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FORMULATION AND *IN VITRO* EVALUATION OF LANSOPRAZOLE FAST-DISSOLVING ORAL THIN FILMS BY USING CENTRAL COMPOSITE DESIGN

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ABSTRACT

Objective: Acid reflux, heartburn, indigestion, and gastro-oesophageal reflux disease (GERD) are treated with it. Additionally, stomach ulcers are prevented and treated with lansoprazole. Oral thin films breakdown quickly in the mouth along with the medication, and most of the medication enters the systemic circulation by way of the buccal mucosa, by-passing first pass metabolism. **Materials and Methods:** Utilising the solvent casting method, Lansoprazole fast dissolving oral thin films were created utilising a variety of film-forming ingredients, including polyethylene glycol 600 as plasticizer, saccharin as a sweetener, HPMC E15 as a polymer, and as a plasticize, citric acid as a saliva stimulating agent. **Results:** The evaluation criteria, which include drug content, folding endurance, thickness, and weight variation and disintegration time were performed for oral thin films. The formulations of oral fast dissolving film were optimized by employing Central composite design from Design Expert-13 Software. Lansoprazole oral thin films had a smooth surface, transparent, and were clear. **Conclusion:** Lansoprazole fast-dissolving oral thin films formulated and optimized by using central composite design were having good percentage cumulative drug release.

Keywords: Lansoprazole, Solvent Casting method, Central composite design, Design Expert -13 and Oral thin films

INTRODUCTION

When these drug delivery systems are placed on the tongue, their water-soluble polymer content causes the drug to dissolve or adhere in the mucosa with saliva in a matter of seconds, releasing the drug quickly, is how oral disintegrating/dissolving films or strips are defined. Because of its thin membrane structure and high vascularization, the sublingual mucosa has a high membrane permeability. Because of this quick blood flow, it has excellent bioavailability **[1]**. A higher blood flow and lymphatic circulation result in improved permeability, and avoiding the first-pass effect enhances systemic bioavailability.

The oral mucosa's wide surface area and easiness of application for absorption make it a highly efficient and selective route of systemic drug delivery **[1, 2]**. OTFs are generally described as a thin-flexible polymer layer, either with or without plasticizers. Since their natural structure is thin and flexible, it can be said that they are less upsetting and more acceptable to patients. Many of the specifications needed for a drug delivery system are met by thin films, which are polymeric systems. Thin films have demonstrated their potential in studies by enhancing the drug's initial and sustained effects, lowering dosage frequency, and boosting its effectiveness.

Thin-film technology has the potential to reduce common metabolism caused by proteolytic enzymes and eliminate drug side effects. The ideal thin film should have all the characteristics of a drug delivery system, including a reasonable formulation stability, a suitable drug loading capacity, quick dispersion or dissolution, or extended application. They also need to be biocompatible, biodegradable, and nontoxic **[3, 4]**.

Proton pump inhibitors, such as lansoprazole, are used to treat hypersecretory disorders like Zollinger-Ellison syndrome, treat symptoms of GERD, and aid in the healing of gastrointestinal ulcers.

Known by the brand name Prevacid, lansoprazole is a proton pump inhibitor (PPI) that is structurally categorised as a benzimidazole substitute.It is useful in treating GERD and other disorders brought on by excessive acid secretion, as well as in promoting healing in ulcerative diseases. It does this by inhibiting the gastric H, K-ATPase pumps in the stomach **[5, 6]**.

METHODOLOGY

PREFORMULATION STUDY:

Organoleptic properties

The organoleptic properties of lansoprazole were examined for its appearance, color and texture. The sample was smelled to detect any characteristic odors, and a small amount was tasted to assess its flavor and intensity. The observations were recorded.

SPECTROSCOPIC STUDIES: [7, 8]

Determination of λ max

A precisely weighed quantity of Lansoprazole was dissolved in 10 µg/ml of 6.8 phosphate buffer to create the standard stock solution, which was then scanned in the 200–400 nm range against the buffer as a blank.

Preparation of stock solutions

Stock solution 1

In a 100 ml decanter. 10 ml from the above solution was diluted with 100ml phosphate buffer to attain a stock solution. The standard 10mg/ml solution was prepared and labelled as stock solution 1.

Stock solution 2

10 ml from the above solution was diluted with 100ml phosphate buffer to attain a stock solution. The absorbance was checked using U.V spectrophotometer at 282 nm. This was carried out by repeating the same method for more aliquots (5, 10, 15, 20, 25 and 30 µg/ml) and their absorbance was measured.

PREPARATION OF LANSOPRAZOLE ORAL THIN FILM [9, 10]

The solvent-casting method was used to create the oral thin film. The necessary amount of ethanol was taken in beaker, and the polymer was immersed in it for roughly an hour. The solvent-casting method was used to create the oral thin film. The necessary amount of ethanol was taken in a beaker, and the polymer was immersed in it for roughly an hour. For thirty minutes, the mixture was stirred using a magnetic stirrer. After dissolving the medication (lansoprazole) in the polymeric solution, it was stirred for fifteen minutes. Later, the excipients—saccharide (PEG) and citric acid—were added, separated by a 5-to 10-minute interval. The polymeric solution and other excipients were mixed for an hour to produce a homogenous mixture. After that, the mixture was set aside for 30 minutes in order to release any trapped air bubbles.

Solution poured into a petri dish, it was either left to dry for 24 hours at room temperature or heated to 40 to 50 degrees for 20 minutes in a hot air oven. After that, the slides were carefully taken out. The films that were clear and transparent were chosen, cut into 4 cm 2 (2) pieces, carefully wrapped in parchment paper, and stored in desiccators for additional evaluations.

EVALUATION OF ORAL THIN FILMS [11, 12]

Visual inspection was used to physically characterize the fast-dissolving oral thin films, looking for traits such as colour, transparency, thickness, brittleness, and surface smoothness. Ssubjected to various evaluation tests, including disintegration time, folding endurance, surface pH, thickness, weight variation, and in-vitro dissolution studies.

1. Weight variation: A cast film measuring 2 by 2 cm square was used to cut each film.

We weighed each film, computed the average, and verified that it was consistent.

2. Film thickness: A digital vernier calliper was used at several locations to measure the thickness of a single film.

3. **Folding Endurance:** The ability of oral thin films to bend is crucial for administering the film without breaking. A 2 by 2centimetre strip was folded repeatedly at 180 degrees in the same spot on the film until a visible crack appeared. The values are recorded.

1. Appearance: The size, shape, and appearance of every film were carefully examined.

2. Uniform drug content: Films were put into graduated flasks with 100 millilitres of pH 6.8 phosphate buffer and constantly swirled. The drug content was determined after the solution was filtered, appropriately diluted, and subjected to spectrophotometric analysis at 282 nm.

Disintegration studies conducted in vitro: The Petridish method was employed. The film was put in a glass petridish with 10 ml of 6.8 pH buffer, and the amount of time it took for the film to dissolve was noted **[13, 14]**.

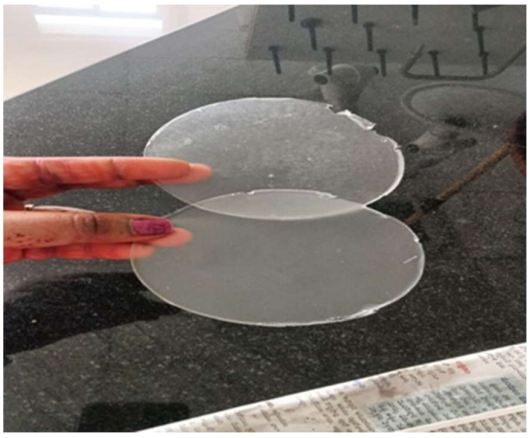

Figure 1: Oral Thin Films

Table 1: Composition of different oral thin films containing Lansoprazole

	Factor 1	Factor 2	Response 1	Response 2	Response 3
Formulation Code	A: HPMC E15	B: PEG 600	Thickness	Folding endurance	Disintegration
	mg	ml	mm		sec
F1	350	0.5	0.09	148	25
F2	350	0.3	0.089	143	26
F3	550	0.1	0.096	142	16
F4	550	0.5	0.098	158	12
F5	450	0.3	0.096	146	19
F6	450	0.1	0.093	138	21
F7	450	0.3	0.095	147	19
F8	550	0.3	0.097	149	15
F9	450	0.3	0.095	147	20
F10	450	0.5	0.096	153	13
F11	350	0.1	0.087	131	28

RESULTS AND DISCUSSION

1. Calibration curve of Lansoprazole

Standard stock solution: Fifty millilitres of phosphate buffer 6.8 were used to dissolve fifteen milligrammes of the medication. Lansoprazole calibration curve in phosphate buffer at pH 6.8: For the above solution, absorbance was measured at 282 nm to achieve dilutions of 5, 10, 15, 20, 25, and 30 µg/ml. **Table 2** displays the linearity plot at 282 nm with absorbance.

2. Compatibility studies

It was evident from FTIR analysis that the drug had not experienced any structural alterations or chemical reactions with the other excipients and polymers employed **[15]**. As a result, it was determined that the drug did not interact with the polymers or excipients in this experiment. FTIR spectra given in **Figure 3 & 4**, FTIR interpretation given in **Table 3**.

OPTIMIZATION BY QBD

Optimization was done by using Design expert 13 software. Effect of independent factors on dependent factors analyzed. Response 1: Thickness ANOVA readings given in **Table 4**.

Given F-value for lack of fit, 0.80, An F-value this large for Lack of Fit is likely to occur by 63.71%. Fit statistics are provided in **Table 5**.

The Predicted R^2 of 0.9650 and Adjusted R^2 of 0.9780 difference is < 0.2. Ratio of 34.127 indicates an adequate signal. Coded factors terms given in **Table 6**. 3D Surface plot for thickness given in **Figure 5**.

F-value is 134.39. This kind of large F-value has a 0.01% probability of being caused by getting noise.

The 7.19 F-value for lack of fit indicates that there is no significant difference between the lack of fit and the pure error.

A large Lack of Fit F-value has a 12.71% probability of being caused by noise. Response 2: Folding endurance given in **Table 7**; Fit statistics given in **Table 8**; ANOVA for Linear Model.

There is less than 0.2 difference between the Adjusted R^2 of 0.9639 and the Predicted R^2 of 0.9384, indicating a reasonable agreement. A desired ratio is an Adeq Precision greater than 4. A ratio of 34.907 suggests a strong enough signal. **Table 9** contains terms of Coded Factors.

Figure 6 displays a 3D surface plot of folding endurance.

F-value is 40.19. This kind of large F-value has a 0.01% probability.

P-value < 0.0500. The Lack of Fit F-value of 12.28 indicates that noise has a 7.72% probability of causing a Lack of Fit F-value this high. This is concerning because the probability is so low (<10%). Response 3 (disintegration) in ANOVA for the linear model is provided in **Table 10**. The Fit Statistics are listed in **Table 11**.

Adjusted R^2 of 0.8869 and the Predicted R^2 of 0.8146 difference indicating a reasonable

agreement. An appropriate signal is indicated by an Adeq Precision ratio of 18.331. Final Equation given in **Table 12** in Terms of Coded Factors.

Overlay plot gives the optimized factors and responses which given by the software. X1-HPMC E 15 quantity is 550 mg and X2-PEG 600 quantity is 0.45 ml as per software. As F4 Run is having similar factors and responses values with software. F4 is considered as optimized formulation.

Table 2: Calibration curve data of Lansoprazole in pH 6.8 phosphate buffer

S. No.	Concentration (µg/ml)	Absorbance
1	0	0
2	5	0.2015
3	10	0.3644
4	15	0.5452
5	20	0.7185
6	25	0.8925
7	30	1.0452

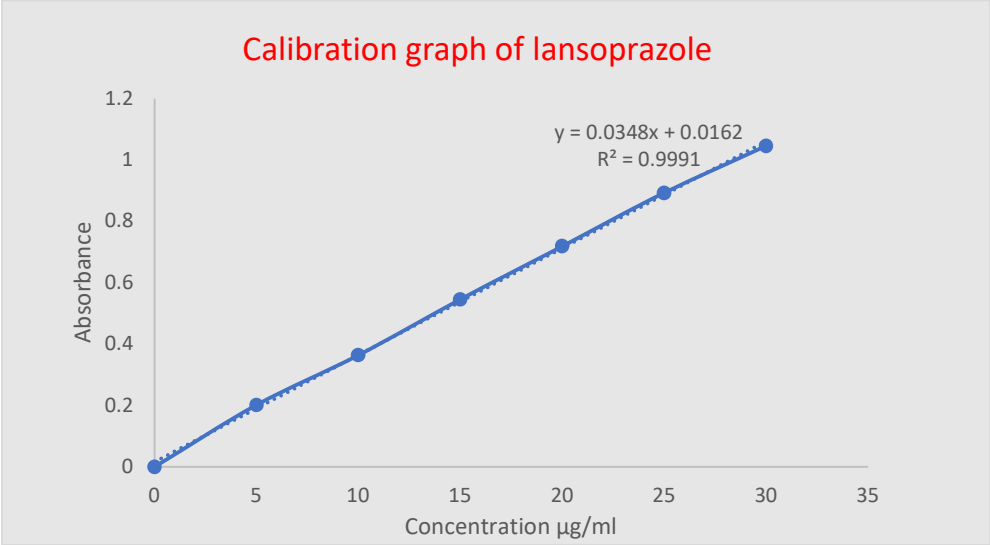

Figure 2: Calibration graph of Lansoprazole

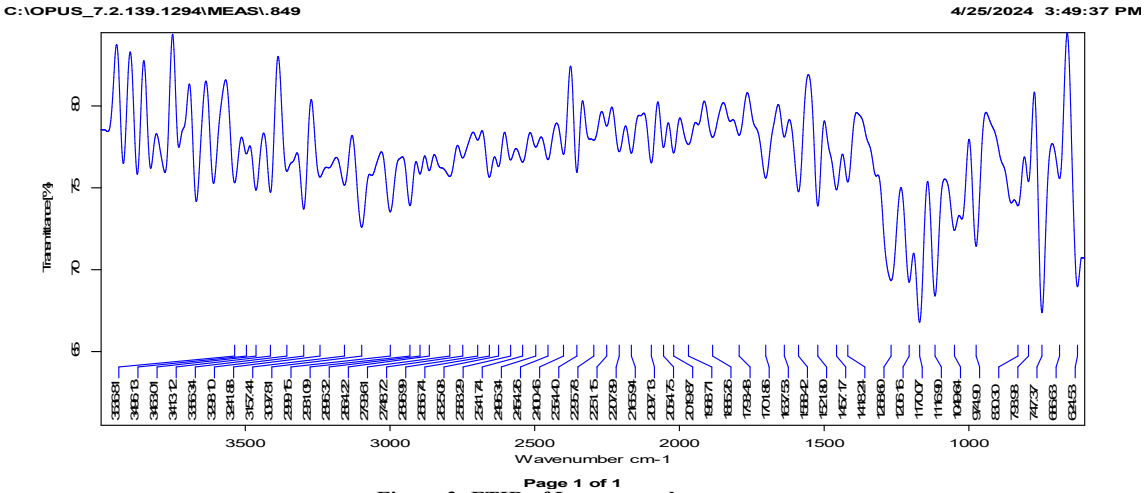

Figure 3: FTIR of Lansoprazole

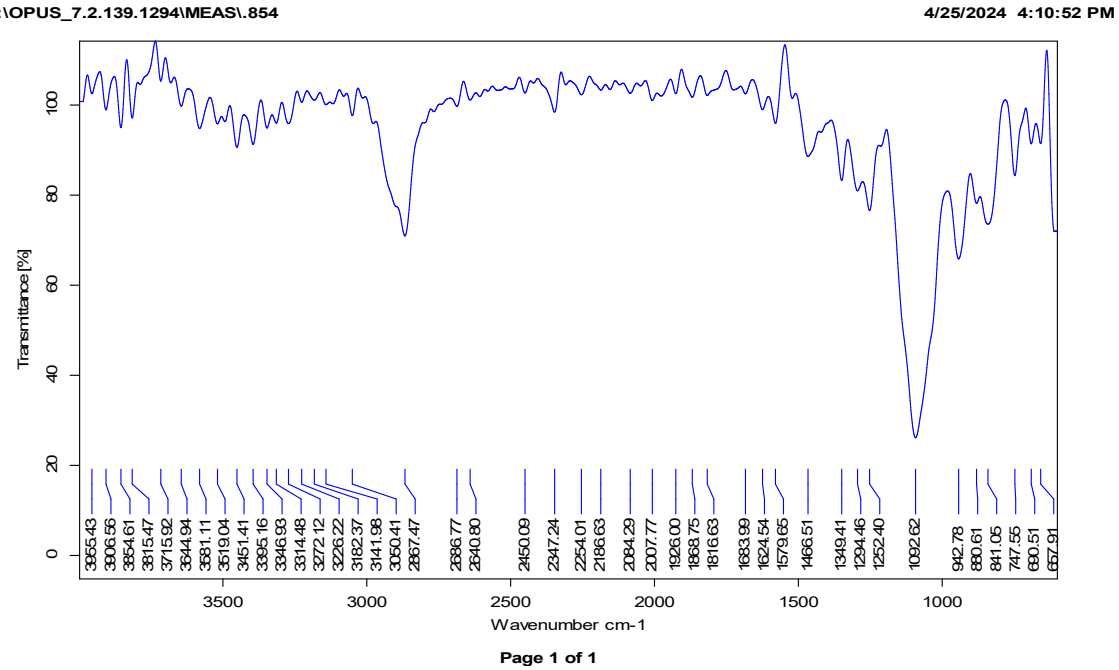

Figure 4: FTIR of Physical Mixture

Table 3: IR Interpretation of Lansoprazole and Physical Mixture

FUNCTIONAL GROUP	RANGE OF WAVE NUMBER (cm^{-1})	DRUG (cm^{-1})	PHYSICAL MIXTURE
C-O-C	1050-1200	1170.07	1092.62
N-H	3000-3500	3463.01	3451.41
C-N	2200-2400	2354.40	2347.24
C=N	2240-2260	2251.15	2254.01
C-0	1000-1300	1268.60	1092.62

Table 4: ANOVA for Reduced Quadratic model, Response 1: Thickness

Source	Sum of Squares	df	Mean Square	F-value	p-value	
Model	0.0001	3	0.0000	148.91	< 0.0001	significant
A-HPMC E15	0.0001	1	0.0001	364.58	< 0.0001	
B-PEG 600	0.0000	1	0.0000	37.33	0.0005	
A^2	0.0000	1	0.0000	44.81	0.0003	
Residual	2.000E-06	7	2.857E-07			
Lack of Fit	1.333E-06	5	2.667E-07	0.8000	0.6371	not significant
Pure Error	6.667E-07	2	3.333E-07			
Cor Total	0.0001	10				

Model's F-value of 148.91 indicates the model is significant

Table 5: Fit Statistics

Std. Dev.	0.0005	R^2	0.9846
Mean	0.0938	Adjusted R^2	0.9780
C.V. %	0.5697	Predicted R^2	0.9650
		Adeq Precision	34.1266

Table 6: Terms of Coded Factors

Thickness	=
+0.0950	
+0.0042	A
+0.0013	B
-0.0022	A^2

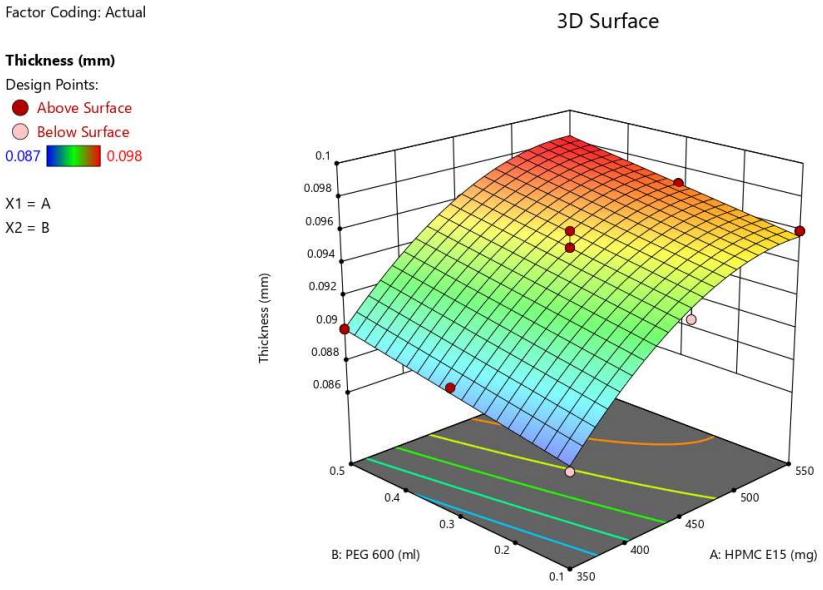

Figure 5: 3D Surface plot for thickness

Table 7: ANOVA for Linear model, Response 2: Folding endurance

Source	Sum of Squares	df	Mean Square	F-value	p-value	
Model	505.50	2	252.75	134.39	< 0.0001	significant
A-HPMC E15	121.50	1	121.50	64.60	< 0.0001	
B-PEG 600	384.00	1	384.00	204.18	< 0.0001	
Residual	15.05	8	1.88			
Lack of Fit	14.38	6	2.40	7.19	0.1271	not significant
Pure Error	0.6667	2	0.3333			
Cor Total	520.55	10				

Table 8: Fit Statistics

Std. Dev.	1.37	R^2	0.9711
Mean	145.64	Adjusted R^2	0.9639
C.V. %	0.9416	Predicted R^2	0.9384
		Adeq Precision	34.9074

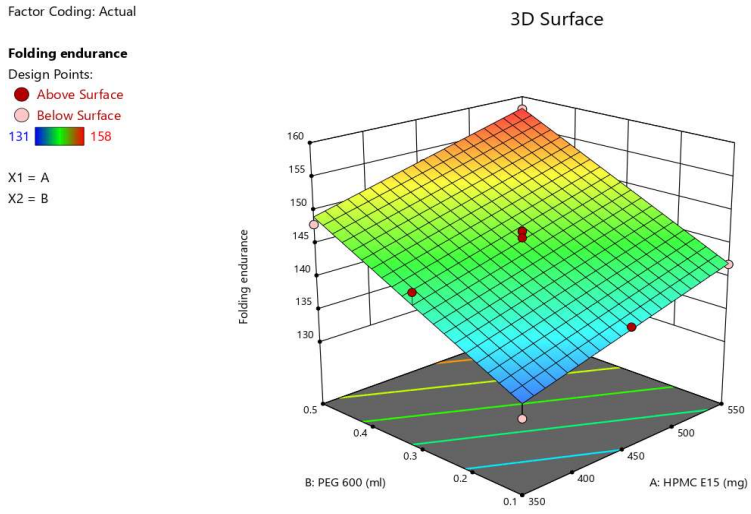

Figure 6: 3D Surface plot of folding endurance

Table 9: Terms of Coded Factors

Folding endurance	=
+145.64	
+4.50	A
+8.00	B

Table 10: ANOVA for Linear model, Response 3: Disintegration

Source	Sum of Squares	df	Mean Square	F-value	p-value	
Model	253.50	2	126.75	40.19	< 0.0001	significant
A-HPMC E15	216.00	1	216.00	68.50	< 0.0001	
B-PEG 600	37.50	1	37.50	11.89	0.0087	
Residual	25.23	8	3.15			
Lack of Fit	24.56	6	4.09	12.28	0.0772	not significant
Pure Error	0.6667	2	0.3333			
Cor Total	278.73	10				

Table 11: Fit Statistics

Std. Dev.	1.78	R^2	0.9095
Mean	19.45	Adjusted R^2	0.8869
C.V. %	9.13	Predicted R^2	0.8146
		Adeq Precision	18.3314

Table 12: Final Equation in Terms of Coded Factors

Disintegration	=
+19.45	
-6.00	A
-2.50	B

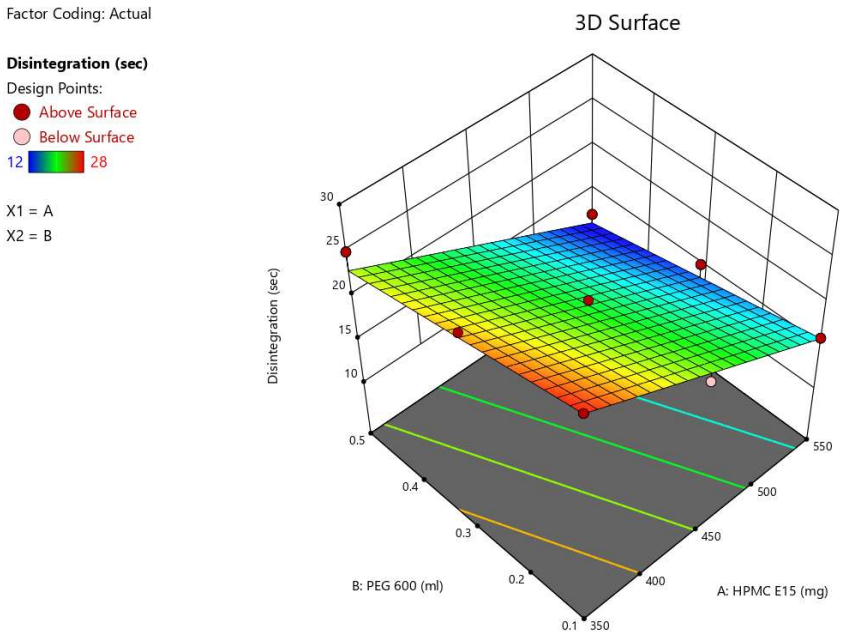

Figure 7: 3D Surface plot of disintegration

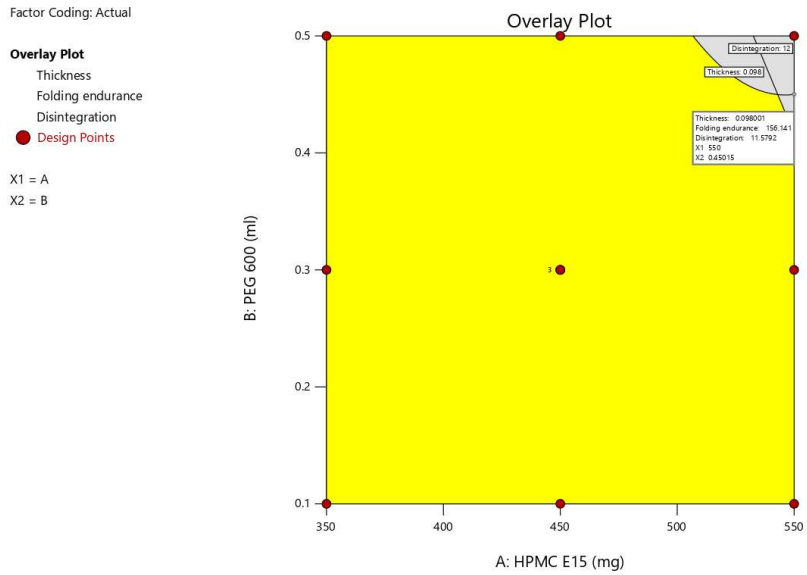

Figure 8: Overplay plot

Table 13: Coefficient table

	Intercept	A	B	A^2
Thickness	**0.095**	**0.00416667**	**0.00133333**	**-0.00216667**
p-values		**< 0.0001**	**0.0005**	**0.0003**
Folding endurance	**145.636**	**4.5**	**8**	
p-values		**< 0.0001**	**< 0.0001**	
Disintegration	**19.4545**	**-6**	**-2.5**	
p-values		**< 0.0001**	**0.0087**	

CONCLUSION

The formulations of Lansoprazole oral fast dissolving film were optimized by employing Central composite design from Design Expert-13 Software. Effect of independent variables (Polymer concentration and plasticizer) on dependent variables (Thickness, Folding Endurance, Disintegration). In preformulation studies, no drug excipients interaction was found. Lansoprazole oral thin films had a smooth surface, transparent, and were clear. In the model P value was found to be < 0.005, which indicates method is significant. F4 is considered as optimized formulation as responses are matching with overlay plot response values. Desirability index is found to be 0.96 which is satisfactory as reaching one which indicates the method is satisfactory.

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