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Preparation And Evaluation Of Mouth Dissolving Tablets Of Domperidone By Sublimation And Effervescence Technique

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ABSTRACT

Mouth dissolving tablets offer a practical alternative to traditional solid dosage forms, enabling rapid disintegration and dissolution in the mouth without the need for water. This property is especially beneficial for patients with swallowing difficulties, such as those in paediatrics, geriatrics, or bedridden populations. Domperidone, a dopamine antagonist commonly used to treat nausea, vomiting, and gastrointestinal disorders, is often administered in tablet form, which may pose challenges for certain patient groups due to its size and delayed onset of action. Formulating Domperidone into mouth dissolving could enhance patient compliance and improve therapeutic outcomes by ensuring faster absorption. The present study involves two innovative techniques namely sublimation and effervescence for developing Domperidone mouth dissolving tablets. The sublimation method utilizes a volatile material to create a porous structure, while the effervescence technique generates gas through an acid-base reaction to facilitate rapid tablet disintegration. Both approaches aim to optimize the dissolution and absorption of Domperidone, thus offering a promising solution for improving patient care, particularly for those requiring prompt relief from gastrointestinal symptoms.

Keywords:

Mouth dissolving tablets, Domperidone, Sublimation method, Effervescent method.

INTRODUCTION

Mouth dissolving tablets are a type of solid dosage form that quickly dissolve or disintegrate when placed in the mouth, allowing for convenient administration without needing water.[1] These tablets provide a convenient and effective alternative to conventional tablets or capsules, especially for patients with swallowing difficulties, such as pediatric, geriatric, or bedridden individuals.[2] The key advantages of Mouth dissolving tablets include convenience of administration, more rapid onset of action, and better patient compliance.[3] These features make them particularly suitable for medications requiring quick absorption or for individuals with trouble swallowing tablets.[4] Domperidone functions as a dopamine antagonist and is frequently utilized in managing nausea, vomiting[5], and various gastrointestinal disorders.[6] It blocks dopamine receptors in the gastrointestinal tract, increasing motility and reducing symptoms[7] However, the conventional tablet form of Domperidone may not be ideal for all patients, as it can be difficult to swallow and may have a delayed onset of action.[8] Thus, formulating Domperidone into an Mouth dissolving tablets offers the potential for improved patient convenience and faster therapeutic effects.[9] The development of Mouth dissolving tablets involves incorporating excipients that facilitate rapid disintegration and dissolution in the mouth.[10] This study explores two innovative techniques—sublimation and effervescence to create Domperidone Mouth dissolving tablets.[11] The sublimation method involves using a volatile material that is removed during processing, leaving behind a porous structure.[12] In contrast, the effervescence method utilizes an acid-base reaction to generate gas, promoting rapid tablet disintegration.[13] Both approaches aim to enhance the speed and effectiveness of Domperidone's release and absorption[14], improving patient outcomes.[15] The development of Domperidone Mouth dissolving tablets utilizing these methods signifies a crucial advancement in enhancing drug delivery for patients with particular requirements.[16]

MATERIALS AND METHODS

Materials

Domperidone API was a gifted sample by Hetero Labs Ltd. (India). Microcrystalline cellulose (Avicel PH102), Sodium bicarbonate, Crosspovidone procured from VIVA PHARM, Camphor, talc, and Citric acid were acquired from Research Lab Fine Chemical Industries, Mumbai, India. Domperidone Tablets (Glenmark as the reference tablets) were purchased from local market. All other chemicals and reagents used in this study were analytical grade.

Methods

Method Development

Domperidone was dissolved in 0.1N HCL at a concentration of 1000 µg/ml and absorbance was measured at between 200–400 nm. The obtained spectrum of selected drug was compared with the Domperidone reference standard UV spectra.

Table 1: Data for the Domperidone Calibration Graph		
Sl.No.	**Conc.(µg/ml)**	**Absorbance(nm)**
1	0.1	0.024
2	0.5	0.121
3	1	0.192
4	1.5	0.267
5	2	0.384
6	2.5	0.521

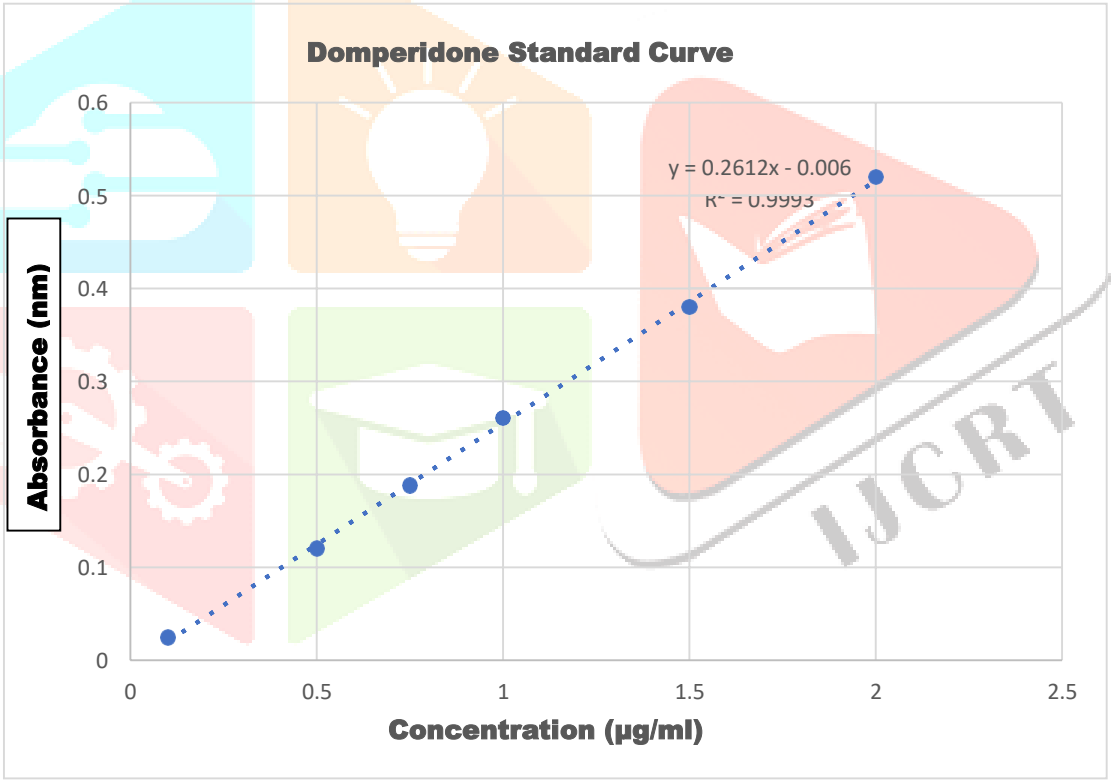

Fig.1 Calibration curve of Domperidone

Differential Scanning Calorimetry (DSC)

A commonly used analytical method that monitors the heat transfer into or out of a sample while exposed to a controlled temperature condition. It is primarily used for examining the thermal behaviour of materials, providing valuable information about their physical and chemical properties.[17]

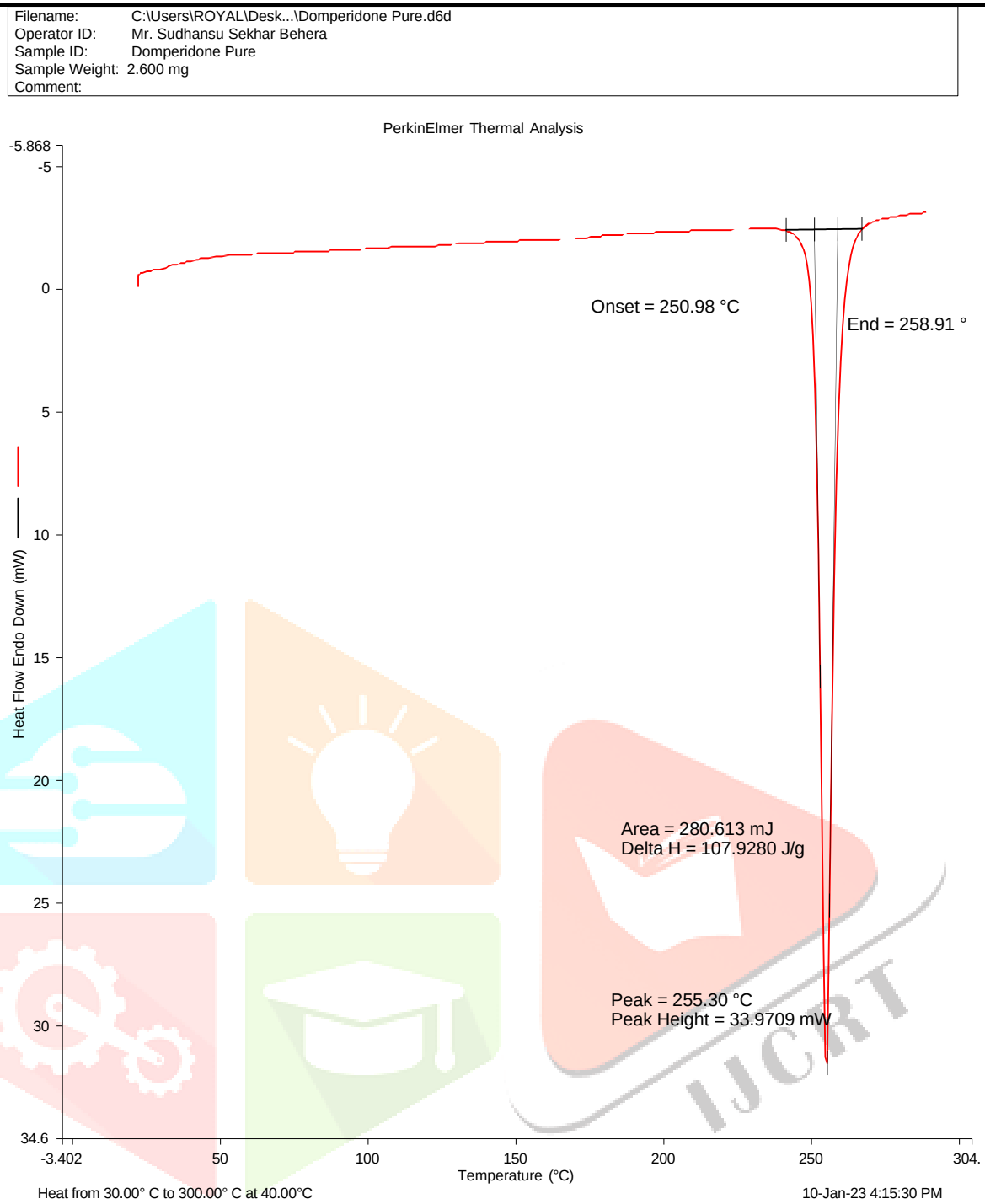

Fig.2 DSC Graph of Domperidone

Sublimation Method

This method is based on adding volatile substances (such as camphor) to other excipients of tablets and then compressing the resultant combination of mixture into tablets.[18] Sublimation is then used to release any trapped volatile substance. This causes a permeable framework to form. Despite their considerable porosity (about 30%), these compressed tablets dissolved in saliva within 15 seconds. Pore-forming agents such as solvents like cyclohexane and benzene can be used for this study. This technique of sublimation will generate Mouth dissolving tablets with excellent porous structure and better mechanical strength. Camphor was eliminated by vaporizing the tablets for 30 minutes at 80^0C to create pores. After that, the water was removed, leaving a very porous tablet.[19]

Direct Compression Method

It is the easiest way to make tablets. Direct compression makes use of conventional instruments, easily available excipients, and a limited number of processing stages. Furthermore, high dosages may be tolerated, and the final tablet weight frequently exceeds that of traditional manufacturing processes. Because of the improved availability of tablet excipients, particularly tablet disintegrants and sugar-based excipients, this approach may now be employed with fast-dissolving tablets. Disintegrants are added to swiftly dissolving tablets to speed up the process and enhance disintegration. Disintegrants primarily influence the rate of disintegration and hence dissolve in numerous direct compression-based fast-dissolving tablet technologies. This technology's popularity has grown due to the development of super disintegrants and a better knowledge of their characteristics. Concentrating the disintegrants helps speed up the breakdown of tablets. The tablet disintegration time is inversely related to the disintegrant concentration below the critical concentration.[20]

Table 2: Formulation for the Mouth dissolving tablets of Domperidone

Sl. No.	Ingredients	SF1	SF2	SF3	SF4	SF5	SF6	SF7	SF8	SF9
1.	Domperidone	10	10	10	10	10	10	10	10	10
2.	Sodium bicarbonate	50	50	50	-	-	-	50	50	50
3.	Citric acid	20	20	20	-	-	-	20	20	20
4.	Camphor	-	-	-	15	20	25	15	20	25
5.	Crosspovidone	10	5	15	10	10	10	10	10	10
6.	Talc	5	5	5	5	5	5	5	5	5
7.	Microcrystalline cellulose	155	160	150	210	205	200	140	135	130
	Total (mg)	250	250	250	250	250	250	250	250	250

Flow Properties Evaluation for Powder Blend

The following techniques were used to evaluate various parameters for the manufactured powder blend.

Angle of repose: The word "angle of repose" refers to the maximum angle that may be developed between the powder pile's surface and the horizontal. To calculate the friction force in loose powder, utilise the angle of repose (θ). This indicates the powder's flow properties.[21]

The angle of repose is determined using the fixed funnel method. This method entailed attaching the funnel to a stand at a predetermined height (h). I placed the graph paper on a flat, horizontal surface. When the conical pile's peak just touched the funnel's tip, the powder mixture was allowed to fall freely onto the paper via the funnel. The pile's height and radius were measured and the angle of repose determined using the formula provided.

The formula to calculate the angle of repose is $\tan(\theta) = h / r$

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

In this equation,

θ represents the angle of repose

h measures the height in centimetres.

r is the radius in centimetres.

Table 3: Angle of Repose and Flow Properties:		
Serial no.	**Angle of Repose (°)**	**Type of Flow**
1	Less than 20	Excellent
2	Between 20-30	Good
3	Between 30-34	Passable
4	More than 34	Very Poor

Bulk Density: The bulk density of a powder is defined as the ratio of its total mass to its total volume. A 2g powder blend that had been carefully weighed and put through a 20mesh sieve was poured into a 10 ml graduated measuring cylinder. The original volume, also known as the bulk volume, was then noticed. Using the above information, the bulk density was determined using the formula below.

$$\rho b = \frac{M}{Vb}$$

Here, ρb represents bulk density.

M is the mass of the powder.

Vb denotes the bulk volume of the powder.

Tapped Density: The tapped density of a powder is calculated by dividing its total mass by its tapped volume.

A meticulously weighed quantity of the powder combination was placed in a measuring cylinder and the volume was measured by tapping the powder 500 times and recording the volume each time.[22]

The tapped density was calculated using the following formula:

$$\rho t = \frac{M}{Vt}$$

Here, ρt = Tapped density.

M = Mass of the powder.

Vt = Tapped volume of the powder.

Compressibility Index: The powder flow qualities are shown by the compressibility index. It is stated as a percentage. The % compressibility of the powder mixture was estimated using the formula below. The bulk and tapped density are combined to calculate the compressibility index.

$$I = \frac{\rho t - \rho b}{\rho b} \times 100$$

Here, I is for compressibility index.

ρt is the powder's tapered density.

ρb is the powder's bulk density.

Table 4: Relationship between % compressibility and flow ability	
% Compressibility	**Flow ability**
Between 5 – 12	Excellent
Between 12 – 16	Good
Between 18 – 21	Fair passable
Between 23 – 35	Poor
Between 33 – 38	Very poor

Hausner Ratio: The Hausner ratio is a proxy for powder flow easiness.

The formula used to calculate it was as follows.

$$\text{Hausner ratio} = \frac{\rho t}{\rho b}$$

In which, ρt is the tapped density.

ρb stands for bulk density.

Formulation of tablets contain Domperidone using the direct compression technique

Nine formulations (SF1 to SF9) of domperidone Mouth Dissolving tablets were prepared as per formulae described in Table 2, all of which kept the tablets' total weight (250 mg) unchanged. Every ingredient was weighed accurately and passed through 60-mesh sieve. The weighed ingredients were made in a geometric arrangement and mixed. All the ingredients are combined with a pestle in a glass mortar. The tablets were prepared using a Rotary tablet compression machine. For every formulation, the compression force was maintained constant.

The prepared orodispersible domperidone tablets was subjected to post-compression characteristics such as hardness, friability, thickness, weight variation, wetting time, dissolution test, and disintegration time.

Evaluation of Orodispersible Tablet of Domperidone

Hardness: The tablet hardness test was carried out using Monsanto tablet hardness tester as per the establish protocols. The amount of force required to break a tablet under diametric compression known as crushing strength often termed as hardness. Six tablets from each batch were tested for hardness and results are expressed in kg/cm^2 and results were presented in Table 7.

Friability: The friability test was carried out using Roche friabilator to determine the impact of shocks and abrasion. The tablets were placed plastic chamber of friabilator and allowed for 25 revolution per minute for 4 mins. The friabilator was loaded with pre-weighed tablets and rotated 100 times. The tablets were then taken out and weighed again. The loss of weight cannot exceed 1.0% of body weight.[23]

The percentage of friability was calculated using the following formula.

$$\%F = \frac{Winitial - Wfinal}{Winitial} \times 100$$

Here, % F represents the proportion of friability.
W initial = Tablet's initial weight.
W final = Tablet's final weight.

Thickness

Vernier callipers were used to measure the tablet thickness. From each batch, five tablets were selected at random, their thicknesses were measured, and average values were calculated. The unit of thickness is expressed as mm.

Weight Variation

As per the protocols mentioned in I.P., the weight variation test was performed. Twenty tablets were chosen at random from each batch and weighed separately. From the total weight of all the tablets, the average weight was then determined. The average weight was used to compare the individual weights. The weight variation test is passed if no more than two tablets deviate from the % limit and if no tablet deviates from the limit by more than twice.[24]

Wetting test

The wetting time was determined by immersing a tablet in a beaker. Sensitive electronic scale was used for each tablet before and after fluid absorption to ascertain the difference in weight and acquire the percent of wetness.[25]

$$R = \frac{Wa - Wd}{Wd} \times 100$$

Here, Wa is tablet after water after and Wd is dry tablet.

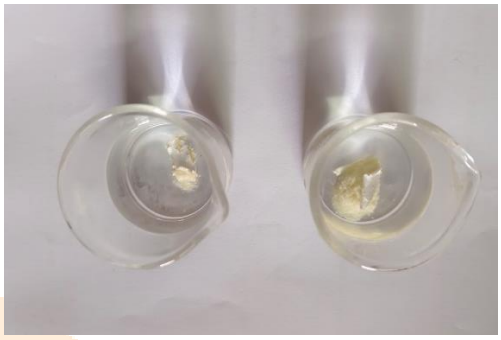

Fig.3: Water absorption (a) Before, (b) After

Water absorption by Mouth Dissolving Tablets. The data showed that F7 had a percentage of drug release ranging from 28 to 44% (mean ± S.D).

The wetting time was evaluated using 10 mL of distilled water in a petri dish. The tablets were immersed in water, and the time it took for the tablet to totally wet was recorded.

Disintegration time

In vitro and In vivo disintegration time was measured using disintegration test instrument and panel of six individuals in each batch respectively. The average disintegration time was recorded. For the in vitro test, six tablets were chosen per batch, and the average disintegration time was determined in a water medium.[26]

Dispersion Time

Tablet was placed in a Petri dish with 10ml of 0.1N HCL solution at 37 ± 0.5°C. After randomly selecting and testing three tablets from each batch, the time it took to completely dissolve was measured. The seconds represent the in-vitro dispersion time.

In-vitro Dissolution Studies

Domperidone Mouth dissolving tablets were subjected to in-vitro release performance using USP apparatus type II at 50 rpm. The dissolution medium, 0.1N HCL (900ml), was kept at a temperature of 37 ± 0.5 °C at different intervals, 10ml aliquots of the dissolution medium were taken, and the amount of domperidone in each aliquot was estimated by measuring the absorbance at 281 nm. 5ml of an aliquot

was taken out at 2min, 5min, 10min, 15min, 20min, 25min and 30min intervals, to be repeated at 5min intervals. And a visible spectrophotometer was used for analysis at 281 nm.[27]

RESULTS AND DISCUSSION

Preformulation Parameters

A) Melting Point: The melting point of Domperidone was performed using melting point apparatus and it was found to be 242.5 °C, which is consistent with the standard reference sample.

B) I.R. Spectroscopy : The identification test was carried out using IR spectroscopy which complies with official reference sample.

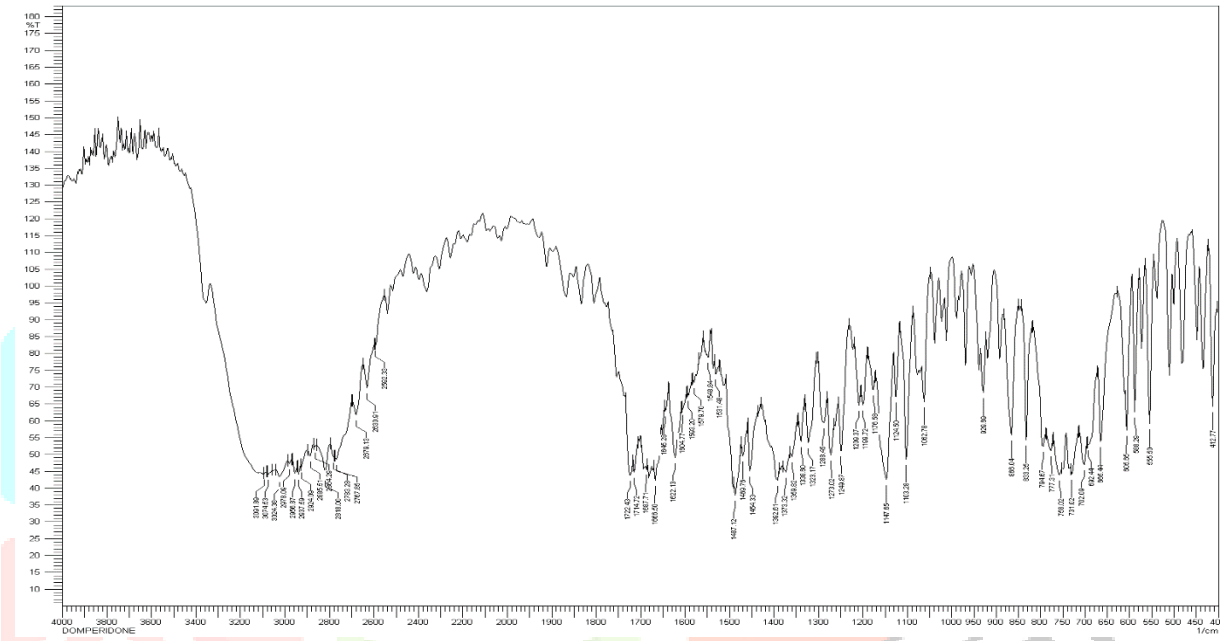

Fig. 4: FTIR Spectrum of Domperidone

The FTIR spectra demonstrated no substantial change or shift in absorption peaks in tablet blends as compared to pure drugs. It shows that there is no substantial interaction between the drug and the excipients.

Table 5: Interpretation of FTIR spectrum of Domperidone	
Transition	**Drug**
N-H	3091
O-H	1722
C-H	1487

C) Solubility: Domperidone has been found to be easily soluble in both water and 0.1N HCL.

Drug and Excipients Compatibility Study:

Drug and excipients compatibility was performed for physical mixture of Domperidone and excipients using IR spectrophotometer. The Fourier transformed infrared (FTIR) spectra was obtained at resolution 1 cm-1, and scanning range 450–4000 cm-1. Domperidone's distinctive absorption peaks and the absorption peaks of physical mixtures are related to one another.

This suggests that the medicine and excipients were compatible.

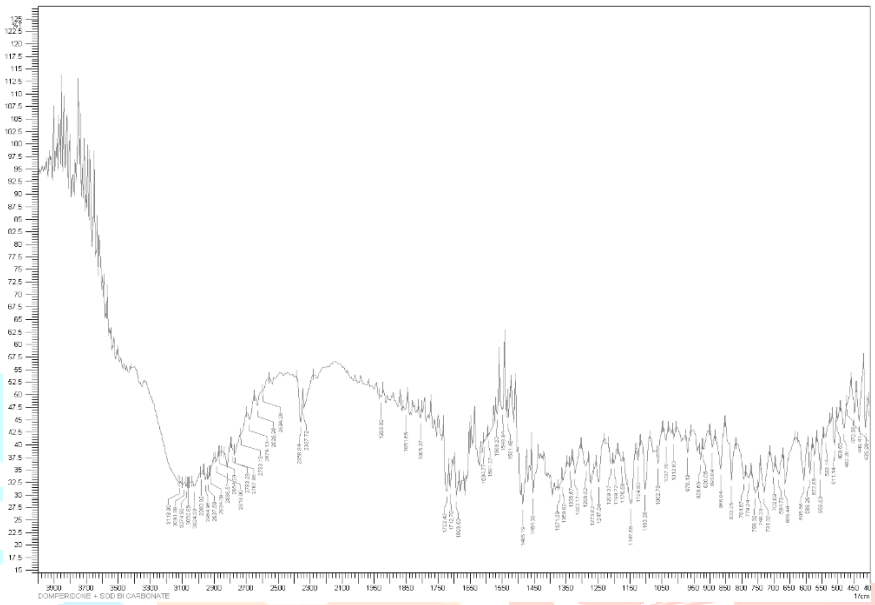

Fig. 5: FTIR Spectra of Domperidone + Sodium bicarbonate

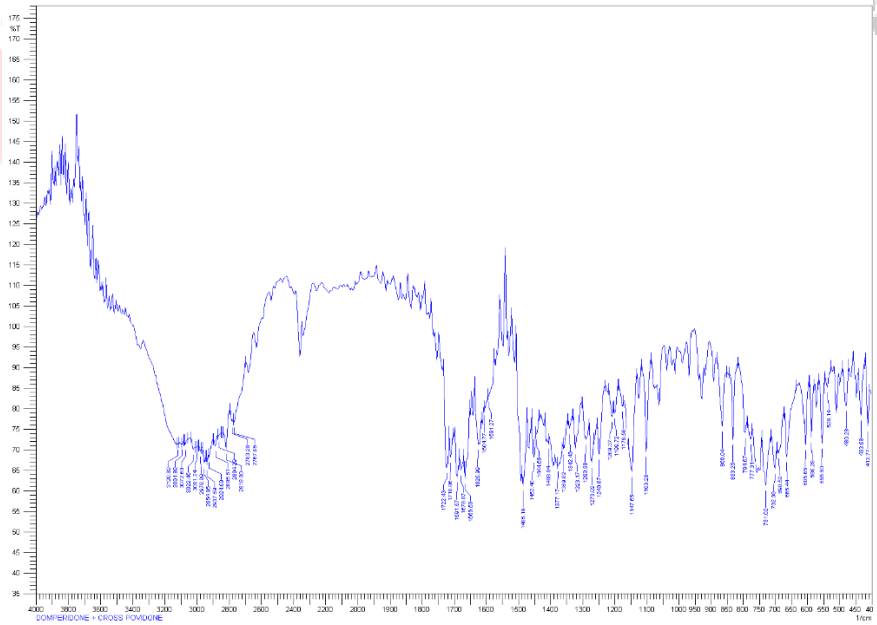

Fig. 6: FTIR Spectra of Domperidone + Crosspovidone

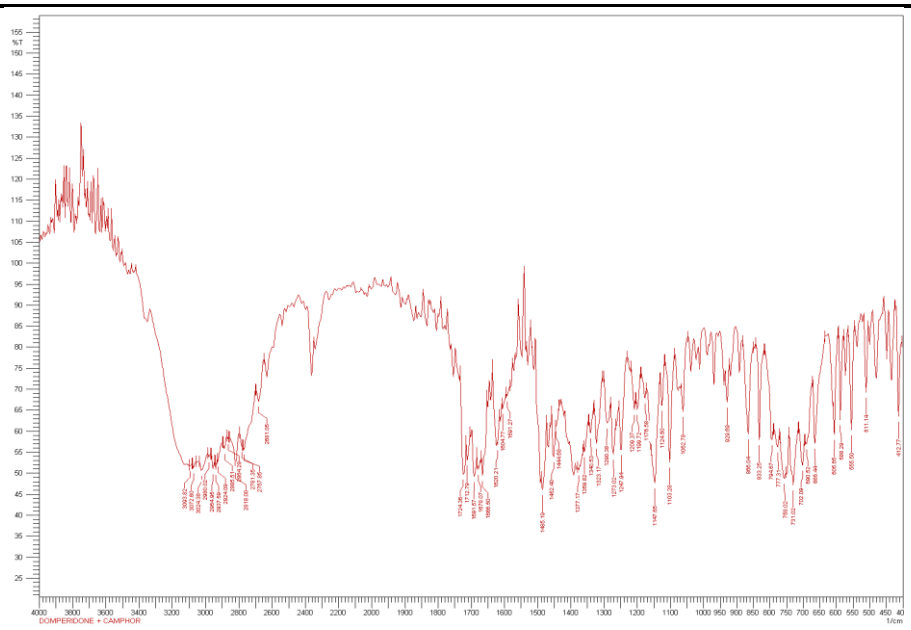

Fig. 7: FTIR Spectra of Domperidone + Camphor

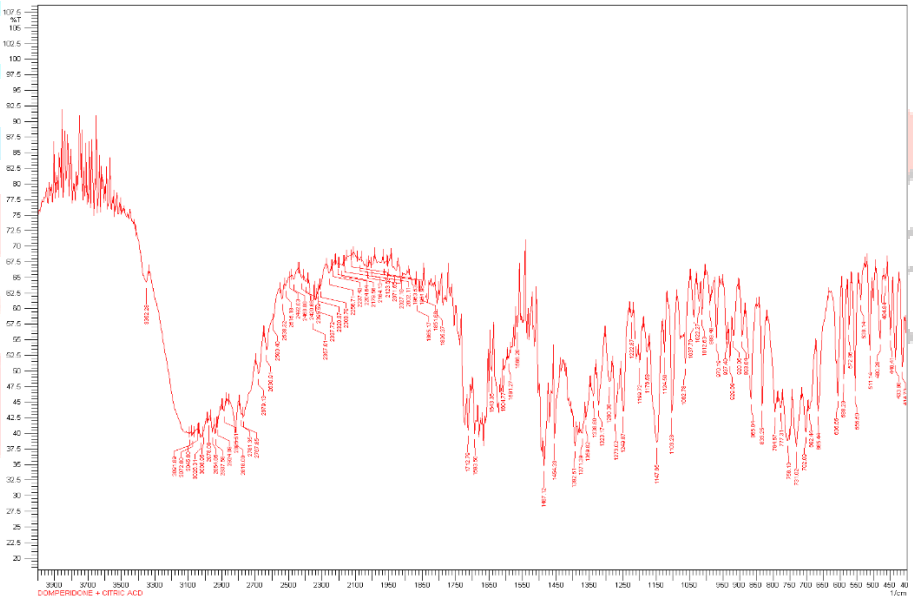

Fig. 7: FTIR Spectra of Domperidone + Citric acid

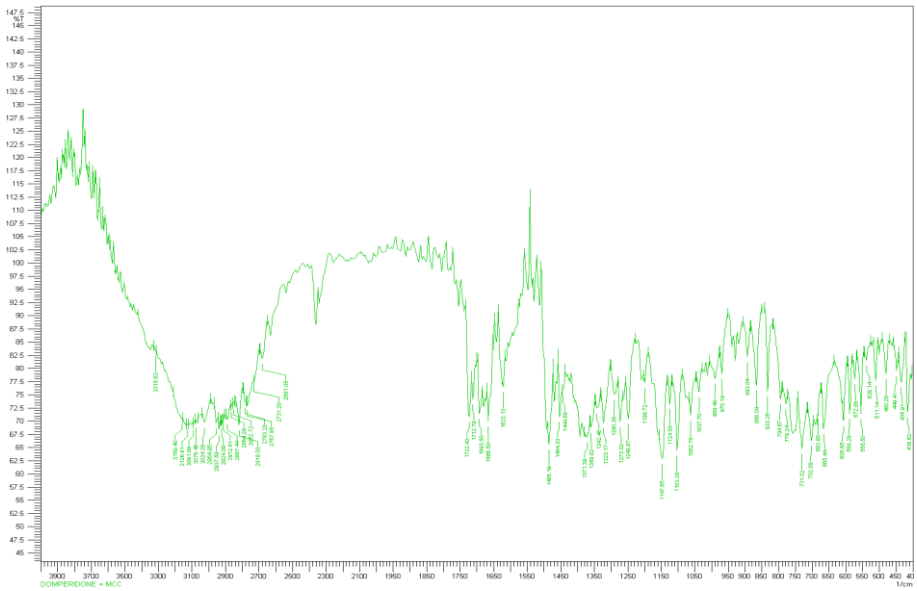

Fig. 8: FTIR spectra of Domperidone + Microcrystalline cellulose

Physico-chemical evaluation of Domperidone:

Table 6: Evaluation of powder blend.

Formulation	Bulk density (gm/cm2)	Tap density (gm/cm2)	Angle of Repose (θ)	Compresibility Index %	Hausner ratio
SF1	0.515± 0.003	0.607± 0.003	30.26± 0.305	15.16± 0.294	1.204± 0.002
SF2	0.511± 0.001	0.623± 0.003	30.76± 0.404	17.98± 0.045	1.214± 0.004
SF3	0.519± 0.002	0.616± 0.002	31.07± 0.081	15.75± 0.056	1.197± 0.002
SF4	0.520± 0.003	0.622± 0.004	29.57± 0.395	16.40± 0.236	1.173± 0.002
SF5	0.559± 0.002	0.625± 0.003	32.21± 0.165	10.56± 0.055	1.216± 0.002
SF6	0.531± 0.042	0.611± 0.004	33.36± 0.208	13.09± 0.068	1.247± 0.003
SF7	0.525± 0.006	0.622± 0.003	26.73± 0.503	15.60± 0.031	1.225± 0.003
SF8	0.517± 0.013	0.601± 0.003	32.07± 0.053	13.98± 0.055	1.216± 0.003
SF9	0.509± 0.005	0.608± 0.002	30.32± 0.259	16.28± 0.061	1.218± 0.006

Angle of Repose (θ)

The angle of repose was measured using the cylinder method for different powder mixtures mixed with various super disintegrants, the results of angle of repose ranged from 26.73 to 33.36, which indicates good flowability.

Bulk density

A measuring cylinder was used to determine the bulk density of several powder-mixed mixes made with various super disintegrants. The bulk density ranged from 0.560 to 0.580.

Tap density

A measuring cylinder was used to determine the tapped density of several powder-mixed mixes made with various super disintegrants. The tapped density was found to be range between 0.606 and 0.628.

Compressibility Index %

The compressibility index of several powder and mixed combinations containing a variety of super disintegrates was determined using bulk density and tapped density data. It was determined in the 14.08–20.00 range.

Hausner ratio

The Hausner ratio of different powdered and mixed combinations containing several super disintegrants was calculated using bulk density and tapped density data. It has been shown between 1.17 and 1.25.

Table 7: Evaluation of Domperidone Mouth Dissolving Tablets

Formulation	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm2)	Dispersion time (sec)	Disintegration time(sec)	% friability
SF1	248.8 ± 0.002	2.590	4 ± 0.02	37	33	0
SF2	239.8 ± 0.007	2.579	4.6 ± 0.04	35	31	0
SF3	242.1 ± 0.006	2.571	4.5 ± 0.02	41	31	0
SF4	243.9 ± 0.004	2.568	4 ± 0.03	33	32	1.0
SF5	246.0 ± 0.005	2.573	4.1 ± 0.02	45	35	0

SF6	244.2 ± 0.003	2.552	4 ± 0.03	42	34	0
SF7	249.2 ± 0.005	2.558	3.5 ± 0.02	29	28	0
SF8	240.6 ± 0.007	2.574	4.9 ± 0.03	40	33	1.2
SF9	247.8 ±0.003	2.559	3.9 ± 0.05	36	30	1.1

Wetting test

The wetting time for the Mouth Dissolving Tablets was 30 seconds, indicating excellent wettability, which suggests rapid disintegration when placed in the mouth.

In vitro and in vivo disintegration time

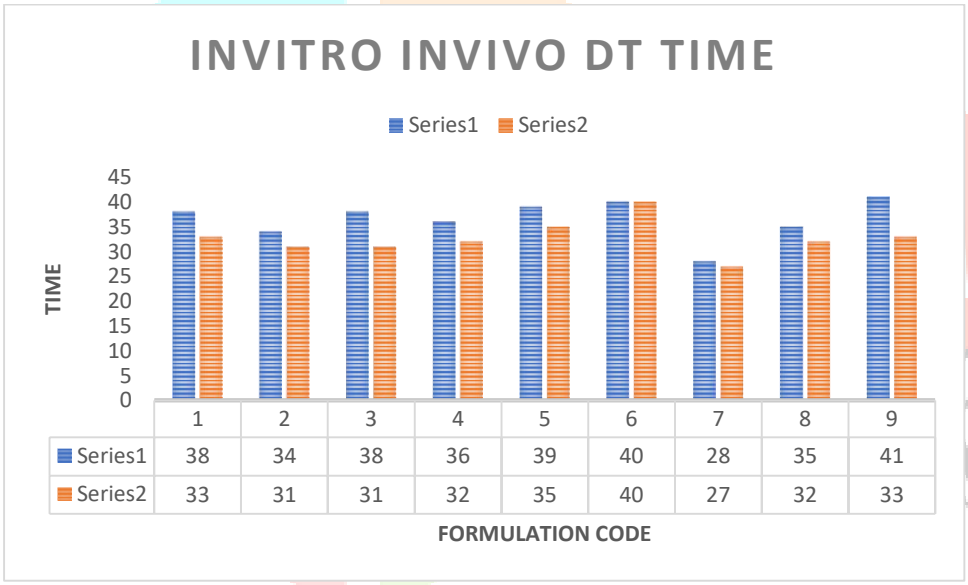

Fig. 9: Graph showing In vitro and in vivo disintegration time

Organoleptic character

The key factor in ensuring patient compliance and satisfaction in Mouth dissolving tablet formulations is enhancing taste and mouthfeel. This is particularly crucial when formulating with bitter drugs such as domperidone. The citric acid was incorporated to enhance sweetness, improve mouthfeel, and mask the drug's bitter taste. To enhance the flavour, a sugar-based diluent, specifically MCC, was added. These sugar-based diluents also give the requisite bulk volume and physical qualities of the tablet, in addition to imparting a better tongue feel to the patients. The problem of mottling, found in SF3, was corrected by modifying the sequence of mixing, as indicated in the production of tablets.

Table 8: Evaluation test by different categories

Code	Mottling	Volunteer 1 (Taste)	Volunteer 2 (Taste)	Volunteer 3 (Taste)
SF1	No	Good	Good	Less bitter
SF2	No	Little bitter	Very bitter	bitter
SF3	Mottling observed	Bitter	Bitterness is tolerable.	Should be improved.
SF4	No	Good	Very good	Good
SF5	No	Good	Good	Good
SF6	Little mottling observed	Good	Bitter is tolerable	Should be improved
SF7	No	Good	Very Good	Very good
SF8	No	Good	Bitter is tolerable	Bitter is tolerable
SF9	No	Good	Good	Good

Table 9: Dissolution profile of the Domperidone Mouth Dissolving Tablet.

Time(min)	**SF1**	**SF2**	**SF3**	**SF4**	**SF5**	**SF6**	**SF7**	**SF8**	**SF9**
0	0	0	0	0	0	0	0	0	0
2	31.94	27.54	18.63	34.9	20.98	22.42	22.47	31.19	20.61
5	50.61	56.79	40.07	58.15	29.89	43.53	57.79	52.43	39.97
10	56.11	59.67	54.62	77.03	50.35	55.8	63.6	60.93	55.51
15	79.63	72.25	73.85	83.4	73.84	70.46	78.76	80.01	73.2
20	86.98	82.03	76.96	88.77	82.29	70.08	83.43	81.14	83.47
25	90.45	83.87	82.9	91.32	85.87	77.97	91.43	80.75	83.16
30	88.52	85.77	84.52	83.32	85.55	79.19	93.32	81.64	80.87

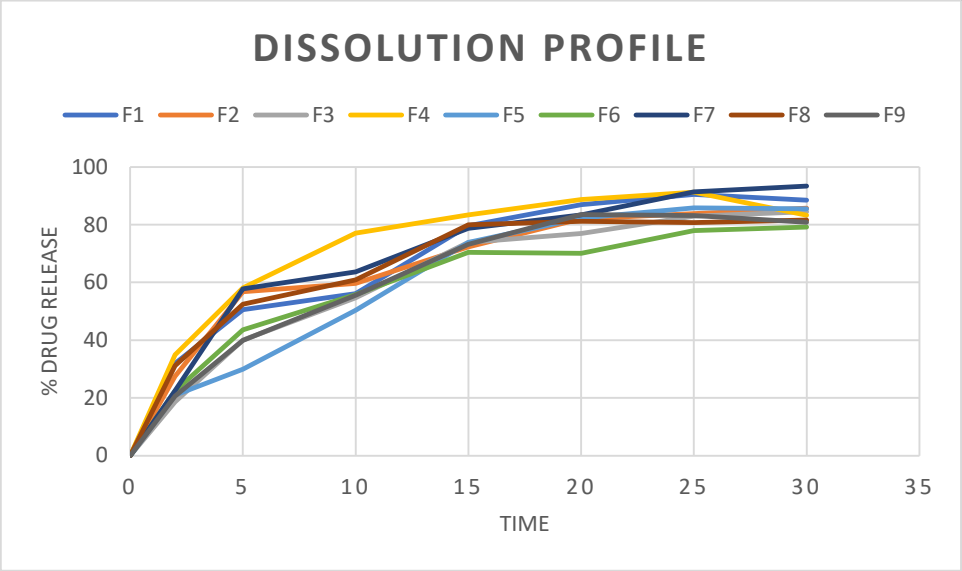

Fig. 10: Dissolution profile of Mouth dissolving tablets of Domperidone.

CONCLUSION

In this present investigation, all the prepared formulations were subjected to various physical evaluation parameters such as hardness, friability, weight variation, and thickness. All the formulations result in acceptable limit except formulations SF2, SF3, SF5, SF8 for hardness test, which varied marginally. The batch SF7 was found to be optimized batch. SF7 formulation was given good dispersion time among all the formulations. The SF7 formulation was good disintegration time and shows better release property. The drug-excipient compatibility was investigated using FTIR, and no substantial interaction of the drug with the excipients was identified.

The preformulation research provides the following details of optimise batch Angle of repose: 26.73 ± 0.503, Bulk density: 0.525 ± 0.006, Tapped density: 0.622 ± 0.003, Compressibility index: 15.60 ± 0.031 excellent flow, Hausner's ratio: 1.225 ± 0.003. Tablets are evaluated post-formulation for hardness: 3.5 ± 0.02, % Friability: 0, Thickness: 2.558, weight variation: 249.2 ± 0.005, Dispersion time in 29sec and Disintegration time in 28sec. The optimised batch of "SF7" was determined to be the best formulation in *IN vitro*, releasing 93.41% in 30 minutes in 0.1N HCl buffer.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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