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DESIGN AND DEVELOPMENT OF CORE IN-CUP TABLET OF LANSOPRAZOLE

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Abstract:

In the present study colon targeted core-in-cup tablets of Lansoprazole was designed for effective treatment of inflammatory bowel disease. Colon targeted core-in-cup tablets were prepared in two steps. Core tablets were prepared by wet granulation technique and cup tablets were prepared by direct compression technique . The core tablets were kept in cup tablets and coated by using 10% cellulose acetate phthalate as enteric coating polymer. FTIR study confirmed that there was no interaction between drug and polymer. The core-in-cup tablets were subjected to various evaluation parameters and the results obtained were within the range. In order to simulate the pH changes along the GI tract, three dissolution media with pH 1.2, 7.4 and 6.8 were sequentially used. The dissolution profiles followed zero order kinetics and the mechanism of drug release was governed by peppas model. The diffusion exponent value(n) values were found to be more than 0.5 (n>0.5) , indicted that the drug release was predominantly controlled by non fickian diffusion. The release rate of drug from the core tablets can be governed by the concentration of natural polymer employed in the preparation of tablets. Among all the formulations Lansoprazole tablets prepared with Moringa olifera gum in 1:1 ratios shown controlled drug release for a period of 12 hours. The obtained results revealed the capability of the designed formulation in delaying drug release for a programmable period of time and to show the targeted drug delivery in the colon region for effective treatment of Peptic ulcer

Keywords: *Lansoprazole , Biodegradable gums, film coat, core in cup tablet*

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INTRODUCTION:

Lansoprazole is an acid proton pump inhibitor. Lansoprazole is a benzimidazole sulfoxide derivative and produces long lasting inhibition of gastric acid secretion. Lansoprazole is effective in the treatment of duodenal or gastric ulcer, gastro esophageal reflux disease and in the treatment of zollinger-ellison syndrome[1] .

In Peptic ulcer patients, pain, gastric distress and acute exacerbation of the disease are most likely in the late evening and early morning hours. Ulcer pain typically occurs after stomach emptying, following daytime meals and in the very early morning, disrupting sleep. This is attributed to high gastric secretion and slows gastric motility and emptying at night. Suppression of nocturnal acid is an important factor in duodenal ulcer healing. Once daily nocturnal administration of proton pump inhibitor medications not only reduce acid secretion more effectively but also promotes ulcer healing and reduce ulcer occurrence[2].

The rational of this study is to design and evaluate an oral site-specific, pulsatile drug delivery system containing Lansoprazole, which can be targeted to colon in a pH and time dependent manner, to modulate the drug level in synchrony with the circadian rhythm of nocturnal acid secretion. In the present research work, we have attempted to develop a novel dosage form by using a chronopharmaceutical approach [3].

Colonic drug delivery is also useful for better systemic absorption of drugs because of less hostile environment prevailing in the colon compared to stomach and small intestine. The present study was undertaken to design the colon targeted drug delivery system of Lansoprazole through core-in-cup tablet technique. Due to the distal location of the colon in the gastrointestinal tract, core-in-cup tablet should prevent drug release in the stomach and small intestine and produce an gradual onset of drug release upon entry into the colon[5]. Most of the strategies in time-dependent drug delivery are dependent on the principle to delay the drug release until approximate influx in the colon region. Although the relative consistency of transit times in the small intestine is because of the potentially large variation in gastric emptying time, the colon influx time cannot be exactly predicted. Therefore, by suppressing drug release in the stomach and thus reducing the effect of variations in gastric residence time, appropriate integration of pH-sensitive and time-dependent systems in a single dosage form should improve colon drug delivery. The release of water-soluble drug from a water-soluble polymeric platform is often rapid, and therefore hydrophobic polymer may be included within the matrix formulation to offer a greater control drug release [6]. Cellulose acetate phthalate coat was employed to delay the penetration of dissolution medium into the matrix, thereby delaying the drug release for a programmable period of time and to show the targeted drug delivery in the colon region [7]. Due to the distal location of the colon in the gastrointestinal tract, core and cup technique should prevent drug release in the stomach and small intestine and produce gradual onset of drug release upon entry into the colon [8].

MATERIALS AND METHODS:

Lansoprazole was generously gifted by RPG Life Sciences Ltd. (Mumbai, India). All the chemicals utilized were of suitable analytical grade and used as and when required. Biodegradable-natural Gums were procured from Nutriroma Company at Hyderabad and all the chemicals required were purchased from national scientifics, Guntur.

Preparation of Lansoprazole core tablet: The controlled release matrix tablet of Lansoprazole was prepared by wet granulation method [9]. The required quantities of Lansoprazole , PVPK-30 (as a binder), Moringa olifera gum or Almond gum(as a polymers) and lactose (as a diluent) were weighed as per formula given in Table 1. These ingredients were mixed uniformly and prepared a wet mass by addition of binder solution. The wet mass was passed through sieve number #12 and allowed to drying for 30 minutes in a tray dryer for 60^0C. The dried granules were passed through the sieve number #16 and finally lubricated with talc and magnesium stearate. The obtained dry granules were weighed into individual tablets and finally compressed into the tablet by 16 station rotary tablet compression machine using 9mm flat punches. (RIMEK, Karnavati Engineering Ltd., Gujarat, India)[10].

Preparation of cup tablet: The cup formulations were formulated by direct compression technique. Ethyl cellulose, microcrystalline cellulose, talc and magnesium stearate were weighed and mixed uniformly according to the formula shown in Table-2. The powder mixture was compressed by 16 station rotary tablet compression machine by using special punch designed and fabricated, to prepare cup tablets. The newly designed upper 12 mm punch has protrusion and lower punch (12mm) remains flat faced [11].

Evaluation of granules

Flow properties of the prepared granules were evaluated using standard reported methods[6].Weight variation test was conducted as per specifications of IP. Hardness and friability of the tablets formulated were evaluated using a Monsanto hardness tester and a Roche friabilater respectively.[12]

Preparation of core in cup tablet: The cups were placed in a 12mm die cavity and core tablet was inserted into the cups and compressed with 12mm flat faced punches. The composition of the core in cup tablets was given in Table 3.

Enteric coating : Core in cup tablet were further coated with enteric coating polymer(cellulose acetate phthalate) by spray coating method. 5% or 7.5 % or 10% w/ w cellulose acetate phthalate in 8:2 (v/v) mixture of acetone: ethanol plasticized with dibutylphthalate (0.75%), was used as a coating solution. Talc (0.1% w/v) was added as anti-adherant and the solution was stirred for 15 min. Placed the core in cup tablets into a coating pan, the coating solution was sprayed over the tablets by R&D coater, rotating with a speed of 15 rpm, the pressure of the spray gun was maintained at 0.1 M.Pa and the air temperature was maintained at 35-40^{0}C.[13]

Post compression evaluation of Lansoprazole tablets [14]:

Weight variation For estimating weight variation, 20 tablets of each formulation were weighed using an electronic balance (Denver Instrument, Gottingen, Germany) and the test was performed according to the official test.

Thickness The thickness of the tablet was measured using a Digital Vernier Calliper (Mitutoya Digimatic Calliper, Kanagawa Japan).

Hardness The crushing strength of ten tablets was measured using Monsanto tablet hardness tester (Interlabs, Ambala, India). A tablet hardness of about 5-7 kg/cm is considered adequate for mechanical stability.

Friability The friability of the tablets was determined in Roche Friabilator (Model 902, EI product, Panchkula, India). Thirty five tablets were weighed accurately from each batch of tablets and placed in the tumbling chamber and rotated at 25 rpm for a period of 4 min. Tablets were taken and again weighed. The percentage loss was determined by using the formula % **Friability**= ***Initial weight of tablets−Final weight of tablets/Initial weight of tablets*** X 100 The results of Post compression parameters were reported in Table-5**.**

Estimation of drug content: The drug content in each formulation was determined by triturating 20 tablets and The drug equivalent to 30 mg was placed in 100 ml volumetric flask and final volume was made up to 100 ml with 6.8 pH phosphate buffer. Then the samples were taken with suitable dilutions and concentration of drug in the samples was measured by using U.V visible spectroscopy at 285 nm.[15]

Determination of post Compressional parameters of cup tablets [16]:

Depth of the cavity: Depth of the cavity of cup tablets was determined by using thread and scale.

Friability: The friability test for cup tablets were determined by using Friabilator .

Thickness: The thickness of the cup tablets were determined by using Vernier calipers .

Evaluation studies of enteric coated Lansoprazole core in cup tablets:

Disintegration test for enteric coated Lansoprazole core in cup tablets: Compendial in-vitro test methods for enteric coated tablets have traditionally relied on a two stage disintegration type test in order to confirm enteric performance. Six tablets were initially treated in tablet disintegration tester using 0.1 M Hcl for 2 hrs, then the tablets were subjected to further 3 hr in 7.4 Ph phosphate buffer[17].

Dissolution test for enteric coated Lansoprazole core in cup tablets:

In-vitro dissolution studies of enteric coated core in cup tablets were possessed by using dissolution apparatus (USP II) paddle method. Enteric coated core in cup tablet formulations were selected based on dissolution studies for the core tablets. In order to simulate the pH changes along the GI tract, three dissolution media with pH 1.2, 7.4 and 6.8 were sequentially used referred to as sequential pH change method. When performing experiments, the pH 1.2 medium was first used for 2 hours (since the average gastric emptying time is 2 hrs.), then removed and the fresh pH 7.4 phosphate buffer saline (PBS) was added. After 3 hours (average small intestinal transit time is 3 hrs.), then the medium was removed and colonic fluid pH 6.8 buffer was added for subsequent hours. Nine hundred milliliters of the dissolution medium was used at each time. Rotation speed was 100 rpm and temperature was maintained at 37±0.5ºC. Enteric coated Lansoprazole core in cup tablets equivalent to 30 mg of Lansoprazole was used in each test. Five milliliters of dissolution media was withdrawn at predetermined time intervals and fresh dissolution media was replaced. The withdrawn

samples were at 285 nm for Lansoprazole respectively, by UV absorption spectroscopy and the cumulative percentage release was calculated over the sampling times[18].

RESULTS AND DISCUSSION:

In the present study colon targeted core-in-cup tablets were prepared in two steps. Core tablets were prepared by wet granulation technique by using natural gums and cup tablets were prepared by direct compression technique by using hydrophobic polymer.

The granules were characterized with respect to angle of repose, bulk density, tapped density, carr's index, and hausner ratio. The granules evaluation results were depicted in Table 4. The angle of repose of different formulation batches from F1 to F6 was found to be less than 30° for all the formulation batches of granules, indicating good flow behavior. Similarly, bulk density and tap density of all the formulation batches from F1 to F6 were found to be good flow properties of the granules. The Carr's index of all formulation batches was in the acceptable range of below 16. The Hausner ratio less than 1.25 indicates good flowability .

The weight of each tablet was determined to be within the range of 200 ± 5 mg in order to maintain the relatively constant volume and surface area. All the formulated preparations were subjected to weight variation, hardness, friability and drug content. All tablets complied I. P. weight variation test requirement. The hardness was found to be in between 4 - 5 kg. The tablets satisfied USP friability requirement, as the % friability values are less than 1%. The percent drug content was found to be with in 98 - 102% of the labeled amount and hence complied drug content requirement. The core tablet was successfully coated by coating technique and further core-in-cup tablet was coated with varying proportion of cellulose acetate phthalate. The results of the *in vitro* dissolution studies of different batches of coated tablets indicated that increase in concentration of cellulose acetate phthalate from 5% to 7.5% w/w and 10% w/w and keeping constant weight gain in thickness of polymers at 10% w/w, the lag time (the time required for drug release in SCF) was significantly increased to 5h. The lag time was determined by separately running dissolution studies of cellulose acetate phthalate coated (5% to 7.5% w/w and 10% w/w) tablets in SCF for 5 hours at minimum time intervals. The amount of cellulose acetate phthalate coat was the key factor for such lag time. Lower amount of cellulose acetate phthalate coat shows shorter lag time, and higher amount shows longer lag time. Core-in-cup tablet with a coating level of 10% w/w showed a lag time of 5 hr corresponds to time required to reach colonic region. During dissolution studies, it was observed that, the enteric coated core in cup tablets was intact for 2 hrs in pH 1.2, and also in intestinal pH 7.4 for 3 hours. With all the formulations, there was absolutely no drug release in pH 1.2 and also in intestinal pH 7.4., thus indicating the efficiency of 10% cellulose acetate phthalate for enteric coating.

From the *In-vitro* release studies of Core-in-cup tablet, it was observed that with all formulation, there was absolutely no drug release in simulated gastric fluid (acidic pH 1.2) for 2 hours and in simulated intestinal fluid (pH 7.4 phosphate buffer). But slow release was found in colonic medium (pH 6.8 phosphate buffer). *In-vitro* release profiles in colonic medium were found to have very good sustaining efficacy and shown in figure 1&2. The tablets prepared with Moringa olifera gum in 1:0.5, 1:1 and 1:1.5 ratios shown sustained drug release for a period of 10 hours, 11 hours and 12 hours respectively and tablets prepared with Almond gumin 1:0.5, 1:1 and 1:1.5 ratios shown sustained drug release for a period of 9 hours, 10 hours and 11 hours respectively.

To ascertain the mechanism of drug release, the dissolution data was analyzed by zero order, first order, and higuchi and peppas equations.When the amount of drug release values were plotted against time straight lines were obtained in all the cases indicating that the rate of drug release from these matrix tablets followed zero order kinetics. The plot of log % Drug Released vs log time (peppas plots) were drawn. The plots were found to be linear with all matrix tablets . Release Kinetics of matrix tablets , the time required to get 50% drug release (T_{50}) and 90% drug release (T_{90}) was calculated and were shown in Table 8.The exponential coefficient (n) values were found to be in between 0.7199 to 0.7908 , indicating that the drug release followed non fickian mechanism. These results indicated that the release rate was found to decrease with increase in concentration of natural polymer employed.

It is concluded from the present study that appropriate combination of a pH-dependent polymer (Eudragit RS100) with a overcoat of cellulose acetate phthalate was suitable for adequately sustained drug release and to protect Lansoprazole from being released in the upper region of the GI system. The in vitro drug release studies indicate that the optimized formulation was a promising system targeting Lansoprazole to the colon. The drug release pattern

from all formulations was best fitted Korsmeyer-Peppas equation with non-Fickian diffusion kinetics. Tablet with a coating level of 10 % w/w showed a lag time of 5 hr corresponds to time required to reach colonic region.The coating polymers exhibited good results in targeting the colonic study.

CONCLUSION:

Formulation- F3 was found to be more efficient controlled release in delivering the drug Lansoprazole to the colonic site . The obtained results showed the capability of the designed formulation in delaying drug release for a programmable period of time and the possibility of exploiting such delay to attain colon targeting.

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Table 1: Lansoprazole Core formulations:

Formula	Moringa oleifera gum			Almond gum		
	F_1	F_2	F_3	F_4	F_5	F_6
	1:1	1:2	1:3	1:1	1:2	1:3
Lansoprazole (mg)	30	30	30	30	30	30
Polymer (mg)	30	60	90	30	60	90
PVP K-30 (mg)	10	10	10	10	10	10
Lactose (mg)	125	95	65	125	95	65
Isopropyl alcohol (ml)	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Magnesium stearate (mg)	3	3	3	3	3	3
Talc (mg)	2	2	2	2	2	2
Total (mg)	200	200	200	200	200	200

Table 2: Lansoprazole Cup formulations

Ingredients	C_1	C_2	C_3	C_4	C_5	C_6
Ethyl cellulose	442	442	442	442	442	442
Mg. stearate	4	4	4	4	4	4
Talc	4	4	4	4	4	4
Total	450	450	450	450	450	450

Table 3: Lansoprazole Core in cup formulations

S.No	Core in cup formulations	Combination of core and cup formulations
1	LCC_1	F_1 (core) + C_1 (cup)
2	LCC_2	F_1 (core) + C_2 (cup)
3	LCC_3	F_1 (core) + C_3 (cup)
4	LCC_4	F_1 (core) + C_4 (cup)
5	LCC_5	F_1 (core) + C_5 (cup)
6	LCC_6	F_1 (core) + C_6 (cup)

Table 4: Micromeritic properties of formulation blend of Lansoprazole core tablets

Formulation	Evaluation parameters				
	Bulk density (g/ml)	**Tapped density (g/ml)**	**Compressibility index (%)**	**Hausner's Ratio**	**Angle of Repose (θ)**
F_1	0.276±0.014	0.314±0.013	12.10±0.024	1.137±0.012	26.94±0.021
F_2	0.350±0.012	0.408±0.011	14.21±0.022	1.161±0.014	26. 6±0.031
F_3	0.320±0.020	0.370±0.009	11.89±0.009	1.134±0.017	26. 42±0.052
F_4	0.319±0.005	0.362±0.021	11.87±0.017	1.130±0.024	26.85±0.024
F_5	0.351±0.009	0.393±0.019	10.68±0.014	1.119±0.014	27.01±0.035
F_6	0.255±0.025	0.291±0.005	12.37±0.024	1.142±0.014	26. 76±0.05

Table 5 : Physical properties of Lansoprazole core tablets

Formulation	Evaluation parameters			
	Drug content(%)	Average weight (mg)	Friability (%)	Hardness (kg/cm^2)
F1	99.45	200±1.2	0.76	4.2±0.021
F2	99.27	200±2.2	0.64	4.3±0.012
F3	99.52	200±1.8	0.52	4.4±0.017
F4	99.57	200±1.4	0.85	4.1±0.032
F5	99.28	200±1.2	0.77	4.2±0.024
F6	100.23	200±1.3	0.69	4.3±0.028

Table: 6: Results of post-compressional parameters for cup tablets

S.No	Post-compressional parameters	C_1	C_2	C_3	**C_4**	**C_5**	**C_6**
1	Depth of the cavity (mm)	3.1±0.02	3.1±0.12	3.1±005	3.1±0.03	3.1±0.09	3.1±0.05
2	Friability (%)	0.47	0.42	0.39	0.52	0.44	0.33
3	Thickness (mm)	4.52	4.68	4.71	4.73	4.66	4.67

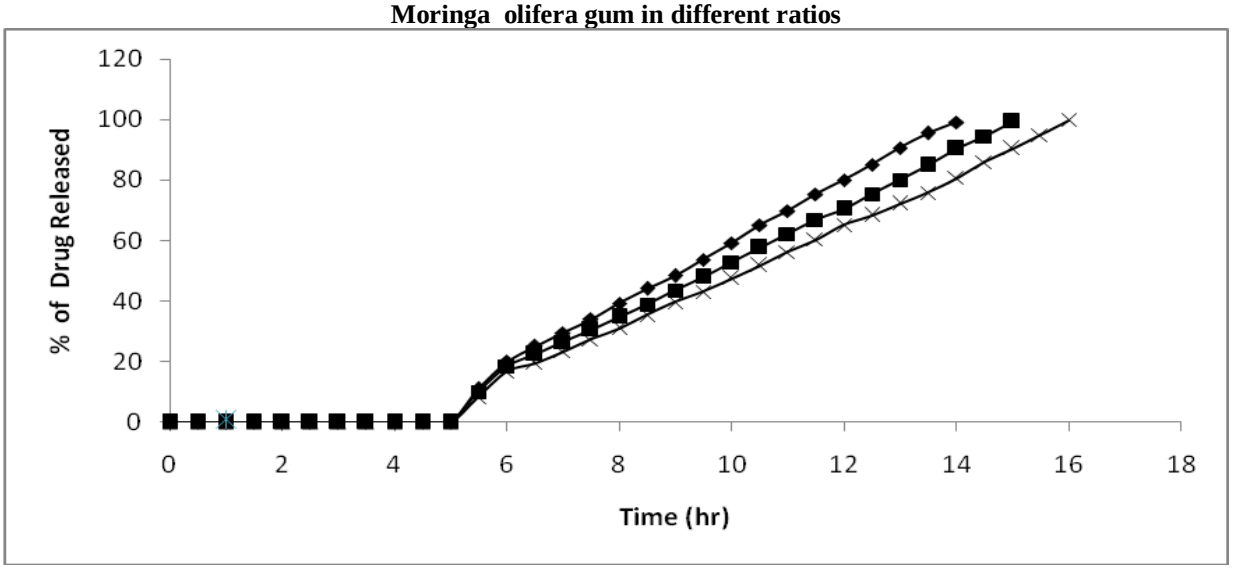
Table 7: Results of Disintegration Test For Enteric coated core in Cup tablets

S.No	**Disintegration signs**	LCC_1	LCC_2	LCC_3	LCC_4	LCC_5	LCC_6
1	1st hour	No sign	No sign	No sign	No sign	No sign	No sign
2	2nd hour	No sign	No sign	No sign	No sign	No sign	No sign
3	3rd hour	No sign	No sign	No sign	No sign	No sign	No sign
4	4th hour	No sign	No sign	No sign	No sign	No sign	No sign
5	5th hour	No sign	No sign	No sign	No sign	No sign	No sign

Table 8: *In vitro* drug release kinetic data of Lansoprazole core in cup tablets prepared with natural polymeres in different ratios

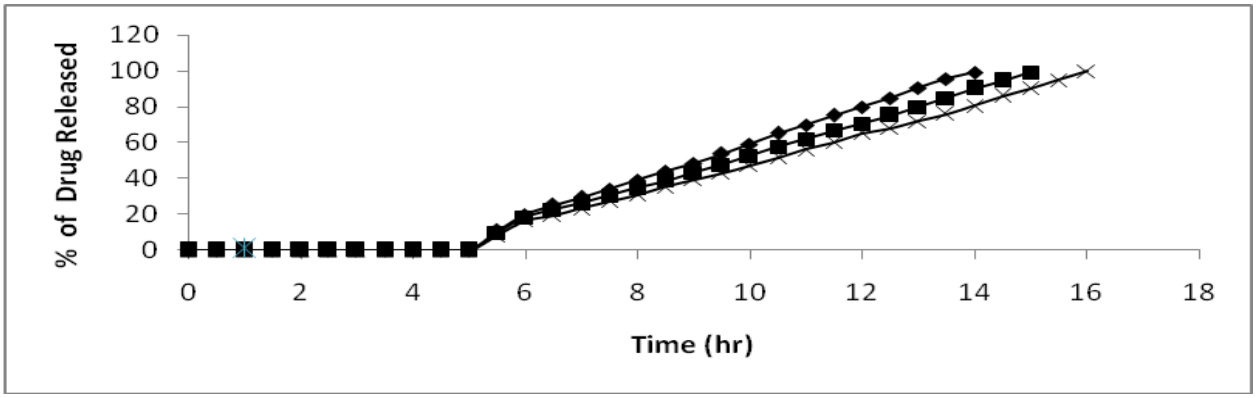
Formulation	Correlation Coefficient Value				Release Rate Constant (mg/hr)k_0	Exponential Coefficient (n)	T_{50} (hr)	T_{90} (hr)
	Zero Order	First Order	Matrix	Peppas				
LCC_1	0.9999	0.9340	0.9879	0.9999	3.73	4.02	7.23	1.003
LCC_2	0.9998	0.9254	0.9877	0.9998	3.03	4.95	8.91	1.019
LCC_3	0.9997	0.9289	0.9862	0.9995	2.49	6.02	10.84	1.018
LCC4	0.9999	0.9396	0.9865	0.9999	3.98	3.76	6.78	1.0181
LCC5	0.9997	0.9266	0.9860	0.9995	3.13	4.79	8.62	1.0188
LCC6	0.9996	0.9233	0.9864	0.9992	2.74	5.47	9.85	1.0245

Figure: 1. Comparative *In-vitro* drug release profile plot of core in cup tablets of Lansoprazole prepared with Moringa olifera gum in different ratios



(-■-)LCC1: Formulation prepared with 1:0.5 ratio of drug and polymer.
(-♦-)LCC2: Formulation prepared with 1:1 ratio of drug and polymer.
(-×-)LCC3: Formulation prepared with 1:1.5 ratio of drug and polymer.

Figure: 2. Comparative *In-vitro* drug release profile plot of core in cup tablets of Lansoprazole prepared with Almond gum in different ratios



(-■-)LCC4: Formulation prepared with 1:0.5ratio of drug and polymer.
(-♦-)LCC5: Formulation prepared with 1:1 ratio of drug and polymer.
(-×-)LCC6: Formulation prepared with 1:1.5 ratio of drug and polymer.