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Design, Development and *In-Vitro* Characterization of Lansoprazole Delayed Release Enteric Coated Pellets in Capsules

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ABSTRACT

The Current scientific work would be "Design, Progress and *In-Vitro* Categorization like Lansoprazole Delayed launch Capsules" indeed a categorization of proton pump inhibitor utilized during diagnosis like gastro esophagus acid reflux disease, erosional esophagitis as well as acid associated conditions. Lansoprazole would really an acid fragile opoid. That as well degrades with inside the acidic environment of it abdomen thereby resulting in therapeutic inefficacy. And thus will be essential to bypass an acidic nature of an abdomen. A current scientific task focus primarily on collection one of opoid would be Lansoprazole but also components like varied by HPC-L as well as eudragit L30 D55 have been also utilized even though enteric polymeric materials. An enteric coated granules seem to have been prepare through suspended layer-based particular method through fluidization processor. 10 compositions (F1 - F10) Lansoprazole enteric coated granules seem to have been ready wide variation a composers like drug loading, barrier coating as well as enteric covering. FT-IR has been manage to perform of about recognise this same suitability (compatibility) of some like the drug with assorted components various and SEM analysis had been done of about realize this same morphological characteristics of something like the pellets. In All 10 formulations were also maintained regarding Stability studies and done as three months there as 40°C/75 %RH but also 25°C/60 % RH as per ICH guidelines. A prepared formulations F 10 would be being shown advantageous *in vitro* acid as well as buffer release of drug in as during consistency timespan but also corresponding to a originator.

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INTRODUCTION

The first objective that use delayed launch items will be to save a opoid through the esophageal secretions, to decrease stomach damage induced whilst also drugs notably irritating toward the abdomen or even to assist normal gastrointestinal for opioids which are highly bioavailable through the stomach. Delayed launch items were being generally enteric-coated but also focused to that same colon [1].

Enteric coatings would those be that also persist untouched inside abdomen, even though this will

dissolve and release this same components once this began to reach a small bowel. With there prime should be defer the discharge of medicine where it also are inactivated by both the stomach content material or it may induce diarrhea and hemorrhaging through irritation of gastric mucosa. It and aims of a research analysis will be to establish to create a pharmaceutically reliable, cost-efficient as well as performance improved composition like Lansoprazole delayed release enteric coated pellets such as capsules [2].

MATERIAL AND METHODS

Lansoprazole was gift sample Lee pharma Ltd, HPC NF (LH-31), Magnesium carbonate heavy, Polysorbate 90, HPC-L, Maize starch, Titanium dioxide, Eudragit L30D55, Talc, Polysorbate 80, Macrogol 6000, Talc, silica colloidal anhydrous was found merck Pvt. Ltd.

All abundant chemical as well as chemical agent utilized in this study are of analytical grade.

Methodology

Drug - Excipient interaction

Fourier Transform Infrared Spectral (FT-IR) Analysis

FT-IR spectra determine the positions and relative sizes of all the absorptions, or peaks, in the IR region. Samples were analyzed by pressed pellet technique using KBr [3].

Formulation Development

Formulation Development of Delayed Release Capsules

Based on preformulation data the assorted excipients have been choosen and their compilation [4].

Preparation of Lansoprazole Enteric Coated Pellets

Lansoprazole enteric coated pellets seem to have been able to prepare besides covering that whole fructose spheroidal with opoid but also polymeric materials as for measure the concentration while utilising suspension layer-based method through fluidization processor [5].

Drug Layering

Weigh all the excipients separately as per formula. Mill sucrose (200 mesh passed) in multi mill using 8.0mm screen, knife forward at fast speed. Sift low substituted-Hydroxy propyl cellulose (LH-31), maize starch and heavy magnesium carbonate through 850mm mesh (ASTM, #20 mesh). Mix lansoprazole geometrically with material of step No: 2 and step No: 3 and sift through 850mm mesh (ASTM, #20 mesh). Load the materials of step 4 in suitable blender and mix for 30mins at low shear. Heat total dispensed quantity of purified water to 40-50^{0}C; Dissolve polysorbate 80 in 40% purified water from total quantity of dispensed purified water to get clear solution. Dissolved HPC-L separately under stirring in remaining 60% purified water to get clear solution. Add step 6 to step 7 under stirring at low shear and cool the solution at room temperature. Filter binder solution through 150mm mesh (ASTM, #100 mesh). Load sugar spheres in Fluid bed processor and adjust rotation speed and inlet air blower as per requirement. Start spraying binder solution on rotating sugar spheres with dusting. Drug layering blend by using dozer at synchronized rate. Continue drug layering to get the 100.71 to 104.71% build up on pellets. Dry rug layered pellets at product temperature 40^{0}C $\pm$ 2^{0}C, in fluid bed processor to achieve LOD of the drug layered pellets should be NMT 2% m/m at 105^{0}C $\pm$2^{0}C auto mode using IR moisture analyzer. Sift drug layered pellets of step No: 12 through 1000mm mesh (ASTM, #18 mesh) and reject the retentions [6].

Size the 1000um mess (ASTM, #18 mesh) passed drug-layered pellets of step 14 through 600mm mesh (ASTM, #30 mesh) and reject the passing. Collect the drug layered pellets retaining on 600mm mesh (ASTM, #30mesh) and store in air tight triple laminated poly-bags with sufficient quantity of silica bags at controlled temp [Table 1].

Seal Coating Process

Weight all the excipients separately as per formula for seal coating. Transfer 20% of preheated (40-50^{o}C) purified water from total quantity of dispensed purified water into a suitable vessel with stirrer. Add HPC-L under stirring vortex to dissolve completely and to get clear solution. Prepare wet paste of low substituted-HPC (LH-31) with 45% purified water from total quantity of dispensed purified water. Prepare solution of sucrose (40/80 mesh) in 20% purified water from total quantity of dispensed purified water with a stirring and add maize starch to it under stirring into vortex to get homogenized dispersion. Suspend titanium dioxides in 15% purified water for total quantity of dispensed purified water within stirring and continue stirring to get a homogeneous suspension and stir for 30mins to get homogenized dispersion of 20%m/m [7].

Filter seal coating through 425um mesh (ATSM, #40 mesh). Load the shifted drug layered pellets in fluid bed processor (Wurster process). Start the spray of coating dispersion, when the product bed tem-

perature is about $35^0C\pm 2^0C$. And maintained the bed temp $35^0C\pm 2^oC$ through the processor. Record the coating parameters and continue coating to get the 29.76 to 33.76% build up on drug layered pellets. Dry seal coated pellets at products temp $40^0C \pm 2^0C$ up to LOD of the seal coated pellets should be NMT 2.0% m/m at $105^0C\pm 2^0C$ auto mode using IR moisture analyzer [Table 1]. Sift the seal coated pellets of step 12 through 1200mm mesh (ASTM, #30 sieve) and reject the retentions. Size the 1200um mesh (ASTM, #16 sieve) passed seal coated pellets of through 600mm mesh (ASTM, #30 sieve) and reject the passing. Collect the seal coated pellets retaining on 600mm mesh (ASTM, #30 sieve) and store in air tight triple laminated poly-bags with sufficient quantity of silica bags at controlled temp [8].

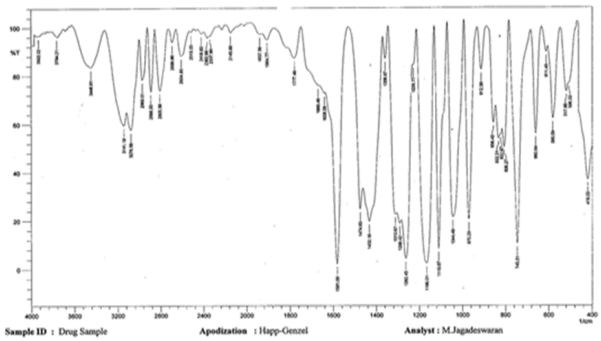

Figure 1: FTIR Spectral Obtained for Pure Drug

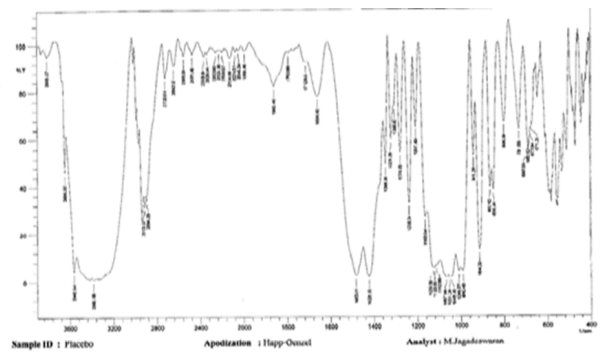

Figure 2: FTIR Spectral Obtained for Excipients of Lansoprazole

Enteric Coating Process

Dispensed all the excipients separately as per formula for enteric coating. Dispense the required quantity of purified water. Suspend Talc in 20% purified water from total quantity of dispensed purified water while stirring and continue stirring to get a homogeneous suspension. Dissolve polysorbate in purified water (quantity approximately twice the quantity of polysorbate 80) heated to 40 to 50^oC. Dissolve macrogol 6000 in 20% purified water from total quantity of purified water to get clear solution and remaining quantity of purified water eudragit

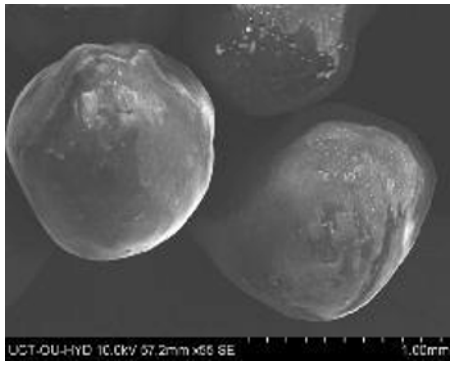

Figure 3: SEM Images Optimized Formulation F10

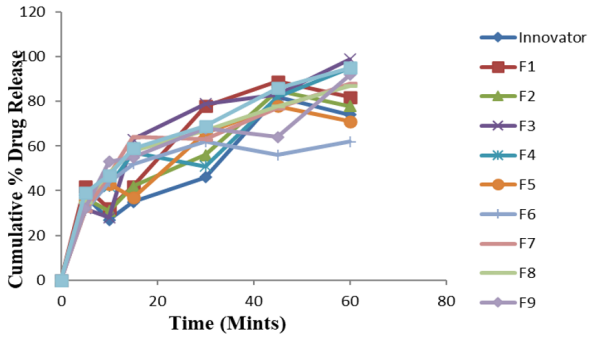

Figure 4: Comparative Dissolution Profiles of Formulations (F1-F10) with Innovator

L 30 D-55 dispersion under low shear stirring and continue stirring 45mins under low shear to get homogenized dispersion. Filter step No: 6 dispersion through 250mm mesh (ASTM, #100 mesh) [Table 1].

Load the seal coated pellets in fluid bed processor (Wurster processor). Start the spray of coating solution with continuous stirring, at the product bed temp is about $30.0C\pm 2.5^oC$. Cary out enteric coating under critical observation of all parameters to get 18 to 22% m/m build up on seal coated pellets. Dry enteric coated pellets at product temp $40^0C\pm 2^0C$, for 2-3 hours to achieve the LOD enteric coated pellets NMT2.0% m/m at $105^0C\pm 2^0C$ / auto mode using IR moisture analyzer.

Sift the enteric coated pellets of step 10 through 1400mm mesh (ASTM, #14 mesh) and reject the retentions. Size the 1400mm mesh (ASTM, #14 mesh) passed enteric coated pellets of step 11 through 710mm mesh (ASTM, #25 mesh) and reject the passing. Collect the enteric coated pellets retaining on 710mm mesh (ASTM, #25 mesh) and store airtight triple laminated poly-bags with sufficient quantity of silica bags at controlled temperature for further processing.

Lubricate the enteric-coated pellets in low shear blender with colloidal silicon dioxide and Talc for

Table 1: Composition of Lansoprazole Capsules F1 to F10

Coating/ layer	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Drug Layering	Sugar spheres	120	120	120	120	120	120	120	120	120	120
	Lansoprazole	40	40	40	40	40	40	40	40	40	40
	Low substituted-HPC NF	19	19	19	19	19	19	19	19	19	19
	Magnesium carbonate heavy	21.4	21.4	21.4	21.4	21.4	21.4	21.4	21.4	21.4	21.4
	Sucrose	19	19	19	18	19	19	19	19	19	19
	Maize starch	19	19	19	19	19	19	19	19	19	19
	Polysorbate 80	4	4	4	4	4	4	4	4	4	4
	HPC-L	1.2	1.2	1.2	2.1	2.1	2.1	2.1	2.1	2.1	2.1
	Purified water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Seal coating	Low substituted-HPC NF	15	15	15	15	15	16	16	16	17	16
	Sucrose	19	19	19	19	19	21	23	21	21	21
	HPC-L	10	10	10	10	10	11	11	11	11	11
	Maize starch	16	16	16	16	16	17	18	17.0	17	17
	Titanium dioxide	7	7	7	7	7	8	8	8	8	8
	Purified water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Enteric coating	Eudragit L30 D55	46	58.460	58.460	58.460	58.460	58.104	60.81	59.460	59.460	59.460
	Talc	5	6	5.946	5.946	5.946	5.810	6.080	7.072	4.872	5.946
	Polysorbate 80	2	3	3	3	3	3	3	2	3	4
	Macrogol 6000	5	6	6	6	6	6	6	6	6	6
	Purified water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Lubrication	Talc	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Silica colloidal anhydrous	0.020	0.020	0.020	0.020	0.020	0.020	0.020	0.020	0.020	0.020

Table 2: API Characterization

Characteristics	Results
Bulk density (gm/cc)	0.39g/ml
Tap density (gm/cc)	0.78g/ml
Compressibility index (%)	50.00%
Angle of repose	55.55%
Hausner,s ratio	2.00
Melting point	178-182^{o}C
Loss on drying (LOD) (%)	1.49
λ_{max}	285nm

Table 3: Physico-Chemical Properties of Formulations F1-F10

Parameters	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Bulk density (g/cc)	0.85	0.88	0.96	0.88	0.87	0.85	0.87	0.86	0.88	0.84
Tapped density (g/cc)	0.80	0.93	0.88	0.91	0.92	0.87	0.92	0.86	0.91	0.87
Angle of repose (θ)	33.2	32.5	32.3	33.6	32.3	34.8	33.5	31.1	34.2	34.5
Carr's Index	6	3.47	4.15	2.64	2.16	2.68	2.16	4.23	4.11	4.73
Hauser's ratio	1.05	2.12	2.14	2.12	2.12	2.12	2.15	2.14	2.14	2.23
Moisture content	1.2	2.4	2.7	3.1	2.7	2.7	2.4	2.7	2.8	2.3
Assay	99.6	88.3	88.3	88.3	88.4	211.2	88.9	88.6	88.5	88.2
Weight variation	1.65	2.31	2.42	2.27	2.26	2.55	2.34	2.57	2.53	2.27

Table 4: *In-vitro* Dissolution Data of Formulations F1-F10

	Cumulative Percent Drug Release in 0.1 N HCl									
Time (min)	Innovator	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
0	0	0	0	0	0	0	0	0	0	0	0
60	4.7	8.6	5.1	4.7	6.8	6.5	6.2	3.9	5.3	5.1	4.5
	Cumulative Percent Drug Release in Phosphate Buffer pH 6.8										
5	38	42	37	32	35	36	31	31	35	32	39
10	27	32	31	28	42	43	44	47	48	53	47
15	35	42	42	63	57	37	52	64	58	55	59
30	46	78	56	79	51	66	62	63	67	68	69
45	82	89	85	83	82	78	56	77	78	64	86
60	74	82	78	99	95	71	62	88	87	92	95

Table 5: Kinetic Data of Lansoprazole Formulations

Kinetic model	ID	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
First order	r	0.998	0.885	0.856	0.889	0.885	0.896	0.856	0.875	0.893	0.868	0.883
	k	0.006	0.118	0.142	0.058	0.126	0.124	0.166	0.138	0.152	0.252	0.162
Zero order	r	0.919	0.866	0.836	0.817	0.871	0.851	0.987	0.855	0.838	0.983	0.923
	k	4.406	2.991	1.372	4.361	2.643	3.882	2.673	3.378	4.171	4.888	4.595
Higuchi	r	0.956	0.864	0.887	0.877	0.885	0.886	0.893	0.888	0.884	0.893	0.887
	k	4.764	6.311	9.966	11.57	8.162	8.352	11.892	9.272	12.14	12.43	11.23
Peppas	r	0.929	0.838	0.832	0.827	0.838	0.837	0.924	0.836	0.87	0.834	0.929
	k	0.687	0.426	0.348	0.278	0.477	0.344	0.242	0.394	0.312	0.246	0.223

Table 6: Stability Studies *In-vitro* Dissolution Profile of F10

Medium	Time	Assay of F10	
		(25°C/60%RH)	(40°C/70%RH)
0.1N HCL	1	0	0
	60	3.6	3.7
	5	25	26
	10	36	37
	15	48	49
pH 6.8	30	59	60
	45	73	73
	60	86	87

10 minutes. The equivalent weight of lubricated enteric coated pellets was filled into hard gelatin capsules (size "1") using automatic capsule filling machine [9].

Pre-Compression Parameters

The powdered blend was analyzed for flow properties as follows [10].

Angle of Repose

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

Bulk density = Weight of powder/ Bulk volume

Tapped density = Weight of powder/ Tapped volume

Carr's Index (I) = (Tapped Density - Bulk Density)/(Tapped Density) x100

Hausner's ratio = Tapped density/Bulk density

Evaluation of Delayed Release Capsules

Surface Characterization

Morphological evaluation of something like the urface must have been done using just a EM (ZEOL J M-6700) [11].

A particulate had been vacuum solidified, absolutely covered with narrow gold-palladium covering through falter coater unit as well as recognized minutely at for an going to accelerate voltage of 10.0 kV.

Particle Size Distribution

To be able for evaluate that whole size of the particles like distribution of able to prepare granules comprising lansoprazole, standard sieve technique has been utilised. Malfunction sifter as for sieve analysis with among both orifices 355-2000 mm have been used by using all the amount of pellets able to prepare. The fraction collected on each one of that whole sieves had been determined by calculating even by a fraction valuation [12].

Weight Variability Test

Individual bodyweight like 20 caplets have been considered and also the recommended weight has been measured while using the formula [13].

$$Weight \quad variation = \frac{(Weight\ of\ capsule - Average\ weight)}{Average\ weight\ of\ capsule} \times 100$$

Water Content

30ml of the methanol must've been considered into the KF titrant bottle as well as titrant to KF reagent till the ultimate actual conclusion to making within the jar resistant to water [14]. Exquisitely lansoprazole granules seem to be relocated fast and accurate measured quantity of about 0.5g sample was

injected to that same titrant jar and so tapered down by consistent trying to stir but also titrant with KF reagent.

Drug Content

Fully ready granules had been forced to listen for said drug content. Weighed and powder 20 capsules. Decided to Weigh the one value like finely ground granules actually contains 30mg of lansoprazole to 100 ml volumetric flask, add 20 ml of 0.1 M Sodium hydroxide, combine with assist of ultrasonic but also solubilise to volume with 0.1 M Sodium Hydroxide [15]. Centrifuge for five mins but also solubilise 5.0 ml of a clarify supernatant fluid to 50.0 ml only with phosphate-buffered pH 6.8. An obtained solution utilizing solution was therefore studied and utilizing UV Spectroscopy at λ max 285 nanometers.

$$\% \; Drug \; content = \frac{Observed \; value}{Actual \; value} \times 100$$

Preparation of Lansoprazole Acid Standard Solution

Weigh and transmission many of 60.0mg of lansoprazole WS into such a 100ml volumetric flask add 50ml of methanol and sonicate to disperse this same contents completely. And make up to the volume with methanol. Transfer 2.0ml of something like this solution into a 100ml flask, dilute to volume with dissolution medium and mix well [16].

Preparation of Acid Sample Solution

Evaluate and transport pellets equivalent to 60 mg to lansoprazole into every other bowl actually contains 500ml of dissolution medium and continue operating the dissolution apparatus for 60 minutes [17].

Mathematical Modeling for Drug Release Profile

The data acquired from the *in vitro* dissolution tests obtain the kinetic track record analysis [8].

Zero-order kinetics: $Q_t = Q_o + K_o t$

First-order kinetics: $Q_t = log\ Q_o + K_1 t/2.303$

Higuchi model: $Q_t = K_H \cdot t^{1/2}$

Korsmeyer-Peppas release model: $Mt / M_\infty = K \cdot t^n$

Stability Studies

The stability literature review as per an aspect of thesis approach for 6 months in different speeded up accelerated temperature plus [18] humidity situations of 25ºC ± 2ºC /60% RH ± 5% RH, 40ºC ± 2ºC /75%RH ± 5%RH.

RESULTS AND DISCUSSION

FTIR Spectroscopic Study

From this it is clear that the characteristic peaks at 3448 (N-H stretching), 1638.58 (C=N stretching), 1358.97 (S=O stretching), 1467 (C-H bending), 1244 (C-N vibrations)$cm^{-1}$are present in both the pure drug, formulation and only excipients even without start changing of their viewpoints, specifying no chemical interaction between opoid but also excipients, just like affirmed even by FTIR studies [Figure 1 & Figure 2].

Preformulation Studies

All those are preliminary characteristics features of the any material which really is helpful through identification of individual substance [Table 2]. Followed by physical qualities like API have been researched.

Surface Characterization

A prepred formulations F10 granules have been noticed of being spherical as implied through SEM. Surface of such coated granules have been noticed to also be standardised but also soft [Figure 3].

Particle Size Distribution

Granules size of the particles throughout all compositions have been usually ranges through the 710mm to 850mm. Average granules size of the particles through prepared formulations F10 has been noticed to also be 710 nm.

Formulation of Delayed Release Pellets

Pellets had been told to prepare besides suspended layer-based method through fluidized processor. 10 formulations of lansoprazole have been evolved whilst also drug compositing here on the sugar spheres using hypromellose as binder, HPC (low substituted) as disintegrate and ranging its compositions of barrier coating and enteric coating employing HPC-L and eudragit as polymers by Fluidized bed processor [Table 3].

Drug Release Kinetics

Stability Studies

The overall stability test was conducted along with F10 which explains well thought out ultimate the best. The formulation was once analyzed since the dissolution chart for reason that a period going from 12 weeks [Figure 4, Table 4, Table 5 and Table 6].

CONCLUSION

The pharmaceutically active component, Lansoprazole had been choosen and developed as enteric coated granules similar to a innovative item. Based really over diluents compatibility info but also prototype preparations, a method such a noticed to just be providing the specified release of drug structure has been regarded as that the prepared formulations as well as further research has been per-

formed here upon the composition F10 to provide either a indepth analysis around with composition. Through field assumptions, this became indicated that now its composition F10 exhibit greater proof against 0.1 N HCl but also improved discharge there as phosphate-buffered pH 6.8. Therefore he prepared formulations F10 must have been comparision with originator item by either through *in vitro* analysis, this proves that the composition F10 has been great even through comparison only with both the originator item. A prepared formulations F10 must have been keep as a Stability studies and execute for three months there as 40°C/75 %RH as well as 25°C/60 % RH so according ICH guidelines. A prepared formulations F 10 had been seen appealing *in vitro* acid but also buffer release of drug as during stabilisation period but also similar to the originator.

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Conflict of Interest

The authors attest that they have no conflict of interest in this study.

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