Patel Rupali *et al*, International Journal of Pharmaceutical Sciences & Medicine (IJPSM),
Vol.8 Issue. 3, March- 2023, pg. 42-66

ISSN: 2519-9889
Impact Factor: 5.9

Formulation and Evaluation of Gastro Retentive Drug Delivery System of Domperidone Mouth Dissolving Tablet by using Super Disintegrating Agents

***Patel Rupali; Upadhyay Nikita; Sonartiya Sunita; Dr. Jain Sourabh; Dr. Dubey P.K.**
Swami Vivekanand College of Pharmacy, Indore
DOI: 10.47760/ijpsm.2023.v08i03.004

Abstract: Direct compression method can be considered as an important method for the formulation of fast dissolving tablets of Domperidone compare to wet granulation method. The rank order for the best 3 formulations is F2>F1.
Formulation F2 having DCP as the super disintegrant is the best formulation of all. Higher the concentration of the lubricating agent (Magnesium Stearate or Talc), higher will be the disintegration time. Formulation having the better Super disintegrants (Ac-Di-Sol) will have better in vitro disintegration time and dissolution along with lesser friability and weight variation. Thus, it may be concluded that the fast-dissolving tablets of Domperidone can be successfully prepared and undoubtedly the availability of various technologies and manifold advantages of fast dissolving tablets will surely enhance patient compliance and its popularity in the near future.
Keywords: Direct compression, Tablets, disintegration**.**

Introduction:

In the present study, Domperidone fast dissolving tablets were prepared by using d-glucose, Di calcium phosphate as Super disintegrants and mg stearate. A total number of 5 formulations were prepared by direct compression and wet granulation technique. The value of pre-compression parameters evaluated was within prescribed limits and indicated good flow property. The data obtained of post compression parameters such as hardness, friability, weight variation, uniformity of content, thickness, wetting time, disintegration time are shown in the table. The hardness was found to be in range of 3 to 4 kg/cm2 in all the formulations indicating good mechanical strength with an ability to withstand physical and mechanical stress conditions while handling. In all the formulations the friability value is less than 1% and meets the IP (Indian Pharmacopoeia) limits.

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Material & Method:

Domperidone, Mann Pharmaceutical Industries (Mehsana, India), D-glucose, Meryer Chemical Technology Co., Ltd, Di calcium phosphate, Colorcon, West Point, Mumbai, India, Magnesium Stearate, Mingtai Chemicals, Mumbai, India, Talc, HGTD LTD, Mumbai, India, Cross povidone, Mingtai Chemicals, Mumbai, India.

Initial studies for the preparation of Domperidone Fast Dissolving Tablets were carried out by the direct compression of powder blend containing drug, glucose, and talc and mg Stearate. Before the compression all the ingredients were passed through 40-mesh sieve and then tablets were prepared using 9 mm diameter punch on single punch single station tablet machine.

PREFORMULATION STUDIES

State = Solid
Melting point = **175**^{o}C
Appearance = **Whitish** powder

Solubility:

Solubility of drug in different solvents:

Table: 2 Solubility of drug in different solvents

TEST SOLVENTS	REFERENCE	OBSERVATION
Ethanol (95%)	Slightly	Soluble
Methanol (95%)	Slightly	Soluble
Water	Insoluble	Sparingly soluble
Acetone	Soluble	Soluble

I. U.V Spectroscopy Determinations

UV Spectra of Dompiridone in pH 6.4 Buffer

Accurately weighed quantity of Dompiridone (10mg) was dissolved in 10 ml of PBS and aliquots are prepared and scanned between 400-200 nm on Shimadzu-1700E UV spectrophotometer against blank. The λ max was found to be 280 nm.

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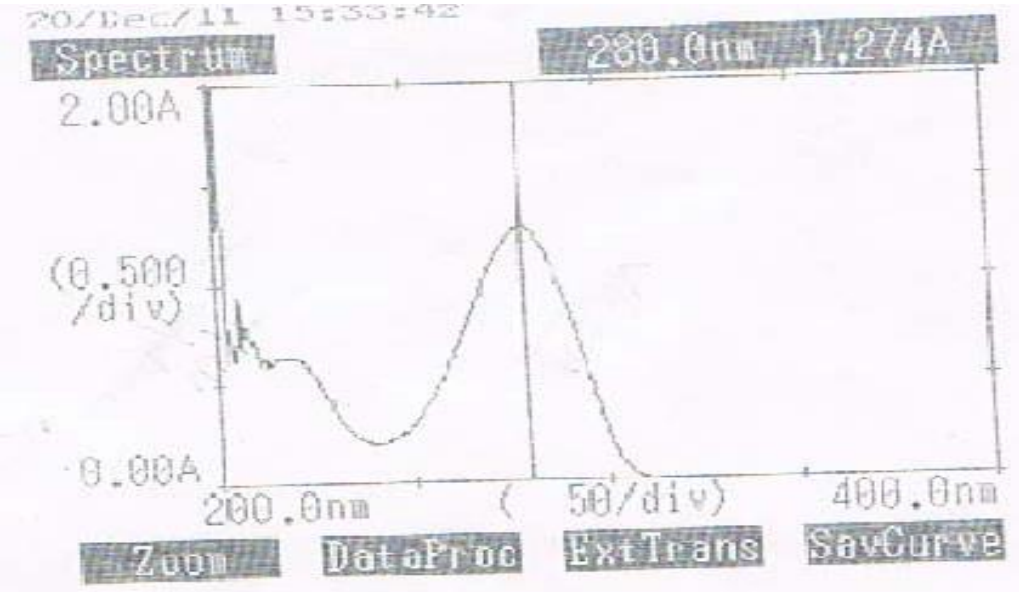

Fig: 7 UV Spectra of Dompiridone

Preparation of Calibration Curve of Domperidone: -

Absorption maximum was determined by the appropriate dilution prepared by dissolving 10 mg of Domperidone in 10 ml of 6.4 PBS Buffer solution.By using the Stock solution further dilution of 5, 10,15,20,25 µg/ml solution was prepared and scanned in the range of 400 – 200 nm in the Shimadzu 1700E UV/ Visible spectrophotometer.

Table. 3 Calibration graph data of Domperidone

S No.	CONCENTRATION	ABSORBANCE
1	0	0
2	10	0.089
3	20	0.155
4	30	0.219
5	40	0.275
6	50	0.345

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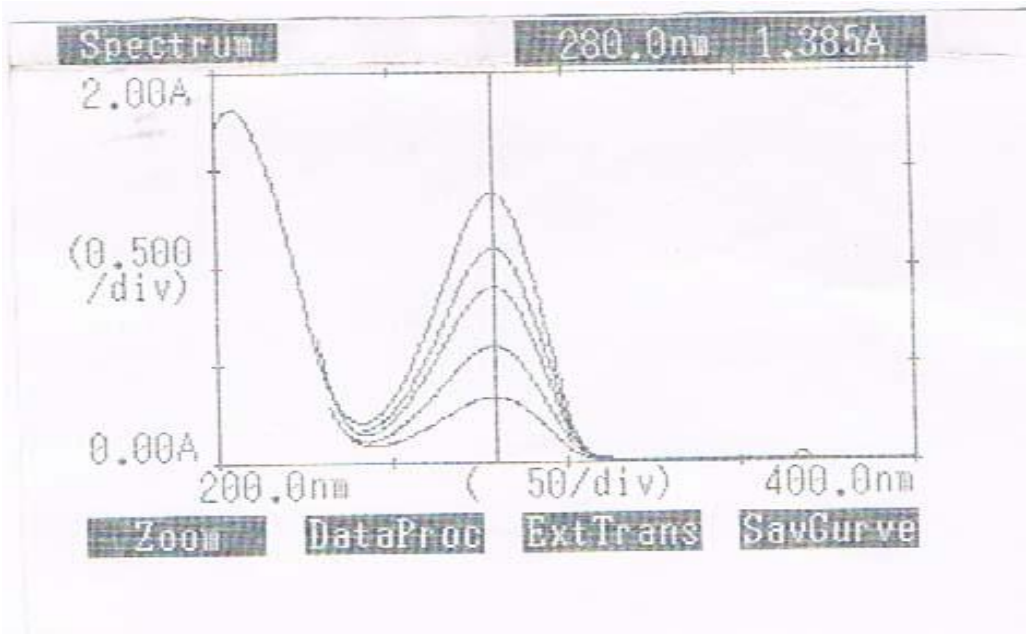

Fig. 8 Overlay spectra of Dompiridone during preparation of Calibration Curve

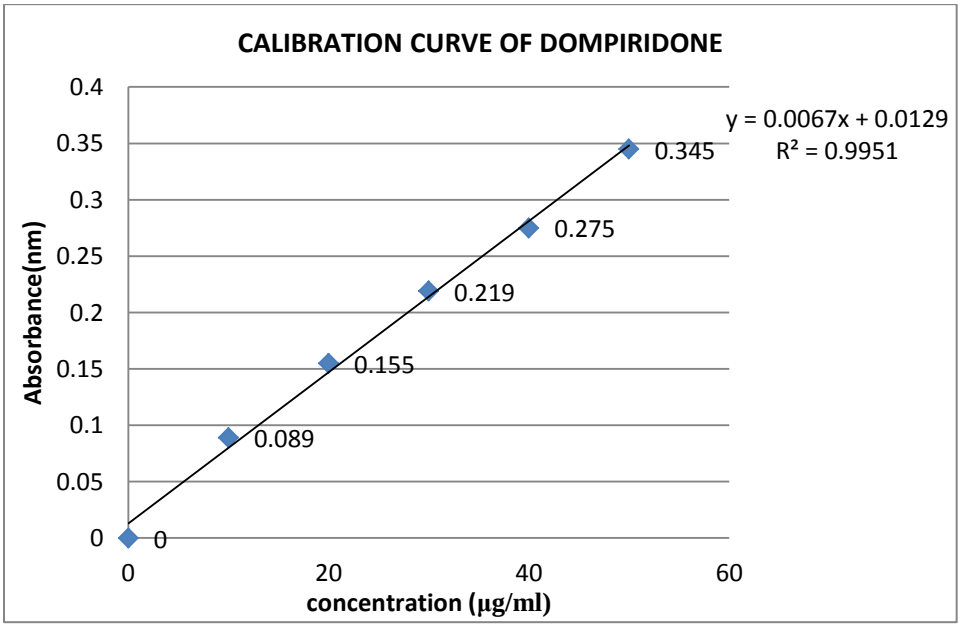

Fig. 9 Calibration Graph of Domperidone

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II. Drug Analysis by IR Spectra

Infra-Red analysis of the drug was done by taking KBr as a standard in the ratio of 1:100 on Shimadzu FTIR spectrophotometer.

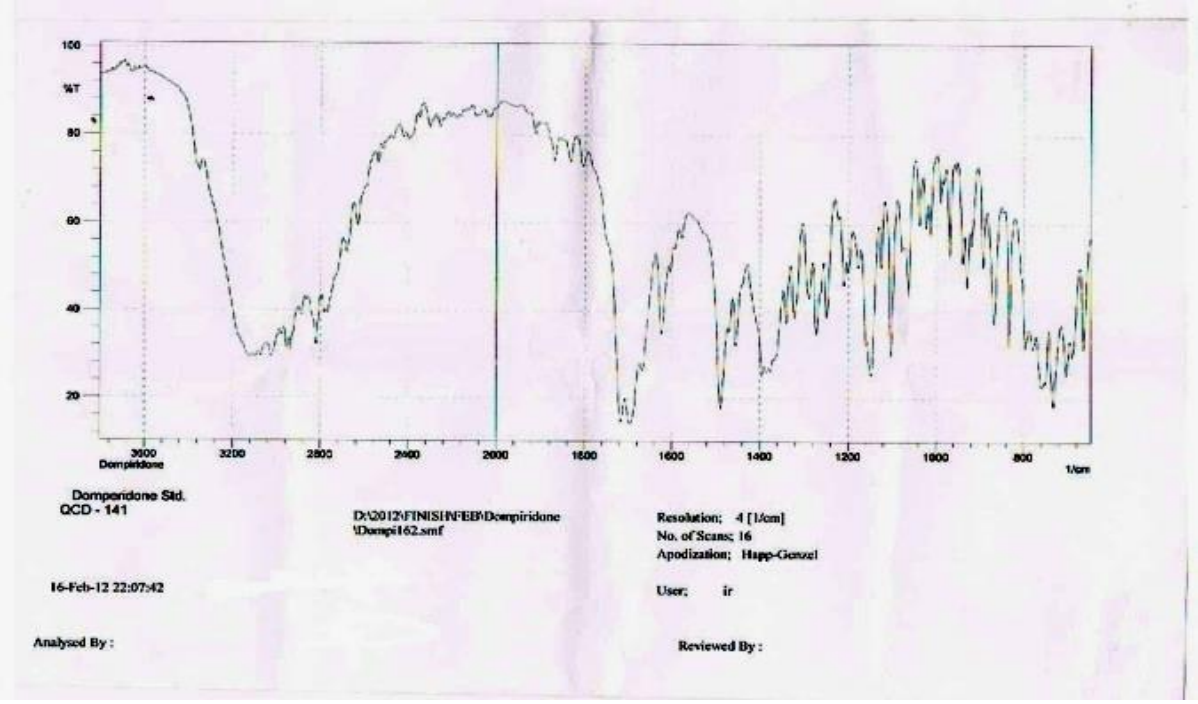

Fig. 10 Graph 1: IR Spectrum of Standard Dompiridone.

Inference:

The peaks coming in the spectra resembled with the peaks found in the spectra Of Domperidone in IP. So, we can say that our drug is pure Domperidone.

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III. DRUG ANALYSIS BY DIFFERENTIAL SCANNING CALORIMETERY (DSC)

DSC OF PURE DRUG DOMPIRIDONE

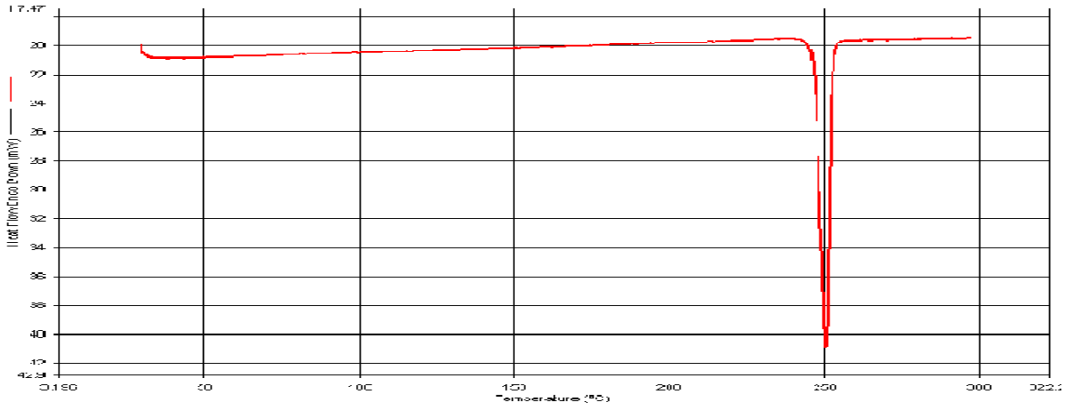

Fig. 11 Drug Analysis By Differential Scanning Calorimetery

1. DRUG-EXCIPIENT COMPATIBILITY STUDIES

Physical compatibility study in different Conditions:

Compatibility testing was performed by using the 1:1 ratio of drug and various excipients. The combination was kept at different conditions for 1 month and the physical difference from control was observed as mention in table.

Table. 4 Drug-Excipients Compatibility Studies

Sr. NO.	ACTIVE + INACTIVE INGREDIENTS	COLOUR	2-8^{O}C	25^{O}C	45^{O}C
1	Drug + D-Glucose	White	White	White	White
2	Drug + Di calcium phosphate	White	White	White	White
3	Drug + Magnesium stearate	White	White	White	White
4	Drug + Talc	White	White	White	White

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Inference:
The physical observance of the different combination does not show any significant change which shows the compatibility of drug with other excipients.

Drug-excipient compatibility study

a. **UV spectrophotometer:**
   Absorption maximum was determined by the appropriate dilution prepared by dissolving 10 mg of Dompiridone in 10 ml of ph 6.4 buffer.By using the Stock solution further dilution of 5, 10,15,20,25 µg/ml solution was prepared and some amount of excipients are added in each dilutions and scanned in the range of 400 – 200 nm in the Shimadzu 1700E UV/ Visible spectrophotometer.

Inference:
There was no major deviations found in absorption maximum of the drug and absorbtion of all the dilutions were coming approximetly same to the dilutions of the pure drug.
Thus, we can say that excipients are not interfering with the λ max and absorbance of drug in different dilutions.

b. **Drug-excipient compatibility study using infra-Red (IR):** Infra-Red analysis of the drug and mixture of drug: exicipients (1:1) was done by taking KBr as a standard in the ratio of 1:100.

The drug and excipient found to be compatible by following graph

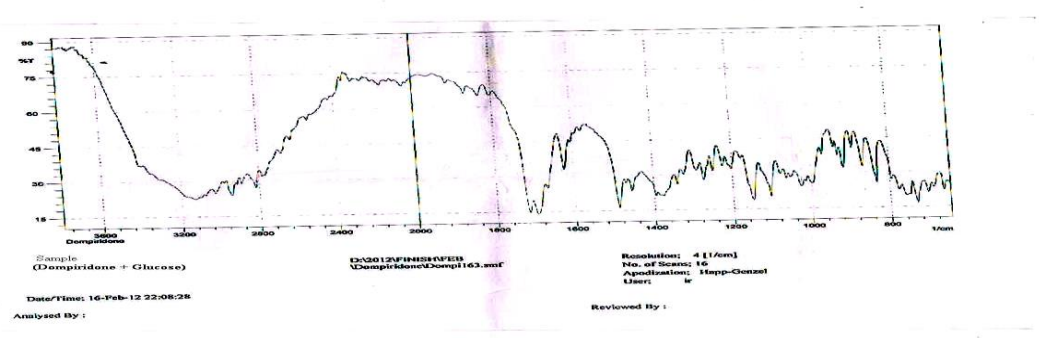

Fig. 12 Graph 2 : IR Spectrum of Dompiridone : D-glucose

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C. Drug-excipient compatibility study using DSC:

1. DSC of Pure Drug Dompiridone + Glucose

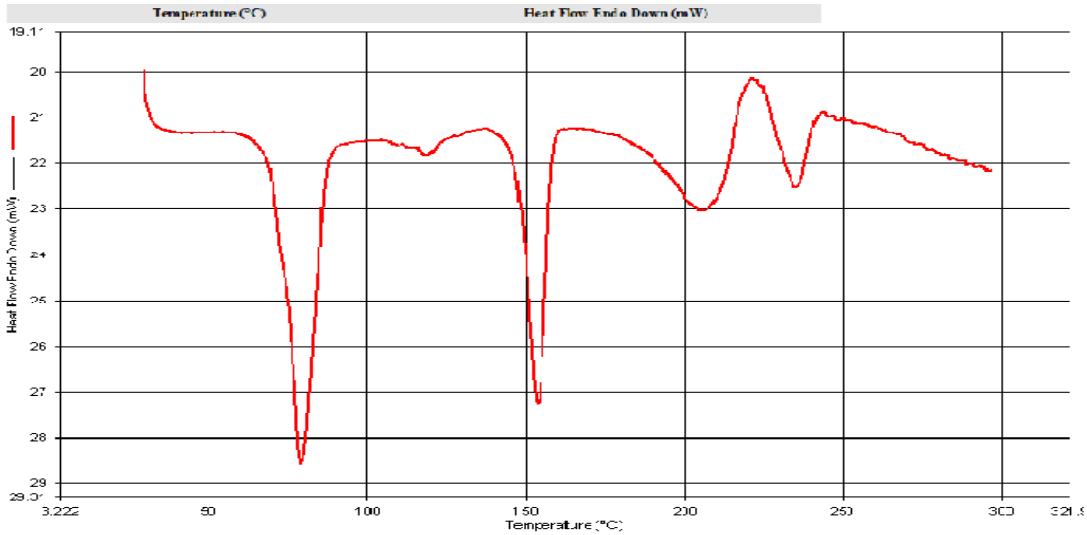

Fig . 13 Dsc Of Pure Drug Dompiridone + Glucose

Inference:

In DSCThermogram of Drug and excipients mixture (1:1) the peak of pure drug was not appeared in the graph, it may be just because theglucose used was marketed glucose and it has contained other ingredients, so it might form dispersion with glucose. The melting point of glucose is 143-145 ^{o}C and it very less than drug.

Now for further studies I had replaced Marketed glucose by Pure D – Glucose and repeated The DSC Analysis and it is found that the D- glucose is compatible with pure drug.

1. DSC of Pure Drug Dompiridone + D – Glucose

Characterization of powder blend used for the preparation of tablet

Dompiridone were mixed homogeneously by pestle mortar. Lactose was used as filler and channeling agent. Sodium bi carbonate and citric acid was used as effervescent agent. The blends were made and evaluated for the various pharmaceutical parameters to check the flow property and compressibility of the blend. The various parameters to be checked are mentioned below.

Bulk density and Tapped density: -

A quantity of 2 gm of powder blend from each formula, previously shaken to break any agglomerates formed, was introduced in to 10 ml measuring cylinder. After that the initial volume was noted and the cylinder was allowed to fall under its own weight on to a hard surface

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from the height of 2.5 cm at second intervals. Tapping was continued until no further change in volume was noted. BD and TD were calculated using the following equations.

Bulk Density = Mass ÷ Bulk Volume

Tapped Density = Mass ÷ Tapped Volume

Compressibility Index

The Compressibility Index of the powder blend was determined by Carr's compressibility index. It is a simple test to evaluate the BD and TD of a powder and the rate at which it packed down. The formula for Carr's Index is as below:

Compressibility index = [tapped density- bulk density/ tapped density] x 100

Hausner's ratio (HR): -

The flow properties were characterized in term of and Hausner's ratio (HR). Hausner's ratio (HR) was calculated according to the following equation

Hauser's ratio = tapped density/ bulk density

Table. 5 Scale of flow ability

Compressibility Index	Flow Character	Hausner Ratio
≤ 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

Angle of repose: -

The angle of repose of powder blend was determined by the funnel method. The accurately weight powder blend were taken in the funnel. The height of the funnel was adjusted in such a way the tip of the funnel just touched the apex of the powder blend. The powder blend was allowed to flow through the funnel freely on to the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation.

Tan θ = h/r

Where, h and r are the height and radius of the powder cone.

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Specifications of Angle of Repose for powder as per IP:

Table. 6 Angle of Repose for powder as per IP

Angle of repose (degrees)	Types of flow
Less than 25	Excellent
25 – 30	Good
30 – 40	Passable
Above 40	Very poor

Results for Different Evaluation Parameters: -

Table. 7 Results for Different Evaluation Parameters

Sr. No.	Parameter	Formulations
1	Bulk density (gm/ml)	0.65
2	Tapped density (gm/ml)	0.75
3	Angle of repose (Ɵ)	32°
4	Compressibility Index (%)	12.40
5	Hausner's ratio	1.15

Characterization of Drug:

Table. 8 Characterization of Drug

Sr. No.	Test	Specification	Result
1	Description	White or yellowish amorphous powder	amorphous powder
2	Identification	Should pass	Pass
3	Solubility	Very soluble in Acetone, slightly soluble in methanol, practically insoluble in water	Complies

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4	pH	5.5-7.5	6.8
5	Water	Not more than 4%	3.04%
6	Absorbance	0.04	Maximum 0.15 at 425nm
7	Heavy metals	Not more than 20ppm	Less than 20ppm
8	Specific optical rotation	+168 to +183	+174.26
9	Assay (Calculated as on dried basis)	Not less than 95% and not more than 102.0%	95.88%

2. EXPERIMENTAL WORK

2.1 LIST OF MATERIAL USED WITH THEIR SOURCE:

Table. 9 List of Material used with their source

Sr. No.	Materials	Manufacturer (Supplier)
1	Domperidone	Mann PharmaceuticalIndustries (Mehsana, India)
2	D-glucose	Meryer Chemical Technology Co., Ltd
3	Di calcium phosphate	Colorcon, West Point, Mumbai, India
4	Magnesium stearate	Mingtai Chemicals, Mumbai, India
5	Talc	HGTD LTD, Mumbai, India
6	Cross povidone	Mingtai Chemicals, Mumbai, India

2.2 Formulation of Domperidone Mouth Dissolving Tablet

Initial studies for the preparation of Domperidone Fast Dissolving Tablets were carried out by the direct compression of powder blend containing drug, glucose, talc and mg stearate. Before the compression all the ingredients were passed through 40-mesh sieve and then tablets were

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prepared using 9 mm diameter punch on single punch single station tablet machine. The formula for compressing the tablet.

2.3 EVALUATION PARAMETER OF MOUTH DISSOLVING TABLE

The evaluation of Mouth Dissolving tablet dosage form with respect to various characteristics is essential to precisely control the dosage form behavior and to ensure batch-to-batch uniformity. The tablets were evaluated for thickness, weight variation, hardness, friability, and *in vitro* drug release.

Tablet Dimensions (Tablet Thickness and Diameter)

Thickness and diameter of tablets were important for uniformity of tablet size. Thickness and diameter were measured using dial vernier calipers. The tablet was placed between the gaps of lower angle and note down the movement of caliper at which value it will fit in the space of lower angle. The thickness of entire batch was in the range of 4.4 ± 2 mm and diameter was found to be 8 mm**.** The thickness was measured by placing tablet between two arms of the Varnier calipers. 5 tablets were taken and their thickness was measured.

Uniformity of the weight (Weigh variation test)

This is important in-process quality control test to be checked frequently (every half in hrs.). Corrections were made during the compression of the tablets. Any variation in the weight of the tablet (for any reason) lead to either under medication are overdose. So, every tablet in each batch should have a uniform weight. 20 tablets were weighted individually**.** Average weight was calculated from the total weight of the tablets. The individual weights were compared with
The average weight. The % difference in the weight variation should be within the permissible limits (±1%). The percent deviation was calculated using the following formula: % Deviation = Individual Weight- Average weight/ Average weight*100Weight variation test was done by weighing 20 tablets individually, by using Sartorius balance (Model CP- 224 S). Calculating the average weight and comparing the individual tablet weight to the average weight.

Table. 11 Uniformity of Tablets

Avg. Wt. of tablets (mg.)	% of deviation
80 or less	10
80 – 250	7.5
More than 250	5

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Wetting time

A piece of tissue paper folded twice was placed in a smallPetridis (internal diameter = 6.5 cm) containing 6 ml ofsimulated saliva pH (phosphate buffer pH 6.8). A tablet was put on the paper, and the time required complete wetting wasmeasured. Six trials for each batch performed; average time for wetting with standard deviation was recorded.

Drug Content Estimation

Ten tablets were taken and amount of drug present in each tabletwas determined as follows: Tablet was crushed in mortar and transferred to 100 ml flask. The powder was dissolved in pH3.2.The sample was mixed by using Remi mixer for 5 minutes, after which it was filtered through what man filter paper. The filtered solutions after appropriate dilution (1 to 10 ml) with 0.1N HCL were analyzed by validated UV spectrophotometric method at λ max 280.5nm.

Tablet Hardness

The tablet hardness, which is the force required to break a tablet in a diametric compression force. The hardness tester used in the study was Monsanto hardness tester, which applies force to the tablet diametrically with the help of an inbuilt spring.

Tablet friability

The friability of the tablets was measured in a Roche friabilator (Camp-bell Electronics, Mumbai). Tablets of a known weight (Wo) or a sample of 20 tablets are dedusted in a drum for a fixed time (100 revolutions) and weighed (W) again. Percentage friability was calculated from the loss in weight as given in equation as below. The weight loss should not be more than 1 %. Determination was made in triplicate.

$$\text{Percentage friability} = \left\{\frac{(\text{Initial weight} - \text{Final weight})}{\text{Initial weight}}\right\} \times 100$$

Friability testing parameters: -

Number of tablets	=	20
RPM (Revolution Per Minute)	=	25
Time (in min)	=	4

In Vitro Disintegration time

In Vitro disintegration time was performed by apparatus specified in USP at 50 rpm. Phosphate buffer 6.4, 900 ml was used as disintegration medium, and the temperature of which maintained at 37±2^{o}C and the time in second taken for complete disintegration of the tablet with no

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palpable mass remaining in the apparatus was measured in second.Disintegration time of The evaluation of Mouth Dissolving tablet dosage form with respect to various characteristics is essential to precisely control the dosage form behavior and to ensure batch-to-batch uniformity. The tablets were evaluated for thickness, weight variation, hardness, friability, and *in vitro* drug release. Tablet of Dompiridone was determined using the disintegration apparatus. One tablet was placed in each of six tubes placed in a beaker containing 1000 ml of purified water maintained at 37 ± 2ºC and the apparatus was operated. Take time taken for the tablets to disintegrate and pass-through mess was note.

Drug release testing (*In vitro* dissolution studies):

In vitro release studies were carried out in the dissolution test apparatus USP Type II. The tests were performed out in 900 ml of pH 6.4 buffer for 1 hrs. at 75 rpm at 37±0.5^{o}C. 10 ml of the aliquot were withdrawn at different predetermined time intervals (10,20,30,40 and 50 min) and filtered. Sample was analyzed at 280 nm using UV/Visible spectrophotometer (Shimazdu UV-1700, Japan), 6.4 buffer solution is used as blank. 10 ml of 6.4 buffer solution was replaced in the vessel after each withdrawal to maintain the sink condition. The percentage drug release was calculated using the calibration curve and was plotted against function of time to study the pattern of drug release from tablets.

PREPARATION OF MOUTH DISSOLVING TABLETS

Procedure: Weigh D-glucose, pass through #40 mesh, then mix it geometrically with Dompiridone again pass the blend through #40 mesh.

Now weigh Di calcium phosphate,pass through #40 mesh, mix it with the above blend.

Then weigh Magnesium Stearate and Talc pass through #60 mesh,lubricate the above blend with magnesium stearate and blend is ready for Compression.

Compression was done on single Station D-tooling machine.

OPTIMIZATION OF FORMULATION

The task of formulating a dosage form to achieve a desirable fast dissolving with the selection of potential excipients that allow the formulation of mouth dissolving characteristics, and it should dissolve slowly enough to serve as a reservoir for the delivery.

Optimization of Drug: G-glucose Ratio

In preliminary trial batches, d-glucose was selected for polymeric delivery system. Ratio of drug and d-glucose were optimized to get better fast dissolving property for the desired time. Three formulations containing changed ratio of d-glucose is mentioned in the table 7.6.

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EVALUATION OF BATCHES F-1 TO F-5

A) Determination of hardness, thickness and diameter of tablets

The Monsanto hardness tester was used to determine the hardness of the tablets. The diameter and thickness of the tablets were determined using measuring scale and vernier calipers and results are shown in the Hardness, thickness and diameter.

B) Determination of weight variation, content variation and friability

Weight variation test, content variation test and friability test for the different batches were performed as per the I.P 2010. Fast dissolving behavior in terms of disintegration times was also calculated as per the procedure mentioned above. The results obtained for the different batches are mentioned in the General characteristics of tablets.

Table. 13 General characteristics of tablets:

Batch Code	Weight variation test (%)	Content Variation	Hardness (Kg/cm^2)	% Friability	Disintegration Time (Sec)
F1	2.1±0.10	100.4	4.0	0.65	38
F2	2.8±0.31	100.00	4.5	0.44	25
F3	1.9±0.78	103.4	4.5	0.40	21
F4	2.1±0.12	103.4	4.4	0.46	30
F5	2.1±0.15	103.4	4.0	0.45	25

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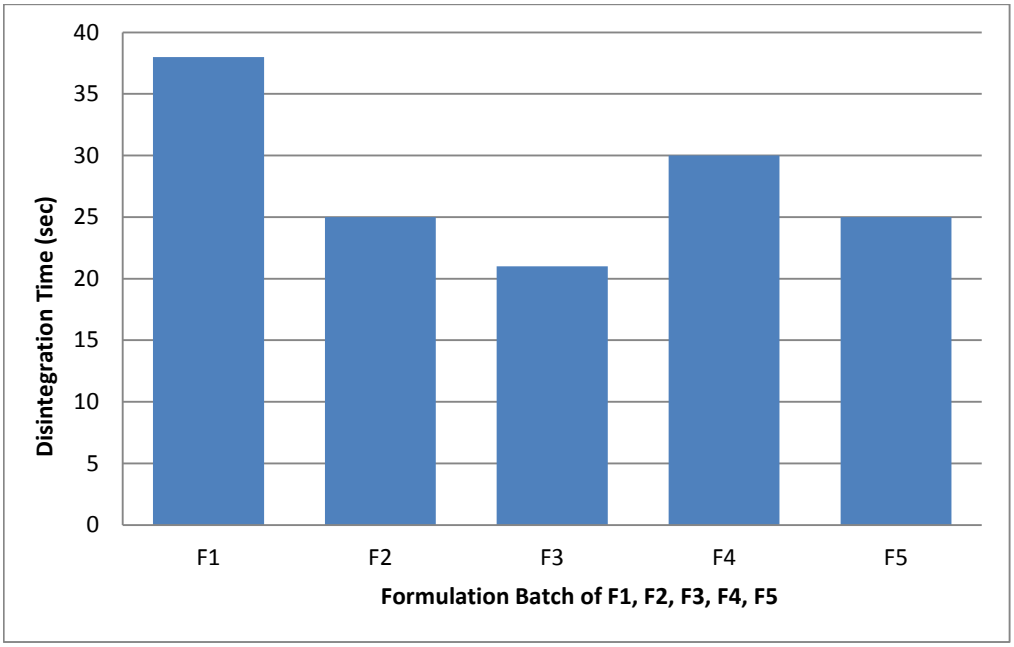

Fig. 14 Disintegration Time curve

Stability testing (General Observations):

All the tablets prepared using the glucose were initial having the better properties of tablets as mentioned in the table 6.6. But after the 15 days it was observed that the tablet was showing the increment in hardness and increase in the disintegration time of the tablet. In this tablet it was also observed that the surface removal of the tablet was almost similar to the initially prepared tablet but it was forming a slowly dissolving core.

Optimization of Concentration of Di calcium phosphate

On the basis of fast dissolving property and release behavior, it has been observed that formulation F-6 was not having optimum disintegration time, so it was discarded for the further study. Formulation F-7 and F-6 both may be considered for further study, but formulation F-7 was selected because it was showing the desired result with low concentration of glucose. At the similar time during the general observations of the stability studies, tablets were failed to reproduce the desired results and causing the formation of a slowly dissolving core during the disintegration time test. So, for the minimization of such problems Di-calcium phosphate was incorporated in the above-mentioned formula and the concentration was optimized for the desired results. The formula used during the optimization study of Di- calcium phosphate are mentioned in the table no.7.9

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Table no. 14 Formula for Mouth dissolving tablet containing different

S. No.	Ingredients (mg/tab)	F-6	F-7	F-8	F-9	F-10
1.	Drug (Dompiridone)	20	20	20	20	20
2.	D-glucose	130	130	120	120	120
3.	Di Calcium Phosphate (DCP)	10	20	30	25	20
4.	Magnesium stearate	15	10	10	10	10
5.	Talc	15	10	10	10	15
6.	Cross povidone	10	10	10	15	15
	TOTAL	**200**	**200**	**200**	**200**	**200**

EVALUATION OF BATCHES F6, F7, F8, F9, F10

(a) Determination of hardness, thickness and diameter of tablets

The Monsanto hardness tester was used to determine the hardness of the tablets. The diameter and thickness of the tablets were determined using measuring scale and vernier calipers and results are shown in the table 7.10

Table .15 Hardness, thickness and diameter

S. No.	Parameter	Formulation code				
		F-6	F-7	F-8	F-9	F-10
1.	Hardness (kg/cm^2)	4.1	4.3	4.5	4.4	4.5
2.	Thickness (mm)	2.76±0.05	2.72±0.02	2.79±0.05	2.72±0.04	2.72±0.03
3.	Diameter (mm)	9	9	9	9	9

(b) Determination of weight variation, content variation and friability

Weight variation test, content variation test and friability test for the different batches were performed as per the I.P. Swelling behavior in terms of swelling Index was also calculated as per

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the procedure mentioned above. The results obtained for the different batches are mentioned in the General characteristics of tablets

Table. 16 General characteristics of tablets:

Code	Weight variation test (%)	Content Variation	Hardness (Kg/cm^2)	% Friability	Disintegration Time (sec)
F6	1.7±0.78	101.4	4.1	0.62	28
F7	2.9±0.42	100.2	4.3	0.50	32
F8	1.8±0.29	103.5	4.5	0.39	34
F9	1.8±0.30	102.5	4.5	0.40	36
F10	1.8±0.34	104.5	4.4	0.44	38

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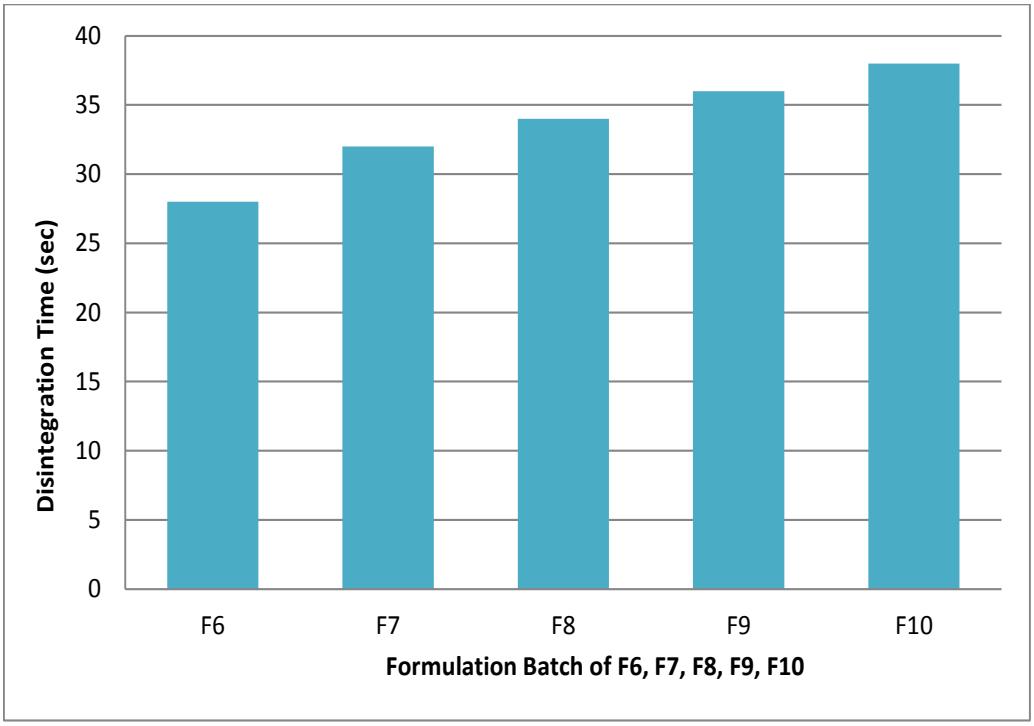

Fig. 14 Disintegration Time of Batch F6, F7, F8, F9, F10

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Fig. 15 Disintegration of tablet in 5,10,15,20,25,30 min respectively

Stability testing (General Observations):

In vitro drug release study

In-Vitro dissolution study was performed by using USP type II Apparatus (Paddle type) [Electrolab (ETC-11L) Tablet Dissolution Tester] at 50 rpm in phosphate buffer solution of pH 6.8 in 900 ml was used as dissolution medium which maintained at 37±0.5 ^{o}C and the sample was withdrawn at specific time intervals (10 min) and was filtered.

The amount of drug dissolved was determined by UV spectrophotometer (shimadzu,Japan) by measuring the absorbance of the sample at 280nm. Three trials for each batch were performed and average percentage drug release with standard deviation was calculated and recorded.

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METHOD OF ANALYSIS

In vitro dissolution study

Apparatus	:	Dissolution Apparatus IP Type II (Paddle)
Medium	:	900 ml of phosphate buffer solution of pH 6.8
Speed	:	50 rpm
Temperature	:	37 ± 0.5ºC
Time Intervals	:	10min, 20min, 30 min , 40 min

Sample preparation

The dissolution test apparatus was kept as per the above conditions. One tablet was placed in each dissolution bowl and the apparatus was runned for 30 min. After 10 min, the 1 ml of sample was withdrawn and filtered through filter paper and sink condition was maintained after the sample collection. Further intervals were 20 min,30min, 40 min. During these intervals, samples were collected and filtered through 0.45 membrane filter paper and sink condition was maintained for the whole experiments. The drug release at different time intervals was measured using an ultraviolet visible spectrophotometer at 280 nm

Procedure

The instrument was switched on and stabilized. The instrument was made auto zero and then absorbance of blank, standard and sample was measured at 280 nm using the dissolution medium as the blank.

i. Data Analysis (Curve fitting analysis)

To analyze the mechanism of the drug release rate kinetics of the dosage form, the data obtained were plotted as:

(1) Cumulative percentage drug released Vs time (In vitro drug release plots).
(2) Cumulative percentage drug released Vs square root of time (Higuchi's plots).
(3) Log cumulative percentage drug remaining Vs time (First order plots).
(4) Log percentage drug released Vs log time (Paper plots)

Formulation F2 was showing the vigorous burst release and disintegration of the tablet was very faster, so it is not further taken for the release study. Further study was continued with the formulation F2 and F7 and these were subjected to the dissolution study with the media and conditions as mentioned above.

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Table .17 In vitro drug release of batch F2&F5		
Time(min)	**Cumulative Percentage Drug Release**	
	F2±SD	**F5±SD**
0	0	0
10	65.95±0.21	75.95±0.30
20	70.85±0.20	84.61±0.75
30	72.30±0.10	90.97±0.71
40	75.95±0.10	95.81±0.50

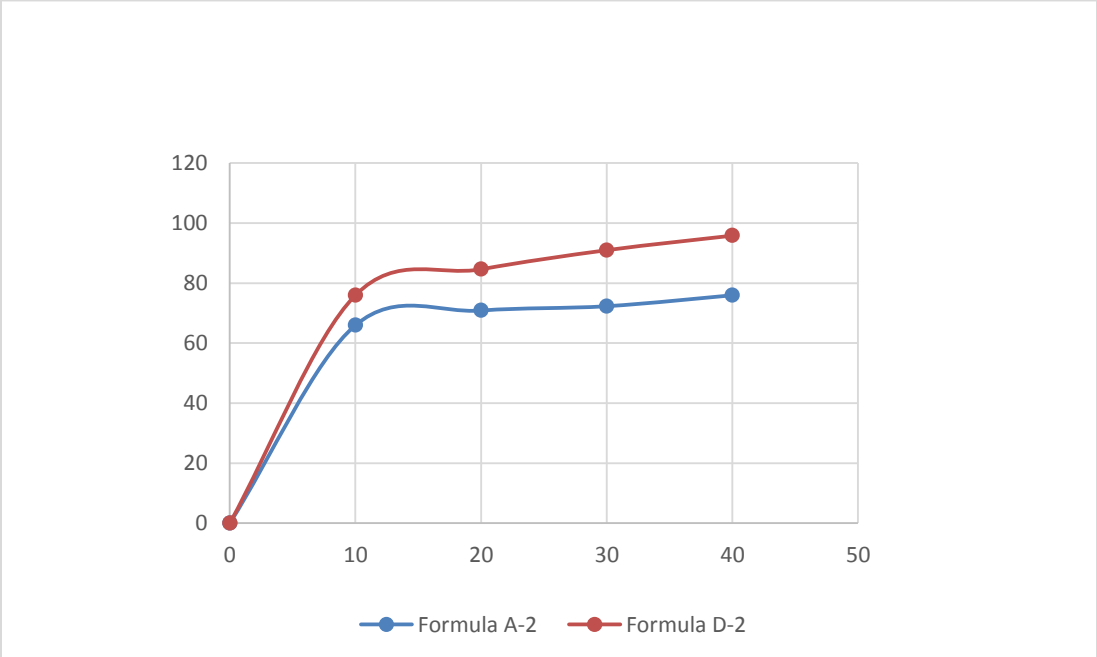

Fig. 16 Graph: - Compression Drug Release ofF2 &F5

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Table: 18 Results of stability studies

PARAMETER	Initial			After 15 Days		
	$2\text{-}8^0$	30^0	40^0	$2\text{-}8^0$	30^0	40^0
Hardness(Kg/cm2)	4.3	4.3	4.1	4.3	4.3	4.1
Friability (%)	0.50	0.51	0.54	0.52	0.51	0.53
Disintegration time(Sec)	32	32	34	32	32	33

RESULT & DISCUSSION:

In the present study, Domperidone fast dissolving tablets were prepared by using d-glucose, Di calcium phosphate as Super disintegrants and mg stearate. A total number of 5 formulations were prepared by direct compression and wet granulation technique. The value of pre-compression parameters evaluated was within prescribed limits and indicated good flow property. The data obtained of post compression parameters such as hardness, friability, weight variation, uniformity of content, thickness, wetting time, disintegration time are shown in the table. The hardness was found to be in range of 3 to 4 kg/cm2 in all the formulations indicating good mechanical strength with an ability to withstand physical and mechanical stress conditions while handling. In all the formulations the friability value is less than 1% and meets the IP (Indian Pharmacopoeia) limits.

All the tablets passed weight variation test as the % weight variation was within the pharmacopoeia limits. The weight of all the tablets was found to be uniform with low standard deviation values indicating efficient mixing of drug, super disintegrants and excipients. The percentage drug content of all the tablets was found to be between 95.04±0.1069 and 104.04±0.0450 % of domperidone, Table which was within the acceptable limits. The percentage drug release by each tablet in the In Vitro drug release studies were base on the mean content of the drug present in respective tablet.

The result of in vitro disintegration of all the tablets were found to be within prescribed limit a satisfy the criteria of Fast Dissolving Tablet. The values were found to be in the range of 77.95±0.21 to 95.81.00±0.10. Overall, the Fast-Dissolving Tablets of Domperidone showed an average of 88 to 100% drug release range at the end of 10 min which is as per IP specifications of 90-110 % and it was also observed that formulations F1 took shortest time to release the maximum amount of drug whereas the other formulations took more than 10 min to release the drug.

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Comparison with other formulations, F2 shows a better drug release of 95.81 % at the end of 30 minutes. Further the formulation F2 was compared with marketed formulation (DOMSTAL, Torrent pharmaceutical industries) and found to be superior in terms of dissolution profile. There was no significant variation in the physicochemical parameters, in vitro disintegration time, and in vitro dissolution profiles. There was no significant variation in the physicochemical parameters, in vitro disintegration time, and in vitro dissolution profiles after 15 days stability (table6.13) study as per ICH guidelines Q1C.

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