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Formulation and Evaluation of fast dissolving tablets of Lansoprazole by Solubility Enhancement Technique

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ABSTRACT

The present study was focused on preparation and evaluation of Lanzoprazole fast dissolving tablets. Lansoprazole (LAN) is a proton pump inhibitor drug and used for the treatment of gastric ulcer. Lansoprazole is acid labile drug and to avoid the acidic pH of the stomach LAN is formulated as oral fast dissolving tablets. Lansoprazole is the class II drug of the BCS classification and has a low aqueous solubility. Hence, to improve the solubility of the drug we have prepared Lansoprazole solid dispersion with poly ethylene glycol and complex with β cyclodextrin. Fast Dissolving tablets of LAN were formulated using different superdisintegrants like Sodium Starch Glycolate, Cross Povidone, Cross Carmellose Sodium by direct compression method. The prepared fast dissolving tablets were evaluated for various parameters like weight variation, hardness, friability, disintegration time, drug content, wetting time, in-vitro drug release and short term stability studies. Percentage weight variation, hardness, friability and drug content uniformity were found to be within the approved range for all the formulations. The in-vitro release studies showed that 99.6% of LAN within 90 sec. Overall, in the formulations prepared by the direct compression method, F3, which contains 6% CCS as super disintegrants release 99% of (LAN) in 2 min was found to be the best formulation. The results concluded that fast dissolving tablets of LAN showing enhanced dissolution might lead to improved bioavailability and effective therapy for gastric ulcer.

Keywords: *β cyclodextrin, Cross Povidone, Fast dissolving tablets, Gastric ulcer, Lanzoprazole, Solid dispersion*.

1. INTRODUCTION

Drug delivery may be defined as the method or process of administering an active pharmaceutical ingredient and delivering it to the desired site inside the body to elicit its therapeutic effect.[1-3] The most common route of drug administration is the oral route due to ease of absorption, pain prevention, flexibility (to handle various types of drug candidates), and, most importantly, patient compliance[4-5]. Oral drug delivery systems do not require sterile conditions and, therefore, are less expensive to manufacture. Several novel technologies for oral delivery have recently become available to address the physicochemical and pharmacokinetics of drugs while improving patient compliance[6-8]. Over the past few years, extensive efforts have been made to design dosages forms with improved patient compliance, enhanced therapeutic effectiveness, reduced side effects, and reduced dosage regimen with less toxicity to treat many acute and chronic diseases[9-12]. Several rapidly disintegrating drug delivery systems are developed and commercialized[13-16]. The oral drug delivery segment has transitioned from simple conventional tablets or capsules to modified-release tablets or capsules into Fast dissolving tablets (FDTs). Fast dissolving tablets are a new, patient-friendly, and more convenient formulation of which can be taken with or without water.

To combine the advantages of tablets and liquids, the research activities have been focused on developing fast dissolving tablets (FDTs), which are solid oral formulations that rapidly disintegrate and dissolve in the oral cavity within 1 minute with improved ease of administration for patients who are physically disabled, un-cooperative, mentally ill, pediatric and geriatric population[17]. Due to these advantages, the pharmaceutical industry adopted oral fast release formulation, majorly orodispersible tablets and oral wafers or films[18].

2. MATERIAL AND METHODS

Lansoprazole was purchased from Alpa Laboratories Limited, Indore. β-Cyclodextrin, Mannitol, Talc, and Microcrystalline cellulose were purchased from S.D. fine chemicals, Mumbai. PVP K30, Cross povidone, CCS, SSG were purchased from Qualigen, Mumbai. Aspartame, Magnesium stearate and Talc were used of LOBA ltd.

2.1 Preformulation Studies of Lansoprazole (LAN)

2.1.1 Melting point of drug

The melting point apparatus measured the melting point of Lansoprazole. A small quantity of Lansoprazole powder was placed into a capillary tube. The capillary tube was sealed at one end and charged with a sufficient amount of dry powder of drug to form a column in the bottom of the tube and packed down as closely as possible by moderate tapping on a solid surface. The capillary tube is inserted into the heating block, and the heating is continued until melting is completed. The temperature range at which powder started to melt to complete melting was observed[19].

2.1.2 FTIR spectroscopy of drug

FTIR is used to identify the functional groups in the molecule. IR transmission spectra were obtained by using KBr pellets method. A small quantity of the drug was used for IR analysis. The drug's pellet of approximately 01 mm diameter was prepared grinding 3-5 mg of the sample with 100-150 mg of Potassium Bromide using a hydrostatic press. The scanning range was 400–4000 cm-1; various peaks in the infrared spectrum were interpreted for a different group. FTIR Spectroscopy also determined compatibility study of drug with the excipients[20]

2.1.3 Preparation of Calibration Curve

The calibration curve of the drug was prepared spectrophotometrically based on UV absorption at λmax 284 nm in PBS pH 6.8 for the quantitative estimation of the drug. Diluents of 5 to 50 µg/ml were prepared using stock solution 0.5 ml, 1.0ml, 1.5ml up to 5.0ml into a series of 10 ml volumetric flasks, and volume was made up to the mark with PBS pH 6.8. PBS pH 6.8 was used as a blank solution. The absorbance of the aliquots was measured at λmax 284 nm. The calibration curve of LAN was prepared by plotting a graph using concentration at X-axis and absorbance at Y-axis[21]

2.1.4 Preparation of β-CD and Lansoprazole drug complex (DC)

Weighed quantities of the drug (500mg) and β-CD (500mg) in a 1:1 ratio will be taken and mixed using pestle mortar (Table 5.3). Solvent (Ethanol: distilled water 1:1) will be added to the mixture of drug and βCD slowly and triturated to obtain a homogenous paste. The paste will be dried at 40ºC for 24 hours and passed through sieve no 40 to get a fine powder[22].

2.1.5 Preparation of solid dispersions of Lansoprazole (SD)

Solid dispersions were prepared by a solvent evaporation method using carriers (i.e., PEG4000, PEG-6000) in proportions, viz. 1:1, 1:2 (Drug: Carrier). Methanol is selected as a common solvent for solid dispersion (Table 1). The respective carrier was dissolved in methanol 20 ml, and LAN was added in parts with continuous stirring. The solvent was then removed by evaporation. The prepared solid dispersion was pulverized and shifted through sieve no. 100 and stored over fused calcium chloride in desiccators for further use[22].

Table 1: Composition of Various Solid Dispersions and drug complex

S. No.	Formulation code	Composition	Ratio
1.	SD1	Drug : PEG 4000	1 : 1
2.	SD2	Drug : PEG 4000	1 : 2
3.	SD3	Drug : PEG 6000	1 : 1
4.	SD4	Drug : PEG 6000	1 : 2
5.	DC1	Drug : β-CD	1 : 1

2.2 Evaluate for solid dispersion and complex of drug

2.2.1 Determination of Solubility of Solid Dispersions and complex

Drug complex, Physical mixture, solid dispersions equivalent to 10 mg of LAN were added to 10 ml of PBS pH 6.8 in a 10 ml

volumetric flask. The volumetric flasks were capped properly and shaken at 25oC in a temperature-controlled water bath (Shaking water bath) for 24 h. Resultant samples containing undissolved solid materials suspended in the volumetric flask were filtered through 0.45µm filters, suitably diluted with PBS pH 6.8, and analyzed by UV spectrophotometer at 284 nm[23]. **Statistical analysis**

2.2.2 Drug content by UV spectrophotometry

Drug content was calculated by dissolving drug complex and solid dispersions equivalent to 50 mg LAN in 10 ml of methanol, filtered using 0.45µm Whatman filter paper, diluted with 100 ml PBS (pH 6.8). About 10 ml of the solution from the volumetric flask was taken and centrifuged. The supernatant solution from the centrifuge tube was collected and again filtered by using Whatman filter and analyzed by using UV spectrophotometer against buffer as blank.

2.2.3 In vitro dissolution studies

Accurately weighed preparations equivalent to 100 mg of LAN were added to 900 ml of dissolution medium in USP II Paddle type apparatus and stirred at speed of 50 rpm at 37±0.5^0 C. 5 ml aliquots were withdrawn at 5, 10, 15, 20, 25 minutes and replaced by 5 ml of fresh dissolution media. The collected samples were analyzed after filtration and dilution at 284 nm using UV-visible spectrophotometer against the blank. Drug release studies were carried out in triplicate. The dissolution of pure LAN was done similarly. The release profile data was analyzed for cumulative percent dissolved at different time intervals[23].

2.3. Precompression Characterization

2.3.1 Bulk density (Db)

It is the ratio of total mass of powder to the bulk volume of powder. 25g of blend of SD4 with excipients was weighed and transferred into 50ml measuring cylinders without tapping during transfer the volume occupied by blend was measured. Bulk density (Db) was calculated by following formula:

$$Db = \frac{M}{Vo}$$

Where, M: Mass of the blend, Vo : Untapped Volume

2.3.2 Tapped density (Dt)

It is the ratio of total mass of the powder to the tapped volume of the powder. 25g of blend of SD4 with excipients were weighed and taken into graduated measuring cylinders. Initial volume occupied by drug blends was noted down. Then cylinder was subjected to 500 taps in tapped density tester (Electro Lab USPII) according to USP. Tapped density was calculated using the tapped volume and mass of powdered drugs using following formula:

$$Dt = \frac{M}{Vi}$$

Where, M: Mass of the blend, Vi : Tapped Volume

2.3.3 Flow properties (Angle of Repose)

The angle of repose of powder was determined by the funnel method. 25g of blend of SD4 with excipients was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap of the powder. The powder was allowed to flow through the funnel freely onto the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation.

$$\text{Tan } \theta = \frac{H}{R} \quad \text{(or) } \theta = \tan^{-1}(H / R)$$

Where, H and R are the height and radius of the pile. Result obtained after calculation was compared with the standard reading given in pharmacopoeia to characterize the flow of the powdered drugs.

2.3.4 Compressibility Index (Carr's index)

It is indirectly related to the relative flow rate, cohesiveness and particle size. It is simple, popular and fast method of predicting powder flow characteristics. It is based on the apparent bulk density and the tapped density, the percentage compressibility of the bulk drug was determined by the following formula-

$$\text{Carr's index (\%)} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \text{ X } 100$$

2.3.5 Determination of Hausner ratio

The Hausner's ratio is a number that is correlated to the flow ability of a powder or granular material. It is measurement of frictional resistance of the drug. It was determined by the ratio of tapped density and bulk density.

$$\text{Hausner Ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

3. Formulation of Lansoprazole Fast Dissolving Tablets by Direct compression

All the ingredients were powdered separately in a dry, clean porcelain mortar and weighed as per the formulation design. After dispensing of the ingredients, all the ingredients were passed through sieve size of 60#. This step used for the uniformity of the ingredients and reduction in the size of particles gives uniform

particle size distribution. Different preliminary batches of FDT tablets were prepared by mixing all ingredients with different superdisintegrants. SD of Lansoprazole (SD4) was selected for the preparation of FDTs due to its superior solubility profile. SD4 with one of the superdisintegrant crospovidone, crosscarmellose sodium and sodium starch glycolate were dry blended for 20min followed by addition of MCC, mannitol and aspartame. Nine formulations were prepared using different superdisintegrants for each of three formulations, in a concentration ranging from 2% to 6%. The mixtures were then mixed with magnesium stearate and talc and further blended for 10 min. Formulation blend was compressed using 8 mm flat round punch into a tablets using tablet compression machine to prepare the FDT tablets containing 30mg of Lansoprazole[24] (Table 2).

Table 2: Composition of FDTs of Lansoprazole (SD4)

Ingredients (mg)	Formulation code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Lansoprazole SD (SD4) (equivalent to 30mg drug)	84	84	84	84	84	84	84	84	84
Crospovidone	3	6	9	-	-	-	-	-	-
Sodium starch glycolate	-	-	-	3	6	9	-	-	-
Cross carmellose Sodium	-	-	-	-	-	-	3	6	9
Mannitol	30	27	24	30	27	24	30	27	24
MCC	30	30	30	30	30	30	30	30	30
Aspartame	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0
Magnesium stearate	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Talc	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Tablet weight (mg)	150	150	150	150	150	150	150	150	150

4. Post compression Evaluation

4.1. Hardness

The tablet should be stable to mechanical stress during handling and transportation. Hardness (Kg/cm^2) of FDTs was determined by Monsanto hardness tester. The results of hardness of various formulations were tabulated[25].

4.2. Friability (F)

FDT formulations (20) were weighed and placed in the Roche Friabillator that revolves at 25 rpm for 4 minutes dropping the from a distance of six inches with each revolution[26]. After operation the tablets were de-dusted and reweighed. The % friability was then calculated by the following formula-

$$F = \frac{\text{Initial Weight} - \text{Final weight}}{\text{Initial weight}} \text{X } 100$$

4.3 Weight variation test

FDT formulations (20) were individually weighed, calculated the average weight, and compared the individual tablet weights to the average. The tablets met the USP tests that were not more than 2 tablets were outside the percentage limit and no tablets differed by more than 2 times the percentage limit. The percentage difference in the weight variation should be within the permissible limits (±7.5%)[26].

4.4 Thickness

Tablets of each batch were selected and measured for thickness using verniour caliper[26].

4.5 Disintegration time

Disintegration time was measured using disintegration test apparatus (Electrolab ED-2L, Mumbai, India). 1 tablet was placed in each of the six tubes of the basket, insert disc and operate the apparatus for the specified time, using distilled water maintained at 37±2°C as the immersion fluid. The time in second was noted when tablets disintegrate completely[27].

4.6 Drug content

Total 10 tablets were weighed and powder equivalent to 30mg of LAN was weighed and dissolved in PBS pH 6.8 then filtered through Whatman filter paper. Solution was analyzed for LAN content by UV Spectrophotometer at 284nm using PBS pH 6.8 as blank.

4.7 Wetting time

The wetting time of the tablets can be measured using a simple procedure. Five circular tissue papers of 10cm diameter are placed in a petridish with a 10cm diameter. 10 ml of PBS pH 6.8 was poured into the tissue paper placed in the petridish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as a wetting time[27].

4.8 *In vitro* Dissolution Studies of FDT tablets

The developed FDT formulations of Lansoprazole were subjected to release studies using USP-II dissolution apparatus (Electrolab TDT-08) at 50 RPM. Dissolution medium used was 900 ml PBS pH 6.8 maintained at 37±0.5ºC, which was found to provide sink conditions. The 5 ml samples were withdrawn at different time intervals and replaced with an equivalent amount of fresh medium. The dissolution samples, after filtration through 0.45-mm filters, were analyzed using a validated UV spectroscopic method at 284nm[28-29].

4.9 Stability Studies

The studies were conducted on best selected formulation F3 on the basis of dissolution studies and as per ICH guidelines which recommend a temperature of 40±2^{0}C, a relative humidity of 75±5% and period of 3 months for accelerated stability studies. However, the stability was also assessed at 4±1^{0}C (refrigerated condition) and at 25±2^{0}C with 60±5% relative humidity. The sampling time was kept at 1, 2 and 3 months. The studies were performed using stability chamber (Thermo Lab, Mumbai). Changes in the appearance and drug content of the stored films were investigated during the period and after 3 month[30].

5. RESULTS AND DISCUSSION

5.1 Preformulation Studies

The objectives of pre-formulation studies were to develop a portfolio of information about the drug substance. So that this information would be useful to develop FDT formulation. A capillary melting point method was used to determine the melting point of the drug. It was observed that the melting point of Lansoprazole was found to be 178-182^{0}C. It is similar to the reported value which proved that the received drug samples meet the reported properties. Any impurity, if present, will cause variation in the melting point of a given drug substance. From the above test it was found that the sample drug complies with the standard test of Lansoprazole.

FTIR spectra of LAN was obtained and compared with reference IR spectra for identification and confirmation of various functional groups. Interpretation of FTIR spectra of LAN suggests that the observed peak list meets with that of the reference peak. The observation confirms that the drug obtained is pure. FTIR analysis was also performed to confirm the drug and excipients interaction. Scan was evaluated for presence of principal peaks of drug, shifting and masking of drug peaks and appearance of new peaks due to excipient interaction. There are no extra peaks seen other than the normal peak in the spectra of the mixture of the drug and excipients and so there is no interaction with the drug and excipient and they are compatible with each other

Calibration curve was prepared in PBS pH 6.8 at 284nm and linearly regressed. The correlation coefficient for standard curves was found to be very near to one which indicates good co-linear correlation between concentration 5-50 µg/ml (Table 3 and Figure 1). Hence, drugs are following Beer Lambert Law in the above range.

Table 3: Calibration curve of LAN in PBS pH 6.8

Concentration (µg/ml)	Absorbance	Statistical Parameters Regressed
5	0.1243	**Correlation Coefficient** $r^2 = 0.999$ **Line Equation** y =0.024 x
10	0.2464	
15	0.3528	
20	0.4746	
25	0.6181	
30	0.7381	
35	0.8462	
40	0.9745	
45	1.0724	
50	1.1963	

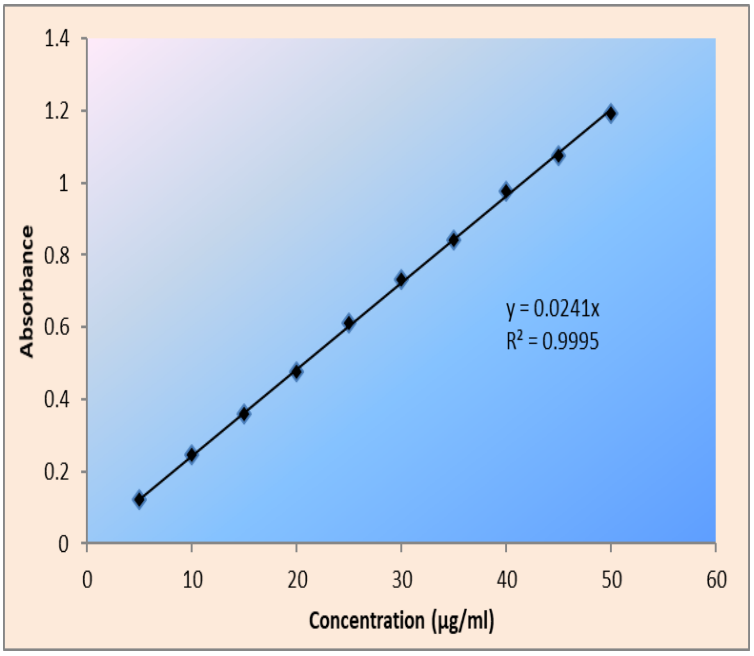

Figure 1: Calibration curve of LAN in PBS pH 6.8 at 284 nm

5.2. Solubility Enhancement of Lansoprazole

To enhance the water solubility of LAN pure drug, solid dispersion of drug with PEG4000 and PEG6000 were prepared. Drug complex with β-CD was also prepared to determine the effect of complex formation on LAN solubility. Prepared drug complex and solid dispersions were evaluated for various parameters and data are shown in Table 4.

The solubility of solid dispersion SD1 to SD4 and drug complex DC1 was found to be in the range of 0.81 mg/ml to 3.91 mg/ml. Drug content of the solid dispersion SD1 to SD4 and DC1 was found to be in the range of 97.24% to 99.31%.

Table 4: Drug content and Solubility of SD and DC of Lansoprazole

Formulation Batch	Amount of Drug Soluble (mg/ml)	Drug Content (%)
SD1	0.81	97.24
SD2	1.42	97.93
SD3	1.82	98.96
SD4	3.91	99.31
DC1	0.92	97.55

% cumulative drug release study is performed by using dissolution test apparatus type II in 900 ml of the phosphate buffer at pH 6.8 at 37± 0.5°C at 50 rpm. From the results it can be seen that more than 50 % of drug was released in less than 10 mins and more than 90 % drug is released in 20 mins. Formulations SD1 & SD2 showed drug release of 97.65 % and 98.13 % at the end of 20 mins. Formulations SD3 & SD4 showed drug release of 98.68 % and 99.17 % at the end of 20 and 15 mins respectively. Formulations DC1 showed drug release of 97.56 % at the end of 20 mins (Table 5 and Figure 2). From the data of % CDR, it is note that as the polymer changes the drug release profile also changes. From the results we concluded that the batch having PEG6000 (1:2) as polymer showed better release profile as compared to other batches and selected for formulation of fast dissolving tablets.

Table 5: In vitro drug release from SD and DC of Lansoprazole

Dissolution time (Min)	Cumulative % Drug Release				
	SD1	**SD2**	**SD3**	**SD4**	**DC1**
0	0	0	0	0	0
5	34.72	37.88	39.12	48.23	33.27
10	53.61	61.23	62.73	71.76	52.76
15	84.26	90.42	91.82	99.17	83.47
20	97.65	98.13	98.68	-	97.56

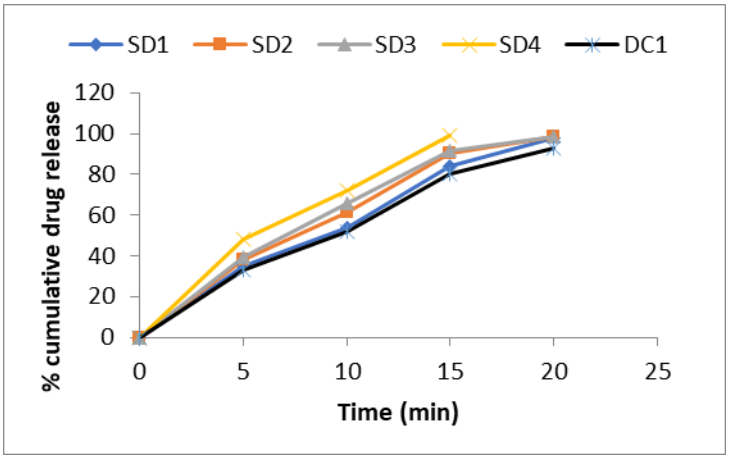

Figure 2: Comparison of in vitro drug release from SD and DC of Lansoprazole

5.3. Pre-compression characterization of Lansoprazole (SD4) and excipients blend

Pre-compression evaluations were done to ensure the flow properties of the powder blend. The powder blend's good flow properties will yield the tablets of desired quality and ease the tableting process. The bulk density of all formulations ranges from 0.36g/cm^3 to 0.45g/cm^3. The results indicate that the powder blends of all nine formulations had good flow properties. The tapped density of all the formulations ranges from 0.45g/cm^3 to 0.56g/cm^3. The angle of repose of all formulations was found in a range of 25˚.5’ to 29˚.6’. It was evident from the results that the powder blends of all formulations possess good flow. The compressibility index of all the formulations ranges from 8.69 to 30.35. The results indicate that the powder blend of all formulations possess good flow properties. The Hausner’s ratio for powder blends of all nine formulations ranges from 1.09 to 1.43. It was observed from the results that the powder blends of all formulations have good flow properties except for formulations (F1, F2 and F7) (Table 6).

5.4 Evaluation of Lansoprazole FDTs

The tablets obtained after compression were evaluated on various parameters to determine their quality and to ensure that the resultant product meets all necessary criteria’s required for the fast dissolving tablets. The hardness for tablets determines the tablet’s resistance to abrasion or breakage under conditions of storage, transformation, and handling before usage.

The hardness for tablets of all the formulations was found to be less than 3 kg/cm^2. The friability test was carried out to ensure the mechanical strength of the tablet to avoid the loss of the tablets' external surface during packing, handling, transit, and storage. Friability below 1% was an indication of good mechanical resistance.

Table 6: Pre-compression characterization of Lansoprazole (SD4) and excipients blend

Formula Code	PARAMETERS				
	Angle of Repose (θ)	BD (g/ml)	TD (g/ml)	CI (%)	HR
F-1	28.2	0.36	0.49	26.53	1.36
F-2	25.5	0.39	0.56	30.35	1.43
F-3	28.1	0.39	0.48	18.75	1.23
F-4	29.6	0.42	0.46	8.69	1.09
F-5	25.7	0.40	0.46	13.04	1.15
F-6	27.2	0.38	0.45	15.55	1.18
F-7	27.1	0.41	0.53	22.64	1.29
F-8	27.8	0.39	0.46	15.21	1.17
F-9	27.4	0.45	0.54	16.66	1.20

The results indicate that the friability for tablets of all formulations was below 1%and hence passes the test. The weight variation test was carried out to ensure that the tablets of each formulation were of uniform weight, which will indicate the uniform distribution of contents of each formulation's powder blends. The weight variation for tablets of all formulations was found to be within the range of 7.5%. The results indicate that all tablets of each formulation were of uniform weight (Table 7).

The thickness of tablets gives the appearance, prevents damage from external forces, and ensures uniform die filling of the powder blends. The thickness for tablets of all nine formulations was found to be 2.2 to 2.5mm (Table 7). The disintegration time was the time taken by the tablet to break down into small particles, in the presence of an aqueous medium. It varies with the type and concentration of the superdisintegrants incorporated in the formulation. As the name implies, disintegration time was the prime most criteria for fast dissolving tablet, which should be less than 30 secs to 3 minutes as per the standards. The results indicate that the disintegration time for tablets of all formulations is within limits (Table 7 and Figure 3).

The drug content of the tablets was estimated to ensure that all the tablets of a formulation contains the therapeutic dosage of the active ingredient meant for the particular dosage form. The drug contents for tablets of all the formulations ranges from 95.46% to 98.84%. The drug content was analyzed at 284nm (Table 7). The wetting time and water absorption ratio indicate the capacity of the superdisintegrants to absorb water and thoroughly wet the tablet at the earliest time possible, which were the significant characteristics of fast dissolving tablets. The minimum tablets' wetting time and the water absorption ratio were within limits (Table 7 and Figure 4).

5.5 In vitro drug release of FDT formulations

In vitro drug release from FDTs was carried out in pH 6.8 phosphate buffer. The superdisintegrants were added to the solid dosage formulations to enhance the disintegration time, thereby enhancing the faster release of active drug from its dosage form, which ultimately resulted in enhanced absorption and bioavailability of the drug. The maximum drug release at a period of five minutes was noted for all the formulations. The results indicate that all the formulation's drug release was found to be above 80% in ten minutes. The release rate of the three superdisintegrants was in the order of Crospovidone> Sodium Starch Glycolate> Croscarmallose (Table 8 and Figure 5 to 7).

5.6 Stability Studies of Formulation F3

Stability studies were performed on best selected formulation F3 on the basis of drug release profile. Formulation F3 was exposed to different storage conditions to determine any changes in final formulation. Initial drug content was considered to

be 100%. It was found that the percent drug content after a period of 3 months for LAN was 99.61±0.34% at 4±1ºC whereas it was 99.52±1.3% at 25±2ºC & 60±5% respectively. On the other hand it was 99.14±1.6% at 40±2ºC & 75±5%. These observations indicate that the formulation is fairly stable with respect to the drug content at all temperatures and conditions of storage.

Table 7: Post-compression evaluation of FDTs of Lansoprazole

Parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9
Hardness (Kg/cm$^{2)}$	2.8	2.7	**2.8**	3.1	2.9	2.9	3.0	2.8	2.7
Weight (mg)	97.8	97.8	**99.2**	97.4	98.5	98.2	100.8	98.6	97.5
Thickness (mm)	2.5	2.4	**2.4**	2.5	2.3	2.2	2.5	2.5	2.4
Friability (%)	0.68	0.66	**0.62**	0.67	0.66	0.62	0.68	0.65	0.63
%Drug Content	95.20	98.84	**98.84**	98.15	98.02	98.26	97.58	98.18	98.37
Disintegration Time (Sec)	63	46	**21**	74	57	35	64	48	36
Wetting time (Sec)	42	34	**30**	44	38	31	44	39	32

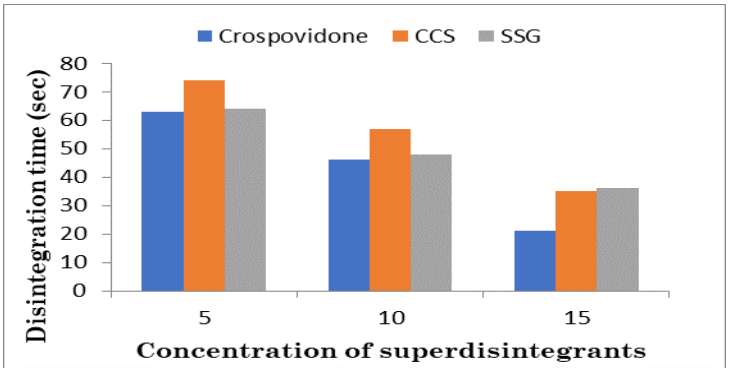

Figure 3: Disintegration time of different superdisintegrants

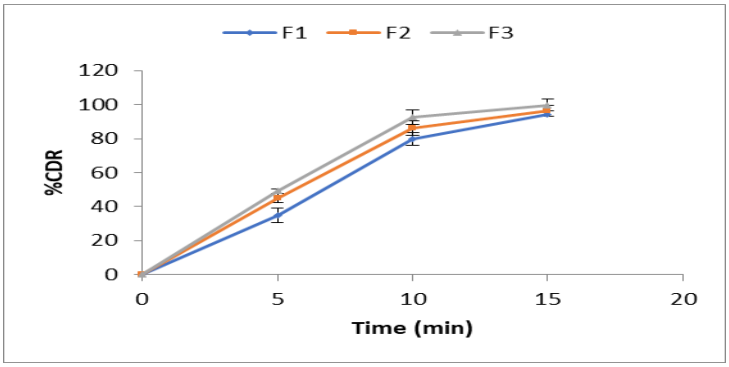

Figure 5: Comparative drug release from formulations F1-F3

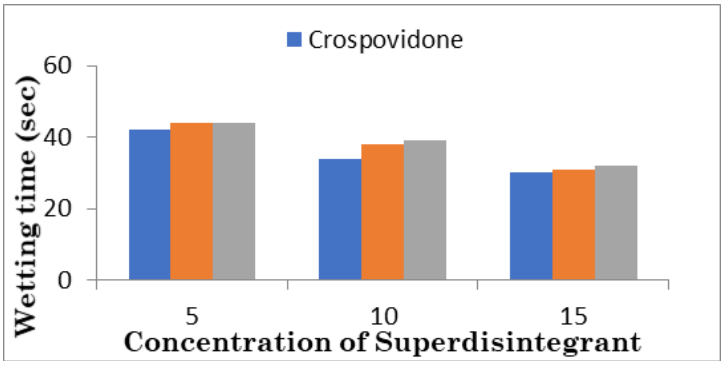

Figure 4: Wetting time of different superdisintegrants

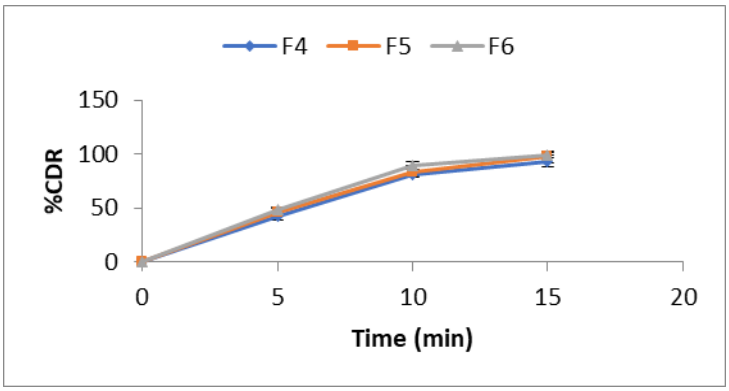

Figure 6: Comparative drug release from formulations F4-F6

Table 8: *In vitro* drug release from FDTs of Lansoprazole

Dissolution Time (Min)	Cumulative % Drug Release (n=3)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	44.72 ±1.4	48.88 ±2.6	49.12 ±4.3	42.23 ±3.4	47.27 ±3.2	48.62 ±2.1	45.08 ±2.8	45.56 ±1.5	48.76 ±2.6
10	81.61 ±4.2	86.23 ±4.3	92.73 ±3.8	80.76 ±1.3	83.76 ±5.5	91.65 ±3.5	83.15 ±2.2	85.51 ±3.6	88.89 ±4.2
15	94.26 ±3.7	96.42 ±3.4	99.82 ±5.8	92.28 ±5.6	96.47 ±5.2	98.96 ±2.6	90.38 ±1.2	94.25 ±3.8	97.33 ±2.7

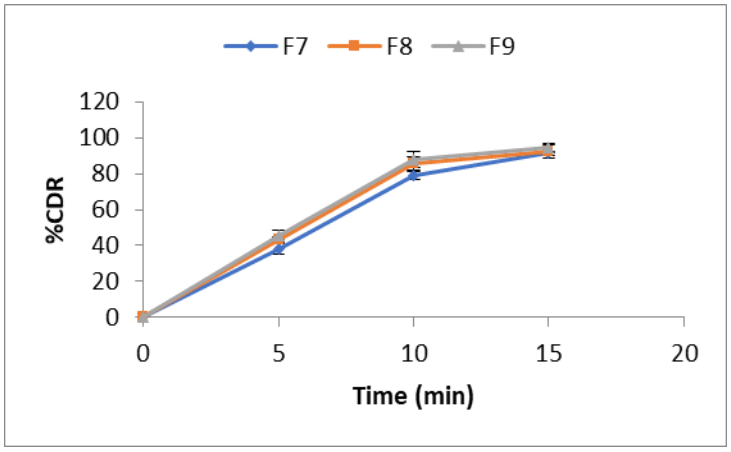

Figure 7: Comparative drug release from formulations F7-F9

6. CONCLUSION

The present study demonstrated the successful formulation and evaluation of a proton pump inhibitor drug as a fast-dissolving tablet. Aqueous solubility drug was enhanced by preparing solid dispersions with PEG4000 and PEG6000 and drug complex with β-Cyclodextrin. In this approach, the fast dissolving tablet was prepared by a direct compression method using various super disintegrating agents in which optimized formula (F3) contains cross povidone (6%) as a super disintegrating agent. in which optimized formula (F3) contains cross povidone (6%) as a super disintegrating agent. The drug excipient compatibility studies carried out using FT-IR revealed no interaction between drug and Excipients

All the pre-and post-compression parameters show the results within the official limits. In-vitro Lansoprazole release was found to be 99.82±5.8% within 15 min, and satisfactory disintegration was achieved within 21 sec. From the above study, it can be concluded that the prepared fast
dissolving tablets accomplish the objective of the research work in treating gastric ulcer problems with a quick release of Lansoprazole.

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