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FORMULATION DEVELOPMENT OF MICROSPONGE BASED DELAYED RELEASE DOSAGE FORM OF LANSOPRAZOLE

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Keywords:

Microsponge, SeDeM, Delayed release, Lansoprazole, Acid labile, Cost effective

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ABSTRACT: The aim of study is to develop microsponge based delayed release dosage form, technique used to manufacture microsponge was quasi emulsion diffusion technique. Eudragit L 100 and Eudragit S 100 polymer is used to incorporate lansoprazole in microsponge. Lansoprazole is acid labile drug hence release of lansoprazole was delayed from acid environment. Microsponge contains porous polymeric microspheres, typically 100 - 250 µm in diameter. Compatibility of the drug with adjuncts was studied by DSC. Production yield, loading efficiency, particle size analysis, surface morphology and *in-vitro* release studies were carried out. Optimized microsponge blended with other diluents and filled in capsules. Blend containing lansoprazole Microsponge were evaluated for SeDeM parameters to check its flow. The microsponge formulation F2 showed delayed release of lansoprazole in buffer stage pH 6.8 bypassing the acidic stage. The result reveals that developed microsponge are cost effective and can be used as a delivery system for acid labile drug lansoprazole to avoid its degradation in acidic media of the stomach. SeDeM technique can be employed for successive prediction powder blend performance.

INTRODUCTION: Lingering the dosage form is a need of a hour in order to achieve specific drug delivery, oral drug delivery still retain more significant route of administration where modified drug release dosage form played a vital role to achieve the target therapeutic action. In this study microsponge based delayed release dosage form is developed. Microsponge is a polymeric system and porous in nature, they vary in size from 10 µm to 200 µm their application and significance is expanding in oral drug delivery system [1].

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Lansoprazole is proton pump inhibitor and binds to one common distinct site on the alpha subunit of the proton pump which decreases acid release by inhibiting H^+, K(+)-adenosine triphosphatase, which is the final step in the secretion of acid [2].

Lansoprazole is acid labile drug which undergo changes when comes in contact with acidic media, this degradation lead to lower bio availability and low potency of lansopraozle [3]. In order to prevent Lansoprazole degradation in initial acidic media of stomach we intended to develop delayed release dosage form, formulation likely to delay drug release in stomach bypassing acidic media which may result in prevention of drug degradation and maximum drug availability for absorption. By formulating dosage form using microsponges we are eliminating different coatings required to get delayed release action this may contribute to cost-

effectiveness. Developed optimized microsponges were incorporated in different blend and all blends were treated with SeDeM technique. SeDeM expert system is predictive tool which predict flow performance of the powder or powder blend [4]. SeDeM expert system may be coined as time saving as this technique may reduce no of trials.

Due to the ability of prediction for deficient part this technique may serve as economic and choice of technique compared to other time consuming conventional trial and error approach or software based prediction model. Marketed formulation of Lansoprazole delayed release capsule was procured and comparatively evaluated with developed formulation for various physical and chemical tests.

MATERIALS AND METHODS: Lansoprazole obtained from Wockhardt Pharmaceuticals Ltd., Aurangabad, Eudragit L 100 and Eudragit LS 100 obtained from Evonik as a gift sample similarly all excipient used in the formulation was obtained from their respective vendor as a gift sample. All solvents used are of analytical grade.

Preformulation Studies:

Confirmation and Characterization of API: Procured API was confirmed and characterized using IR, DSC and UV spectroscopy and other tests, values obtained were compared with reported literature value.

Infra-Red Spectrometry (IR): The IR absorbance spectrum of drug was recorded using IR 200 spectrometer (Thermo Electron Corporation) over a range of 500 to 4000 cm^{-1}. The drug sample was directly placed in the sample cell in IR chamber and spectrum was recorded. The obtained graph was interpreted for different functional group.

Differential Scanning Colorimetry (DSC): The thermal behaviour of Lansoprazole was studied using a differential scanning calorimeter Shimadzu Japan (DSC 60) at a heating rate of 20 °C /min. The measurements were performed at a heating range of 50 ° - 225 °C under nitrogen atmospheres.

Melting Point: The melting point determined using melting point apparatus VEEGO Model VMP-D, drug sample placed in the sample collector, heater knob started and observed for reading.

Solubility Study: Determination of solubility of API is an important aspect due to targeting delayed release dosage form also the process aims to involve diffusion method for microsponge preparation hence solubility study was performed in different physiological pH ranges as well as in organic solvents by taking 0.5 mg per ml and similar dilutions for all pH ranges [5].

Excipient Compatibility Study: Compatibility of API with the excipient present in formulation will lead to stable dosage form therefore in order to check the compatibility API and all excipient were mixed in 1:5 ratio together and blend of mixture was kept in stability chamber (HMG India) at condition 40 °C 75% RH, sample withdrawn and compatibility checked using DSC (Differential Scanning Colorimetry).

UV Spectrometry and Method Development: UV spectrometry was performed in order to confirm the received API and to develop analytical method. The ultraviolet absorption spectrum of Lansoprazole was obtained using Shimadzu 1700-PC UV visible spectrophotometer and 1 cm quartz cells, over a wavelength range of 400 to 200 nm in 0.1N HCl solution. The wavelength maxima λ_{max} was analyzed by using UV Probe software. A stock solution was prepared by weighing 10 mg of Lansoprazole in 100 mL of volumetric flask and dissolved in Distilled Water to obtain a concentration 0.1 mg/mL or 100 µg/mL (stock). Method is successfully developed and validated as per ICH and can be utilized in quality control analysis of lansoprazole from formulation [6].

Development of Lansoprazole Microsponge: Microsponges were prepared using quasi emulsion solvent diffusion technique in which organic phase was prepared by adding drug lansoprazole and polymer Eudragit L 100 and LS 100 in methanol and ethyl acetate as per composition mentioned in **Table 1**. Aqueous phase was prepared by adding Poly Venyl Alcohol (PVA) in water under stirring to get some degree of elasticity in microsponges. Organic phase is added in aqueous phase slowly and stirring done for 1 h. Dispersion was filtered using Whatman filter paper equipped with vacuum containing assembly and dried at room temperature [7, 14].

TABLE: 1 COMPOSITION FOR MICROSPONGE PREPARATION

S. no.	Ingredients	M1	M2	M3
1	Lansoprazole	30	30	30
2	Eudragit L100	90	45	0
3	Eudragit LS 100	0	45	90
4	Polyvenyl alcohol (PVA)	10	10	10
5	Methanol	75	75	0
6	Ethyl acetate	0	75	75
	Total Microsponge weight (solid content in mg)	130	130	130

Evaluation of Microsponges:

Production Yield: Obtained microsponges were checked for production yield, as filtration process involves use of vacuum it was anticipated that production yield may obtain relatively low. Production yield for all batches calculated as below equation 1.

Production yield =

$$\frac{\text{Practicle yield}}{\text{Theorotical yield}} \times 100 \quad \ldots\ldots\ldots\ldots (1)$$

Determination of Moisture Content (Loss on Drying): Inorganic solvents were used while preparing microsponges, hence it is important to measure any residue after drying. Dried microsponges were kept in halogen moisture analyzer at 100 °C for 20 min and checked for % moisture content present in dried product.

Loading Efficiency: The weighed amount of microsponge were dissolved in methanol and sonicated for 10 min. The drug content was measured spectrophotometrically at 281.8 nm for Lansoprazole, by preparing required dilutions and employing below formula equation 2.

% Loading efficiency =

$$\frac{\text{Actual drug content in microsponges}}{\text{Theorotical drug content}} \times 100 \quad \ldots\ldots\ldots\ldots (2)$$

Particle Size of Microsponge: The microsponges were evaluated for the particle size using electronic microscope (Olympus stream industrial micro-scope) was used. The microscope was equipped with the software, Olympus Stream Image Analysis Software version 1.2. Analysis was carried out on the microsponges kept on slide without dispersion. The average particle size of the microsponges expressed in µm.

Surface Electron Microscopy (SEM): The morphology of the optimized microsponge (M1) was studied using a scanning electron microscope (JSM 6390 India) operated at an accelerating voltage of 20 kV, 5000X and 5 µm Scale.

Preparation of Ready to Fill Blend: Microsponges giving maximum yield and loading efficiency were selected for further formulation development. Microsponges (M1) was selected and weighed as per their actual weight containing one dose of lansoprazole and mixed with different ingredients shown in composition **Table 2**. Prepared blend further evaluated for its flow using SeDeM technique and filled in empty hard gelatin capsule shell size '0'.

TABLE 2: COMPOSITION FOR CAPSULE FILLING

S. no.	Ingredients	F1	F2	F3
1	Lansoprazole Microsponge (M1)	130	130	130
2	Lactose SD	50	25	0
3	Polyox N750	0	25	50
4	HPMC K15	8	8	8
4	Colloidal Silicon Dioxide	2	2	2
	Total fill weight	190	190	190
	Total Capsule weight	280	280	280

Determination of Flow of Blend using SeDeM: To fill the blend in empty capsules it is important to have flow to prepared blend, flow of blend is predicted using 12 parameters of SeDeM Technique employed to determine the flow of blends. Formulation having higher radius value considered as optimized formulation to be consider for capsule filling [8, 9, 10] mention in **Table 3**.

Physical and Chemical Testing: Filled capsule were evaluated for various in process quality control test *viz.* weight variation test, disintegration time, locking length *etc.* and chemical test like assay and *in-vitro* dissolution test.

Stability: The optimized batch was stored in stability chamber (HMG India) at 40 °C and 75 % RH for 3 month and observed for the, physical appearance, weight variation, disintegration, locking length, particle size, assay and dissolution at 1 month interval.

TABLE 3: PARAMETERS OF SeDeM EXPERT SYSTEM ALONG WITH LIMITS AND FACTORS

Incidence factor	Parameter (Symbol)	Unit	Equation	Limit value	Conversion factor applied
Dimensions	Bulk Density (Da)	gm/ml	Da= P/Va	0-1	10v
	Tapped Density (Dc)	gm/ml	Dc= P/Vc	0-1	10v
Compressibility	Interparticle porosity (Ie)	-	Ie= DC-Da/Dc x Da	0-1.2	10v/1.2
	Carr index (Icd)	%	IC = (Dc-Da/Dc)	0-50	10-(v/5)
	Cohesion index (IC)	N	Experimental	0-200	v/20
Powder Flow	Hausner Ration (IH)	-	IH=Dc/Da	3-0	10-(10v/3)
	Angle of repose (α)	-	A =$\tan^{-1}$h/r	50-0	10-(v/5)
	Flowability (t^n)	S	Experimental	20-0	10-(v/2)
Stability	Loss on Drying (% LOD)	%	Experimental	10-0	10-v
	Hygroscopicity (%H)	%	Experimental	20-0	10-(v/2)
Lubricity	Particles <50 m (%Pf)	%	Experimental	50-0	10-(v/5)
	Homogeneity index (IΘ)	-	Eq. (1)	0-0.02	500v

RESULT AND DISCUSSION:

Preformulation Studies: Drug Lansoprazole was confirmed and compared with reported values with literature, the results of UV (λ_{max}), melting point, DSC, solubility study and excipient compatibility study expressed in **Table 4**. From the table it can be concluded that chemical received is matches the characteristics with Lansoprazole drug and Lansoprazole is compatible with the excipients intended to use in the formulation.

TABLE 4: RESULTS OF PREFORMULATION STUDIES

S. no.	Test	Results	Reported literature value
1	Physical appearance	White to brownish-white odorless crystalline powder	white to brownish-white odorless crystalline powder [11]
2	UV wavelength maxima (λ_{max})	281.8 nm	281[12]
3	Melting point	176°C	178-182°C[13]
4	Solubility [5]	mg/ml	% Solubility
	pH 1.2	0.366	73.20%
	pH 4.5	0.394	78.80%
	pH 6.8	0.466	93.2
5	DSC	Peak observed at 175.28°C (Fig. 1)	
6	Infra-Red spectroscopy (Fig. 2)		
	Functional groups	Observed values	Standard values
	C-O-C	1116.78	1050-1150
	benzene	3240.40	3100-3200
	C=C	1686.86	1620-1680
	C-S	1176.58	1000-1200
	S=O	1786.08	1670-1820
	C-f	1400.32	1000-1400
	N-H	3240.41	3300-3500
7	Excipient compatibility study	As per the DSC results, drug is compatible with all excipients present in formulation	

DSC Thermogram of Lansoprazole:

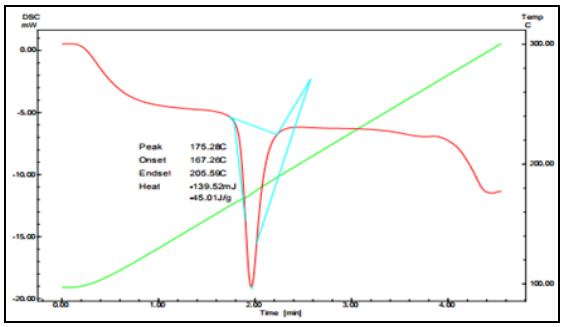


FIG. 1: DSC THERMOGRAM OF LANSOPRAZOLE

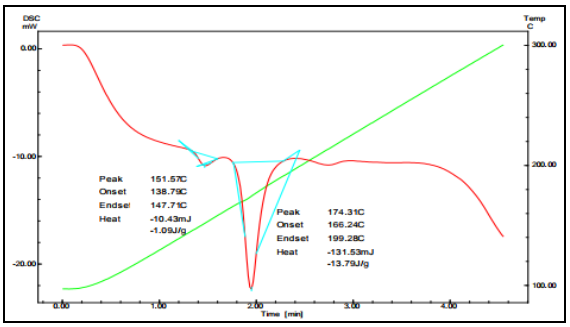


FIG. 3: DSC GRAPH OF EXCIPIENT COMPATIBILITY STUDY

Infra-Red Spectrometry (IR) of Lansoprazole:

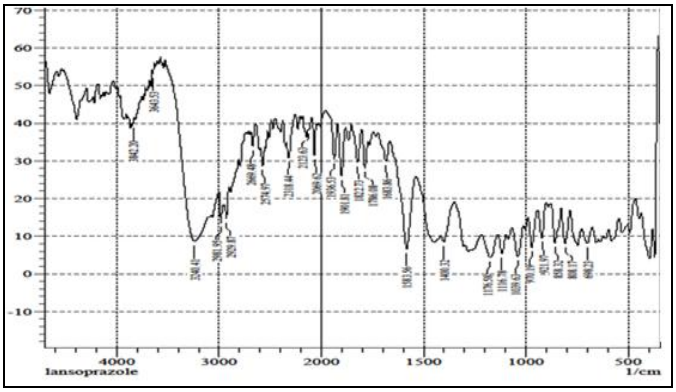


FIG. 2: INFRA-REDSPECTROMETRY (IR) GRAPH OF LANSOPRAZOLE

UV Method Development: Lansoprazole drug showed λ_{max} at 281.6nm. The calibration curve yielded correlation coefficient (r^2) of 0.99732. The regression equation was found to be Y = 0.0057 x - 0.02407 with good linearity.

Development of Microsponges: Production yield was found in the range between 85 - 95%. These relatively low values may be due to the use of vacuum during filtration process. Loading efficiency was in the range of 85 - 98%. Moisture content was less than 1% in all formulation, while particle size of microsponges varies from 50 µ to 250 µ, all these values reported in table.

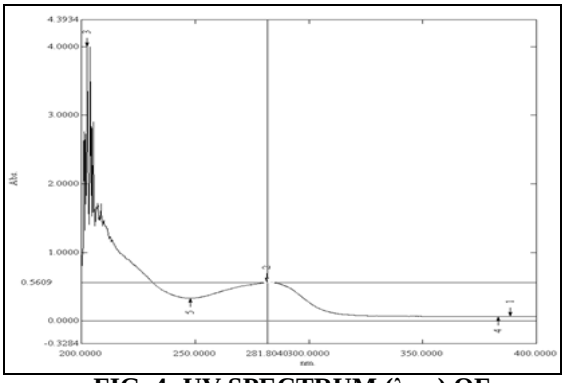


FIG. 4: UV SPECTRUM (λ_{max}) OF LANSOPRAZOLE

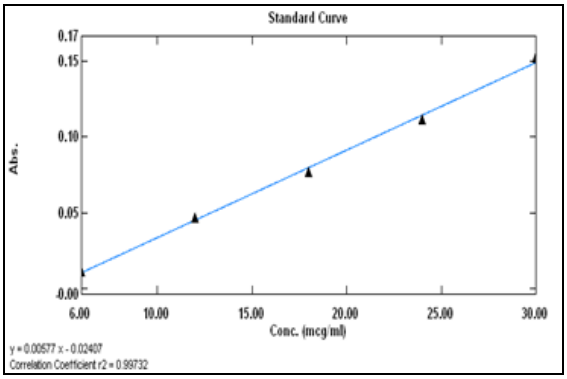
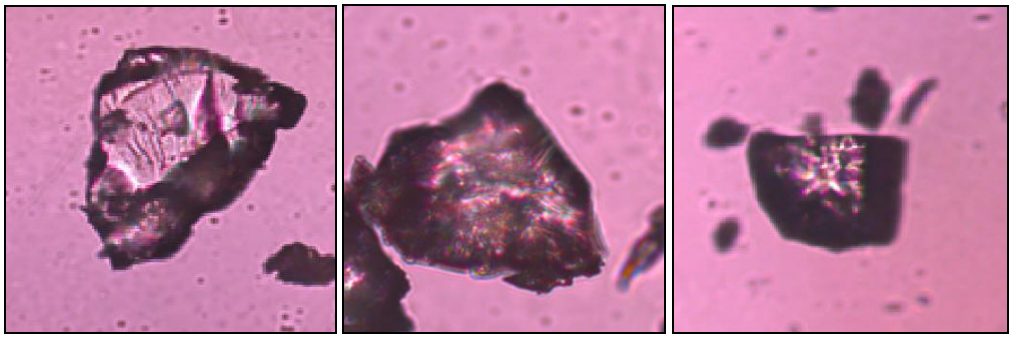


FIG. 5: CALIBRATION CURVE OF LANSOPRAZOLE

Lansoprazole Microsponge under Electronic Microscope:



M1 **M2** **M3**

FIG 6: MICROSPONGE OF M1, M2 & M3 FORMULATION UNDER ELECTRONIC MICROSCOPE

TABLE 5: EVALUATION OF MICROSPONGES

Formulation code	Production yield (%)*	Loading efficiency (%)	Moisture content (%)	Particle Size (µm)
M1	95.75 ± 1.56	97.90 ± 1.53	0.95	150
M2	92.66 ± 1.96	88.34 ± 2.14	0.90	175
M3	88.12 ± 0.87	85.52 ± 2.09	0.95	128

Surface Electron Microscopy (SEM): The optimized formulation M1 was analyzed by SEM for studying microsponge shape and surface structure **Fig. 7**. The microsponges were spherical in shape and possessed a slight rough surface.

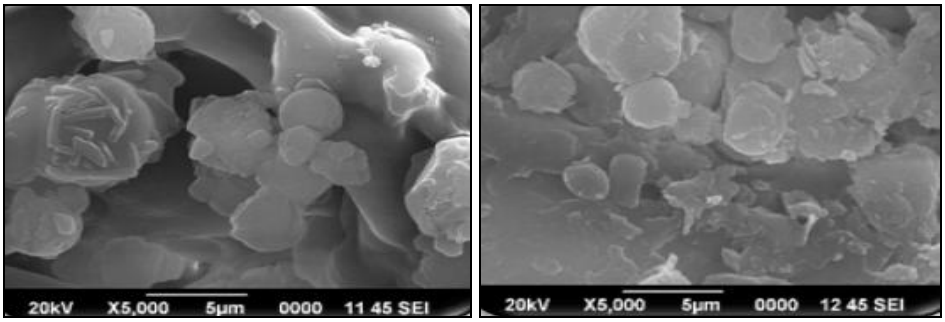


FIG. 7: SURFACE ELECTRON MICROSCOPY OF OPTIMIZED FORMULATION M1

Preparation of Ready to Fill Blend using SeDeM Method: Microsponge M1 has given satisfactory performance in all the tests therefore microsponge M1 considered to be incorporated in the formulation. 3 different blend was formulated for capsule filling, all 3 different blend were treated with 12 parameters of SeDeM techniques in order to select best suitable blend for capsule filling, result obtained were tabulated in **Table 6**, Formulation which has given highest average radius value (IPP value) was selected for capsule filling.

TABLE 6: RADIUS VALUES OF ALL 3 FORMULATION BLEND BY SEDEM TECHNIQUE

S. no.	Parameter (Symbol)	Acceptable value Limit	Acceptable Radius Limit	Corresponding Radius (R)		
				F1	F2	F3
1	Bulk Density (Da)	0-1	0-10	4.55	3.89	3.11
2	Tapped Density (Dc)	0-1	0-10	5.89	5.81	4.95
3	Interparticle porosity (Ie)	0-1.2	0-10	4.18	7.27	7.94
4	Carr index (Icd)	0-50	0-10	5.44	3.33	2.56
5	Cohesion index (IC)	0-200	0-10	6.37	7.84	4.90
6	Hausner Ration (IH)	3-0	0-10	3.53	5.02	4.69
7	Angle of repose (α)	50-0	0-10	1.11	2.85	3.08
8	Flowability (tn)	20-0	0-10	3.00	5.00	4.00
9	Loss on Drying (% LOD)	10-0	0-10	8.08	9.05	8.75
10	Hygroscopicity (%H)	20-0	0-10	7.45	8.10	7.15
11	Particles <50 m (%Pf)	50-0	0-10	2.60	8.18	9.36
12	Homogeneity index (IΘ)	0-0.02	0-10	7.00	9.00	6.50
	Average Radius Value (IPP)			4.93	6.27	5.58

*IPP= Parametric profile index

SeDeM Graphs of All Blends:

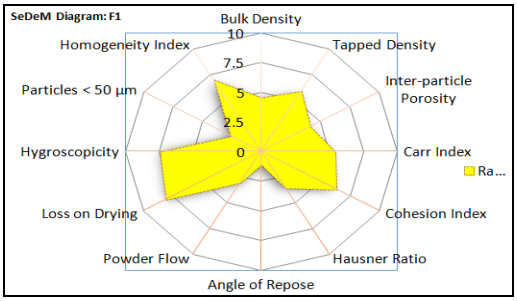


FIG. 8: SeDeM GRAPH OF F1 FORMULATION

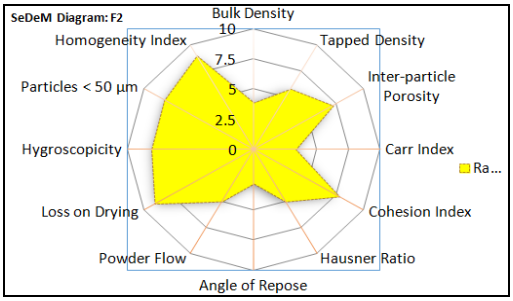


FIG. 9: SeDeM GRAPH OF F2 FORMULATION

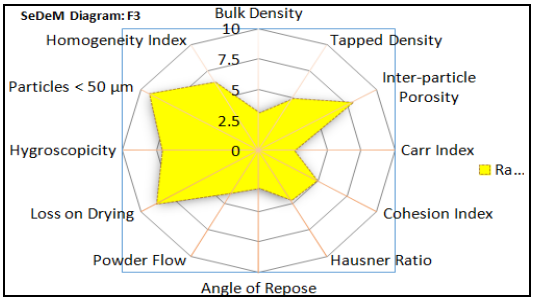


FIG. 10: SeDeM GRAPH OF F3 FORMULATION

In Process Quality Control (IPQC) Results:

TABLE 7: IN PROCESS AND COMPARATIVE EVALUATION OF OPTIMIZED FORMULATION F1 WITH MARKETED PRODUCT

S. no.	Tests	USP Monograph Limit	LAN-30 Capsules (Marketed Sample) Mfg. By: Intas	F2 Microsponge Based DR Capsules
1	Description	NA	Red/white hard gelatin capsule shell containing off white to yellowish white coated pellets	Orange/yellow hard gelatin capsule shell containing white to off white granular powder
2	Capsule weight (n=20)	±10% (90-110 mg)	190 mg	280 mg
3	Locking Length (n=10)	NA	21.12mm	21.05 mm
5	Disintegration Time (in water at 37°C) (n=6)	NMT 15 min	5 min 30 sec	3 min 30 sec

Determination of Assay and Dissolution: Result obtain after evaluation of lansoprazole capsules for assay and dissolution test was tabulated in **Table 8**.

TABLE 8: ASSAY AND DISSOLUTION VALUES OF OPTIMIZED FORMULATION AND COMPARISON WITH MARKETED PRODUCTS

S. no.	Test	Limits	Reference Sample (LAN 30 Capsule)	F2
1	Assay	95-105	100.2	98.5
2	Dissolution Acid Stage	Limit: NMT 10% (Q) of the labelled amount of Lansoprazole is dissolved in 60 min		
	Condition; Media:	Time (h)	% drug dissolved	
	0.1N HCl, Volume: 500ml,	5	0	0
	Apparatus: USP Type II (Paddle),	10	0	1
	RPM: 75, Unit = 6	30	3	4
	(as per OGD & USP recommendation)	45	5	6
		60	6	7
3	Dissolution Buffer Stage	Limit: NLT 80% (Q) of the labelled amount of Lansoprazole is dissolved in 60 min		
	Condition; Media: make up to pH 6.8	Time (h)	% drug dissolved	
	Volume: 500ml,	5	8	12
	Apparatus: USP Type II (Paddle), RPM: 75,	10	37	48
	Unit = 6	30	79	85
	(as per OGD & USP recommendation)	45	92	95
		60	99	101
3	Difference factor (F1)	NMT 15 =	8	
4	Similarity factor (F2)	NLT 50 =	64	

Stability Study: Stability studies of the optimized lansoprazole DR Capsules (F2) was carried out at various atmospheric conditions like room temperature, 40 °C/75% RH and 30 °C/65% RH. Even after the period of three month exposure at various atmospheric conditions different stability parameters like average weight, Locking length, disintegration time, moisture content, and assay were satisfactory **Table 9**. Thus, these results confirmed that the optimized lansoprazole DR capsule (F2) was stable enough.

TABLE 9: STABILITY RESULT OF OPTIMIZED FORMULATION F2

Condition	Avg. wt (mg) (N=20)	Locking length (N=10)	DT (Min) (N=6)	Moisture content (LOD % w/w)	Assay (%)
Initial	281.2	21.01	4	1.45	99.5
40 °C/75% RH-1M	280.5	21.06	5	1.60	100.1
40 °C/75% RH-3M	281.6	21.11	4	1.82	99.9
30 °C/ 65% RH-3M	279.5	20.98	3	1.15	99.8
Control room Temperature - 3M	280.4	20.95	3	1.27	100.2

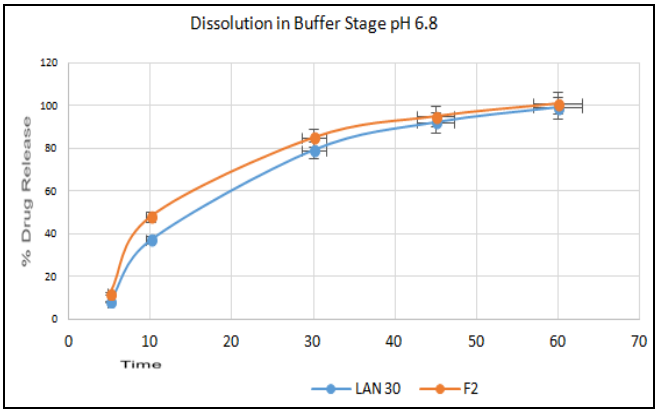


FIG. 11: COMPARATIVE DISSOLUTION OF LAN 30 VS F2 FORMULATION

CONCLUSION: A stable microsponge based delayed release dosage form is developed for the treatment of stomach acidity, lansoprazole shows promising presence in all aspects like it solubility in intended pH range, compatibility with polymer and other ingredients, and its detectability in different spectroscopic methods. SeDeM expert system has predicted the flow of the blends and provided the best one from the list, in order to fill in the capsule shell.

This developed dosage form may be a cost effective as the numerous coatings involved in the process is reduced and prepared by simple diffusion of drug in polymer by means of microsponge structure. Production yield and Loading efficiency has encouraged for further development. Developed dosage form behaves similar to the marketed formulation in OGD and USP recommended dissolution media. It is recommended to have *in-vitro in-vivo* correlation using convolution and deconvolution technique for the optimized formulations.

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CONFLICT OF INTEREST: All authors declare no conflict of interest.

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