



Dissolution Enhancement of Domperidone Maleate by Preparing Fast Dissolving Tablets Using Liquisolid Compact Technique

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ABSTRACT

Domperidone maleate is dopamine receptor blocking agent and first choice drug in antiemetic category. Major drawback of this drug is its very low water solubility and low erratic absorption from gastrointestinal tract. The purpose of present investigation was to increase the solubility and dissolution rate of Domperidone maleate by preparation of liquisolid compacts and preparation of fast dissolving tablets by direct compression method. Superdisintegrants used were Croscopovidone, Croscarmellose Sodium and Sodium Starch glycolate. Propylene glycol, Polyethylene glycol 200, Polyethylene glycol 400 was used as a liquid vehicle and Avicel-PH 102, Aerosil-200 as a carrier and coating material respectively. Tablets were prepared and evaluated for various parameters like hardness, thickness, friability, weight variation, wetting time, *in-vitro* disintegration time, *in-vitro* dispersion time, *in-vitro* dissolution study. Formulation F13 showed 95.5 % drug release within 30 min. It was inferred that liquisolid compact technique is useful in enhancement of dissolution rate and bioavailability of Domperidone maleate.

Keywords: Domperidone maleate, liquisolid compact, Croscarmellose Sodium, Sodium starch glycolate.

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INTRODUCTION

Tablets are the most widely used dosage form existing today because of its convenience in terms of self-administration, compactness and ease in manufacturing. However, geriatric, pediatric and mentally ill patients experiences difficulty in swallowing conventional tablets, which leads to poor patient compliance. To overcome these problems, scientists have developed innovative drug delivery system known as mouth dissolving tablets (MDTs) or fast dissolving tablets¹. Domperidone maleate is a dopamine receptor blocking agent. It is first choice drug in antiemetic category. It is BCS class-II drug i.e. poorly soluble and highly permeable in water. So the purpose of present investigation was to enhance the rate of drug dissolution and bioavailability. For that purpose it became necessary to formulate fast dissolving tablet which can enhance rate of drug dissolution and ultimately bioavailability. For that purpose liquisolid compact method had chosen which can speed up rate of drug dissolution and onset of action. A Liquisolid compact is a new and promising approach towards dissolution enhancement². A Liquisolid compact possesses acceptable flowability and compressibility properties. They are prepared by simple blending with selected powder excipients referred to as the carriers and the coating materials. Many grades of cellulose, starch, lactose, etc. can be used as carriers, whereas silica derivatives of very fine particle size can be used as coating materials^{3,4}. This technique was successfully applied for low dose and water-insoluble drugs⁵. The technique is based upon the dissolving the insoluble drug in the non-volatile solvent and admixture of drug loaded solutions with appropriate carrier and coating materials to convert into acceptably flowing and compressible powders. In such systems, the drug existed in a molecular state of subdivision and systems were free flowing, non-adherent, dry looking powders. The selection of non-toxic hydrophilic solvent, carrier, coating materials and its ratios are independent of the individual chemical moieties. The increased bioavailability is due to either increased surface area of drug available for release, an increased aqueous solubility of the drug, or improved wettability of the drug particles⁶. Due to significantly increased wetting properties and surface area of drug available for dissolution, liquisolid compacts of water insoluble substances may be expected to display enhanced drug release characteristics and, consequently, improved oral bioavailability⁷.

MATERIALS AND METHOD

Domperidone maleate drug sample was obtained from Wockhardt Pharmaceuticals Pvt. Ltd. Aurangabad, India. Croscarmellose sodium, Sodium Starch glycolate and Crospovidone were

procured from AGIO pharmaceutical Pvt. Ltd. All other reagents and chemicals used were of analytical grade.

Preparation of Fast Dissolving Tablets of Domperidone Maleate by Liquisolid Compact Method

Fast dissolving tablets of Domperidone maleate were prepared by direct compression method⁸. All the ingredients were passed through 60-mesh separately. Initially, the weighed quantity of non-volatile solvent (PG, PEG-200, PEG-400) was taken and drug was mixed in it and formed liquid medication is poured to carrier material Avicel-PH 102 and coating material Aerosil-200 then the blend was mixed well. To the above mixture weighed quantity of superdisintegrants and sweetener were added. The final mixture was compressed using 8,10 and 12 mm flat punches on 12 station rotary tablet machine (Karnavati Rimek Minipress). A batch of 50 tablets of each formulation was prepared for all the designed formulations. Different formulation compositions are given in Table 1.

Table 1: Formulation chart of Domperidone maleate Fast Dissolving Tablets

Formulation Code	Vehicle	% Drug Conc.	Dose (mg)	Weight of liquid medication (mg)	Ratio	Weight of carrier material (mg)	Weight of coating material (mg)	Superdis-integrant (mg)	Sweetener (mg)	Total weight of tablet (mg)
F1	PG	20	10	50	10	101.83	10.18	8.10	48.6	218.71
F2	PG	20	10	50	20	153.6	7.68	10.56	63.38	285.22
F3	PG	30	10	33.33	10	67.88	6.78	5.39	32.39	145.77
F4	PG	30	10	33.33	20	102.39	5.11	7.04	42.24	190.11
F5	PG	40	10	25	10	50.91	5.09	4.00	24.05	108.23
F6	PG	40	10	25	20	76.80	3.84	5.28	31.69	142.61
F7	PEG-200	20	10	50	10	121.06	12.10	9.15	54.94	247.25
F8	PEG-200	20	10	50	20	230.41	11.52	14.59	87.57	394.09
F9	PEG-200	30	10	33.33	10	80.07	8.07	6.105	36.63	164.83
F10	PEG-200	30	10	33.33	20	153.59	7.67	9.72	58.37	262.68
F11	PEG-200	40	10	25	10	60.53	6.05	4.57	27.47	123.63
F12	PEG-200	40	10	25	20	115.20	5.76	7.29	43.78	197.03
F13	PEG-400	20	10	50	10	151.05	15.1	10.80	64.84	291.79
F14	PEG-400	20	10	50	20	297.61	14.88	18.12	108.74	489.35
F15	PEG-400	30	10	33.33	10	100.69	10.06	7.20	43.22	194.50
F16	PEG-400	30	10	33.33	20	198.39	9.91	12.08	72.48	326.19
F17	PEG-400	40	10	25	10	75.52	7.55	5.40	32.42	145.89
F18	PEG-400	40	10	25	20	148.80	7.44	9.06	54.37	244.67

All the values represent mean \pm Standard deviation (n=3)

Evaluation of Domperidone Maleate Fast Dissolving Tablets

The formulations were evaluated for pre-compression parameters and post-compression parameters. Pre-compression parameters like bulk density, tapped density, Carr's index, Hausner's ratio, angle of repose and post-compression parameters like hardness, weight variation, friability, *in-vitro* disintegration time, wetting time, dispersion time, drug content, *in-vitro* dissolution studies were performed and shown in Table 2 and 3.

Table 2: Evaluation of Physical Parameters

Formulation Code	Bulk density (gm/cm ³)	Tapped density (gm/cm ³)	Carr's index (%)	Hausner's ratio	Angle of repose
F1	0.33±0.01	0.44±0.01	27.48±0.2	1.37±0.05	23.91±0.05
F2	0.33±0.01	0.42±0.01	19.47±0.05	1.24±0.01	32.96±0.03
F3	0.24±0.01	0.31±0.01	24.96±0.07	1.33±0.02	29.32±0.03
F4	0.24±0.01	0.32±0.01	27.23±0.06	1.37±0.07	31.28±0.02
F5	0.26±0.01	0.35±0.02	25.72±0.05	1.34±0.06	27.21±0.02
F6	0.25±0.01	0.35±0.02	33.30±0.05	1.50±0.02	34.43±0.03
F7	0.33±0.01	0.42±0.02	25.52±0.07	1.34±0.05	34.28±0.01
F8	0.33±0.01	0.44±0.01	27.19±0.06	1.37±0.03	36.36±0.02
F9	0.26±0.01	0.31±0.02	21.26±0.05	1.26±0.04	25.34±0.06
F10	0.31±0.01	0.43±0.01	26.15±0.16	1.35±0.02	29.05±0.06
F11	0.32±0.01	0.44±0.01	28.72±0.07	1.40±0.01	36.25±0.02
F12	0.32±0.01	0.44±0.01	28.82±0.17	1.40±0.05	34.28±0.01
F13	0.34±0.01	0.42±0.03	24.33±0.09	1.32±0.05	24.20±0.02
F14	0.34±0.02	0.44±0.02	26.55±0.05	1.36±0.06	22.30±0.03
F15	0.31±0.02	0.43±0.01	26.16±0.55	1.35±0.04	26.22±0.02
F16	0.32±0.01	0.45±0.02	25.88±0.05	1.34±0.02	24.77±0.02
F17	0.31±0.01	0.44±0.02	26.15±0.03	1.35±0.01	28.92±0.01
F18	0.32±0.01	0.42±0.02	23.78±0.05	1.31±0.05	32.00±0.02

All the values represent mean ± Standard deviation (n=3)

Table 3: Standard Physical Tests for Fast Dissolving Tablets

Formulation Code	Hardness (kg/cm ²)	Thickness (mm)	Friability (%)	Percentage purity of Blend (%)	Percentage purity of tablet (%)	Weight Variation (mg)
F1	2.44±0.08	5.00±0.00	0.48±0.00	96.60±0.05	97.30±0.15	213.9±4.03
F2	2.73±0.09	7.10±0.31	0.74±0.01	87.00±0.03	86.92±0.20	282.6±6.25
F3	2.95±0.10	5.00±0.00	0.67±0.00	100.00±0.05	99.23±0.10	148.05±4.75
F4	3.11±0.05	4.20±0.40	0.57±0.05	94.61±0.03	93.84±0.24	188.35±6.20
F5	2.78±0.07	4.90±0.31	0.96±0.1	90.00±0.10	90.76±0.20	104.75±4.19
F6	2.42±0.09	3.00±0.48	0.77±0.08	97.69±0.02	98.46±0.08	137.8±5.02
F7	2.47±0.04	5.00±0.01	0.42±0.12	100.00±0.18	99.61±0.22	244.7±4.90
F8	2.45±0.07	3.00±0.08	0.25±0.15	95.76±0.15	95.38±0.00	396.9±5.59
F9	2.71±0.09	5.00±0.12	0.61±0.18	97.69±0.20	98.46±0.00	162.95±4.37
F10	2.40±0.08	5.00±0.06	0.77±0.01	94.61±0.12	94.61±0.12	259.5±6.34
F11	2.55±0.07	4.80±0.42	0.78±0.2	85.76±0.15	90.00±0.05	119.85±5.86

F12	2.45±0.07	4.20±0.42	0.52±0.52	110.38±0.08	110.76±0.22	198.45±5.66
F13	2.65±0.07	7.00±0.00	0.36±0.2	97.39±0.02	98.07±0.23	286.65±7.93
F14	2.74±0.06	7.10±0.31	0.21±0.3	101.92±0.5	101.15±0.12	486.40±10.1
F15	2.97±0.06	4.10±0.31	0.52±0.32	106.92±0.3	102.69±0.08	192.10±4.2
F16	2.74±0.10	4.00±0.00	0.35±0.3	99.61±0.40	99.61±0.25	325.00±7.72
F17	3.18±0.09	4.00±0.00	0.74±0.06	96.92±0.20	97.69±0.15	144.15±6.44
F18	2.77±0.04	6.10±0.31	0.42±0.14	107.30±0.2	97.69±0.20	242.00±5.14

All the values represent mean ± Standard deviation (n=3)

Hardness

Ten tablets from each formulation were taken for performing this test⁹. Pfizer hardness tester was used for the determination of the hardness of tablets. Tablets were placed in contact between the plungers, and the handle was pressed, the force of the fracture was recorded.

Thickness

The thickness and diameter of three tablets were recorded during the process of compression using Vernier calipers⁹.

Weight Variation

For weight variation twenty tablets were randomly selected from each formulation and weighed individually using a Contech electronic balance. The individual weights were compared with the average weight for the weight variation⁹.

Friability

The friability of a sample of twenty tablets was measured using a USP-type Roche friabilator. Pre-weighed tablets were placed in a plastic chambered friabilator attached to a motor revolving at a speed of 25 rpm for 4 min. The tablets were then dusted, reweighed and percentage weight loss (friability) was calculated¹⁰.

Assay of Tablets

Each tablet contains 10 mg of Domperidone maleate. In this assay each tablet was taken and crushed into fine powder and transferred to 50 ml volumetric flask. Volume was made up with 0.1 M HCL. The solution was then sonicated to 15 min and then filtered by using Whatmann filter paper. From that filtrate 1 ml of solution was pipetted out and transferred to the 10 ml volumetric flask and volume made up with 0.1 M HCL. Concentration of this last dilution became 20µg/ml. The content of Domperidone maleate in each tablet was estimated spectrophotometrically at λ_{\max} of 283.2 nm¹¹.

Wetting Time and Water Absorption Ratio

Wetting time of dosage form is related with the contact angel. Wetting time of the fast dissolving tablets is another important parameter, which needs to be assessed to give an insight into the

disintegration properties of the tablet. Lower wetting time implies a quicker disintegration of the tablet. The wetting time of the tablets was measured using the simple procedure. Five circular tissue papers of 10 cm diameter are placed in a petridish. 6 ml of simulated saliva buffer (pH 6.8) was added to petridish. A tablet was carefully placed on the surface of the tissue paper. The time required for buffer solution to reach upper surface of the tablet was noted as the wetting time¹². For measuring water absorption ratio the weight of the tablet was recorded before keeping in the petridish was noted (Wb). The wetted tablet from the petri dish was taken and reweighed (Wa). The water absorption ratio R was determined according to the following equation.

$$R = \frac{W_a - W_b}{W_b} \times 100$$

Where,

R = Water absorption ratio

Wa = Weight of wetted tablet

Wb = Weight of tablet before wetting

***In-Vitro* Dispersion Time**

The *in-vitro* dispersion time was measured by dropping a tablet in a measuring cylinder of 10 ml containing 6 ml of pH 6.8 (simulated saliva fluid). Three tablets from each formulation were randomly selected and *in-vitro* dispersion time was expressed in seconds¹³.

***In-Vitro* Disintegration Time**

The *in-vitro* disintegration time of the tablets was determined using disintegration apparatus as per I.P. specifications. One tablet was placed in each of the basket. Discs were added to each tube and run the apparatus using phosphate buffer pH 6.8 maintained at $37^{\circ} \pm 2^{\circ} \text{C}$ as the immersion liquid. The assembly was raised and lowered between 30 cycles per minute in an immersion liquid. The time in seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was recorded¹³.

***In-Vitro* Dissolution Study**

The *in-vitro* dissolution study was carried out in the USP XXIII type-II dissolution test apparatus (Electrolab TDT-08 L)¹⁴. 900 ml of the dissolution medium HCL 0.1 M was taken in the vessel and the temperature was maintained at $37 \pm 0.5^{\circ} \text{C}$. The speed of the paddle was set at 50 rpm. At every withdrawal 5 ml of the dissolution medium was used and the same amount of fresh medium was replenished to the dissolution medium. The samples were filtered through 0.45 μm Whatmann filter papers and analyzed for drug content by measuring the absorbance at 283.2 nm.

Drug concentration was calculated from the standard calibration curve and expressed as cumulative percent drug dissolved. The release studies were performed in replicates of three.

Characterization of Domperidone Maleate Tablets by FTIR Studies

The Fourier-transform infrared spectrum of Domperidone maleate and mixture of Domperidone maleate with other excipients were obtained by using Shimadzu-580 FTIR spectrophotometer. Samples were prepared by KBR press-pellet technique.

RESULTS AND DISCUSSION

The values of pre-compression parameters evaluated were within prescribed limits and indicated good free flowing property, were given in Table 2. The data obtained from post-compression parameters in all the formulations, friability is less than 1%, indicated that tablets had a good mechanical resistance and is given in Table 3. Hardness of the tablets was found to be in the range of 2 to 3kg/cm². Drug content was found to be in the range of 86% to 110%, which is within acceptable limits. *In-vitro* disintegration time and *in-vitro* dispersion times were found to be in the range of 23 to 117 sec and 13 to 88 sec and shown in Figure 1 and 4 respectively and the relevant data is given in Table 4. The wetting time and water absorption ratio which are important criteria for understanding the capacity of disintegrants to swell in presence of little amount of water, were found to be in the range of 8 to 73 sec and 25.50 to 156 % respectively and is given in Table 4 and shown in Figure 2 and 3 respectively. The dissolution profiles of formulations are shown in Table 5. Among all the formulations F13 showed maximum amount of cumulative percentage drug release i.e. 95.50 % within 30 min was shown in Figure 9. Cumulative percentage drug release of the other formulations is as shown in Figure 5, Figure 6, Figure 7, Figure 8 and in Figure 10. FTIR studies revealed that there was no physicochemical interaction between Domperidone maleate and other excipients. The infra-red spectrum of compatibility study is shown in Figure 11.

Table 4: *In-Vitro* Disintegration Time, Wetting Time, and Water Absorption Ratio of Formulated Tablets

Formulation Code	Disintegration time (sec)	Wetting time (Sec)	Water absorption ratio (%)	Dispersion Time (Sec)
F1	28.00±1.00	23.00±1.00	128.57±0.01	27.33±1.15
F2	23.00±1.00	32.00±2.00	107.40±0.02	13.33±1.00
F3	23.67±1.53	13.00±1.00	151.31±0.01	26.00±1.53
F4	87.67±2.52	64.33±4.04	138.82±0.01	53.33±2.00
F5	37.67±2.52	8.33±1.53	156.86±0.01	22.00±2.52
F6	75.33±3.51	23.67±1.53	146.15±0.05	67.67±1.00
F7	77.67±2.52	60.00±2.00	110.83±0.08	43.00±1.53

F8	35.33±1.53	51.67±1.53	79.54±0.02	53.33±1.00
F9	97.67±2.52	20.67±1.15	43.75±0.03	45.00±2.08
F10	87.67±2.52	73.67±1.53	50.38±0.02	84.33±1.53
F11	115.00±5.00	30.00±2.00	40.70±0.02	63.33±1.00
F12	117.67±2.52	12.33±0.58	25.50±0.01	68.00±2.08
F13	112.33±2.52	20.67±1.15	38.67±0.02	79.67±1.53
F14	107.67±2.52	24.00±2.00	44.13±0.01	66.00±1.00
F15	77.33±2.52	35.00±1.00	72.94±0.02	61.00±1.00
F16	42.33±2.52	21.00±1.00	54.08±0.02	42.33±1.53
F17	117.67±2.52	80.00±2.00	47.18±0.03	61.00±1.00
F18	127.67±2.52	70.67±1.15	33.61±0.01	88.00±2.00

All the values represent mean ± Standard deviation (n=3)

Table 5: Dissolution Profile of Formulations F1-F18

Formulation Code	Cumulative percentage drug release within 30 min							
	1	2	5	10	15	20	25	30
F1	21.46±0.01	36.34±0.01	44.30±0.01	48.8	52.96	57.11	60.21	64.03±0.00
F2	28.38±0.01	39.42	42.84	47.07	50.53	54.63	59.5	64.38±0.00
F3	27.69	31.15	41.53	48.46	55.38	58.84	62.3	66.46±0.00
F4	25.96	28.38	32.19±0.01	40.84	43.96	52.3	54.00±0.02	61.61±0.00
F5	43.26	48.11	52.26	54.34	59.18	62.64	66.11±0.00	68.53±0.00
F6	27.63	45.27	56.76	57.80	58.50	61.96	65.40±0.00	67.15±0.00
F7	30.06±0.02	48.42	55.71	60.57	64.03	68.19	77.88±0.00	89.30±0.00
F8	39.80±0.05	47.46	56.00	59.50	61.96	66.8	80.06±0.00	90.99±0.00
F9	40.50	47.07	50.88	57.11	60.57	65.07	79.62±0.00	91.70±0.00
F10	34.56	41.13	45.63	49.10	54.63	57.42	60.84±0.00	63.99±0.00
F11	40.77	47.07	52.20	57.42	62.28	70.92	83.07±0.00	92.42±0.00
F12	42.23±0.05	48.40	53.65	63	68.19	78.50	87.50±0.00	93.10±0.00
F13	34.61	43.26	55.00	60.9	66.11	78.57	87.57±0.00	95.50±0.00
F14	34.26±0.08	43.26	52.56	60.84	61.20	64.71	79.50±0.00	90.99±0.00
F15	39.46	46.38	52.26	55.73	62.65	68.88	78.57±0.00	91.38±0.00
F16	33.90	43.61	53.33	61.61	63.69	67.14	78.51±0.00	88.61±0.00
F17	33.57	45.63	56.07	63.69	78.46	82.73	88.61±0.00	91.38±0.00
F18	33.84	43.56	49.50	54.00	59.88	67.80	78.92±0.00	89.30±0.00

All the values represent mean ± Standard deviation (n=3)

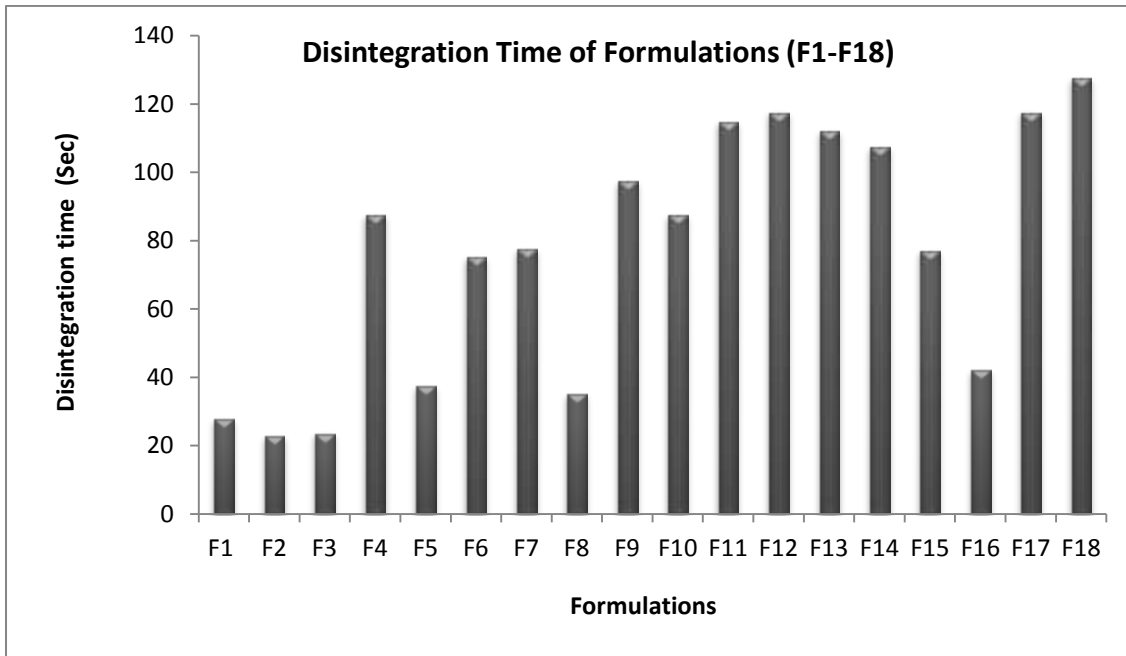


Figure 1: Disintegration Time of Formulations (F1-F18)

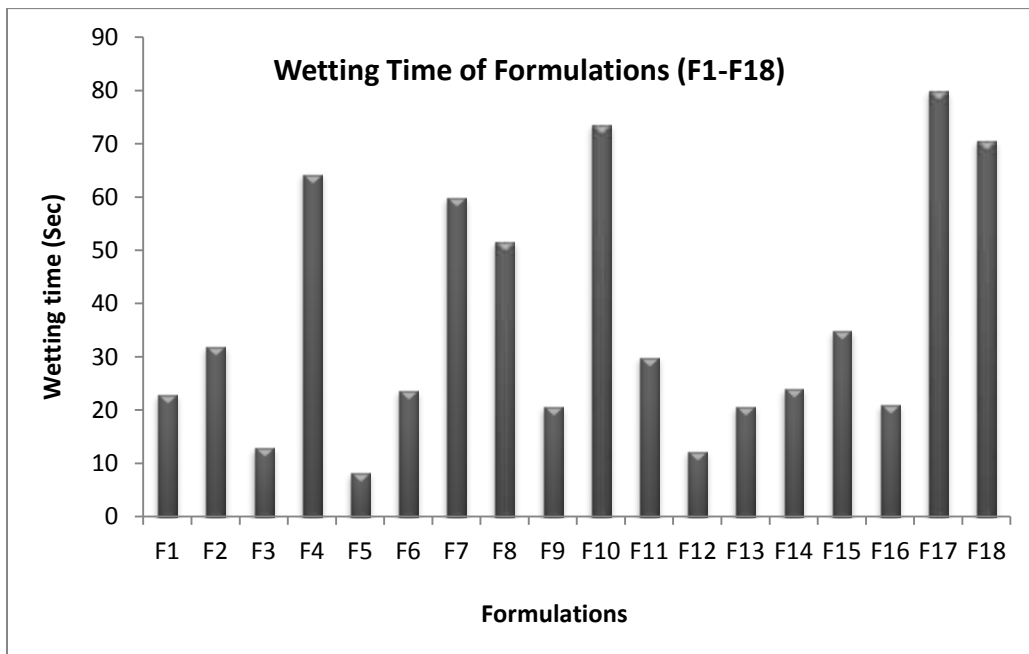


Figure 2: Wetting Time of formulations F1 to F18

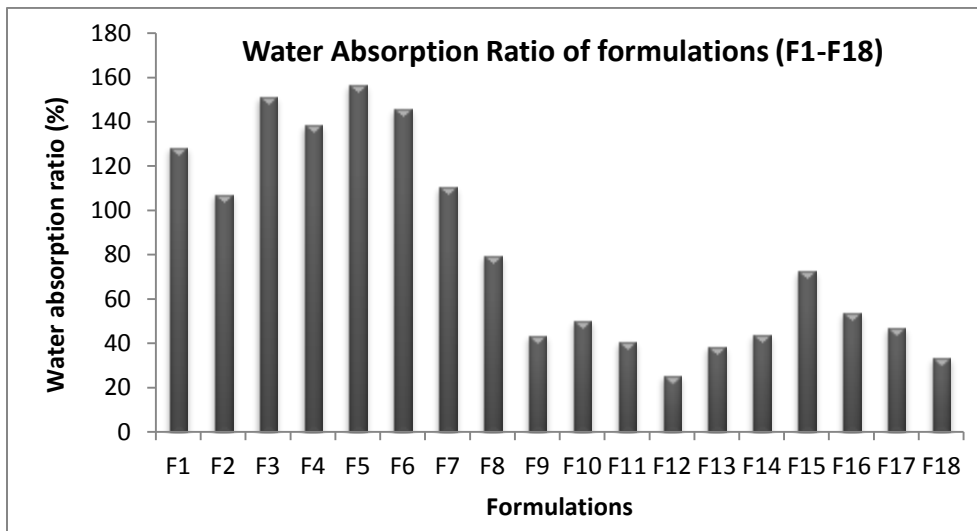


Figure 3: Water Absorption Ratio of Formulations (F1-F18)

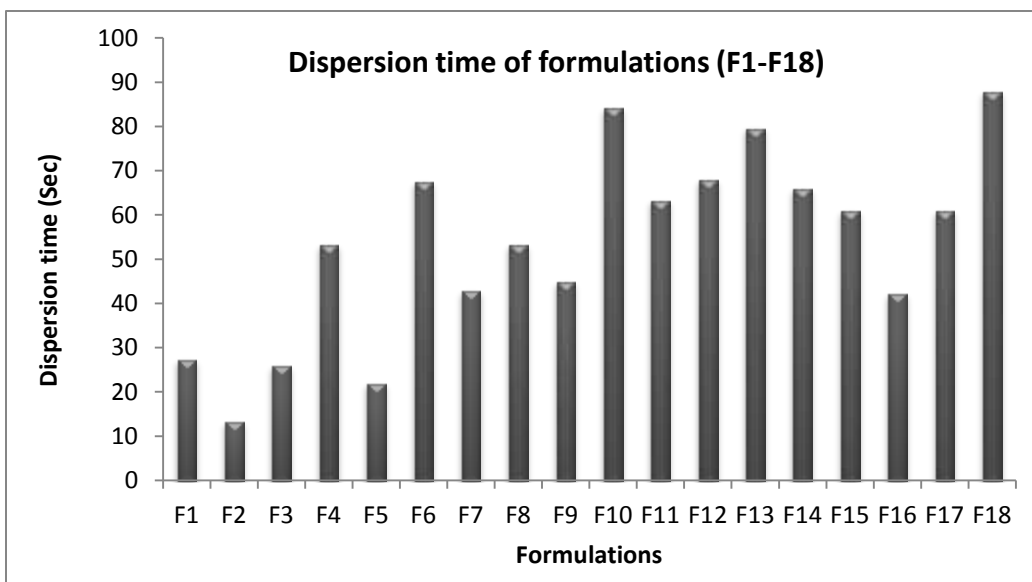


Figure 4: Dispersion Time of Formulations (F1-F18)

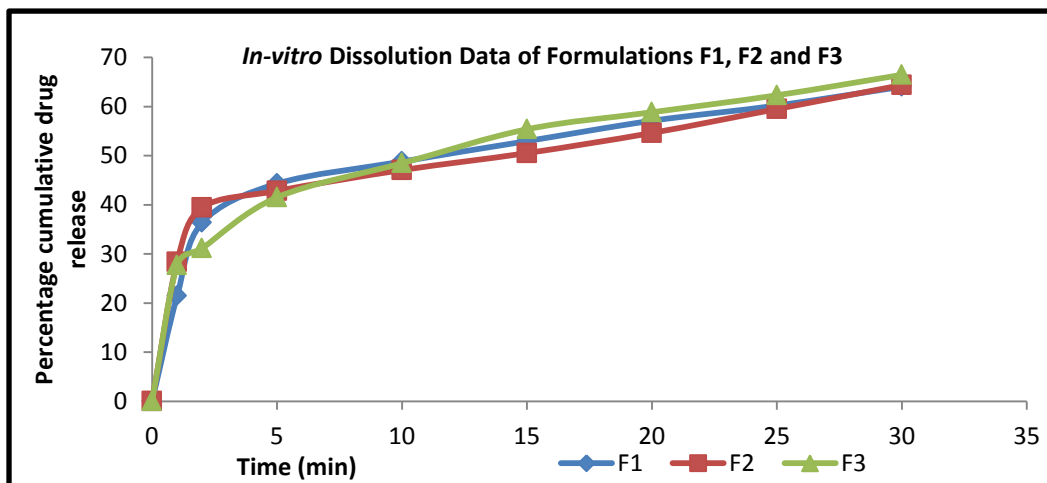


Figure 5: In-Vitro Dissolution Data of Formulations F1, F2 and F3

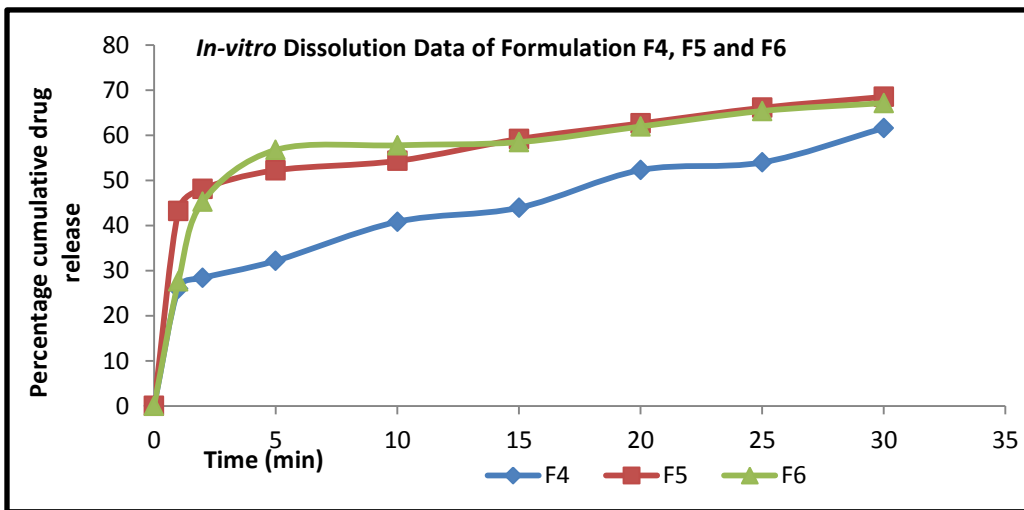


Figure 6: *In-Vitro* Dissolution Data of Formulations F4, F5 and F6

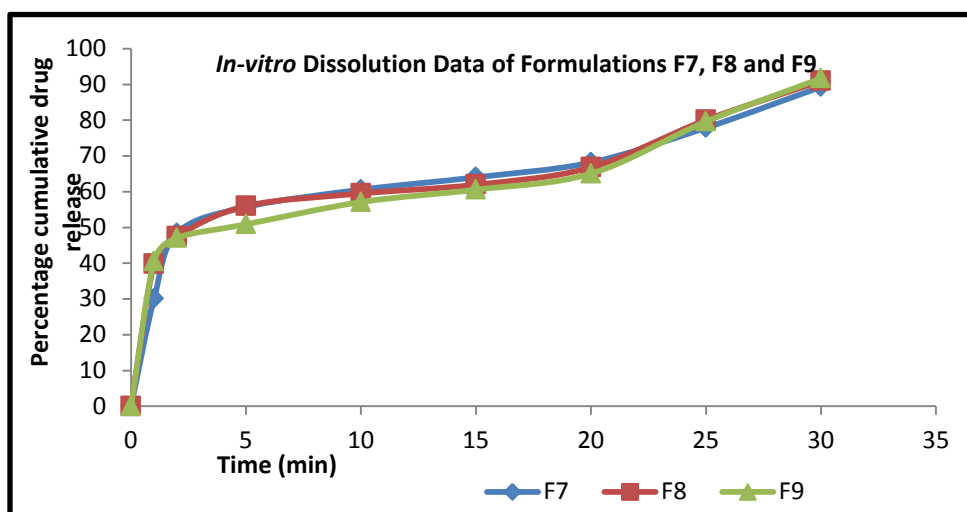


Figure 7: *In-Vitro* Dissolution Data of Formulations F7, F8 and F9

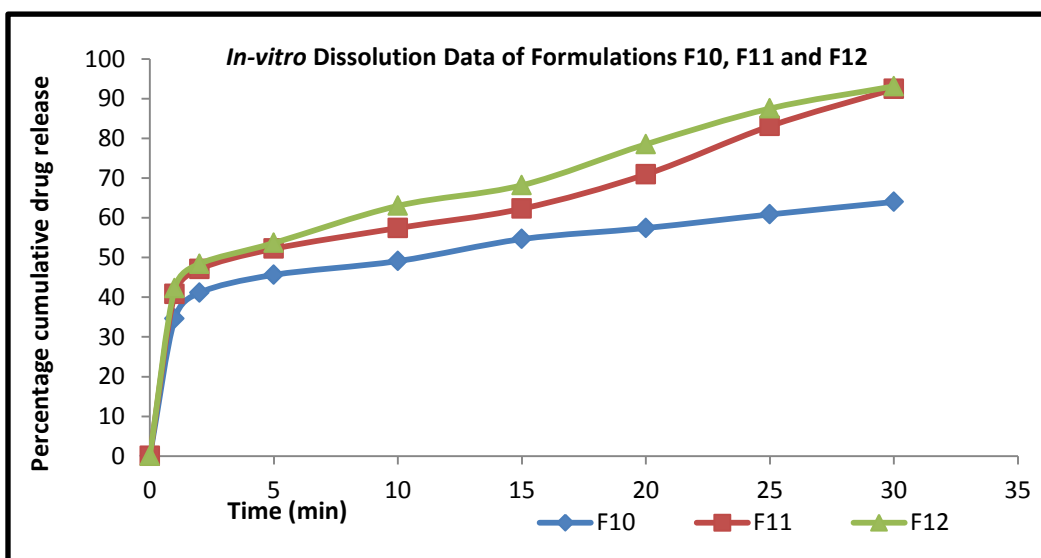


Figure 8: *In-Vitro* Dissolution Data of Formulations F10, F11 and F12

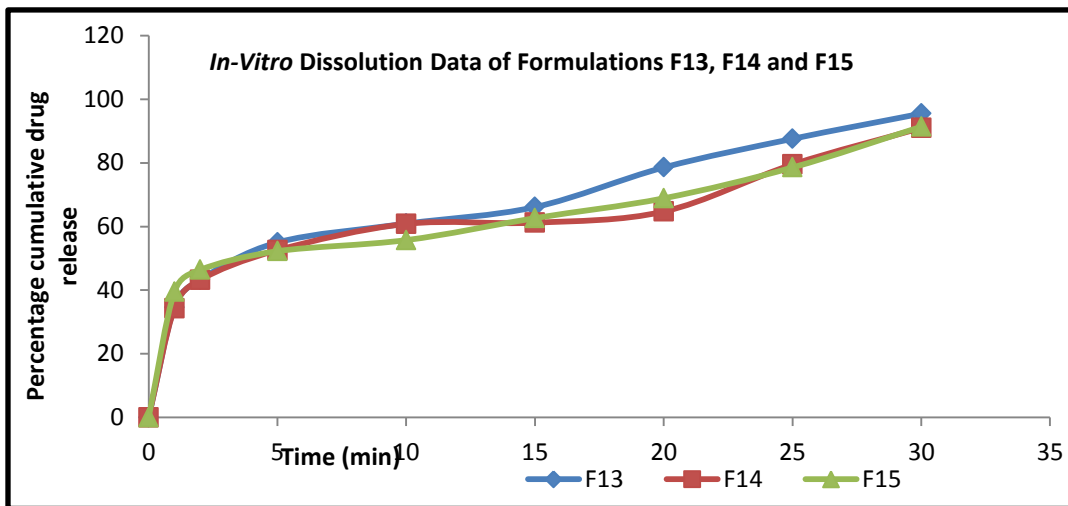


Figure 9: In-Vitro Dissolution Data of Formulations F13, 14 and 15

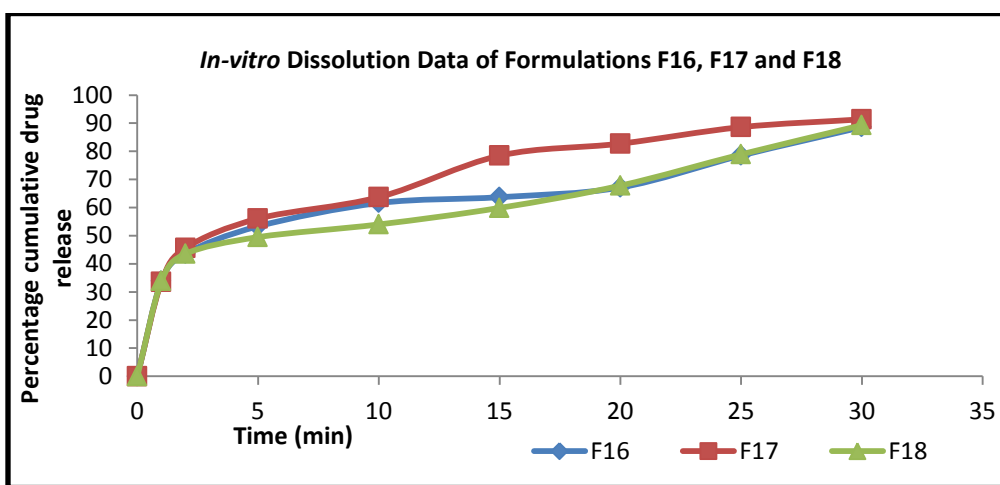


Figure 10: In-Vitro Dissolution Data of Formulations F16, F17 and F18

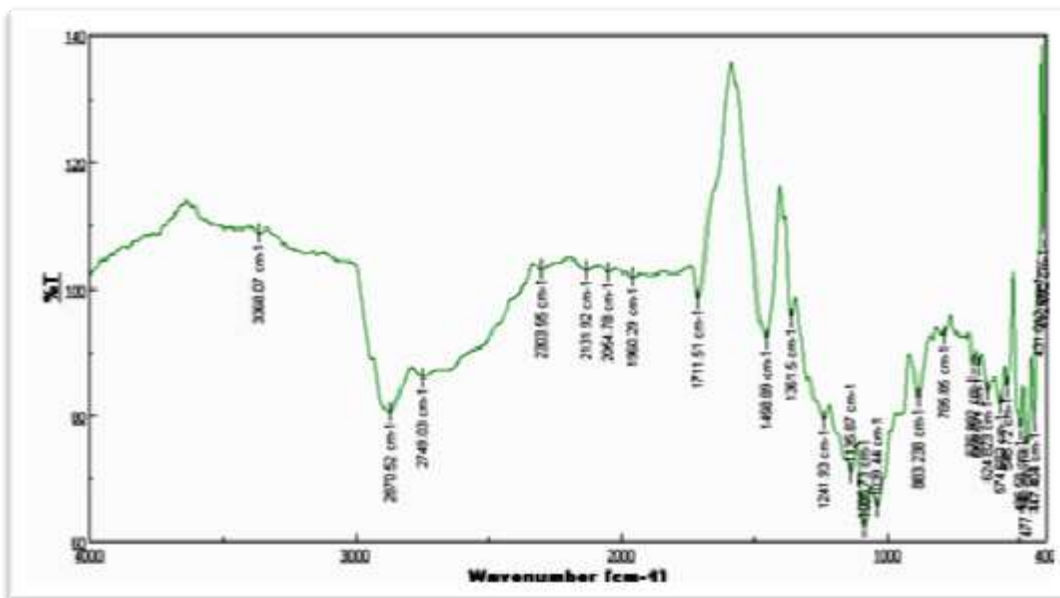


Figure 11: IR Spectra of Drug and Excipients (Optimized Batch F13)

CONCLUSION

In the present study the effects of different concentrations of superdisintegrants and different concentrations of carrier to coating material ratio on drug release of fast dissolving tablets of Domperidone maleate was studied. It was found that tablets pass the tests for hardness, friability, wetting time, *in-vitro* disintegration time, and *in vitro* drug release. It was observed that when Crospovidone (2.5%) and Sodium Starch Glycolate (2.5%) were used in combination; the drug release was 95.50 % in 30 minutes which is highest as compared to other batches. Therefore, it was concluded that among 18 formulations F13 was the best batch in which Crospovidone in combination with Sodium Starch Glycolate was used, carrier to coating material ratio was 10 and percentage drug concentration used was 20 % and liquid vehicle was PEG-400. Hence it was concluded that the liquisolid compact technique is useful in enhancement of dissolution rate and bioavailability.

Abbreviations

BCS : Biopharmaceutical Classification System

PG : Propylene glycol

PEG : Polyethylene glycol

FTIR : Fourier Transform Infra-red

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