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Formulation, In-Vitro Evaluation of Cilostazol Gastrorententive Floating Tablets Using Different Polymers

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Abstract

The present research was undertaken to formulate and evaluate gastroretentive floating tablets of **Cilostazol** with the aim of improving gastric residence time and sustained drug release. Cilostazol, a poorly soluble drug with limited bioavailability, was selected as the model drug. The analytical method was standardized by UV spectrophotometry, showing a λmax at 258.2 nm and a calibration curve obeying Beer–Lambert's law with good linearity (R^2 = 0.997).Powder blends of different formulations (F1–F6) were subjected to preformulation studies including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio, all of which indicated good flow and compressibility properties. The prepared floating tablets were evaluated for weight variation, hardness, friability, thickness, drug content, floating lag time, and total floating time. All formulations complied with pharmacopoeial standards, exhibiting acceptable physicochemical and mechanical characteristics.In vitro dissolution studies revealed that the formulation **F3**, containing **150 mg guar gum**, provided sustained drug release up to 12 hours with **99.81% cumulative release**, thereby showing the best performance among all formulations. Kinetic modeling of dissolution data demonstrated that drug release followed **Korsmeyer–Peppas model**, indicating a non-Fickian diffusion mechanism. Compatibility studies using FTIR confirmed no significant drug–excipient interactions.In conclusion, the optimized formulation

Keywords: Cilostazol, Guar Gum, and HPMC K15M, Buoyancy, Invitro Drug Release, Stability Study.

INTRODUCTION

Oral route of administration remains the most preferred and convenient means of drug delivery due to its patient compliance, safety, and ease of production. However, conventional oral dosage forms are often associated with limitations such as variable gastric emptying, reduced bioavailability of poorly soluble drugs, and short gastric residence times, which compromise therapeutic efficacy. To overcome these challenges, gastroretentive drug delivery systems (GRDDS) have been developed. These systems are designed to prolong the residence time of dosage forms in the stomach, thereby ensuring controlled and sustained release of drugs with narrow absorption windows, poor solubility, or instability in the intestinal environment.Cilostazol, a phosphodiesterase III inhibitor, is widely used in the management of intermittent claudication and other cardiovascular disorders due to its vasodilatory and antiplatelet properties. Despite its therapeutic potential, Cilostazol exhibits poor solubility and undergoes extensive first-pass metabolism, leading to low and variable oral bioavailability. A gastroretentive floating tablet approach offers an effective strategy to enhance the solubility, dissolution rate, and sustained release of Cilostazol by retaining the dosage form in the gastric region for prolonged periods.Floating drug delivery systems (FDDS) function on the principle of buoyancy, where the formulation remains afloat on gastric fluids due to its lower density, thereby releasing the drug gradually in a controlled manner. Various polymers such as hydroxypropyl methylcellulose (HPMC) and natural gums like guar gum are employed to achieve desired swelling, floating ability, and drug release characteristics.The present study focuses on the formulation and evaluation of gastroretentive floating tablets of Cilostazol using different polymers. Preformulation, physicochemical characterization, in vitro buoyancy, and dissolution studies were carried out to optimize the formulation. Drug release kinetics and compatibility studies were also investigated to ensure stability and therapeutic effectiveness.

Chemicals and Reagents:
cilostazol was provided by Amsal Pvt Ltd (Gujrat, India). HPMC K15Mand Guar gumwax came from Dr. Reddy's Laboratories, Citric acid ,Aerosol,Talc, Magnesium stearate and Sodium Bicarbonate were sourced from SD Fine Chemicals Pvt Ltd.

Preformulation Studies
Preformulation testing is the first step in developing drug dosage forms. It examines the physical and chemical properties of the drug, both alone and with excipients. The goal is to gather essential information for creating stable and bioavailable formulations.

Identification of Pure Drug:
Cilostazol was identified utilizing Infrared Absorption Spectroscopy.

Melting Point Determination:
The melting point of cilosatzol was assessed using the open capillary method.

Solubility Studies:
Solubility is a crucial physicochemical parameter for a drug, as it influences bioavailability, the rate of drug release into the dissolution medium, and ultimately, the therapeutic efficacy of the pharmaceutical product. To evaluate the solubility of cilostazol, the equilibrium solubility method was employed. In this method, an excess quantity of the drug is placed in 10 ml of solvent within a conical flask, which is then placed on a rotary shaker. The flask is shaken at a speed of 100 rpm for 24 hours. Following this, the solution is filtered, and the absorbance is measured using a UV-visible spectrophotometer to determine the concentration. The solvents used in these solubility studies included water and 0.1N HCl.

Drug-Excipient Compatibility Studies:
A stable and effective solid dosage form depends on selecting the right excipients, which aid in administration, ensure consistent drug release and bioavailability, and protect the drug from degradation. Compatibility studies are essential when using new excipients with an active substance. The compatibility of Cilostazol with various polymers and excipients was assessed using Fourier Transform Infrared Absorption (FTIR) analysis.

Flow Properties

Angle of Repose:
The angle of repose is the maximum angle between a pile of powder and a horizontal plane, used to assess flow characteristics. Poor powder flow results from frictional forces between particles, which the angle of repose quantifies.
The angle of repose (θ) was elegantly determined using the following formula:

$$\text{Tan } \theta = h / r$$

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

Tan θ = height of pile in cm/ radius of pile in cm
θ = tan-1 (height of pile in cm/ radius of pile in cm)

Bulk density:
Bulk density is defined as the ratio of the total mass of a powder to its bulk volume. It is mathematically represented as follows:

$$Db = \text{Mass} / \text{bulk volume}$$

Bulk density is measured using a bulk density apparatus. A sample of 50 g of powder is added to a 100 ml graduated cylinder, which is then tapped 100 times. The final volume occupied by the powder is recorded and used to calculate the bulk density.

Tapped density:
The procedure involved placing a graduated cylinder filled with a known mass of a drug-excipient blend onto a mechanical tapping apparatus. The tapped volume was determined by tapping the powder until a constant volume was achieved. This volume is expressed in grams per milliliter (g/ml).

Tapped density = M/Vt
Where
M= mass of powder and
Vt= tapped volume of the powder.

Compressibility Index (Carr's Consolidation Index):

One method for measuring free-flowing powder is compressibility, calculated from the powder's density using a specific formula.

Percentage Compressibility = [Tapped density-bulk density/tapped density] x 100

Hausner's Ratio:

Hausner's ratio is an indirect measure of powder flow ease. If the Hausner's ratio of a powder is close to 1.25, it indicates better powder flow. It is calculated using the following formula.

= Dt / Db

Where, Db represents the bulk density of the powder, and Dt represents the tapped density of the powder.

Procedure for direct compression method:

1) Drug and all other ingredients were individually passed through sieve no ≠ 60.
2) All the ingredients were mixed thoroughly by triturating up to 15 min.
3) The powder mixture was lubricated with talc.
4) The tablets were prepared by using direct compression method by using 9 mm punch.

FORMULATION OF TABLETS:

Table: Formulation composition for Floating tablets

Ingredients	F1	F2	F3	F4	F5	F6
Cilastazol	100	100	100	100	100	100
Guar gum	50	100	150	-	-	-
HPMC K15M	-	-	-	50	100	150
Sodium bi Carbonate	10	10	10	10	10	10
Citric acid	8	8	8	8	8	8
Aerosil	5	5	5	5	5	5
Magnesium Stearate	5	5	5	5	5	5
MCC	122	72	22	122	72	22
Total weight	300	300	300	300	300	300

All the quantities were in mg

Evaluation of post compression parameters for prepared Tablets

The designed compression tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability and drug content.

Weight variation test:

To study the weight variation, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of deter mining the drug content uniformity. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the following table and none deviate by more than twice the percentage. The mean and deviation were determined. The percent deviation was calculated using the following formula.

% Deviation = (Individual weight – Average weight / Average weight) × 100

Hardness:

Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. For each

formulation, the hardness of three tablets was determined using Monsanto hardness tester and the average is calculated and presented with deviation.

Thickness:

Tablet thickness is an important characteristic in reproducing appearance. Tablet thickness is an important characteristic in reproducing appearance. Average thickness for core and coated tablets is calculated and presented with deviation.

Friability:

It is measured of mechanical strength of tablets. Roche friabilator was used to determine the friability by following procedure. Pre weighed tablets were placed in the friabilator. The tablets were rotated at 25 rpm for 4 minutes (100 rotations). At the end of test, the tablets were re-weighed, and loss in the weight of tablet is the measure of friability and is expressed in percentage as

% Friability = [(W1-W2) / W1] × 100

Where, W1 = Initial weight of tablets

W2 = Weight of the tablets after testing

Determination of drug content:

Both compression-coated tablets of were tested for their drug content. Ten tablets were finely powdered quantities of the powder equivalent to one tablet weight of Cilastazol were accurately weighed, transferred to a 100 ml volumetric flask containing 50 ml water and were allowed to stand to ensure complete solubility of the drug. The mixture was made up to volume with water. The solution was suitably diluted and the absorption was determined by UV –Visible spectrophotometer. The drug concentration was calculated from the calibration curve.

***In vitro* Buoyancy studies:**

The in vitro buoyancy was determined by floating lag time, and total floating time. (As per the method described *by Rosa et al*) The tablets were placed in a 100ml beaker containing 0.1N HCL. The time required for the tablet to rise to the surface and float was determined as floating lag time (FLT) and duration of time the tablet constantly floats on the dissolution medium was noted as Total Floating Time respectively (TFT).

***In vitro* drug release studies**

Dissolution parameters:

Apparatus	--	USP-II, Paddle Method
Dissolution Medium	--	0.1 N HCL
RPM	--	50
Sampling intervals (hrs)	--	1,2,3,4,5,6,7,8,10,11,12
Temperature	--	37°c ± 0.5°c

As the preparation was for floating drug release given through oral route of administration, different receptors fluids are used for evaluation the dissolution profile.

Procedure:

900ml 0f 0.1 HCL was placed in vessel and the USP apparatus –II (Paddle Method) was assembled. The medium was allowed to equilibrate to temp of 37°c ± 0.5°c. Tablet was placed in the vessel and the vessel was covered the apparatus was operated for 12 hours and then the medium 0.1 N HCL was taken and process was continued from 0 to 12 hrs at 50 rpm. At definite time intervals of 5 ml of the receptors fluid was withdrawn, filtered and again 5ml receptor fluid was replaced. Suitable dilutions were done with media and analyzed by spectrophotometrically at 258.2 nm using UV-spectrophotometer.

7.5: Application of Release Rate Kinetics to Dissolution Data:

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:

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To study the zero–order release kinetics the release rate data are 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
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.
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.

RESULTS AND DISCUSSION

b. Calibration curve

calibration curve for Cilostazol in methanol

Table no 8.1: Observations for graph of Cilostazol in Methanol

Concentration (µg/ml)	Absorbance
0	0
5	0.213
10	0.424
15	0.627
20	0.827
25	1.032

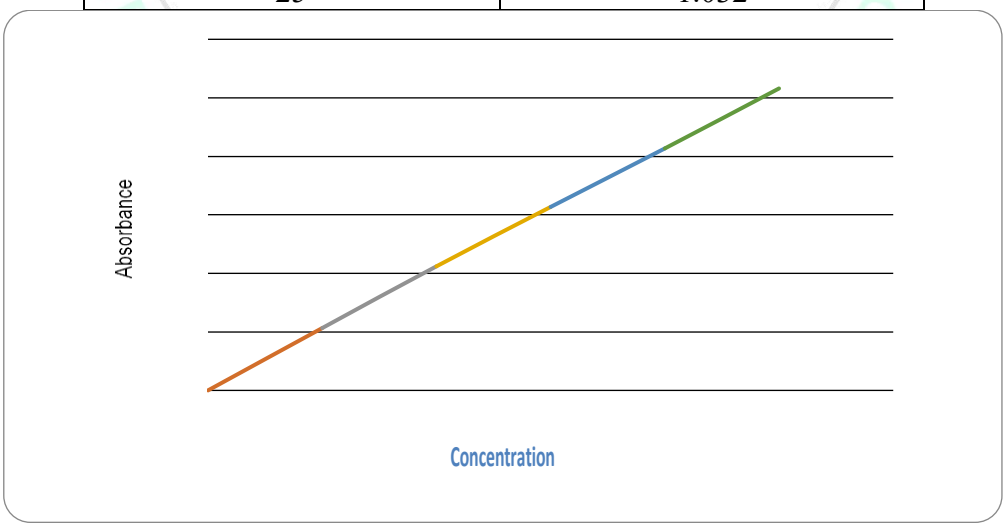

Fig 8.1 Standard graph of Cilostazol in 0.1N HCL Preformulation parameters of powder blend:

Table: Pre-formulation parameters of blend

Formulation Code	Angle of Repose	Bulk density (gm/mL)	Tapped density (gm/mL)	Carr's index (%)	Hausner's Ratio
F1	34.60 ±0.55	0.56 ±0.007	0.69±0.0095	12.88 ±2.20	1.14 ±0.03
F2	31.30 ±0.92	0.58±0.0075	0.71 ±0.015	20.31 ±2.81	1.25 ±0.041
F3	30.09 ±0.21	0.56 ±0.017	0.70±0.0052	17.95 ±1.64	1.21 ±0.026
F4	30.74 ±0.83	0.56±0.0065	0.64 ±0.012	14.83 ±0.70	1.17 ±0.011
F5	34.20 ±0.74	0.56±0.0080	0.70±0.0072	14.71 ±0.70	1.24 ±0.05
F6	34.05 ±0.93	0.56 ±0.014	0.66±0.0068	15.76 ±1.85	1.18 ±0.02

In vitro quality control parameters

Formulation codes	Average Weight (mg)	Hardness (kg/cm^2)	Friability (% loss)	Thickness (mm)	Drug content (%)	Total Floating Time (hrs)	Floating Lag time (sec)
F1	298.73	3.74	0.68	4.65	99.86	12	12
F2	300.55	3.88	0.74	4.77	97.37	11	16
F3	299.92	3.67	0.66	4.55	100.52	12	10
F4	298.01	3.49	0.71	4.64	99.96	12	13
F5	300.30	3.62	0.85	4.72	98.48	12	15
F6	300.22	3.48	0.64	4.59	99.12	12	18

All the parameters for Floating Tablets such as weight variation, friability, hardness, thickness, drug content were found to be within limits.

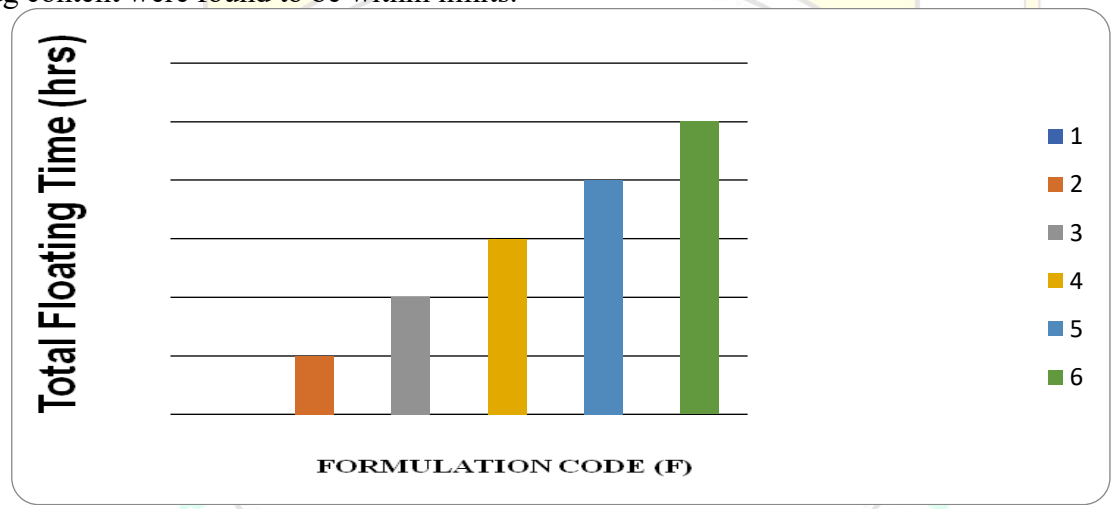

Figure 8.2: Total Floating Time (hrs)

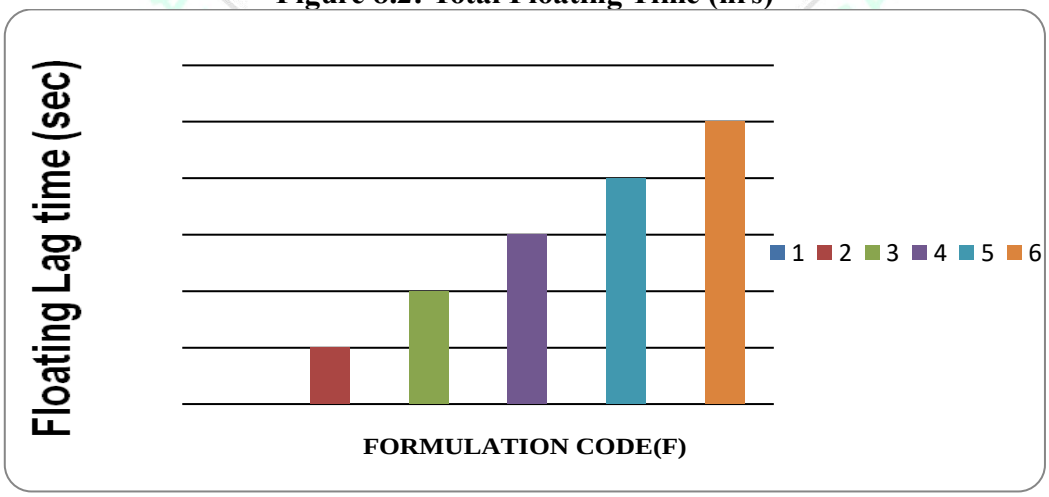

Figure 8.3: Floating Lag time (sec) ***8.6. In vitro*** **drug release studies**

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Table no 8.4: Dissolution data of Floating Tablets

Time (hrs)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
1	26.53	26.77	18.49	21.94	19.33	17.58
2	32.12	33.64	25.66	24.45	21.26	19.86
3	47.88	49.31	33.05	32.72	27.85	22.26
4	58.32	55.22	41.38	40.98	30.14	28.64
5	64.09	61.68	55.16	44.21	33.25	33.02
6	71.66	73.92	62.41	57.58	42.98	46.68
7	77.15	79.17	76.16	62.12	49.21	53.16
8	84.48	86.23	82.71	68.84	55.11	58.01
9	91.32	91.73	88.66	73.22	61.26	63.92
10	92.34	94.52	92.65	77.04	72.81	69.75
11	94.41	94.19	98.16	79.46	77.55	75.91
12	95.44	97.37	99.81	82.17	79.78	78.86

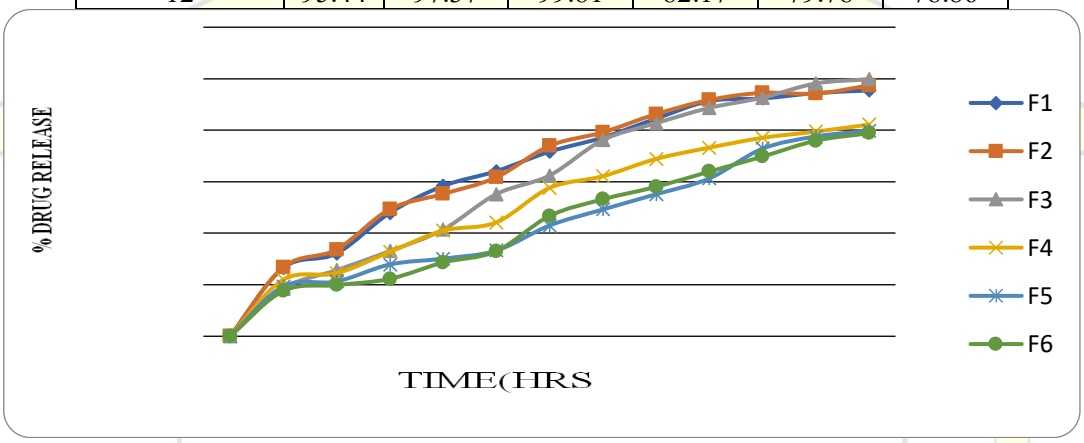

Fig: 8.5 : Dissolution data of Cilostazol Floating tablets containing Guar gum and HPMCK15M

Formulations prepared with Guar gum retarded the drug release in the concentration of 150mg (F3 Formulation) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 99.81 % in 12 hours with good drug release.

The Formulation Containing HPMCK15M in 50 mg Concentration Showed good retarding nature with required drug release in 12 hours i.e., 82.17 %.

Hence from the above dissolution data it was concluded that F3 formulation was considered as optimised formulation because good drug release (99.81%) in 12 hours.

Application of Release Rate Kinetics to Dissolution Data for optimised formulation:

Table no 8.5 Application kinetics for optimised formulation

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG (%) RELEASE	LOG (T)	LOG (%) REMAIN	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			2.000				100	4.642	4.642	0.000
18.49	1	1.000	1.267	0.000	1.911	18.490	0.0541	-0.733	81.51	4.642	4.336	0.306
25.66	2	1.414	1.409	0.301	1.871	12.830	0.0390	-0.591	74.34	4.642	4.205	0.437
33.05	3	1.732	1.519	0.477	1.826	11.017	0.0303	-0.481	66.95	4.642	4.061	0.581
41.38	4	2.000	1.617	0.602	1.768	10.345	0.0242	-0.383	58.62	4.642	3.885	0.757
55.16	5	2.236	1.742	0.699	1.652	11.032	0.0181	-0.258	44.84	4.642	3.553	1.089
62.41	6	2.449	1.795	0.778	1.575	10.402	0.0160	-0.205	37.59	4.642	3.350	1.292
76.16	7	2.646	1.882	0.845	1.377	10.880	0.0131	-0.118	23.84	4.642	2.878	1.764
82.71	8	2.828	1.918	0.903	1.238	10.339	0.0121	-0.082	17.29	4.642	2.586	2.056
88.66	9	3.000	1.948	0.954	1.055	9.851	0.0113	-0.052	11.34	4.642	2.247	2.395
92.65	10	3.162	1.967	1.000	0.866	9.265	0.0108	-0.033	7.35	4.642	1.944	2.697
98.16	11	3.317	1.992	1.041	0.265	8.924	0.0102	-0.008	1.84	4.642	1.225	3.416
99.81	12	3.464	1.999	1.079	-0.721	8.318	0.0100	-0.001	0.19	4.642	0.575	4.067

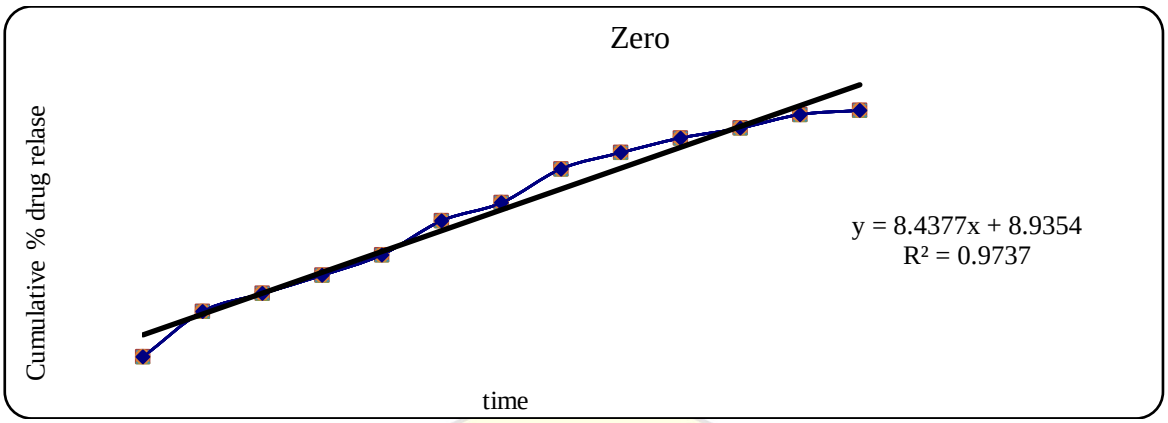

Fig no 8.7: Zero order release kinetics

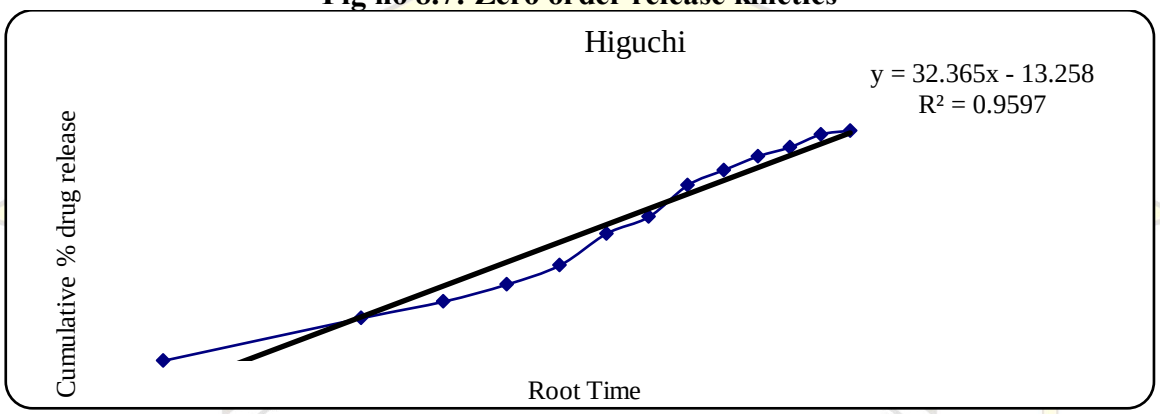

Fig no 8.8: Higuchi release kinetics

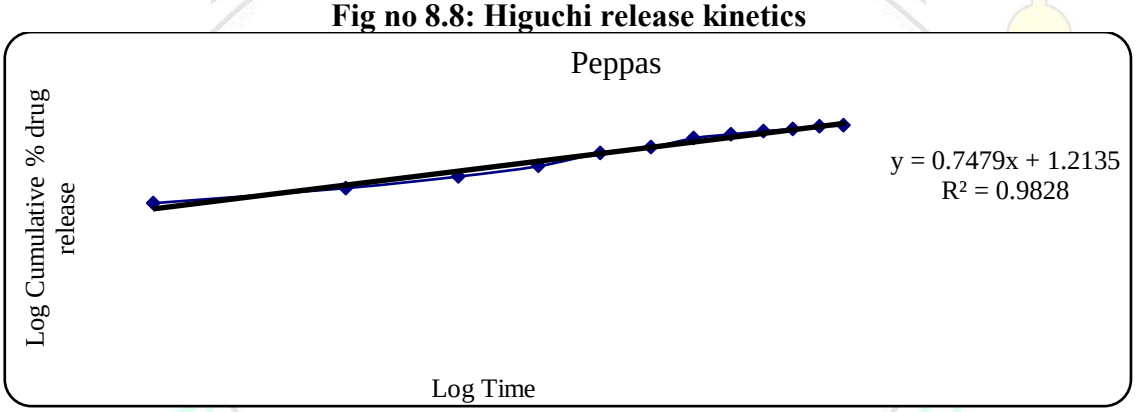

Fig8.9 : Kors mayer peppas release kinetics

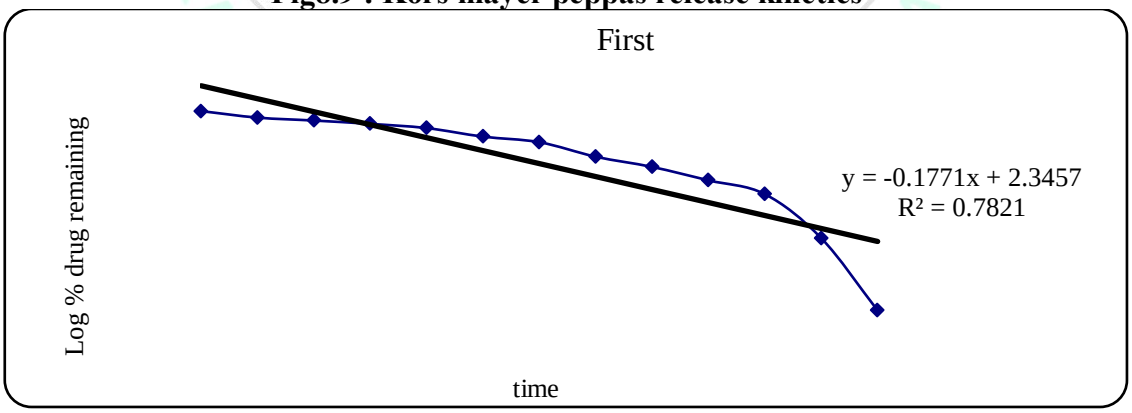

Fig 8.10: First order release kinetics

Optimised formulation F3 was kept for release kinetic studies. From the above graphs it was evident that the formulation F3 was followed Kors mayer peppas release kinetics mechanism.

Drug – Excipient compatability studies

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Fourier Transform-Infrared Spectroscopy:

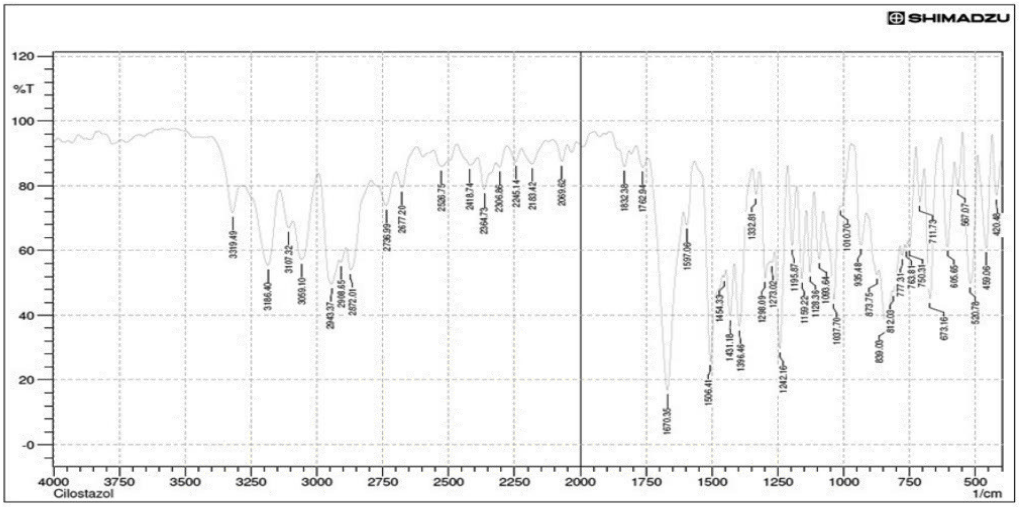
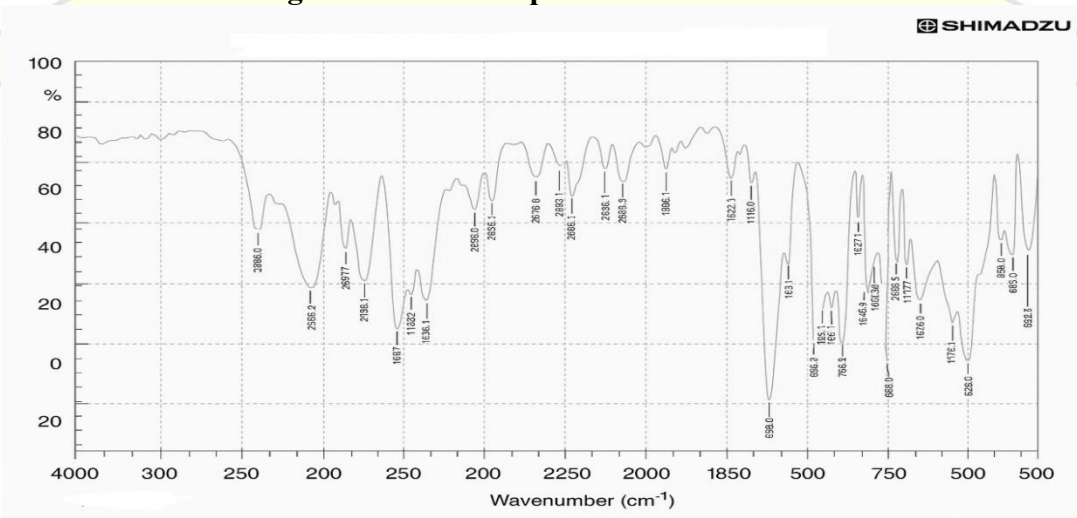
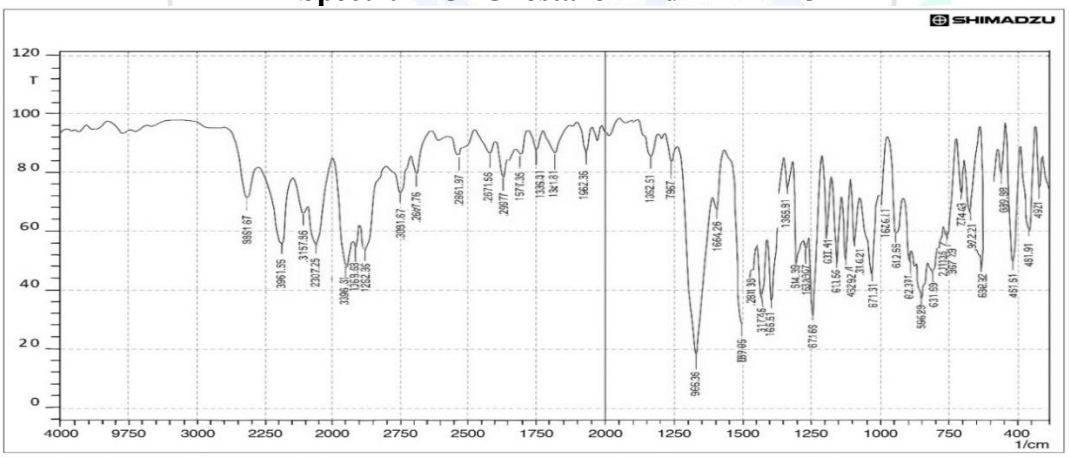


Figure 8.11: FTIR Spectrum of Cilostazol



FTIR Spectrum Of Cilostazol And HPMK15M



FTIR SPECTRUM OF OPTIMIZED FORMULATION (F3 –FORMULATION WITH GUAR GUM 150mg)

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