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RESEARCH ARTICLE

FORMULATION AND EVALUATION OF LANSOPRAZOLE FAST DISSOLVING TABLETS

RAVELA NAVYA DURGA, YEGNOOR ANAND KUMAR*

Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Karnataka.

Correspondence
Dr.Y. ANAND KUMAR
Professor, Department of Pharmaceutics
V.L.College of Pharmacy
Raichur -584103, Karnataka-INDIA.

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ABSTRACT

Background: Fast dissolving tablets are those when put on tongue disintegrate/dissolve/disperse instantaneously releasing the drug which dissolve or disperses in the saliva with Their characteristic advantages such as administration without water, anywhere, anytime lead to their suitability to geriatric and paediatric patients.

Objective: lansoprazole is prescribed to elderly patients whose swallow function is reduced with high frequency. Therefore, a new lansoprazole preparation that is useful for swallow function deficient patients is needed. Keeping an objective an attempt is made to develop fast dissolving tablets of lansoprazole.

Methods: Fast dissolving tablets of lansoprazole were prepared using natural super disintegrating agents viz., pregelatinized starch and treated agar at different concentrations. The prepared fast dissolving tablets evaluated for pre compression and post compression parameters studies to check the compatibility of drug and excipients and properties of tablets. Optimized fast dissolving tablets were compared with controlled and marketed tablets.

Results: FTIR and DSC studies suggest there is no interaction between drug and the superdisintegrants. Precompression studies and post compression studies suggest that the values were found to be within the limits and are in accordance with pharmacopoeial standards. The wetting time, dispersion time and disintegration time were directly proportional to the concentration of super disintegrants.

Conclusions: The results of *in vitro* dissolution studies suggest a direct relationship of concentration of super disintegrants with drug release irrespective diluents used in the studies. As the amount of superdisintegrant increases the drug release also increases.

INTRODUCTION

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules. The tablet is the most widely used dosage form because of its convenience in terms of self administration, compactness, and ease in manufacturing. One important drawback of this dosage forms for some patients, is the difficulty to swallow especially geriatric and paediatric patients, which leads to poor patient compliance.

To overcome this drawback, formulation scientists have developed innovative drug delivery systems known as fast dissolving tablets. Fast dissolving tablets are those when put on tongue disintegrate/dissolve/disperse instantaneously releasing the drug which dissolve or disperses in the saliva. Their characteristic advantages such as administration without water, anywhere, anytime lead to their suitability to geriatric, pediatric, mentally ill, and bedridden patients. The benefits, in terms of patient compliance, rapid onset of action, increased bioavailability, and good stability make these tablets popular as a dosage form of choice in the current market (1-4).

Lansoprazole is a strong proton pump inhibitor having an inhibitory activity on gastric ulcer formation and accelerates the ulcer healing by inhibiting the acid production in the parietal cells through the inhibition of H^+, K^+-ATPase (5-7). Lansoprazole is widely used for the therapy of gastric ulcer, duodenal ulcer, reflux esophagitis and Zollinger-Ellison syndrome (8). Clinically, lansoprazole is prescribed to elderly patients whose swallow function is reduced with high frequency (9). Therefore, a new lansoprazole preparation that is useful for swallow function deficient patients is needed. By introducing a fast disintegrating tablet technology that makes tablet swallowable without water as an easily intake pharmaceutical preparation, lansoprazole fast dissolving tablets has been developed.

In the present study an attempt was made to prepare and evaluate lansoprazole fast dissolving tablets using super disintegrating agents of natural origin viz., pregelatinized starch and treated agar.

MATERIALS AND METHODS

MATERIALS

Lansoprazole obtained as gift sample from Cipla Ltd., Mumbai, India. All chemicals and solvents were of analytical grade and natural super disintegrating agents were prepared from standard methods.

METHODS

Preparation of pregelatinized starch (10, 11): 10 gm of corn starch was added into 40 ml of distilled water and was heated with continuous stirring till the uniform paste is obtained. Then to this paste 60 ml of boiling distilled water was added and the resulting paste was stirred for 15 min and spread uniformly over the slab and was kept for drying in the hot air oven at 45°C for 12 h. The resulting thin films of gelatinized starch was scrapped out, and powdered with the help of mortar and pestle. This powder was then passed through sieve no 100 and stored at 40°C, in air tight container until use.

Preparation of treated agar (12): Suitable quantity of agar powder (20 gm) weighed and added in distilled water (200 ml). Agitation is continuously by stirrer for one day to swell. The swollen contents were dried on a tray for three days at a room temperature. The dry powder was grinded by pestle and mortar. Then grinded powder was passed through sieve no 100 and stored in air tight container for further use.

Preparation and evaluation of lansoprazole fast dissolving tablets

Preparation of powder blend of drug and excipients

All the ingredients were passed through sieve no 60. Weigh accurately required quantities of drug viz., lansoprazole, super disintegrants (natural origin) viz., pregelatinized starch, treated agar, diluents viz., microcrystalline cellulose, mannitol and other manufacturing additives such as aerosol, sodium saccharin and magnesium state were mixed well and were subjected for grinding into desired fineness.

Evaluation of powder blend: The powder blend was evaluated for precompressional properties viz., bulk density, tapped density, Compressibility index or Carr's index, Hausner's ratio and Angle of repose to check the flow property and compressibility behaviour and further subjected for drug interaction studies viz., FTIR and DSC.

Bulk density[13]: It is the ratio of powder to bulk volume. Apparent bulk density was determined by pouring the powder blend into a graduated cylinder. The bulk volume (V) and weight of the powder (M) was determined. The bulk density was calculated using the formula. Bulk density is expressed in gm/cc and is given by,

$$\text{Apparent bulk density } D_b = \frac{\text{Mass(M)}}{\text{Volume(V)}}$$

Tapped density: Accurately weighed quantity of powder blend was introduced into a clean, dry 100 ml measuring cylinder. The cylinder was then tapped 100 times from a constant height and tapped volume was read. It is expressed in gm/cc and is given by,

$$\text{Tapped density } D_t = \frac{\text{Mass(M)}}{\text{Tapped volume(V)}}$$

Compressibility index or Carr's index[14]: The percentage compressibility of powder was a direct measurement of the potential powder arch or the bridge strength and stability. Carr's index of each formulation was calculated according to equation given below,

$$\text{Carr's index } CI = \frac{D_t - D_b}{D_t} \times 100$$

Where Dt is tapped density of powder blend;

D_b is bulk density of powder blend.

Hausner's ratio: This is an indirect index of ease of powder flow. It is calculated by the following formula,

$$\text{Hausner's Ratio } HR = \frac{D_t}{D_b}$$

Where D_t is tapped density of powder blend;

D_b is bulk density of powder blend.

Angle of repose[15]: The frictional forces in a loose powder can be measured by angle of repose. This is the maximum angle possible between the surface of a pile of powder and the horizontal plane. The powder was allowed to flow through the funnel fixed to a stand at definite height (h). The angle of repose was then calculated by measuring the height and radius of the heap of powder formed.

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

Where, Θ is angle of repose; h is height of the heap and r is radius of the heap

FTIR studies: Fourier transform infrared (FTIR) spectra were recorded on a Shimadzu FTIR-281-spectrophotometer. The spectrum recorded for lansoprazole, pregelatinized starch, treated agar. Similarly spectrum recorded for powder blend of lansoprazole with pregelatinized starch, treated agar. Samples were prepared in KBr disks prepared with a hydrostatic press at a force of 5.2Tcm^{-2} for 3 min. The scanning

range was 450-4000cm^{-1} and the resolution was 1cm^{-1}.

Differential scanning calorimetry: The thermograms for lansoprazole, pregelatinized starch, treated agar recorded on Seiko, DSC 220C model Differential scanning calorimeter (Tokyo, Japan). Similarly thermogram for powder blend of lansoprazole with pregelatinized starch, treated agar recorded on Seiko, DSC 220C model Differential scanning calorimeter (Tokyo, Japan). About 10 mg of samples were sealed in aluminium pans and heated at a rate of 10^{o}C/min from 30^{o}C-300^{o}C.

Compression of powder blend into lansoprazole fast dissolving tablets: Weighed quantities of lansoprazole with appropriate concentrations of super disintegrants and other excipients as shown in the table 1 were weighed and mixed in geometric progression in a dry and clean mortar. Then the blend was passed through sieve no 60 for direct compression. The powder blend was then compressed into tablets using 10 mm flat faced punches in 10 station rotary tablet machine (Cadmach, India). The different formulae were given in table 1.

Evaluation of fast dissolving tablets: Fabricated fast dissolving tablets were evaluated for post compression parameters viz., thickness, diameter, weight variation, hardness, friability, drug content uniformity, wetting time, *in vitro* dispersion time, *in vitro* disintegration time and *in vitro* dissolution studies.

Thickness and diameter: 10 tablets were taken and their thickness was measured using vernier calipers and is expressed in mm. Similarly diameter of the tablets was measured using vernier calipers and is expressed in mm.

Weight variation: Weight variation test was carried out as per I.P procedure. Twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of tablet was determined and standard deviation was calculated. **Hardness:** Hardness test was carried out as per I.P. The Monsanto hardness tester was used to determine the tablet hardness. The tablet was held between a fixed and moving jaw. Scale was adjusted to zero, load was gradually increased until the tablet fractured. The value of the load at that point gives a measure of hardness of the tablet. Hardness was expressed in Kg/cm^{2}. **Friability:** Friability of the tablets is measured using Roche Friabilator. Preweighed sample of 10 tablets was placed in the friabilator and operated for 25 rpm for 4 m/100 revolutions.

Tablets were taken out and were dedusted using a soft muslin cloth and reweighed. The weight loss was calculated as percentage friability by,

$$\text{Percentage friability } F = \frac{W_{int} - W_{final}}{W_{int}} \times 100$$

Where, W_{int} Initial weight of the tablets; W_{final} Final weight of the tablets

Drug content: Twenty tablets were weighed and powdered. An amount of powder equivalent to 15 mg of lansoprazole was dissolved in 100 ml of phosphate buffer pH 6.8, filtered, diluted suitably and analyzed for drug content at 284 nm. The studies were carried out in triplicate.

Wetting time: A piece of tissue paper folded twice was placed in a small petridish (internal diameter-6.5 cm) containing 6 ml of buffer pH 6.8. A tablet was placed on the paper and the time for complete wetting of the tablet was measured in seconds. The studies were carried out in triplicate.

Dispersion time: *In vitro* dispersion time was also measured by placing a tablet in petridish containing 6 ml of phosphate buffer pH 6.8 (simulated saliva fluid). The time for the tablet to completely disintegrate into fine particles was noted. The studies were carried out in triplicate.

Disintegration time: The disintegration time of the tablets was determined as per IP. The time required for disintegration of six tablets from each batch placed in each tube of disintegration test apparatus and were measured at 37 ± 0.5ºC using 900 ml of simulated fluid. The time required to obtain complete disintegration of tablets was noted.

Dissolution studies: *In vitro* drug release studies for the fast dissolving tablets/control tablets and marketed tablets of lansoprazole were studied using USP type II apparatus (paddle). For the dissolution studies 900 ml of phosphate buffer pH 6.8 used as dissolution medium and rotated at 50RPM . A sample of 5 ml was withdrawn at different intervals of time and was filtered through Whatmann filter paper. The filtrate was diluted suitably with phosphate buffer pH 6.8 and measures the absorbance at 284nm and cumulative percentage drug release was calculated from the calibration curve. The dissolution data was calculated by using dissolution software PCP Disso V3.0.

Results and Discussion

The bulk density was found to be in the range of 0.379±0.002 to 0.401±0.003g/cm^3 for F-1 to F-6 formulations and 0.399±0.004 to 0.367±0.006g/cm^{3}for F-7 to F-12 and tapped density was found to be in the range of

0.440±0.004 to 0.491±0.004g/cm^3 for F-1 to F-6 formulations and 0.426±0.002 to 0.496±0.002g/$cm^3$for F-7 to F-12. The compressibility index value 11-25 indicates a powder with good flow properties, whereas above 25 indicate poor flowability. The Carr's index/compressibility index was found to be in the range of 13.76 to 18.32 for F-1 to F-6 formulations and 13.84 to 19.55 for F-7 to F-12 formulations showing that the blend of powder in all formulations having good flowability and compressibility. The Hausner's value <1.3 indicates better flow properties, whereas above 1.3 indicate poor flow properties. The Hauser's value was found to be in the range of 1.15 to 1.22 for F-1 to F-6 formulations and 1.16 to 1.24 for F-7 to F-12 formulations showing that the blend of powder in all formulations having good flowability. The angle of repose <30 indicates free flowing and >40 with poor flow properties. The angle of repose was found to be in the range of 25'23˚ to 28'23˚ for F-1 to F-6 formulations and 25'33˚ to 28'22˚ for F-7 to F-12 formulations showing that the blend of powder in all formulations was free flowing and can be used for direct compression, The good flowability of the powder blend was justified with the values of Carr's index and Hauser's ratio. The pre compression data were depicted in table 2.

The FTIR characteristic absorption bands of lansoprazole appeared at 3234.14 cm^{-1} corresponds to -NH stretching vibration and 2984.26 cm^{-1}, 1579.47cm^{-1}, 1284.11 cm^{-1}, 1118.42 cm^{-1} denoting stretching vibration of -CH_2, aromatic ring, C-O and ether bond respectively. The characteristic -NH stretching vibration band of lansoprazole was shifting slightly towards higher wavelengths whereas other bands were shifting slightly towards lower wavelengths. Slight alteration could be due to minor distortion of bond angles and are not clear indication of negligible or no interaction. The comparative FTIR spectra were given figure 1.

The DSC thermogram of pure lansoprazole exhibited a sharp melting endothermic peak at 182.93°C corresponding to its melting point and DSC thermogram of pregelatinized starch and treated agar showed broad endothermic peaks at 97.47°C and 99.35°C respectively. The DSC thermogram of powder blend consisting of lansoprazole and pregelatinized starch shows sharp endothermic peak at 184.63°C and broad endothermic peaks at 97.69°C which were shifted to higher temperature when

compared to pure lansoprazole and pregelatinized starch. Similarly The DSC thermogram of powder blend consisting of lansoprazole and treated agar shows sharp endothermic peak at 183.90°C and broad endothermic peaks at 103.49°C which were shifted to higher temperature when compared to pure lansoprazole and pregelatinized starch with negligible decrement in the peak area and intensity clearly shows there is minor or no interaction, these results were justified with FTIR results. The comparative DSC spectra were given figure 2.

The results of thickness and diameter of all the fast dissolving tablets were within the limits and are in accordance with pharmacopoeial standards. The drug content was found to be uniform in all the formulated tablets with low SD values. The hardness of fast dissolving tablets was found to be below 4.2kg/cm^2 and friability was below 1% indicating sufficient mechanical integrity and good mechanical strength/resistance to the tablets. The wetting time/ disintegration time decreases with increase in concentration of super disintegrants. The dispersion time (figures 3, 4) of the tablets was considerably reduced in tablets containing more concentration of superdisintegrants which may be attributed due to the wicking and swelling type of disintegrants thus facilitating the faster disintegration. The post compression data were depicted in tables 3, 4.

The cumulative percentage drug was found to be 18.00±1.95, 73.20±0.66, 74.22±0.92, 85.17±0.74 for pure lansoprazole, control tablets and marketed formulation respectively at the end of 15 min. The cumulative percentage drug was found to be 93.80 ± 1.47, 94.11 ± 1.90, 95.43 ± 0.85, 93.80 ± 1.64, 94.21 ± 1.29 and 95.85 ± 1.45 for F-1, F-2 F-3, F-4 F-5, and F-6 at the end of 15 min. The cumulative percentage drug was found to be 94.01 ± 0.60, 94.69 ± 0.51, 96.52 ± 0.78, 95.32 ± 0.52, 96.01 ± 0.60 and 97.65 ± 0.35 for F-7, F-8 F-9, F-10 F-11, and F-12 at the end of 15 min. Among the formulations F-6 and F-12 were selected as optimized formulations and their dissolution properties were compared with marketed sample and the pure drug. The comparative dissolution parameters data were given in table 5 and profiles were depicted in figures 5-10.

The results of *in vitro* dissolution studies suggest a direct relationship of concentration of superdisintegrants with drug release irrespective diluents used in the studies. As the amount of superdisintegrant increases in the acceptable range, the drug

release also increases. The improved/increased drug release may be due to the minimum wetting time and lesser *in vitro* disintegrating time. Overall the results of the dissolution rate studies indicated greater dissolution rate of lansoprazole from fast dissolving tablets than the marketed sample which intern greater than the controlled tablets and the pure drug. The dissolution data obtained were subjected for model fitting and the model that fits the observed dissolution data was evaluated by correlation coefficient (r) between the variables involved. In all the formulation the best fit model was found to be Hixon crowel and release rate was following first order kinetics. One-way ANOVA was used to test the statistical significant difference between pure lansoprazole, controlled tablets, marketed sample and prepared fast dissolving tablets. Significant differences in the means of DP_{10} and DE_{10} were tested at 95% confidence. The DP_{10} and DE_{10} values of fast dissolving tablets were significantly higher ($P<0.05$) when compared to DP_{10} and DE_{10} values of marketed sample, controlled tablets and the pure drug.

Conclusions: Fast dissolving tablets of lansoprazole were conveniently formulated by direct compression method using at 4%, 8% and 12% of pregelatinized starch/treated agar as natural disintegrating agents and different proportions of microcrystalline cellulose and mannitol as diluents. The results of *in vitro* dissolution studies suggest a direct relationship of concentration of superdisintegrants with drug release irrespective diluents used in the studies. As the amount of superdisintegrant increases the drug release also increases. The improved/increased drug release may be due to the minimum wetting time and lesser *in vitro* disintegrating time. Overall the results of the dissolution rate studies indicated greater dissolution rate of lansoprazole from fast dissolving tablets than the marketed sample which intern greater than the controlled tablets and the pure drug.

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Table 1: Different formulae of lansoprazole fast dissolving tablets.

Drug/ excipients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	Control-1	Control-2
Lansoprazole	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Pregelatinized starch	10	20	30	10	20	30	-	-	-	-	-	-	-	-
Treated agar	-	-	-	-	-	-	10	20	30	10	20	30	-	-
Microcrystalline cellulose	50	100	150	165	105	45	50	100	150	165	105	45	100	125
Mannitol	165	105	45	50	100	150	165	105	45	50	100	150	125	100
Aerosil	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Sodium saccharin	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Magnesium stearate	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Total weight of each tablet	250	250	250	250	250	250	250	250	250	250	250	250	250	250

Table 2: Precompression data of lansoprazole fast dissolving tablets.

Parameters	Bulk density	Tapped density	Carr's index	Hausner's ratio	Angle of repose
Prepared with Pregelatinized starch					
F1	0.401± 0.003	0.491 ± 0.004	18.32	1.22	25'23˚
F2	0.391± 0.003	0.466 ± 0.006	16.09	1.19	26'23˚
F3	0.382± 0.002	0.443 ± 0.004	13.76	1.15	27'34˚
F4	0.392± 0.003	0.477 ± 0.002	17.81	1.21	26'47˚
F5	0.381± 0.002	0.459 ± 0.002	16.99	1.20	28'23˚
F6	0.379± 0.002	0.440 ± 0.004	13.86	1.16	25'66˚
Prepared with Treated agar					
F7	0.399± 0.004	0.496 ± 0.002	19.55	1.24	26'33˚
F8	0.358± 0.006	0.468 ± 0.002	17.73	1.21	25'33˚
F9	0.379± 0.003	0.444 ± 0.003	14.63	1.17	27'33˚
F10	0.387± 0.004	0.465 ± 0.003	16.77	1.20	26'41˚
F11	0.379± 0.005	0.448 ± 0.003	16.51	1.19	28'22˚
F12	0.367 ± 0.004	0.426 ± 0.001	13.84	1.16	26'44˚

Table 3: Post compression data of F1 to F-6 lansoprazole fast dissolving tablets.

Parameters	F1	F2	F3	F4	F5	F6
Weight variation	250.07±0.02	250.01±0.002	250.1±0.015	249.95±0.03	249.92±0.021	250.05±0.005
Thickness(mm)	2.91± 0.02	3.04 ±0.04	3.05 ± 0.011	3.12±0.02	3.12 ± 0.02	3.08 ± 0.015
Diameter(mm)	10.03±0.057	10.13± 0.057	10.06±0.115	10.14±0.058	10.13 ± 0.057	10.10 ± 0.1
Hardness(kg/cm^2)	4.06± 0.057	3.93± 0.057	3.96 ±0.115	4.07±0.057	3.97 ± 0.058	4.0 ± 0.1
Friability (**%**)	0.48±0.0025	0.42 ±0.0011	0.123±0.0012	0.43±0.002	0.90 ± 0.0006	0.673±0.0005
Drug content (**%**)	99.42±0.83	99.29 ± 0.39	99.29±0.548	99.42±0.57	99.23 ± 0.38	99.55 ± 0.401
Wetting time(sec)	25.33± 0.58	23.66 ± 0.57	22.60 ± 0.577	26.60±1.15	23.70 ± 0.577	21.60± 1.528
Dispersion time(sec)	33.66 ±1.53	30.66 ± 0.58	22.7± 0.57	29±0.57	20.05 ± 0.59	18.7 ± 1.0
Disintegration time(sec)	13.6 ± 0.577	8.6 ± 0.578	9.3 ± 0.57	10.3±1.528	8.3 ± 1.528	8.0 ± 1.0

Table 4: Post compression data of F7 to F-12 lansoprazole fast dissolving tablets.

Parameters	F7	F8	F9	F10	F11	F12
Weight variation	250.05±0.015	249.97±0.005	249.98±0.021	250.03±0.03	250.1±0.035	250.0±0.011
Thickness(mm)	2.75 ± 0.01	2.75 ± 0.011	2.88 ± 0.026	2.98 ± 0.005	2.96±0.0110	2.76 ± 0.015
Diameter(mm)	10.03 ± 0.057	10.16 ± 0.058	10.10 ± 0.1	10.14±0.058	10.13±0.057	10.10 ± 0.0
Hardness(kg/cm^2)	4.0 ± 0.1	4.1 ± 0.1	4.06 ± 0.057	4.20 ± 0.0	4.06±0.0580	3.93 ± 0.057
Friability (**%**)	0.573 ± 0.002	0.89 ± 0.001	0.71 ± 0.0006	0.32±0.0005	0.296±0.005	0.414±0.0011
Drug content (**%**)	98.85 ± 0.828	99.54± 0.109	99.67± 0.295	98.28 ± 0.57	99.82±0.306	98.406 ± 0.58
Wetting time(sec)	24.60 ± 0.577	23.60 ± 0.578	21.00 ± 1.0	21.66 ± 0.57	20.00±0.012	17.40 ± 0.57
Dispersion time(sec)	36.7 ± 0.53	25.4 ± 0.58	25.32 ± 1.52	35 ± 0.57	15.33±0.580	13.7 ± 2.0
Disintegration time(sec)	12.0 ± 1.0	10.4 ± 0.57	10.3± 0.529	10.0 ± 1.0	9.0 ± 1.000	9.0 ± 1.0

Table 5: Comparative dissolution profiles pure druf, control-1, control-2, marketed product and fast dissolving tablets.

Batches	DP_{10} (%)	t_{50} min	DE_{10}	RDR_{10}	Hix.Crow $K_{HC} \times 10^2$ ($mg^{1/3}.min^{-1}$) R	First order rates $K_1 \times 10^2$ (min^{-1}) R
Pure drug	13.6	43.4	6.18	1	0.9941	0.9933
Control-1	47.1	10.6	21.25	3.46	0.9633	0.9427
Control-2	49.1	10.2	22.97	3.61	0.9697	0.9512
Marketed Product	68.2	6.5	43.87	5.01	0.9946	0.9362
F1	77.7	5.2	43.01	5.71	0.9974	0.9706
F2	79.1	5.1	45.13	5.81	0.9991	0.9784
F3	80.4	4.9	45.51	5.91	0.9980	0.9669
F4	73.6	5.8	42.96	5.41	0.9969	0.9712
F5	74.5	4.5	46.53	5.47	0.9938	0.9693
F6	76.6	4.3	48.75	5.63	0.9912	0.9603
F7	75.2	5.3	45.52	5.52	0.9975	0.9730
F8	80.7	4.9	48.54	5.93	0.9991	0.9839
F9	83.9	4.5	51.21	6.16	0.9982	0.9775
F10	75.3	5.4	44.80	5.53	0.9945	0.9592
F11	75.8	4.9	46.62	5.57	0.9929	0.9524
F12	77.9	4.7	48.27	5.72	0.9918	0.9407

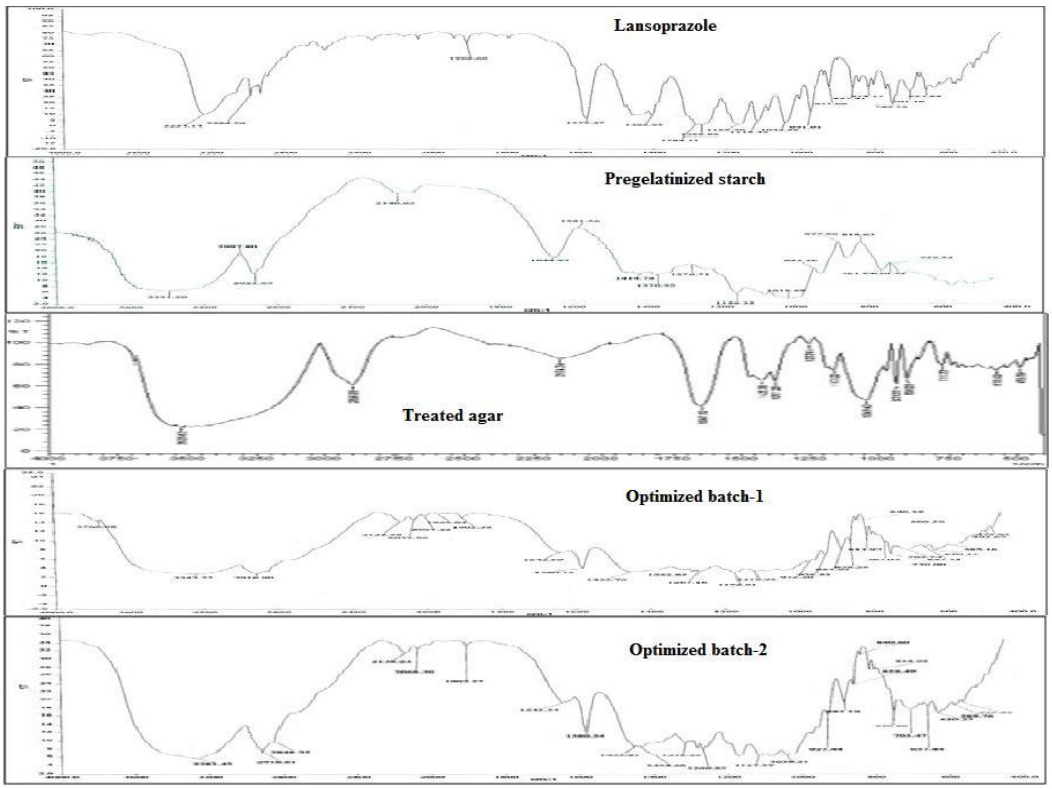

Figure 1: Comparative FTIR spectra.

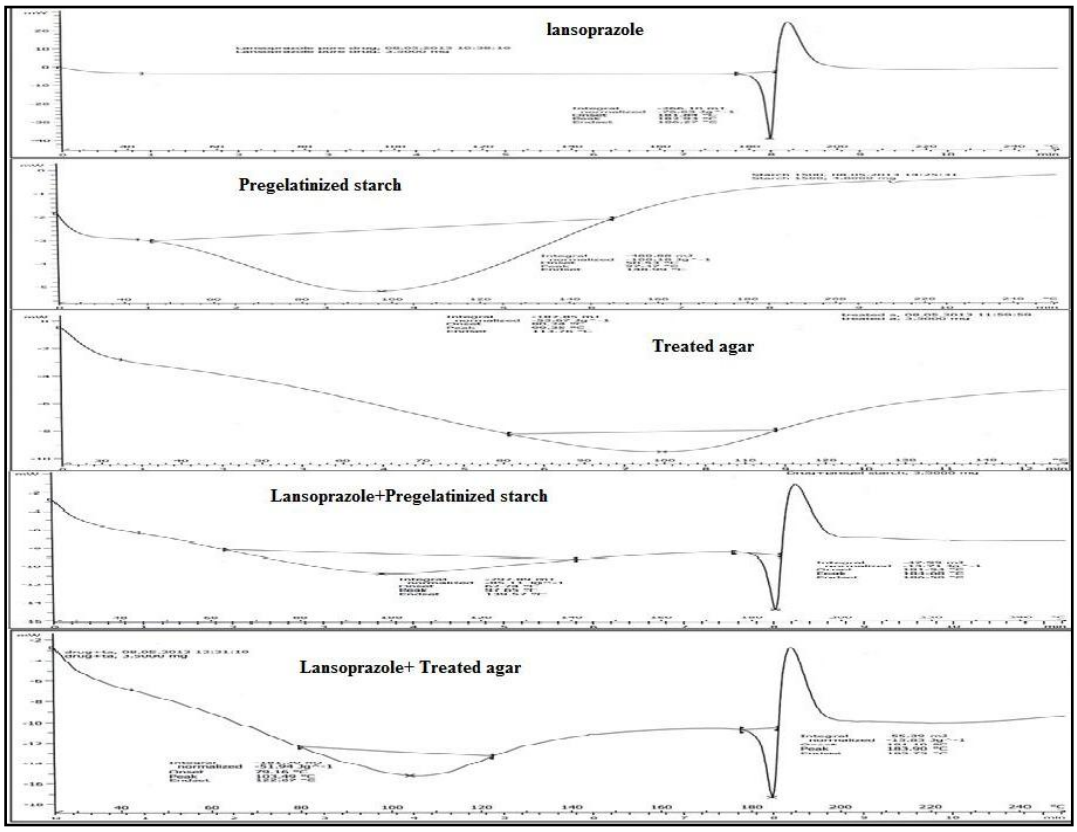

Figure 2: Comparative DSC spectras.

Figure 3: *In vitro* dispersion profile of F6 formulation.

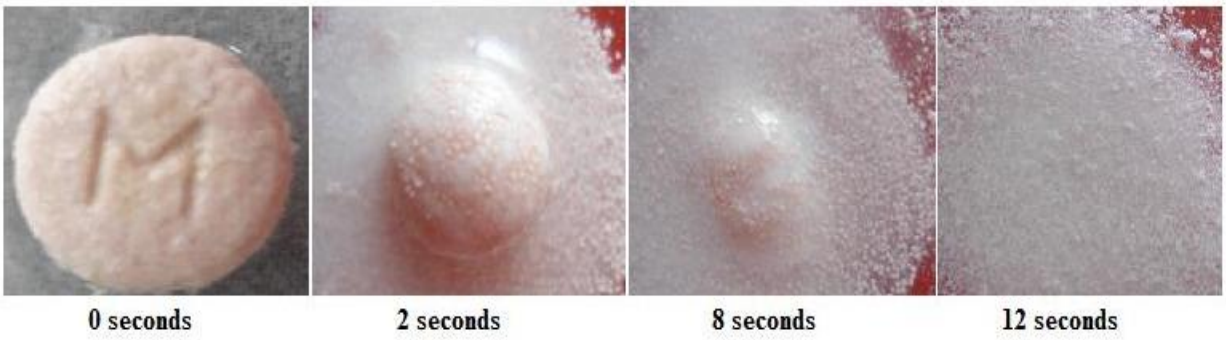

Figure 4: *In vitro* dispersion profile of F12 formulation.

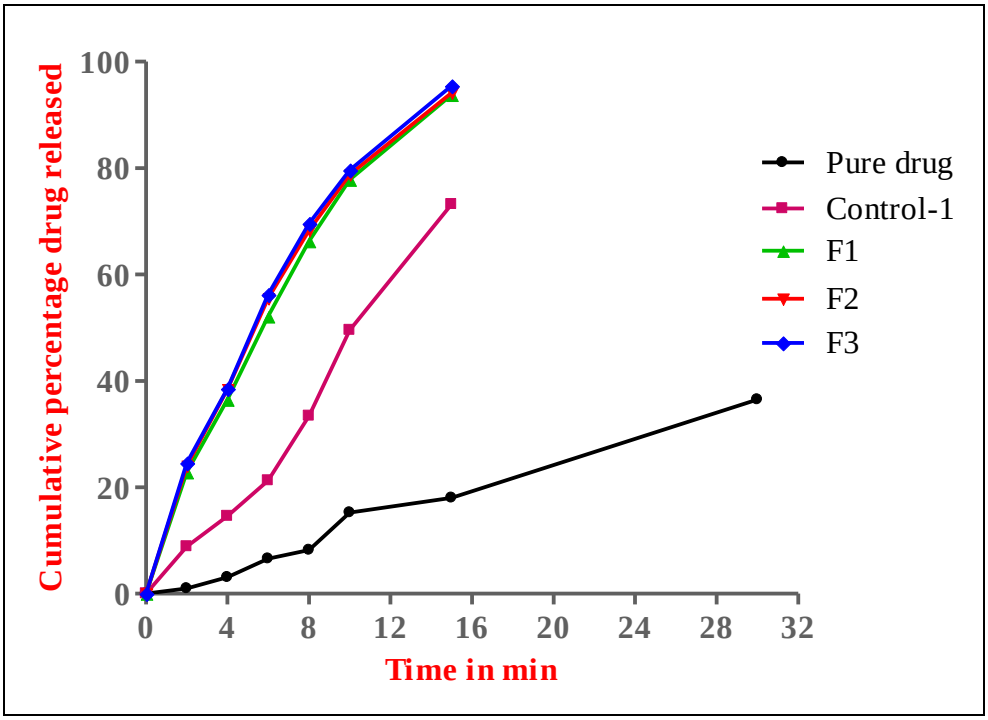

Figure 5: Comparative dissolution profiles of pure drug, control-1 and F1, F2 and F3 formulations.

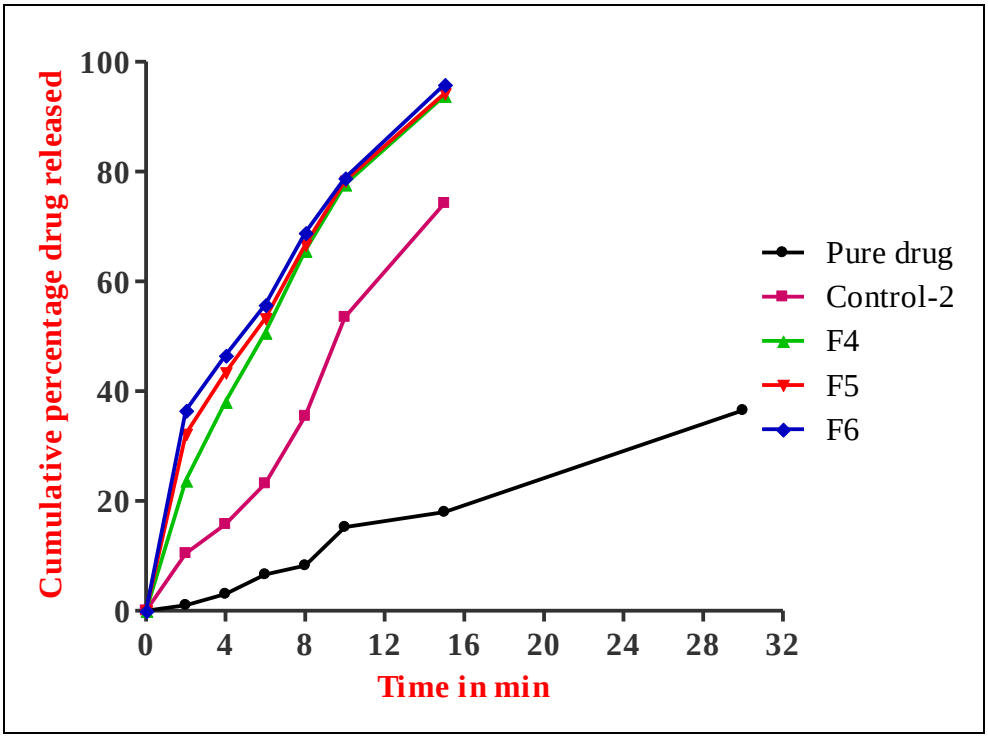

Figure 6: Comparative dissolution profiles of pure drug, control-2 and F4, F5 and F6 formulations.

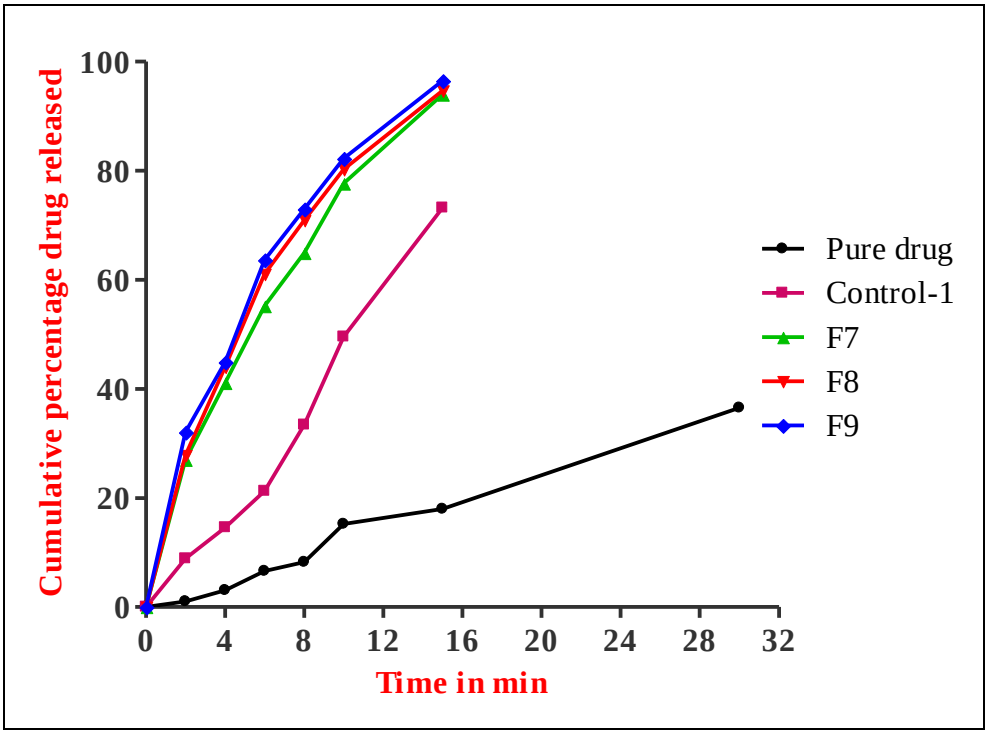

Figure 7: Comparative dissolution profiles of pure drug, control-1 and F7, F8 and F9 formulations.

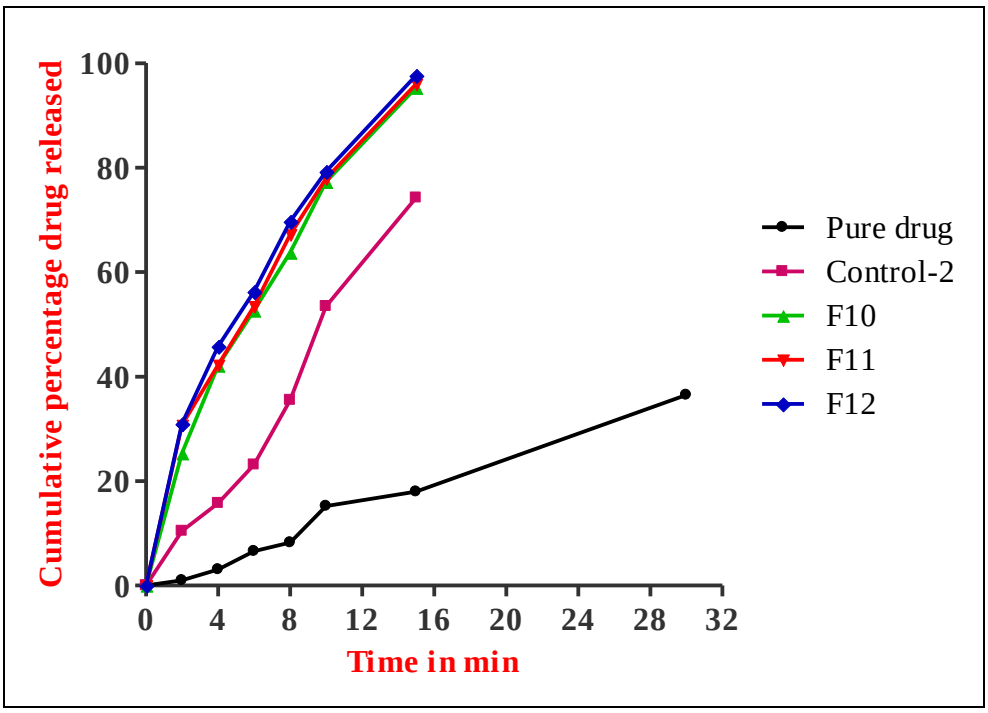

Figure 8: Comparative dissolution profiles of pure drug, control-2 and F10, F11 and F12 formulations.

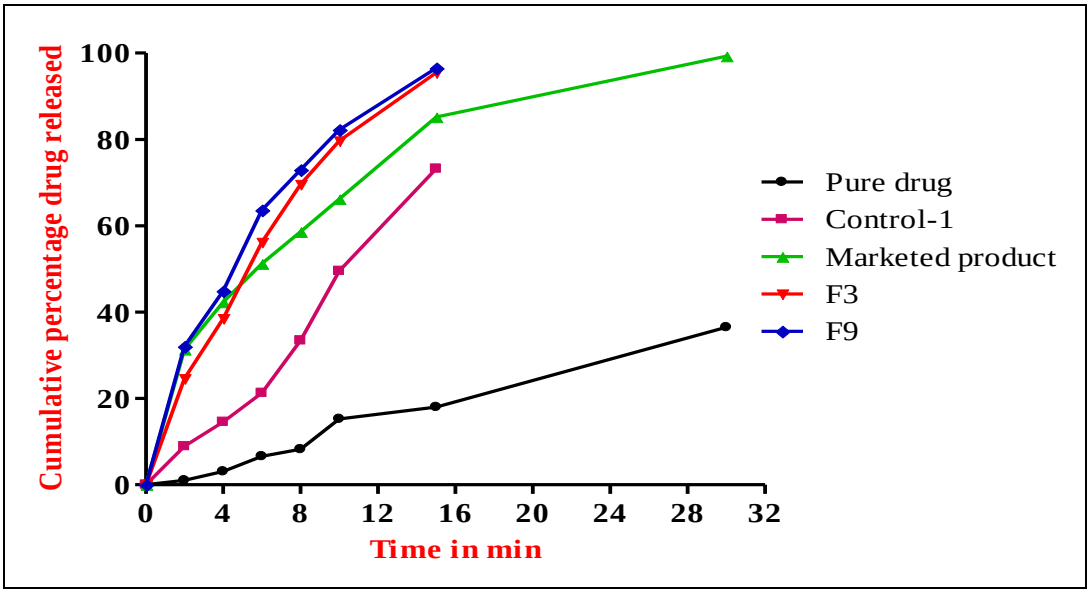

Figure 9: Comparative dissolution profiles of pure drug, control-1, marketed product, F3 and F9 formulations.

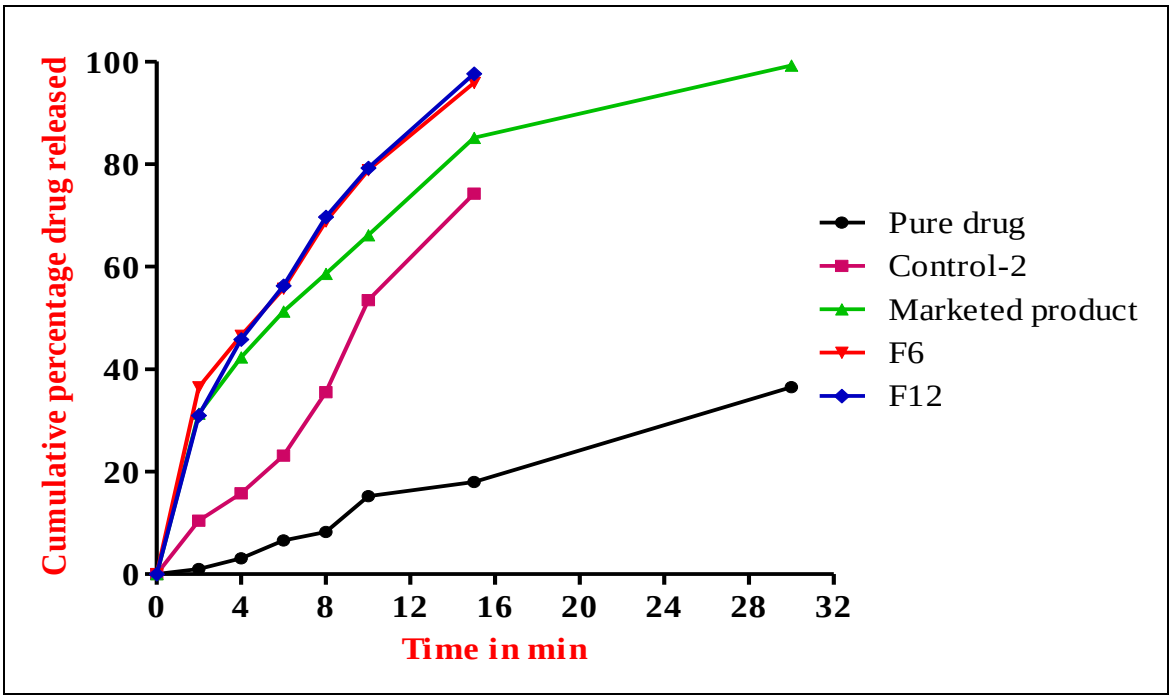

Figure 10: Comparative dissolution profiles of pure drug, control-2, marketed product, F6 and F12 formulations.