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FORMULATION AND EVALUATION OF LANSOPRAZOLE AND DOMPERIDONE MOUTH DISSOLVING TABLETS

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Keywords:

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ABSTRACT: Lansoprazole and Domperidone, used as Proton pump inhibitor and antiemetic agents, especially for disease related to gastric ulcer. The purpose of the research was to improve aqueous solubility of drugs by β-CD using a different method, and perform phase solubility study of both drugs using β-CD and calculate Ks, and ΔG_t. Prepare Complex of LAN and DOM with β-CD using different methods like physical mixture, kneading and co evaporation. Complexes were evaluated for drug content. Based on characterization and dissolution study, kneading method based complex was optimized and tablet prepared using different superdisintegrants like Sodium Starch Glycolate, Cross Povidone, Cross Carmellose Sodium as a synthetic super disintegrating agent and Isphagula, Banana powder and Mango powder as a natural super disintegrating agent. Prepared tablets were evaluated for pre-compression and post-compression parameters such as hardness, friability, disintegration time, wetting time, dissolution study and accelerated stability study. Prepared tablets loaded with complex were compared with a marketed tablet for dissolution study. Optimized complex molar ratios for both drugs were 3:1 and have acceptable data for dissolution enhancement, and the optimized method was kneading method. F3 batch of tablets shows only 25 sec of disintegration time and 96.16 and 93.14% for Lansoprazole and Domperidone drug release within 6 min. Pass accelerated stability testing also better than its available marketed tablets (marketed tablet had 32% drug release within 30 min. and 55 sec disintegration time). Aqueous solubility of both drugs successfully improved by β-CD and achieve a rapid onset of action of drugs by preparing mouth dissolving tablets.

INTRODUCTION: The oral route is still considered the most preferable for both patients and industry. Being natural, non-invasive, and safe method of drug delivery, oral delivery is, always associated with high degree of patient compliance.

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On the other hand, oral delivery systems are able to accommodate various physicochemical properties of drugs, do not require strict sterile conditions, and, therefore, less expensive to manufacture.

Thus, even small improvements in oral drug delivery technology can make a significant difference in enhancing patient compliance and drug delivery fields in general. But the important drawback of this dosage form is Dysphagia or it also is known as difficulty in swallowing. Nearly 35% of the general population affected by this problem.

However, for pediatrics and geriatrics mouth dissolving tablet is favoured because of its ease of administration.

The MDT is also known as "Fast melting, Fast dispersing, Rapid dissolve, Rapid melt, and Quick disintegrating tablet". All MDTs approved by the Food and Drug Administration (FDA) are classified as orally disintegrating tablets. When there is an imbalance between the mucus layer and acid secretion, it causes peptic ulceration along with vomiting. In this condition, quick actions are required. Lansoprazole (LAN) is a proton pump inhibitor (PPI). Domperidone (DOM) is a widely used antiemetic drug acting by inhibition of dopaminergic receptors. In a combination of Lansoprazole and Domperidone is effectively treating these conditions [1].

MATERIALS AND METHODS: Lansoprazole and Domperidone were purchased from Intas Pharmaceuticals, Ahmedabad. β-Cyclodextrin, Mannitol, Talc, and MCC were purchased from ACS Chemicals, Ahmedabad. PVP K30, Cross povidone, CCS, SSG were purchased from Astron research ltd Ahmedabad. Banana Powder, Isabgol powder, Banana powder, Mango Powder were purchased from Lallubhai Vrilal Gandhi Ayurvedic store, Ahmedabad.

Preparation of Standard Calibration Curve: Calibration curve of Lansoprazole and Domperidone was prepared by the first derivative method. Stock solution 50 µg/mL was prepared in 6.8 pH buffer, and UV scan was taken between 200 to 400 nm. The Zcp values (the λ_{max} value of one drug will become Zcp value of another drug in first derivative UV spectrophotometry, and for further study, absorption should be taken on that determined Zcp values) were found to be 281.0 nm for Lansoprazole and 292.0 nm for Domperidone and were used for the further analytical studies [2, 3].

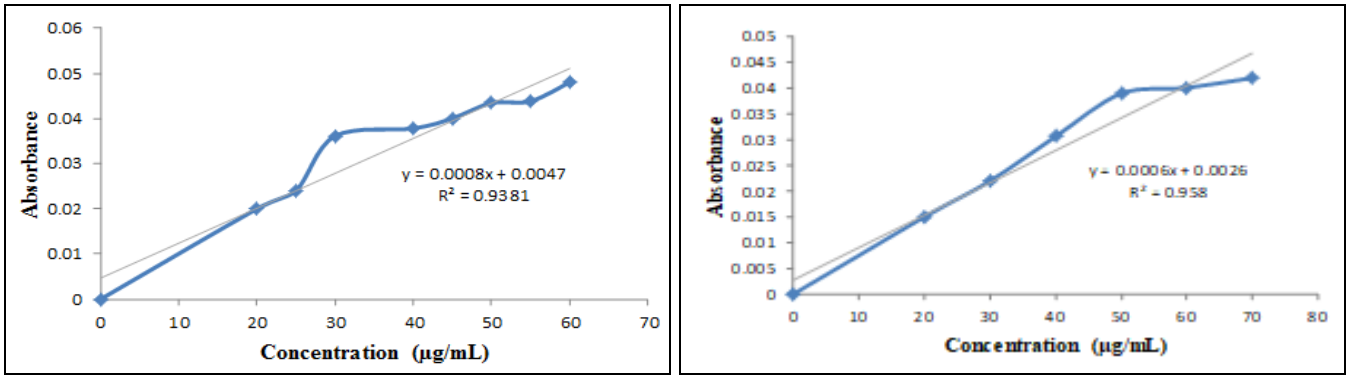

FIG. 1: CALIBRATION CURVE OF DOM AND LAN

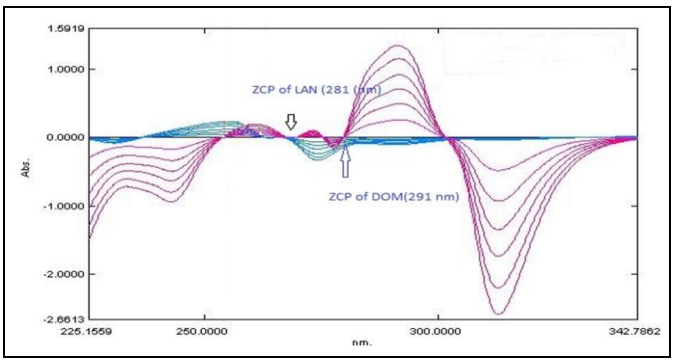

FIG. 2: FIRST DEVIATION ZERO CROSSING POINT OF LAN (LANSOPRAZOLE) & DOM (DOMPERIDONE)

Phase Solubility Study: The stoichiometric ratio and quantitative expression of stability constant were determined by using phase solubility. Defined quantities of the drugs were transferred to 20 mL of aqueous solution of β-CD (molecular weight = 1134.98) in various molar concentrations (0, 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0 mM/L) contained in screw-capped vials. These solutions were stirred on electromagnetic stirrer at room temperature 25ºC for 24 h and 400 rpm. After 24 h, samples were filtered through a 0.22 µm membrane filter. The filtrate was analyzed spectrophotometrically for drug content at the wavelength of the difference of 281 nm LAN and 292 nm for DOM using spectrophotometer (U.V. visible spectrophotometer, Shimazdu-1601). Data obtained from the phase solubility diagram was used to determine the stoichiometric ratio by plotting the graph of concentration of LAN and DOM against the concentration of β-CD. The stability constant K_S (stability constant) for the complex was determined from the graph using the following equation, where slope and intercept is obtained from graph [4, 5].

Stability Constant K_S:

$$KS = Slope/S_0 (1-slope)$$

Where, S_0 = Concentration of pure drug.

Preparation of Inclusion Complexes: Inclusion Complex of LAN and DOM with β-CD were prepared by different methods like physical mixture, and Kneading method with using the molar ratio of 1:3. (Drug: polymer).

Dissolution Studies: Dissolution studies of LAN Pure, DOM Pure, PML, PMD, KNL, KND in powder form were performed to evaluate the *in-vitro* drug release profile. Dissolution studies were carried out using USP dissolution apparatus type II with 900 ml dissolution medium (water) at 37 ºC ± 0.5 ºC and 50 rpm for 30 min. At different time intervals, 10 ml aliquots were withdrawn, filtered, suitably diluted, and then assayed for LAN and DOM content by measuring the absorbance at 281 nm and at 292 nm, respectively using spectrophotometer (U.V. visible spectrophotometer, Shimadzu-1601).

Pre-compression Parameters:

Angle of Repose: The angle of repose of tablet blends was determined by the funnel method

$$\text{Tan } \theta = h/r$$

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

Bulk and Tapped Density: An accurately weighed quantity of the blend (W), was carefully poured into the graduated cylinder, and the volume (V0) was measured. The cylinder was tapped for about 100, and bulk density and tapped density were calculated.

Carr's Index: The Compressibility Index of the powder blend was determined by Carr's compressibility index. It is a simple test to evaluate the Bulk Density and Tapped Density of a powder and the rate at which it packed down. The formula for Carr's Index is as below [6, 7].

$$\text{Carr's Index} = [(D_t - D_b) \times 100] / D_t$$

Where D_t is the tapped density of the powder. D_b is the bulk density of the powder.

Hausner's Ratio: It is a number that is correlated to the flowability of a powder or granular material.

$$\text{Hausner's ratio} = D_t / D_b$$

Where D_t is the tapped density of the powder. D_b is the bulk density of the powder.

Preparation of Mouth Dissolving Tablets: The Mouth dissolving tablet of LAN and DOM was prepared by using various types of excipients and different super disintegrating agents in various quantities by direct compression technique listed in **Table 1**.

TABLE 1: FORMULATIONS FOR PREPARATION OF DIFFERENT BATCHES OF MOUTH DISSOLVING TABLETS

Batch	Drug + BCD Complex	Cross povidone (%)	CCS (%)	SSG (%)	Isabgol Powder (%)	Banana Powder (%)	Mango Powder (%)	PVP K30 (%)	MCC (%)	Talc (%)	Mg. stearate (%)
F1	120	2	-	-	-	-	-	5	Q.S	2	4
F2	120	3	-	-	-	-	-	5	Q.S	2	4
F3	120	4	-	-	-	-	-	5	Q.S	2	4
F4	120	-	2	-	-	-	-	5	Q.S	2	4
F5	120	-	3	-	-	-	-	5	Q.S	2	4
F6	120	-	4	-	-	-	-	5	Q.S	2	4
F7	120	-	-	2	-	-	-	5	Q.S	2	4
F8	120	-	-	3	-	-	-	5	Q.S	2	4
F9	120	-	-	4	-	-	-	5	Q.S	2	4
F10	120	-	-	-	2	-	-	5	Q.S	2	4
F11	120	-	-	-	3	-	-	5	Q.S	2	4
F12	120	-	-	-	4	-	-	5	Q.S	2	4
F13	120	-	-	-	-	2	-	5	Q.S	2	4
F14	120	-	-	-	-	3	-	5	Q.S	2	4
F15	120	-	-	-	-	4	-	5	Q.S	2	4
F16	120	-	-	-	-	-	1	5	Q.S	2	4
F17	120	-	-	-	-	-	2	5	Q.S	2	4
F18	120	-	-	-	-	-	3	5	Q.S	2	4

Evaluation Parameters of Mouth Dissolving Tablets:

Weight Variation: 20 tablets were weighed individually. The average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight. The percentage difference in the weight variation should be within the permissible limits

Friability: Roche friabilator was used to measure the friability of the tablets. It was rotated at a rate of 25 rpm. After 100 rotations (about 4 min), the tablets were taken out from the friabilator, and intact tablets were again weighed collectively. The permitted friability limit is 1.0%.

Disintegration Test: One tablet is placed in each tube, and the basket rack is poisoned in 1 lit beaker of distilled water at 37 ± 2 °C, such that the tablets remain below the surface of the liquid on their upward movement and descend not closer than 2.5 cm from the bottom of the beaker [8, 9].

Hardness: Hardness was measured using the Monsanto hardness tester. Measure the pressure required to break the diametrically placed matrix tablet by a coiled spring.

Thickness: The thickness of the tablets was determined using a digital Vernier caliper (Edison Mumbai).

Wetting Time: This test is especially meant for MDT's A piece of tissue paper (10cm diameter folded twice will be placed in small Petridis containing 6 ml of phosphate buffer, a tablet will put on the paper, and the time for complete wetting was measured [4, 5].

***In-vitro* Dispersion Time:** It will measure by dropping a tablet in a measuring cylinder containing 6 ml of pH 6.8. *In-vitro* dispersion time was measured.

***In-vitro* Dissolution Studies:** The *In-vitro* dissolution tests were performed using the USP apparatus (Paddle method). The total no. of tablets used for each test was six (6) units. The Dissolution medium was 900 ml of pH 6.8 maintained at 37 ± 0.5 °C as mentioned in the monograph. The Paddle rotation speed was kept at 50 rpm. In all experiments, an aliquot of 10 ml dissolution samples was withdrawn at predetermined time intervals [6, 7] and replaced with an equal volume of the fresh medium to maintain total volume constant (sink condition). Samples were filtered through filter and analysed. Cumulative fractions of drug released from the tablets were calculated and plotted as function of time.

RESULTS AND DISCUSSION:

Phase Solubility Study: The phase solubility curve of LAN and DOM in the aqueous solution of β-CD is shown in **Fig. 3**. This curve indicated a linear increase of solubility of LAN and DOM with an increase in concentration of β-CD in water due to the formation of an inclusion complex between LAN and DOM and β-CD. Increasing amounts of β-CD increased the amount of LAN and DOM going into water up to 7 mM/L concentration of β-CD, improving the aqueous solubility of LAN and DOM. Solubility of LAN and DOM were increased by 7.2 -fold and 33 –fold at 25 °C. Increased solubility may be due to improved dissolution of LAN and DOM particles in water by β-CD.

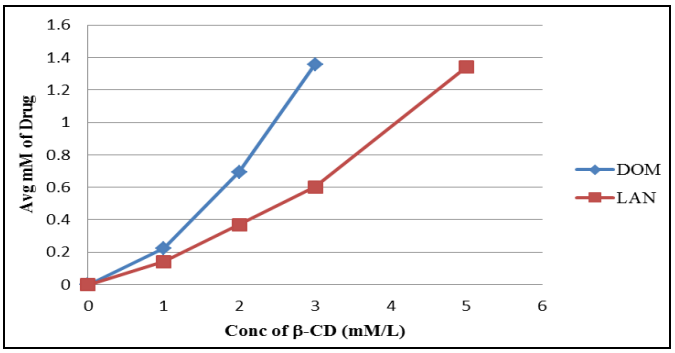

FIG. 3: PHASE SOLUBILITY CURVE OF LAN AND DOM

TABLE 2: GIBBS FREE ENERGY OF TRANSFER $\Delta G_0 T$ FOR SOLUBILISATION PROCESS OF LANSOPRAZOLE IN AQUEOUS SOLUTION OF β-CD AT 25 °C

Conc. of HP-β-CD mM/L	ΔG(KJ/mol)
1	-4.06
2	-6.895
3	-7.14
5	-8.50
7	8.39

An indication of the process of transfer of LAN and DOM from pure water to aqueous solution of β-CD were obtained from the values of Gibbs free energy change the Gibbs free energy values provide the information whether the reaction condition is favorable or unfavorable for drug solubilization in the aqueous carrier solution. Negative Gibbs free energy values indicate favorable conditions.

TABLE 3: GIBBS FREE ENERGY OF TRANSFER ΔG0T FOR SOLUBILISATION PROCESS OF DOMPERIDONE IN AQUEOUS SOLUTION OF β-CD AT 25 °C

Conc. of HP-β-CD mM/L	ΔG(KJ/mol)
1	-3.02
2	-5.05
3	-8.14
5	-7.40
7	-6.73

Characterization of Complexes: The Infrared spectrum of moisture-free powdered samples of LAN and DOM, KN complex of LAN, and DOM were recorded on the IR spectrophotometer (FTIR – 8300, Shimadzu) by potassium bromide (KBr) pellet method.

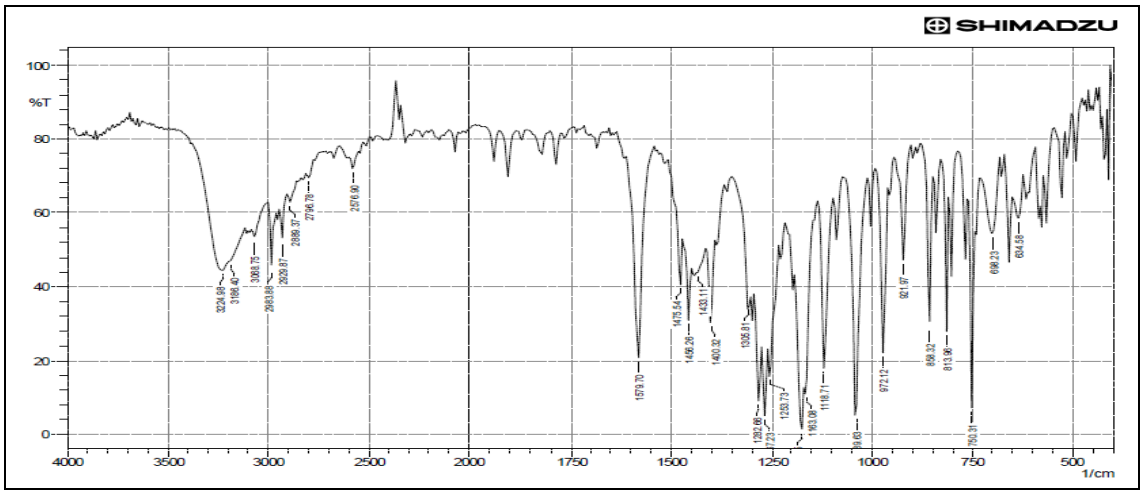

FIG. 4: FTIR SPECTRA OF LANSOPRAZOLE

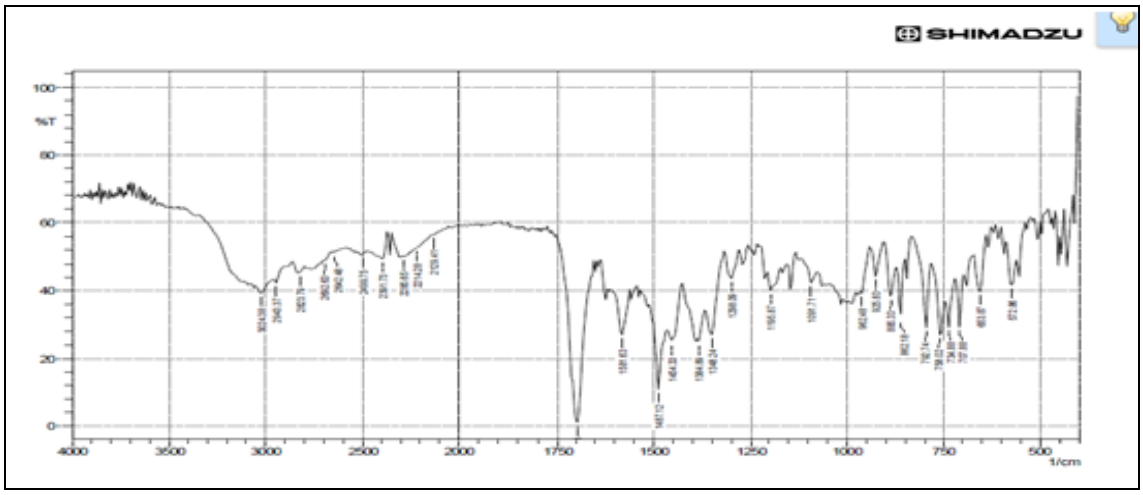

FIG. 5: FTIR SPECTRA OF DOMPERIDONE

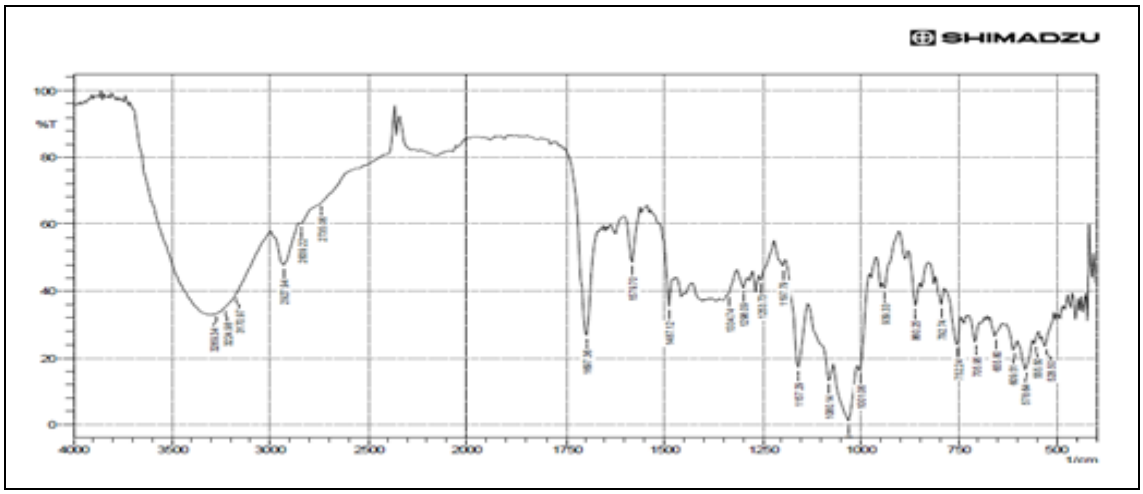

FIG. 6: FTIR SPECTRA OF KNEADING COMPLEX

The characteristic absorption peaks of LAN appeared at 1,579.70, 1,282.66, 1,118.7, and 972.12 cm^{-1}, respectively.

IR spectrum of DOM is characterized by principal absorption peaks at 2943 cm^{-1} (C-H stretch), 1681 cm^{-1} (C=O strong peak), 758 cm^{-1} (ortho-disubstituted ring), 1062 cm^{-1}, 1091 cm^{-1}, 1195 cm^{-1} (C-N stretching 3º aromatic amine), 3024 cm^{-1} (carboxylic acid).

IR spectrum of β-cyclodextrin is shown prominent peaks at 3392 cm^{-1} (O-H), 2927 cm^{-1} (C-H), 1630 cm^{-1} (H-O-H bending), 1156 cm^{-1} (C-O), 1029 cm^{-1} (C-O-C).

All identical peaks of DOM and LAN remained as such, which indicates that there was no interaction between both drugs. In the IR spectra of the inclusion complex, the peaks of LAN and DOM almost disappeared.

Differential Scanning Calorimetry (DSC) Analysis: DSC scans of the powdered sample of LAN, DOM, β-CD, KN complex of LAN, and DOM were recorded using DSC-Shimadzu 60 with TDA trend line software. The thermal traces were obtained by heating from 50 ºC to 300 ºC with a heating rate of 10 ºC under inert N_2 dynamic atmosphere (100 mL/min) in open crucibles.

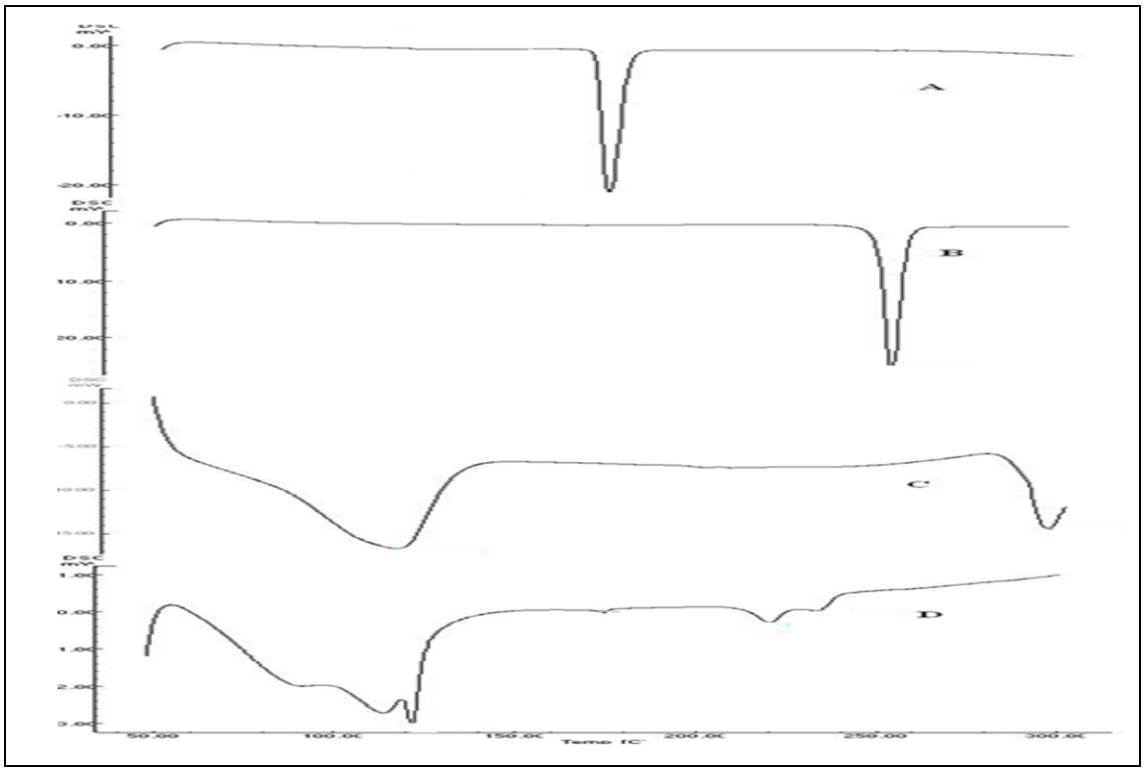

FIG. 7: DSC GRAPH

Dissolution Studies:

Statistical Analysis of Lansoprazole and Domperidone: A value of 100% for the similarity factor (f2) suggests that the test and reference profiles are identical. Values between 50 and 100 indicate that the dissolution profiles are similar whilst smaller values imply an increase in dissimilarity between release profiles

TABLE 4: SIMILARITY FACTOR (F_2) FOR RELEASE PROFILES OF COMPLEXES AND PURE LAN, PML, KNL IN WATER

Sample	PML	KNL
Lansoprazole	79.2	40.61

TABLE 5: SIMILARITY FACTOR (F_2) FOR RELEASE PROFILES OF COMPLEXES AND PURE DOM, PMD, KND IN WATER

Sample	PMD	KND
Domperidone	77.2	41.27

Evaluation of Tablets: Before compression powder blend evaluated for bulk density, taped density, compressibility index (%), Hausner's ratio, Angle of repose. All data of Pre and Post compression parameters shown in **Table 6** and **Table 7** from that we found that all batches have a good compressibility parameter. So the tablets were prepared by the direct compression method.

Then prepared tablet evaluated for hardness, friability, wetting time, in-vitro disintegration time. All batches pass from weighing uniformity test. Data shown in table 6from that we found that batch F3 has good all post-compression parameters compare to other batches.

TABLE 6: PRE-COMPRESSION PARAMETERS OF POWDER

Batch	Bulk density (g/cm^3)	Tapped density(g/cm^3)	Carr's index (%)	Hausner's ratio	Angle of repose
LAN	0.581±0.021	0.643±0.043	9.63±1.129	1.106±0.021	23.83
DOM	0.57±0.025	0.68±0.042	16.17±1.124	1.192±0.027	29.13
F1	0.621±0.027	0.702±0.043	11.53±1.472	1.13±0.029	25.97°
F2	0.627±0.025	0.718±0.043	12.67±1.282	1.14±0.033	24.37°
F3	0.637±0.023	0.723±0.043	11.81±1.382	1.13±0.020	25.27°
F4	0.616±0.020	0.706±0.043	12.67±1.232	1.14±0.041	25.52°
F5	0.622±0.021	0.717±0.043	13.23±1.362	1.15±0.035	24.80°
F6	0.624±0.022	0.716±0.043	12.75±1.214	1.14±0.040	24.65°
F7	0.615±0.020	0.704±0.043	12.62±1.312	1.14±0.033	23.32°
F8	0.618±0.019	0.727±0.043	14.97±1.412	1.17±0.044	27.39°
F9	0.633±0.022	0.729±0.043	13.14±1.382	1.15±0.049	24.61°
F10	0.623±0.018	0.768±0.057	20.44±2.252	1.25±0.075	32.12°
F11	0.584±0.026	0.676±0.043	13.59±1.612	1.15±0.045	23.40°
F12	0.593± 0.047	0.687±0.024	13.62±1.129	1.16±0.021	22.67°
F13	0.612±0.021	0.604±0.033	12.52±1.311	1.13±0.035	25.32°
F14	0.620±0.019	0.767±0.023	14.87±1.414	1.17±0.045	29.39°
F15	0.623±0.022	0.739±0.025	12.14±1.382	1.16±0.049	28.61°
F16	0.633±0.020	0.668±0.055	21.44±2.252	1.26±0.056	35.12°
F17	0.684±0.026	0.776±0.023	14.59±1.612	1.15±0.045	32.40°
F18	0.595±0.037	0.689±0.022	12.62±1.129	1.16±0.022	33.67°

TABLE 7: POST-COMPRESSION PARAMETERS

Batch	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Disintegration Time (sec)	Wetting time (sec)	*In-vitro* Dispersion time (sec)
F1	2.8±0.030	2.9±.0.058	0.43±0.009	52±1	39±1	35±1
F2	2.9±0.580	2.9±0.058	0.41±0.007	43±1	38±3	28±2
F3	2.9±0.019	3.0±0.058	0.37±0.469	25±3	38±1	17±1
F4	2.8±0.900	2.9±0.058	0.60±0.010	68±1	40±4	51±1
F5	2.8±0.150	2.9±0.100	0.70±0.019	55±4	41±1	43±3
F6	2.8±0.460	3.0±0.000	0.51±0.010	43±1	39±1	31±1
F7	2.9±0.030	3.0±0.058	0.42±0.015	70±2	43±2	49±2
F8	2.8±0.150	2.9±0.115	0.54±0.036	62±1	42±1	43±1
F9	2.8±0.126	2.9±0.058	0.46±0.019	59±1	42±3	32±4
F10	3.7±0.080	2.0±1.235	1.25±0.045	90±3	65±1	65±1
F11	2.7±0.105	2.8±0.089	0.78±0.065	75±1	55±2	52±5
F12	2.7±0.070	2.8±0.067	0.75±0.045	55±1	44±1	39±1
F13	3.0±0.032	3.0±0.058	0.52±0.015	72±2	54±2	45±2
F14	3.1±0.150	2.8±0.115	0.55±0.036	59±4	52±4	39±3
F15	2.9±0.126	2.6±0.058	0.49±0.019	55±1	48±1	32±1
F16	3.2±0.082	2.5±1.235	0.98±0.045	85±5	72±5	69±2
F17	2.9±0.104	2.9±0.089	0.89±0.065	72±1	65±2	61±1
F18	2.8±0.070	3.0±0.067	0.78±0.045	42±2	52±1	53±5

***In-vitro* Dissolution Study (pH 6.8 Buffer):** *In-vitro* dissolution study of tablets was conducted using USP dissolution apparatus II at 50 rpm, using pH6.8 buffer containing as dissolution media maintaining at 37 ± 0.5 °C. *In-vitro* dissolution study of all batches (F1-F18) shown in **Table 8** & **Table 9**.

TABLE 8: *IN-VITRO* DISSOLUTION PROFILE FOR LANSOPRAZOLE

Batch	Time (min)					
	02	04	06	08	10	12
F1	13.65±1.20	39.58±1.22	53.51±1.20	67.31±1.29	75.50±1.20	82.71±1.20
F2	06.06±1.22	55.12±1.23	82.50±1.22	85.83±1.28	91.93±1.28	93.51±1.22

F3	18.78±1.25	56.33±1.25	96.16±1.25	97.81±1.22	99.64±1.29	99.66±1.20
F4	00.58±1.28	09.11±1.26	33.46±1.29	50.41±1.65	64.25±1.20	85.63±1.24
F5	03.61±1.29	18.25±1.28	38.11±1.28	55.01±1.20	80.98±1.32	97.95±1.20
F6	12.71±1.32	56.26±1.29	65.83±1.27	99.30±1.28	99.97±1.32	100.12±1.28
F7	00.58±1.28	10.63±1.32	28.38±1.28	50.31±1.20	65.76±1.20	70.48±1.20
F8	12.71±1.35	56.26±1.95	62.80±1.27	67.11±1.32	72.92±1.58	81.93±1.29
F9	15.75±1.42	24.45±1.28	50.31±1.32	64.25±1.29	79.56±1.20	85.50±1.20
F10	02.15±1.63	09.13±1.36	18.30±1.35	24.46±1.28	45.76±1.58	53.58±1.32
F11	00.58±1.58	10.63±1.28	21.35±1.39	29.05±1.28	48.85±1.20	66.96±1.25
F12	02.19±1.20	13.68±1.22	28.96±1.22	39.75±1.20	64.13±1.22	75.01±1.20
F13	00.58±1.22	13.66±1.32	24.41±1.28	50.31±1.22	65.78±1.20	70.48±1.29
F14	03.61±1.36	18.25±1.34	25.98±1.29	54.88±1.20	71.88±1.56	81.16±1.27
F15	06.65±1.28	21.31±1.39	27.53±1.28	59.49±1.28	74.96±1.29	85.75±1.22
F16	00.58±1.28	04.56±1.95	09.15±1.25	18.33±1.20	30.53±1.27	39.76±1.21
F17	03.61±1.23	09.15±1.22	16.78±1.28	24.45±1.25	35.15±1.22	44.36±1.32
F18	06.65±1.20	16.76±1.20	25.96±1.22	33.65±1.20	44.35±1.20	64.18±1.35

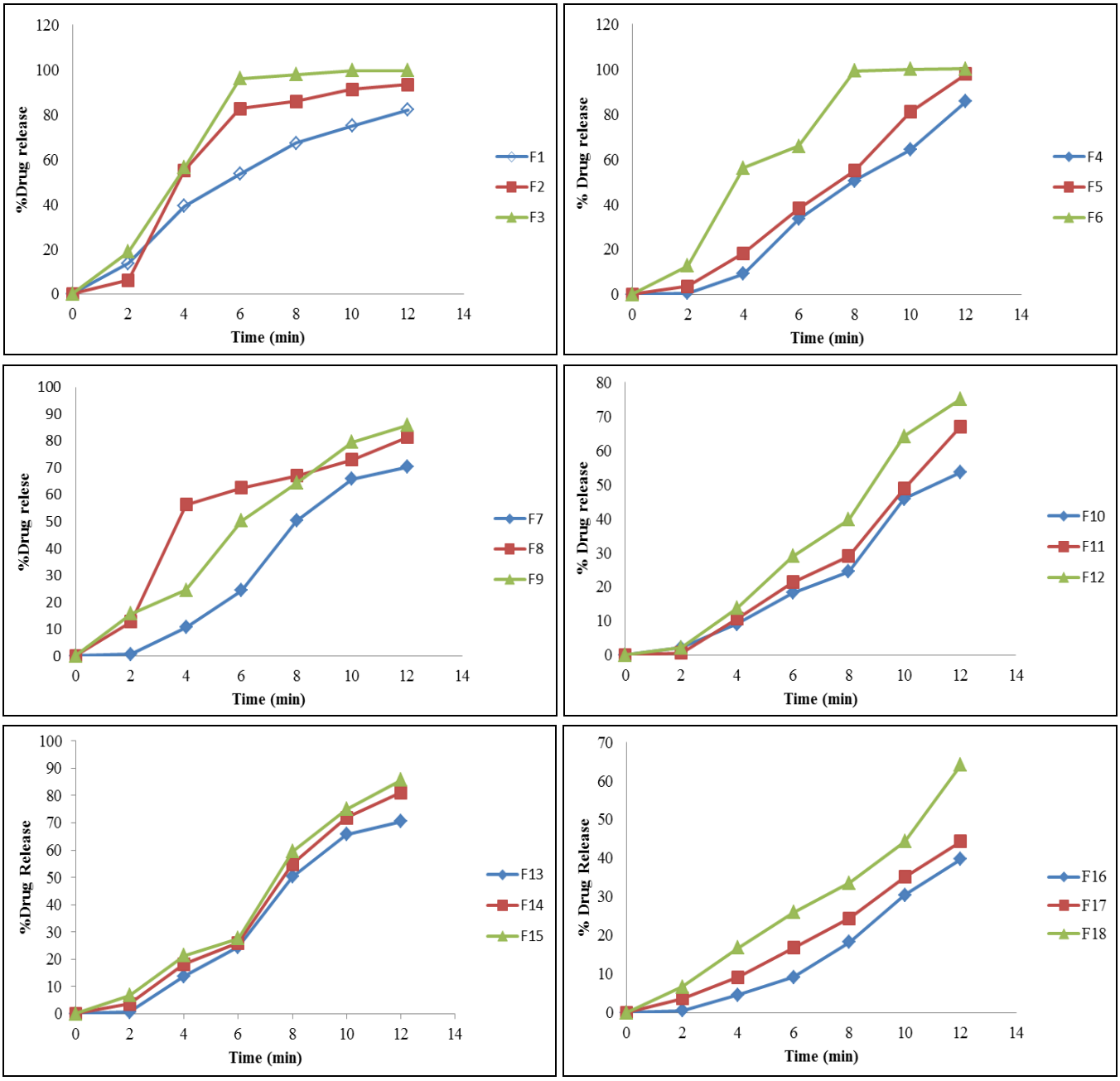

FIG. 8: DISSOLUTION PROFILE FOR LAN BATCH F1-F18

TABLE 9: *IN-VITRO* DISSOLUTION PROFILE FOR DOMPERIDONE

Batch	Time (min)					
	02	04	06	08	10	12
F1	00.48±1.20	07.60±1.20	19.80±1.32	30.55±1.22	50.38±1.28	73.35±1.20
F2	02.00±1.22	10.65±1.22	24.68±1.20	41.97±1.32	73.25±1.32	82.73±1.28
F3	29.20±1.20	57.66±1.25	93.14±1.28	98.14±1.35	100.87±1.00	101.45±1.20
F4	00.48±1.89	04.56±1.29	19.71±1.20	45.71±1.35	88.46±1.20	96.51±1.29
F5	01.03±1.32	03.03±1.20	25.81±1.22	47.30±1.28	55.11±1.34	90.08±1.32
F6	02.00±1.20	31.88±1.29	56.46±1.20	77.96±1.30	85.78±1.20	90.41±1.35
F7	02.00±1.22	06.10±1.28	19.78±1.22	45.71±1.20	76.33±1.28	88.82±1.20
F8	03.51±1.20	16.73±1.26	32.03±1.20	57.52±1.26	87.07±1.20	92.12±1.38
F9	20.20±1.28	41.18±1.28	57.78±1.20	73.11±1.29	98.58±1.24	99.56±1.22
F10	00.48±1.27	15.18±1.20	25.95±1.92	35.15±1.28	44.36±1.38	56.68±1.28
F11	03.51±1.29	19.71±1.26	29.03±1.85	41.26±1.20	50.55±1.58	62.73±1.32
F12	06.55±1.29	15.25±1.20	35.05±1.32	44.36±1.32	55.08±1.20	65.81±1.69
F13	00.48±1.25	09.11±1.27	19.81±1.29	30.55±1.20	41.28±1.48	55.05±1.29
F14	03.51±1.28	12.18±1.32	25.91±1.22	35.16±1.32	45.88±1.42	61.16±1.28
F15	09.58±1.28	15.28±1.65	30.50±1.28	41.28±1.35	56.56±1.29	71.90±1.23
F16	00.48±1.25	04.56±1.82	15.21±1.29	25.95±1.28	35.16±1.27	47.40±1.22
F17	03.51±1.22	10.66±1.25	19.83±1.25	30.55±1.85	41.28±1.28	55.05±1.30
F18	09.58±1.22	15.28±1.20	27.46±1.25	35.18±1.45	56.50±1.22	71.90±1.35

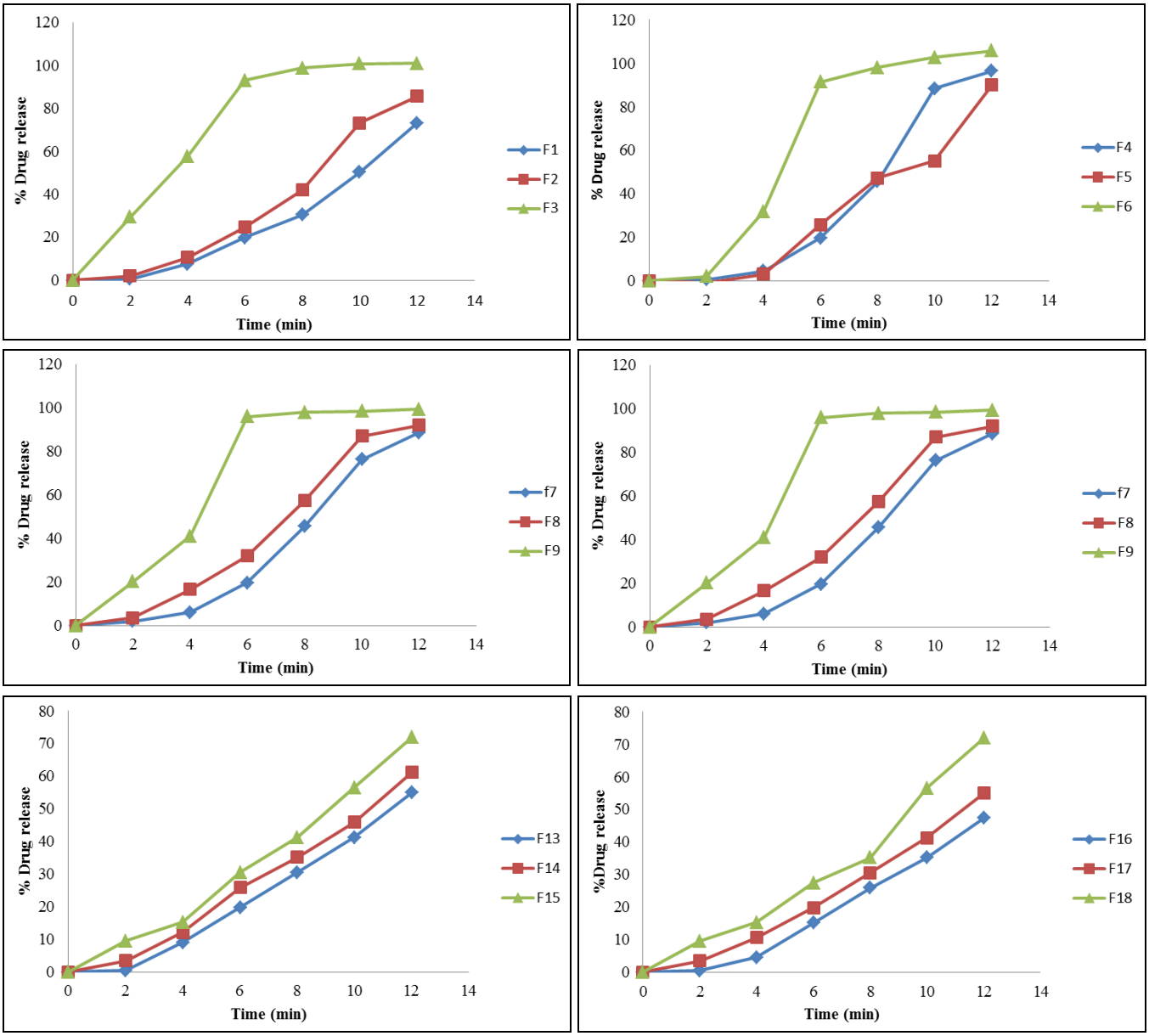

FIG. 9: DISSOLUTION PROFILE FOR DOM BATCH F1-F18

Accelerated Stability Study of Batch F3: In order to determine the change in the *in-vitro* release profile on storage, stability study of batch F3 was carried out at 40 °C in a humidity chamber having 75% RH. The sample was withdrawn after the three-week interval and evaluated for change in the *in-vitro* drug release pattern, which shown in **Table 10, Fig. 10.** Hardness and disintegration time, friability showed negligible change, and release pattern also remains the same with f_2 value 58.008; so dosage form remains as such and passes from stability testing.

TABLE 10: RESULT OF STABILITY STUDY OF F3

Parameter	Initial	After storage at 40 °C for 3 weeks
Hardness (kg/cm^2)	3.0±0.058	2.9±0.058
Disintegration time (sec.)	25±1	29±1
Friability	0.37±0.469	0.41±0.311

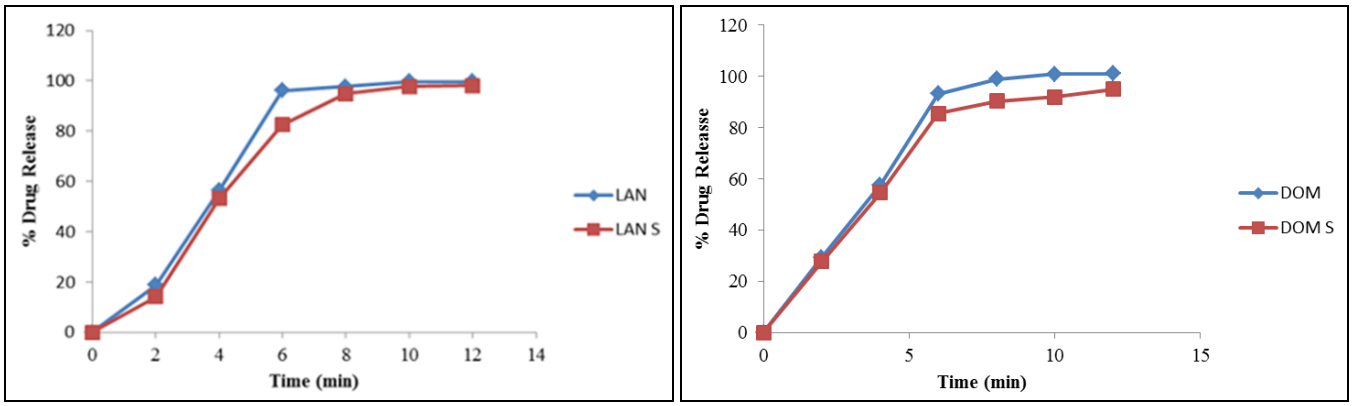

FIG. 10: RELEASE PATTERN OF F3 BATCH BEFORE (LAN& DOM) AND AFTER (LAN S& DOM S) STORAGE OF ACCELERATED CONDITION

CONCLUSION: The present study demonstrated the successful formulation and evaluation of an anti-emetic and proton pump inhibitor drugs in a single dosage form as a mouth dissolving tablet. Phase solubility study of both drugs has been found satisfactory in a 3:1 ratio by using the kneading method. In this approach, the Mouth dissolving tablet was prepared by a direct compression method using various super disintegrating agents in which optimized formula (F3) contains cross povidone (4%) as a super disintegrating agent. The drug excipient compatibility studies carried out using FT-IR and DSC revealed that there was no interaction found between drugs and Excipients. All the pre- and post-compression parameters show the results within the official limits. *In-vitro* release studies revealed that both drugs were found to be 96.16 and 93.14 % for Lansoprazole and Domperidone, respectively, within 06 min and satisfactory disintegration time achieved within 25 sec. From the above study, it can be concluded that the prepared mouth dissolving tablets achieve the objective of the research work in treating vomiting and nausea along with the ulceration problem with a quick release of two drugs.

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