International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Research Article

Articulate In Addition To Emancipate Behavior Of Long-Acting Dexlansoprazole Grid Tablets

Zakir Hussian[1], R.Suthakaran[2], M.Mahesh[3], Naseeb Basha Shaik[4], P.Ushasree[5], K.Vijay[6]

[1,2]Professor & HOD Dept. of Pharmaceutics, Vijaya College of Pharmacy-Hyderabad.
[3]Professor & Principal Dept. of Pharm chemistry, Vijaya College of Pharmacy-Hyderabad.
[4]Professor & Vice Principal Dept. of Pharma Analysis, Tirumala College of Pharmacy. Nizamabad.
[5]Professor & HOD Dept. of Pharmaceutics, G. Pulla Reddy College of Pharmacy –Hyderabad.
[6]Assistant Professor Dept. of Pharmaceutics, Vijaya College of Pharmacy-Hyderabad.

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Corresponding Author:

Zakir Hussian
Professor & HOD Dept. of Pharmaceutics, Vijaya College of Pharmacy-Hyderabad

Received: 25-09-2025
Accepted: 06-10-2025
Available online: 20-10-2025

ABSTRACT

Objective: The aim of the present study was to develop sustained release formulation of Dexlansoprazole
Methodology: This Study was performed in department of Pharmaceutics by using various methods, materials, tools, and process to maintain constant therapeutic levels of the drug for over 24 hrs. By using different ratios of synthetic polymers like HPMC K100M, Ethyl cellulose Natural polymer like Xanthan gum was employed as polymers.
Results: The present work was designed to developing Sustained tablets of Dexlansoprazole using various polymers. All the formulations were evaluated for physicochemical properties and in vitro drug release studies. All the formulations were passed various physicochemical evaluation parameters and they were found to be within limits. Whereas from the dissolution studies it was evident that the formulation (F3) showed better and desired drug release pattern i.e., 96.61% in 24 hours. It contains the HPMC K100M 1:3 ratio as sustained release material. It followed Higuchi release kinetics mechanism.
Conclusion: The present study concludes that sustained drug delivery of Dexlansoprazole can be a good way to prolong duration of action of drug by reducing the dosing frequency of Dexlansoprazole. Present study concludes that Sustained drug delivery system should be a suitable method for Dexlansoprazole administration. The optimised formulation was found to be F3 formulation.

Keywords*: Dexlansoprazole, Sustained release tablets.*

INTRODUCTION

A "Pharmaceutical progression structure" (DDS) is a set of guidelines that governs the administration of sedatives and supplements, including their timing, duration, and dosage. The commanding dissent, the existence of the protest's smart overhauls, and the subsequent interchange of embellishments to the area of action through the usual levels are all strengthened by this collaborative effort1. A "unfaltering substance" suggests a meticulously orchestrated mediation, such as an exceptional therapy that would stimulate the in-vivo development of a one-of-a-kind master focused on healing. It may be required to take the tablet three times daily, or even more often, in order to have the desired impact.4, the dosage that is prescribed differs across the various plans. When using delayed-release medications, which are often taken every twelve hours, this is usually the case. Using the same medication over an extended period of time has several advantages, such as more predictable and consistent results, better clinical evaluation of the medication for its intended use, and more predictable and consistent drug levels in the blood2.

MATERIALS

Dexlansoprazol, HPMC K100M, Ethyl cellulose, Xanthan gum, PVP, Iso propyl Alcohol,Talc, Magnesium Stearate, Microcrystalline cellulose.

Analytical method development:

Determination of absorption maxima:

100mg of Dexlansoprazole pure drug was dissolved in 15ml of Methanol and make up to 100ml with 0.1N HCL (stock solution-1). 10ml of above solution was taken and make up with100ml by using 0.1 N HCL (stock solution-2 i.e., 100μg/ml).From this 10ml was taken and make up with 100 ml of 0.1 N HCL (10μg/ml). Scan the 10μg/ml using Double beam UV/VIS spectrophotometer in the range of 200 – 400 nm.

Preparation calibration curve:

100mg of Dexlansoprazole pure drug was dissolved in 15ml of Methanol and volume make up to 100ml with 0.1N HCL (stock solution-1). 10ml of above solution was taken and make up with100ml by using 0.1 N HCL (stock solution-2 i.e 100μg/ml). From this take 1, 2, 3, 4 and 5 ml of solution and make up to 10ml with 0.1N HCL to obtain 10, 20, 30, 40 and 50 μg/ml of Dexlansoprazole per ml of solution. The absorbance of the above dilutions was measured at 271nm by using UV-Spectrophotometer taking 0.1N HCL as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight line Linearity of standard curve was assessed from the square of correlation coefficient (R2) which determined by least-square linear regression analysis. The above procedure was repeated by using pH 6.8 phosphate buffer solutions.

Drug – Excipient compatibility studies

Fourier Transform Infrared (FTIR) spectroscopy:

Drug excipient interaction studies are significant for the successful formulation of every dosage form. Fourier Transform Infrared (FTIR) Spectroscopy studies were used for the assessment of physicochemical compatibility and interactions, which helps in the prediction of interaction between drug and other excipients. In the current study 1:1 ratio was used for preparation of physical mixtures used for analyzing of compatibility studies. FT-IR studies were carried out with a Bruker, ATR FTIR facility using direct sample technique.

Formulation development of Sustained release Tablets:

All the formulations were prepared by Wet granulation method. The compositions of different formulations are given in Table. The tablets were prepared as per the procedure given below and aim is to prolong the release of Dexlansoprazole.

Procedure:

1) Dexlansoprazole and all other ingredients except Mg stearate and Aerosil were individually passed through sieve no □ 40.
2) Dexlansoprazole, MCC, and polymer mix thoroughly than add the binder solution mix properly up to 15 min.
3) Dry the above mixture at 65-70°C by using dryer.
4) After completion of drying the mixture is passed through sieve no □ 22.
5) The powder mixture was lubricated with Mg stearate and Talc.
6) Finally go for compression.[15]

Table 1: Formulation of Sustained release tablets

Formulation code	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
Dexlansoprazole	30	30	30	30	30	30	30	30	30	30	30	30
HPMC K100M	30	60	90	120	-	-	-	-	-	-	-	-
Ethyl cellulose	-	-	-	-	30	60	90	120	-	-	-	-
Xanthan gum	-	-	-	-	-	-	-	-	30	60	90	120
PVP	15	15	15	15	15	15	15	15	15	15	15	
Iso propyl alcohol	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	
Talc	3	3	3	3	3	3	3	3	3	3	3	
Magnesium Stearate	3	3	3	3	3	3	3	3	3	3	3	3
MCC	119	89	59	29	119	89	59	29	119	89	59	29
Total weight	200	200	200	200	200	200	200	200	200	200	200	

Evaluation Parameters Pre Compression parameters Bulk density (D_B)

Bulk density is the ratio between a given mass of the powder and its bulk volume.

Bulk density = Mass of Powder / Bulk volume of the powder Bulk density (D_B) = W /V_0

Procedure: An accurately weighed quantity of granules (w) (which was previously passed through sieve No: 40) was carefully transferred into 250 ml measuring cylinder and measure the bulk volume.[14]

Tapped Density (D_T)

Tapped density[3] is the ratio between a given mass of powder (or) granules and the constant (or) fixed volume of powder or granules after tapping.

Tapped density = mass of the powder/ tapped volume
Procedure: An accurately weighed quantity of granules (w) (which was previously passed through sieve No: 40) was carefully transferred into 250 ml measuring cylinder and the cylinder was tapped on a wooden surface from the height of 2.5 cm at two second intervals. The tapping was continued until no further change in volume (until a constant volume) was obtained (V_f). The tapped density was calculated by using the formula

Tapped density (D_T)=W/V_f
Hausner's ratio
Hausner's ratio[4] is an indirect index of ease of powder flow and was calculated by the formula, **Hausner's ratio = D_T/D_B**
Where, D_T is the tapped density D_B is the bulk density

Compressibility index
Compressibility index (CI) [5] was determined by measuring the initial volume (V_o) and final volume (V_f) after hundred tapping's of a sample in a measuring cylinder. It indicates the powder flow properties and expressed in terms of percentage and given in table no. 14 and calculated by using the formula[13]

% Compressibility index = V_o - V/V_o x 100
Angle of repose: Angle of repose [6] was measured by fixed funnel method. It determines flow property of the powder. It is defined as maximum angle formed between the surface of the pile of powder and the horizontal plane.
The powder was allowed to flow through the funnel fixed to a stand at definite height (h).
$\theta = \tan^{-1}$ (h / r)

Where, θ is the angle of repose h is the height in cm r is the radius in cm
Post Compression parameters
Weight variation test [7]: Twenty tablets were randomly selected and weighed, to estimate the average weight and that were compared with individual tablet weight. The percentage weight variation was calculated as per Indian Pharmacopoeial Specification. Tablets with an average weight 250 mg so the % deviation was ±5 %.

Friability test[8]: Twenty tablets were weighed and subjected to drum of friability test apparatus. The drum rotated at a speed of 25 rpm. The friabilator was operated for 4 minutes and reweighed the tablets. % loss(F) was calculated by the following formula.
F =100 (W0-W)/W0

Where W0 = Initial weight, W = Final weight
Hardness test
The hardness of tablets was measured by using Monsanto hardness tester. The results were complies with IP specification.
Thickness test [8]

The rule of physical dimension of the tablets such as sizes and thickness is necessary for consumer acceptance and maintain tablet uniformity. The dimensional specifications were measured by using screw gauge. The thickness of the tablet is mostly related to the tablet hardness can be used as initial control parameter.
Drug content [8]

The amount of drug in tablet was important for to monitor from tablet to tablet, and batch to batch is to evaluate for efficacy of tablets. For this test, take ten tablets from each batch were weighed and powdered. Weighed equivalent to the average weight of the tablet powder and transferred into a 100 ml volumetric flask and dissolved in a suitable quantity of media. The solution was made up to the mark and mixed well. Then filter the solution. A portion of the filtrate sample was analyzed by UV spectrophotometer.

***In vitro* drug release studies**

Apparatus	--	USP-II, Paddle Method
Dissolution Medium	--	0.1 N HCL , p H 6.8 Phophate buffer
RPM	--	50
Sampling intervals (hrs)	--	1, 2, 4, 6, 8, 10, 12, 16, 20, 24.
Temperature	--	37°c $\pm$ 0.5°c

Procedure:
900ml 0f 0.1 HCL was placed in vessel and the USP apparatus –II (Paddle Method) was assembled. The media was allowed to equilibrate to temp of 37°c $\pm$ 0.5°c. Tablet was placed in the vessel and apparatus was operated for 2 hours. Then 0.1 N HCL was replaced with Ph

6.8 phosphate buffer and process was continued upto 24 hrs at 50 rpm. At specific time intervals, withdrawn 5 ml of sample and again 5ml media was added to maintain the sink condition. Withdrawn samples were analyzed at 285 nm wavelength of drug using UV- spectrophotometer.

Application of Release Rate Kinetics to Dissolution Data[5]
Various models were tested for explaining the kinetics of drug release. To analyze the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Zero order release rate kinetics:
To study the zero–order release kinetics the release rate data ar e fitted to the following equation.
$$F = K_o t$$

Where, 'F' is the drug release at time't', and 'K_o' is the zero order release rate constant. The plot of % drug release versus time is linear.
First order release rate kinetics: The release rate data are fitted to the following equation
$$\text{Log } (100-F) = kt$$
A plot of log cumulative percent of drug remaining to be released vs. time is plotted then it gives first order release.
Higuchi release model: To study the Higuchi release kinetics, the release rate data were fitted to the following equation.[12]
$$F = k\, t1/2$$

Where, 'k' is the Higuchi constant.
In higuchi model, a plot of % drug release versus square root of time is linear.

Korsmeyer and Peppas release model:
The mechanism of drug release was evaluated by plotting the log percentage of drug released versus log time according to Korsmeyer- Peppas equation. The exponent 'n' indicates the mechanism of drug release calculated through the slope of the straight Line.

$$M_t / M_\infty = K\, t^n$$
Where, M_t / M_∞ is fraction of drug released at time 't', k represents a constant, and 'n' is the diffusional exponent, which characterizes the type of release mechanism during the dissolution process. For non-Fickian release, the value of n falls between 0.5 and 1.0; while in case of Fickian diffusion, n = 0.5; for zero-order release (case I I transport), n=1; and for supercase II transport, n > 1. In this model, a plot of log (M_t / M_∞) versus log (time) is linear[11]

RESULTS AND DISCUSSION
The present work was designed to developing Sustained tablets of Dexlansoprazole using various polymers. All the formulations were evaluated for physicochemical properties and *in vitro* drug release studies.

Standard graph of Dexlansoprazole in 0.1N HCL:
The scanning of the 10µg/ml solution of Dexlansoprazole in the ultraviolet range (200- 400nm) against 0.1 N HCL the maximum peak observed at λ_{max} as 285 nm. The standard concentrations of Dexlansoprazole(10-50 µg/ml) was prepared in 0.1N HCL showed good linearity with R^2 value of 0.999, which suggests that it obeys the Beer-Lamberts law.

Table 2: Standard curve of Dexlansoprazole in 0.1N HCL

Concentration (µg/ ml)	Absorbance
0	0
10	0.119
20	0.221
30	0.323
40	0.431
50	0.531

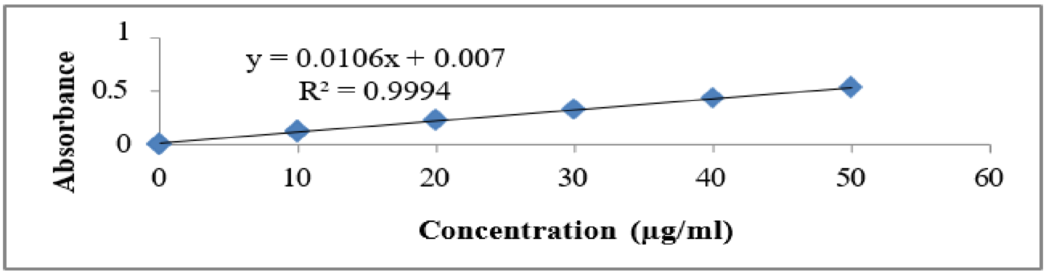

Fig 1: Calibration curve of Dexlansoprazolein 0.1 N HCL at 285 nm

Standard Curve of Dexlansoprazole in Phosphate buffer pH 6.8

The scanning of the 10µg/ml solution of Dexlansoprazole in the ultraviolet range (200-400nm) against 6.8 pH phosphate the maximum peak observed at the $\square_{max}$ as 284 nm. The standard concentrations of Dexlansoprazole (10-50µg/ml) prepared in 6.8 pH phosphate buffer showed good linearity with R^2 value of 0.999.[10]

Table 3: Standard curve of Dexlansoprazole in Phosphate buffer pH 6.8

Concentration (µg / ml)	Absorbance
0	0
10	0.125
20	0.22
30	0.333
40	0.440
50	0.536

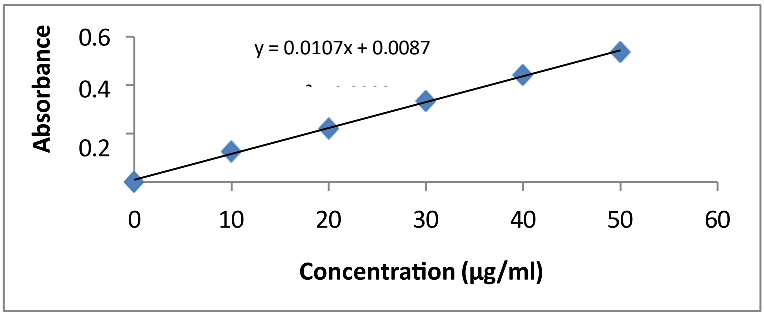

Fig.2: Calibration of Dexlansoprazole in Phosphate buffer pH 6.8

Drug and Excipient Compatibility Studies FTIR study:

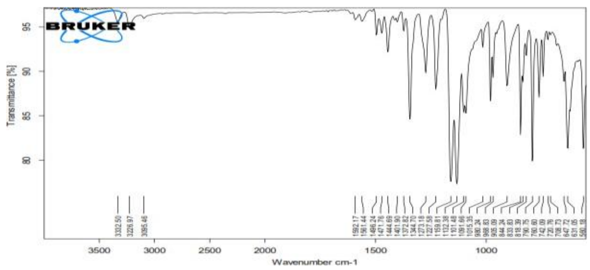

Fig.3 FTIR Graph of Pure Drug

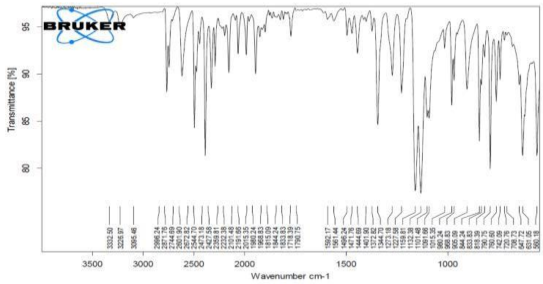

Fig. 4: Optimized formulation FTIR

Evaluation parameters: Pre-compression parameters

Table 4: Pre-compression parameters of powder blend

Formulation Code	Angle of Repose	ulk density (gm/ml)	pped density (gm/ml)	Carr's index (%)	Hausner's Ratio
F1	25.15 ± 0.58	0.49 ± 0.01	0.56 ± 0.08	12.5 ± 0.21	1.14 ± 0.012
F2	28.53 ± 0.57	0.48 ± 0.06	0.56 ± 0.08	14.28 ± 0.47	1.16 ± 0.032
F3	28.38 ± 0.56	0.47 ± 0.08	0.54 ± 0.01	12.96 ± 0.42	1.14 ± 0.031
F4	27.61 ± 0.63	0.53 ± 0.09	0.61 ± 0.071	13.1 ± 0.15	1.15 ± 0.021
F5	25.41 ±0.65	0.52 ±0.091	0.59 ±0.064	14.21 ±0.17	1.25 ±0.022

F6	26.08 ± 0.51	0.55 ± 0.011	0.62 ± 0.06	11.29 ± 0.35	1.12 ± 0.023
F7	25.25 ±0.52	0.43 ±0.022	0.61 ±0.033	11.20 ±0.03	1.10 ±0.06
F8	25.46 ± 0.57	0.55 ± 0.08	0.62 ± 0.011	11.29 ± 0.57	1.12 ± 0.015
F9	26.43 ±0.62	0.56 ± 0.07	0.63 ± 0.012	11.11 ± 0.12	1.12 ± 0.056
F10	24.16 ±0.68	0.54 ± 0.051	0.64 ±0.013	11.21 ±0.21	1.14 ±0.051
F11	26.12 ± 0.1	0.44 ± 0.03	0.50± 0.061	12 ± 0.58	1.13 ± 0.012
F12	27.26 ± 0.56	0.52 ± 0.055	0.59 ± 0.08	11.86 ± 0.57	1.13 ± 0.026

Tablet powder blend was subjected to various pre-compression parameters. The angle of repose values was showed from 25 to 30; it indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.44±0.03 to 0.56 ± 0.07 (gm/cm3) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.50± 0.061to 0.63 ± 0.012 showing the powder has good flow properties. The compressibility index of all the formulations was found to be ranging from 11 to 14.28 which showed that the powder has good flow properties. All the formulations were showed the hausner ratio ranging from 0 to 1.25 indicating the powder has good flow properties.9

Post Compression Parameters for tablets:

Table.5: Post Compression Parameters of Tablets

rmulation codes	age Weight (mg)	Hardness (kg/cm2)	riability (%loss)	hickness (mm)	g content (%)
F1	200.23 ±0.25	4.8±0.03	0.52±0.03	4.7±0.04	103.5 ± 0.14
F2	201.53 ± 0.34	4.5 ± 0.02	0.561 ±0.03	4.2 ±0.02	99.50 ± 0.22
F3	199.25 ± 2.02	4.6±0.09	0.48±0.08	4.6 ±0.09	104.3 ± 012
F4	198.25± 1.15	4.7±0.01	0.45±0.02	4.3 ±0.05	97.2 ± 0.19
F5	202.5 ± 0.86	4.7±0.04	0.55±0.07	4.3 ±0.05	98.3 ± 0.20
F6	203.26 ± 1.25	4.7±0.01	0.45±0.02	4.4±0.05	98.2 ± 0.19
F7	199.5 ± 0.95	4.8±0.07	0.51±0.04	4.3 ±0.03	102.3 ± 0.28
F8	202.26 ± 0.81	4.5±0.01	0.55±0.02	4.6±0.06	98.2 ± 0.15
F9	201.36 ± 1.17	4.7±0.04	0.56±0.04	4.7±0.08	100.8 ± 0.17
F10	199.95 ± 1.72	4.8±0.01	0.45±0.05	4.4 ±0.05	98.8 ± 0.14
F11	202.15 ± 1.31	4.7±0.05	0.54±0.07	4.6±0.04	99.3 ± 0.13
F12	201.5 ± 0.25	4.8±0.04	0.51±0.04	4.6±0.03	102.3 ± 0.21

Table 6: Dissolution Data of Dexlansoprazole Tablets Prepared with HPMC K100M in Different Ratios

TIME (hr)	**CUMULATIVE PERCENT DRUG RELEASED**			
	F1	**F2**	**F3**	**F4**
0	0	0	0	0
1	21.56	22.67	38.31	28.20
2	29.56	27.19	46.57	36.58
4	35.43	33.86	53.86	45.69
6	44.95	39.60	58.48	53.55
8	52.12	47.86	65.77	59.38
10	63.76	56.78	71.68	65.60
12	68.27	62.41	79.54	71.42
16	72.54	79.17	85.43	78.31
20	78.45	84.33	90.38	86.34
24	89.14	91.01	96.61	90.29

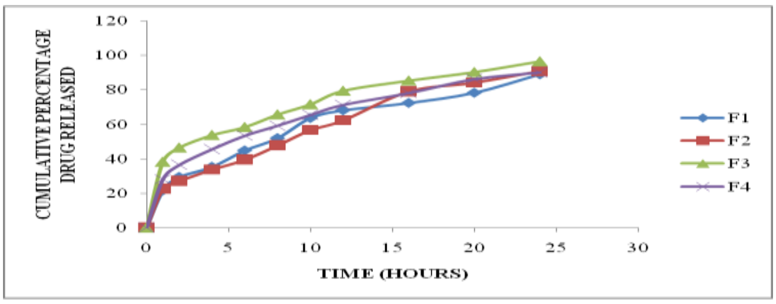

Figure 5: Dissolution study of Dexlansoprazole Sustained tablets (F1 to F4)

The % drug release of formulations (F1 to F4) containing HPMC K100M depends on the concentration of polymer. The concentration of HPMC K100M 1:1 and 1:2 was unable to retard the drug release up to desired time. When the concentration of polymer increased to 1:3 was able to retard the drug up to 24 hours. In F3 formulation 1:3 ratio (drug: polymer) concentration was used, showed maximum % drug release up to 24 hours i.e., 96.61%.

Table 7: Dissolution Data of Dexlansoprazole Tablets Prepared With Ethyl cellulose in Different Concentrations

TIME (hr)	CUMULATIVE PERCENT DRUG RELEASED			
	F5	F6	F7	F8
0	0	0	0	0
1	19.32	20.16	27.50	19.55
2	26.49	28.33	31.50	28.17
4	31.42	36.45	37.41	36.27
6	36.50	45.62	48.34	47.44
8	39.56	54.89	59.49	59.15
10	44.24	61.30	63.56	67.80
12	51.45	66.31	67.65	72.83
16	59.50	72.79	74.42	75.61
20	65.72	79.31	80.43	77.86
24	71.34	85.66	89.25	80.10

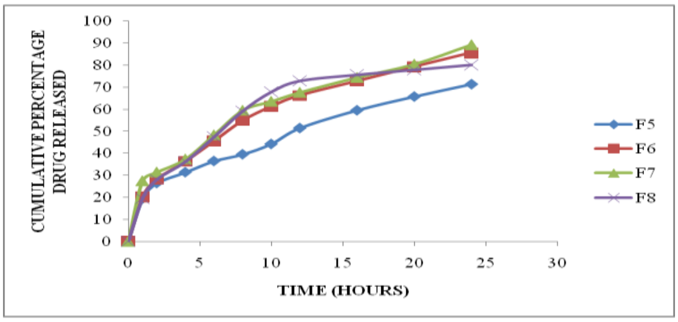

Figure 6: Dissolution study of Dexlansoprazole tablets (F5 to F8)

The % drug release of F5 to F8 formulations depends on ratio of polymer in the solution. The concentration of Ethyl cellulose polymer 1:1 was More retard the drug release up to desired time. When the ratio of polymer 1:2 was retard the drug up to desired time period i.e 85.66% at 24 hours. In F7 formulations, polymer ratio is 1:3 showed maximum % drug release i.e 89.25% at 24 hours.

Table 7: Dissolution Data of Dexlansoprazole by using Xanthan gum

TIME (hr)	CUMULATIVE PERCENT DRUG RELEASED			
	F9	F10	F11	F12
0	0	0	0	0
1	20.97	25.78	14.93	12.71
2	31.94	38.13	26.93	22.99
4	43.3	49.00	35.41	31.96
6	50.41	56.10	45.22	42.28
8	57.48	68.11	55.72	51.60
10	66.42	75.56	63.16	59.19
12	70.09	81.95	67.84	63.19
16	74.56	86.79	71.30	67.67
20	80.06	88.71	83.55	70.44
24	83.53	90.78	86.64	71.83

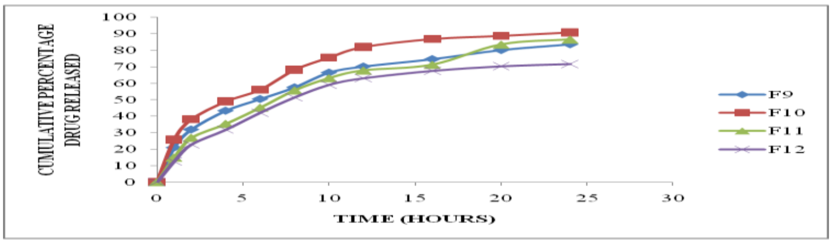

Figure 7: Dissolution study of Dexlansoprazole tablets with different ratios of Xanthan gum (F9 to F12)

The % drug release of F9 to F12 formulations depends on ratios of polymer in the solution. The Xanthan gum natural polymer 1:1 ratio was more to retard the drug release up to desired time. When the ratio of Xanthan gum natural polymer 1:2 was retard the drug up to desired time period i.e 90.78 % at 24 hours. In F10 formulations, gumr ratio is 1:2 showed maximum % drug release i.e 90.78% at 24 hours but the maximum drug is released at within 24 hours.

Hence based on dissolution data of 12 formulations, F3 formulation showed better release (96.61%) up to 24 hours. So F11 formulation is optimised formulation.

Table 9: Release kinetics data for optimized formulation (F11)

CUMULATIVE (%) RELEASE Q	TIME (T)	RELEASE RATE (CUMULATIVE % RELEASE / t)	1/CUM% RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	**0**	0	0	0	100	4.642	4.642	0.000
38.31	**1**	38.310	0.0261	-0.417	61.69	4.642	3.951	0.690
46.57	**2**	23.285	0.0215	-0.332	53.43	4.642	3.766	0.875
53.86	**4**	13.465	0.0186	-0.269	46.14	4.642	3.587	1.055
58.48	**6**	9.747	0.0171	-0.233	41.52	4.642	3.463	1.179
65.77	**8**	8.221	0.0152	-0.182	34.23	4.642	3.247	1.395
71.68	**10**	7.168	0.0140	-0.145	28.32	4.642	3.048	1.593
79.54	**12**	6.628	0.0126	-0.099	20.46	4.642	2.735	1.907
85.43	**16**	5.339	0.0117	-0.068	14.57	4.642	2.442	2.199
90.38	**20**	4.519	0.0111	-0.044	9.62	4.642	2.127	2.515
96.61	**24**	4.025	0.0104	-0.015	3.39	4.642	1.502	3.139

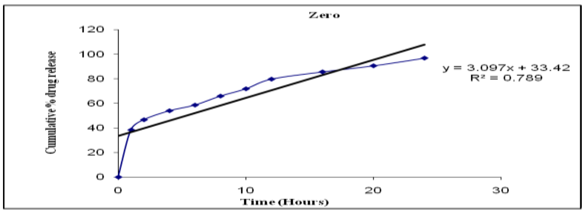

Figure 9: Graph of Zero order kinetics

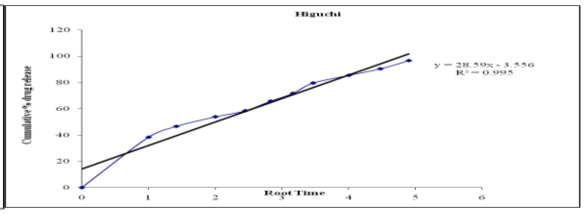

Figure 10: Graph of Higuchi release kinetics

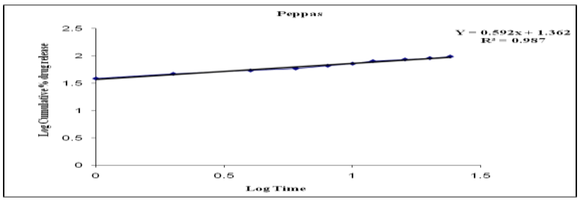

Figure 9.11: Graph of Peppas release kinetics

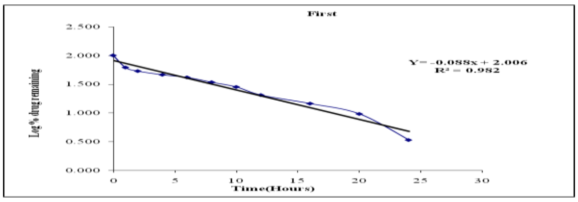

Figure 9.12: Graph of First order release kinetics

Conflicts of interests: The authors declare no conflicts of interest.
Author contribution: All authors have contributed in the manuscript.
Author funding: Nill

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