
- Pass them through 80 mesh sieve individually
- Take required Quantity of Drug and Lactose in mortar
- Add 40% required amount of Super-disintegrant(SSG) in mortar
- Mix well with the use of pistal
- Add required amount of Starch Paste to make lump of blended mixture
- Add required amount of Magnesium stearate and mix well
- Take a lump mass and form granules with the help of sieve
- Dry the granules at 40°c for 15 min
- Add rest 60% of required amount Super-disintegrant and Required amount of Talc and mix well
- Weigh the exact quantity(300mg) of this granules mixture for tablet punching
- Fill the die no. 7 in rotary automatic tablet Punching machine with weighted amount of granules mixture
- Domperidone Tablet (300mg)

Formulation of Starch Paste

1. Take require amount of Starch powder in beaker
2. Add little distill water to make a thick slurry
3. Heat this thick slurry with the help of burner
4. Heating continue till the translucent gel form.
5. Off the burner and keep aside the beaker in atmosphere for normal temperature.

- According to above Procedure we formed 5 batches of tablet as F1, F2, F3, F4 and F5. Which contains 10 tablets in each batch. There are two variables in quantity such as Superdisintigrant, Dilluent varies in concentration for optimization of desire need.
- For Imparting the Fast dissolving characteristics we used Super-disintegrant as SSG (Sodium Starch glycolate) in Intra and Inter granular concept in which the 40% amount of total SSG was added before granulation and 60% was added after granulation Process when granules were in dry state.
- Intra-granular[27]:- Inside the granules, i.e. Addition of 40% Super-disintegrant of total amount before granulation Process, leads to formation of granules which contains Super-disintegrant inside granules. This phenomena result in fast disintegration of granules into powder after administration.
- Inter-granular[27]:- Between the granules, i.e. Addition of 60% Super-disintegrant of total amount after granulation Process when granules in dry state. This leads to result in Fast disintegration tablet into granules.
- The application of both inter-intra granular concept in Formulation gives the Fast dissolving tablet then normal conventional tablet.

Formulation batches

Ingredients	F1	F2	F3	F4	F5
Drug	10	10	10	10	10
SSG	15	20	25	35	40
Starch (Paste)	18	17	17	17	17
Lactose	248	244	239	229	224
Magnesium stearate	3	3	3	3	3
Talc	6	6	6	6	6
Total wt.	300	300	300	300	300

Evaluation of domperidone fast dissolving tablets

Pre formulation studies[20]

(A) Angle of Repose

The conventional method used to determine the static repose angle includes measuring the height and radius of the pile of the powder formed by suspending it through a funnel on a platform. Following equation use for the determine angle of repose. The results are shown in table 1.

$\Theta = \tan^{-1}(h / r)$

Where, Θ = angle of repose

h = height of the cone

r = radius of the cone base

(B) Bulk density and tapped density

Loose bulk density (LBD) and tapped density (TBD) were determine by take a 2 gm of powder of the drug powder and previously lightly shaken to break any agglomerates particle and after that it introduce in to the 10 ml measuring cylinder. Then initial volume was observed. The cylinder was allowed to fall under its weight onto a hard surface from the height of 2.5cm at 2second intervals. The tapping is continue for the 100 times and after that observed to certain changes in the volume.

We are calculate LBD and TBD using the following equation:

LBD: Weight of powder / Volume of the packing

TBD: Weight of powder / Tapped volume of the packing. The results are shown in table …

(C) Compressibility Index

Compressibility index of powder is determine by the carr's compressibility index

Carr's compressibility index (%) = [(TBD- LBD) X 100] / TBD

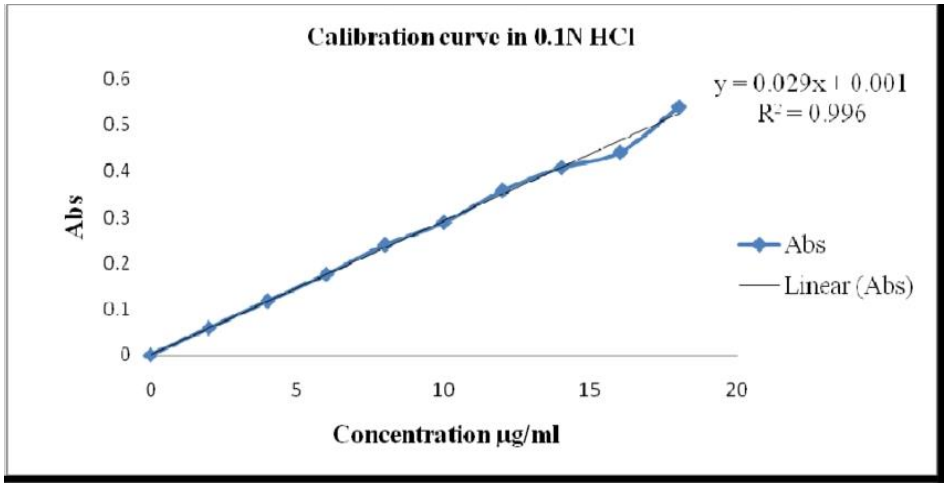
Or it can be expressed as Carr's Index relates the poured density of the material to the tapped density and was calculated by using the following relationship:

Carr's Index=Tapped density−Poured density/ Tapped density X 100

Carr's Index values for pure drug, and granules were determined by measuring the initial volume (Vp) and final volume (Vt) of known weight (W) of material after subjecting to 100 tapping in a graduated measuring cylinder. From these volumes, the poured density (W/Vp) and the tapped density (W/Vt) values were calculated and were substituted in the above equation to determine Carr's Index.

(D) Melting Point

Melting point was determined by capillary fusion method in melting point apparatus. A capillary was sealed at one end filled with a small amount of domperidone and the capillary was kept inverted i.e. sealed end downwards into the melting point apparatus.



Evaluation of Physicochemical Properties of Tablets

(A) Hardness[21]

The tablet was held along its oblong axis in between the two jaws of the tester. At this point, reading should be zero kg/cm2. Then constant force was applied by rotating the knob until the tablet fractured. For every formulation, the hardness of tablets from each formulation batch was taken randomly and the average reading was noted. Results are shown in table2

(B) Weight variation Test[22]

Weight variation test was done by weighing 10 tablets individually by using digital weighting balance. Calculate the average weight and compare the individual tablet weight to the average weight of 10 tablets. Results are shown in table2.

(C) Friability Test[23]

The friability of the tablets was measured in a Roche friabilator. Tablets of a known weight (W1) or sample 10 tablets are dedusted in a drum for a fixed time (100 revolutions) and weighed (W2) again. Percentage friability was calculated from the loss in weight as given in the equation as below. The weight loss should not be more than 1% Results are shown in table 2.

$$\% \text{ Friability} = \frac{W1 - W2}{W1} \times 100$$

(D) In Vitro Disintegration Test[24]

The disintegration time of the tablet was measured in water (37 ± 2° C) according to using Tablet Disintegration Tester. The time in seconds taken for the complete disintegration of the tablet with no palpable mass in the apparatus was measured in seconds. 3 tablets from each batch (formulation) were tested for the disintegration time calculations. Results are shown in table2.

In-Vitro Release Studies (Dissolution study)[25]

Dissolution studies for Domperidone fast dissolving tablets were performed in pH 0.1 N HCL buffer using USP dissolution test apparatus with a paddle stirrer. The paddles are allowed to rotate at speed of 50 rpm. The dissolution medium was maintained at a temperature of 37+0.5OC and samples are withdrawn at an interval of every 5 min the volume of the withdrawn samples are replaced by fresh dissolution medium in order to kept the volume of the dissolution medium as constant. The withdrawn samples are filteredand absorbance was measured at absorption maxima of 284 nm using UV-visible spectrophotometer.

RESULT AND DISCUSSION

Results of pre formulation studies

(A) The angle of Repose: The ascertain values of angle of repose has been 26º.01' To 28º.75', which mention in the table1.

(B) Bulk density: The Ascertain worth of bulk density of formulation was Cite in the Table1. The obtained values are 0.497 To 0.537 gm/cm^2.

(C) Tapped density: The ascertain values of exploited density of formation were cited in the table3. The obtained values are 0.543 To 615 gm/cm^2.

(D) Compressibility indicator: The ascertain values of compressibility of the Formulations are mention in the table1. The ascertain values are 4.09 To 19.18%.

Table 1: Results of Pre formulation studies for the fast dissolving tablets.

Formulations	Bulk density* (g/cc)	Tapped density* (g/cc)	Angle of repose* (Ɵ)	Compressibility Index (%)	Melting Point (°C)
F1	0.521	0.543	26º.70'	4.05	238-241
F2	0.497	0.615	26º.01'	19.18	236-239
F3	0.512	0.550	27º.65'	6.90	238-242
F4	0.537	0.594	28º.75'	9.59	232-237
F5	0.508	0.587	26º.27'	13.45	236-240

Results of Physicochemical Properties of Tablets

A. Hardness: The every formula of formulated Tablets possess the hardness Together with the Array of 3 kg/cm2 To 6 kg/cm2. Which mention in the table 2.

B. Weight Variation: The weight variation of all batches were cited in the table 2 The all formulated tablets are passed in weight variation test. The values have been 299.7 ± 2.43 To 300.2 ± 2.77 mg.

C. Friability: The obtained values of friability evaluation of formulation were cited in the table2. The values are 0.233 To 0.66%. The friability of pills of the formulation isn't greater than 1 percent.

D. In vitro disintegration test: The obtained results for disintegration test are shown in table2. The values are 6 min 20 sec To 2 min 40 sec.

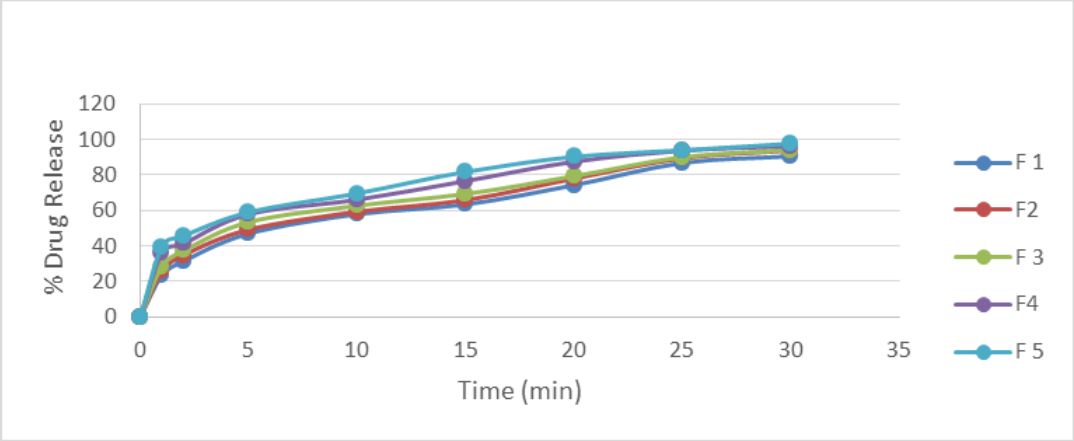
E. In vitro dissolution test: The obtained various values are shown in table 3.

Table 2: Results of physicochemical properties of the fast dissolving tablet.

Formulations	Hardness (kg/cm^2)	Weight variation (mg)	Friability (%)	Disintegration time (sec)
F1	5.6 ± 0.211	300.2 ± 2.72	0.2333%	380 sec
F2	5.1 ± 0.259	299.7 ± 2.43	0.533%	337 sec
F3	4.3 ± 0.2	300.4 ± 1.86	0.33%	295 sec
F4	3.9 ± 0.148	300.2 ± 2.77	0.433%	200 sec
F5	3.1 ± 0.122	300.6 ± 1.27	0.66%	160 sec

Table 3: Results of in vitro studies of dissolution test for fast dissolving tablet.

Sr. no.	Sampling time (min).	Percentage drug release				
		F1	F2	F3	F4	F5
1	0	0	0	0	0	0
2	1	23.506	25.627	28.41	36.275	39.531
3	2	31.375	34.851	37.289	41.301	45.692
4	5	46.948	49.209	53.421	57.886	58.972
5	10	57.864	59.239	62.632	66.032	69.608
6	15	63.386	65.792	69.301	76.552	81.713
7	20	74.219	77.921	79.289	87.442	90.211
8	25	86.739	89.390	90.023	93.678	93.929
9	30	90.528	93.791	93.991	96.158	97.634



Graph: Cumulative Percentage Drug release Profile.

DISCUSSION

After Performing Projectwork we conclude that increasing the concentration of superdisintegrant (SSG) is expected to decrease the disintegration time while increasing the concentration of binder (starch paste) is expected to increases the disintegration time. Sodium starch glycolate 13.33% w/w and starch paste 3.66% w/w were selected as the optimum concentration that showed minimal disintegration time of 160 seconds. It was observed that further increase in concentration of binder led to the increase in disintegration time. Such delay in disintegration may be because of the tight binding between molecules which ultimately slow down the water uptake by the tablets and thus super disintegrant do not get sufficient water to swell. The water uptake by the tablet is facilitated by the starch, while the tablet disintegration is facilitated by the swelling force exhibited by sodium starch glycolate at their optimum concentration. When higher percentage of starch paste is used, higher binding between granules is expected in the tablets and tablet became harder, so an increase in the concentration of starch leads to a decrease in friability. The increase in the incorporated amounts of sodium starch glycolate resulted in increase in the friability due to its less compressibility which ultimately results in weak tablets.

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