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FORMULATION AND EVALUATION OF EXTENDED-RELEASE TABLETS OF AN ANTI-ISCHEMIC AGENT TRIMETAZIDINE HCL

Asutosh Kar, Ashish Pandab, Satya Ranjan Dalai, Pravat Ranjan Guru.

[1] Department of Pharmaceutics, Dadhichi College Of Pharmacy, Vidya-Vihar, Sundargram, Cuttack, Odisha-754 002.

Abstract:

The present study focuses on the Formulation and Evaluation of Extended-Release Tablets Of Trimetazidine Hcl, an anti-ischemic agent used in the management of angina pectoris. The primary objective was to develop a sustained-release dosage form to maintain consistent plasma drug levels, reduce dosing frequency, and improve patient compliance. Various formulations were prepared using suitable polymers and evaluated for both pre-compression and post-compression parameters, including flow properties, hardness, friability, weight variation, drug content, and in vitro drug release. All evaluated parameters were found to be within the acceptable limits as per IP standards.

Among the formulations, F2 was identified as the optimized batch, demonstrating a desirable extended drug release profile with 99.32% cumulative drug release over 12 hours. The drug release followed controlled-release kinetics, indicating the effectiveness of the matrix system used. This study concludes that the optimized formulation of Trimetazidine HCl extended-release tablets offers a promising approach for sustained therapy in ischemic conditions, ensuring better therapeutic outcomes and improved patient adherence.

Keywords: *Extended-Release Tablets of Trimetazidine Hcl*

Corresponding author:

Asutosh Kar*.,

Department of Pharmaceutics,
Dadhichi College Of Pharmacy,
Vidya-Vihar, Sundargram, Cuttack.
Email Id- dcparan@rediffmail.com.

QR CODE

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1.INTRODUCTION:

Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes. All the pharmaceutical products formulated for systemic delivery via the oral route of administration, irrespective of the mode of delivery (Immediate, Extended or Controlled release) and the design of dosage forms (either solid, dispersion, or liquid), must be developed within the intrinsic characteristics of GI physiology.[1]

The most convenient and commonly employed route of drug delivery is oral ingestion. The oral route remains the preferred route of drug administration due to its convenience, better patient compliance, and low production costs.[2]

A drug delivery system is defined as a formulation or a device that enables the introduction of a therapeutic substance in the body and improves its efficacy and safety by controlling the rate, time, and place of release of drugs in the body. This process includes the administration of the therapeutic product, the release of the active ingredients by the product, and the subsequent transport of the active ingredients across the biological membranes to the site of action. The term therapeutic substance also applies to an agent such as gene therapy that will induce in vivo production of the active therapeutic agent. Drug delivery system is an interface between the patient and the drug. It may be a formulation of the drug to administer it for a therapeutic purpose or a device used to deliver the drug. This distinction between the drug and the device is important, as it is the criterion for regulatory control of the delivery The advantage of administering a single dose of a drug that is released over an extended period of time to maintain a near–constant or uniform blood level of a drug often translates in to better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use.[3-5]

Out of the many routes of administration available, the oral route remains the most popular dosage form among patients as it is easy to administer, carry around, formulation design flexibility, cost-effectiveness, causes minimal discomfort for many patients, and least sterility restrictions during manufacturing. Most of the newly discovered drugs are lipophilic in nature and have poor aqueous solubility, thereby posing problems in their formulation into delivery systems[6]

System by the drug or medicine control agency. If a device is introduced into the human body for purposes other than drug administration, such as therapeutic effect by a physical modality or a drug may be incorporated into the device for preventing complications resulting from the device, it is regulated strictly as a device. Traditional drug delivery system has been characterized by immediate release and repeated dosing of the drug which might lead to the risk of dose fluctuation, this arises the need of a formulation with control release that maintain a near-constant or uniform blood level. The desire to maintain a near-constant or uniform blood level of a drug often translates into better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use. Sustained release, sustained action, prolong action, controlled release, extended action, depot are terms used to identify drug delivery systems that are designed to achieve prolong therapeutic effect by continuously releasing medication over an extended period of time after administration of single dose.[7-10]

Oral administration is the mainstay of antiepileptic drug (AED) delivery for patients with chronic epilepsy.[11] Efforts to enhance the ease of administration are important because lack of adherence or partial adherence to medication can have immediate detrimental consequences, such as uncontrolled or recurrent seizures, or can lead to adverse effects (AEs) associated with restarting a previous dose without titration.

Some drugs are inherently long lasting and require only once a day oral dosing to sustain adequate drug blood levels and the desired therapeutic effect. These drugs are formulated in the conventional manner in the form of immediate release dosage forms. However, many other drugs are not inherently long lasting and require multiple daily dosing to achieve the desired therapeutic results. Multiple daily dosing is inconvenient for the patient and can result in missed doses, made up doses and non-compliance with the regimen. When conventional immediate-release dosage forms are taken on schedule and more than once daily, they cause sequential therapeutic blood level peaks and valleys (troughs) associated with the administration of each dose. However, when doses are not administered on schedule, the resulting peaks and valleys reflect less than optimum drug therapy. For example, if doses are administered too frequently, minimum toxic concentrations of drug may be reached, resulting in toxic side effects. If doses are missed, periods of sub therapeutic drug blood levels or those below the minimum effective concentration may result, with no benefit to the patient. Extended-release tablets and capsules are commonly taken only once or twice daily, compared to their counterpart conventional forms which may have to be taken three or four times daily to achieve the same therapeutic effect. Typically, extended-release products provide an immediate release of drug that promptly produces the desired therapeutic effect, followed by gradual release of additional amounts of drug to maintain this effect over a predetermined period. The sustained plasma drug levels provided by extended-release products often

at times eliminate the need for night dosing which benefits not only the patient but also the caregiver. It forms produces wide range of fluctuation in drug concentration in the blood stream and tissues with consequent undesirable toxicity and poor efficiency. The maintenance of concentration of drug in plasma within therapeutic index is very critical for effective treatment.[12-15]

LIST OF MATERIALS

Trimetazidine Hcl Provided by SURA LABS, Dilsukhnagar, Hyderabad.
HPMC K100M Degussa India Ltd. (Mumbai, India).
Carbopol 71 G Laser Chemicals, Ahmadabad, India.
Eudragit RSPO Merck Specialities Pvt Ltd, Mumbai, India
PVP K 30 Merck Specialities Pvt Ltd, Mumbai, India
Talc Merck Specialities Pvt Ltd, Mumbai, India
Magnesium Stearate Merck Specialities Pvt Ltd, Mumbai, India
MCCph102 Merck Specialities Pvt Ltd, Mumbai, India

LIST OF EQUIPMENTS

Weighing Balance Sartourious
Tablet Compression Machine (Multi station) Lab Press
Hardness tester Monsanto, Mumbai, India.
Vernier callipers Mitutoyo, Japan.
Roche Friabilator Labindia, Mumbai, India
Dissolution Apparatus Labindia, Mumbai, India
UV-Visible Spectrophotometer Labindia, Mumbai, India
pH meter Labindia, Mumbai, India
FT-IR Spectrophotometer Bruker, Germany

METHODOLOGY:

Formulation development of Tablets:

All the formulations were prepared by direct compression. 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 Trimetazidine Hcl. Total weight of the tablet was considered as 250mg.

Procedure:

1) Trimetazidine Hcl 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.

Table7.3: Formulation composition for tablets

INGREDIENTS (MG)	FORMULATION								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Trimetazidine Hcl	30	30	30	30	30	30	30	30	30
HPMC K100M	30	60	90	-	-	-	-	-	-
Carbopol 71 G	-	-	-	30	60	90	-	-	-
Eudragit RSPO	-	-	-		-	-	30	60	90
PVP K 30	15	15	15	15	15	15	15	15	15
Talc	12	12	12	12	12	12	12	12	12
Magnesium Stearate	8	8	8	8	8	8	8	8	8
MCCph102	QS	QS	QS	QS	QS	QS	QS	QS	QS
Total weight	250	250	250	250	250	250	250	250	250

All the quantities were in mg

Evaluation of post compression parameters for prepared Tablets

The designed formulation 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

Table7.4: Pharmacopoeial specifications for tablet weight variation

Average weight of tablet (mg) (I.P)	Average weight of tablet (mg) (U.S.P)	Maximum percentage difference allowed
Less than 80	Less than 130	10
80-250	130-324	7.5
More than	More than 324	5

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, loss in the weight of tablet is the measure of friability and is expressed in percentage as

$$\% \text{ Friability} = [(W1-W2) / W] \times 100$$

Where, W1 = Initial weight of three tablets
W2 = Weight of the three tablets after testing

Determination of drug content:
Tablets were tested for their drug content. Ten tablets were finely powdered quantities of the powder equivalent to one tablet weight of drug 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 media. 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* drug release studies**

Dissolution parameters:

Apparatus -- USP-II, Paddle Method
Dissolution Medium -- 0.1 N HCl, p H 6.8 Phosphate buffer
RPM -- 50
Sampling intervals (hrs) -- 1,2,3,4,5,6,7,8,9,10,11,12
Temperature -- 37°c ± 0.5°c

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 apparatus was operated for 2 hours and then the media 0.1 N HCl were removed and pH 6.8 phosphate buffer was added process was continued up to 12 hrs.' at 50 rpm. At definite time intervals withdrawn 5 ml of sample, filtered and again 5ml media was replaced. Suitable dilutions were done with media and analyzed by spectrophotometrically at required wavelength using UV-spectrophotometer.

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:
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

$$\text{Log } (100-F) = kt$$

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.

$$F = k\ t1/2$$

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 Fickians 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.

Hixson-Crowell release model:

$$(100\text{-}Q_t)^{1/3} = 100^{1/3} - K_{HC}.t$$

Where, k is the Hixson-Crowell rate constant.

Hixson-Crowell model describes the release of drugs from an insoluble matrix through mainly erosion. (Where there is a change in surface area and diameter of particles or tablets).

7.5. Drug – Excipient compatibility studies

Fourier Transform Infrared (FTIR) spectroscopy:

The compatibility between the pure drug and excipients was detected by FTIR spectra obtained on Bruker FTIR Germany (Alpha T). The solid powder sample directly place on yellow crystal which was made up of ZnSe. The spectra were recorded over the wave number of 4000 cm^{-1} to 400cm^{-1}.

8. RESULTS AND DISCUSSION:

The present study was aimed to developing extended-release tablets of Trimetazidine Hcl using various polymers. All the formulations were evaluated for physicochemical properties and *in-vitro* drug release studies.

8.1. Analytical Method

Graphs of Trimetazidine Hcl were taken in 0.1N HCl and in pH 6.8 phosphate buffer at 232 nm and 235 nm respectively.

Table 8.1: Observations for graph of Trimetazidine Hcl in 0.1N HCl (232nm)

Conc. [µg/ml]	Absorbance
0	0
2	0.121
4	0.237
6	0.345
8	0.461
10	0.577

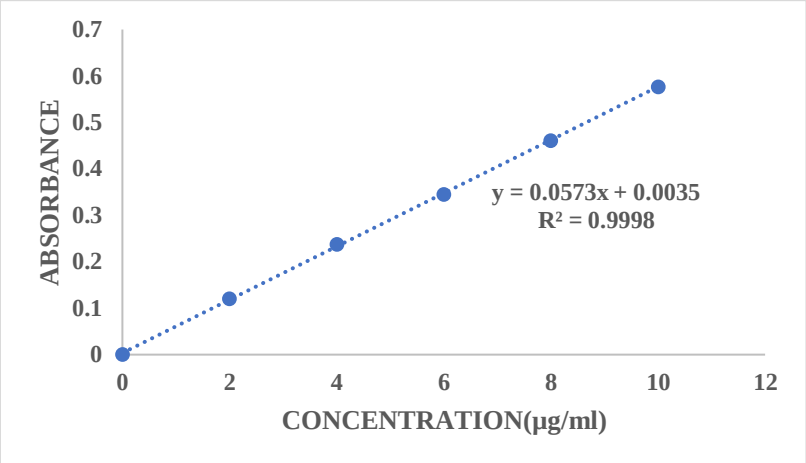

Figure 8.1: Standard graph of Trimetazidine Hcl in 0.1N HCl

Table 8.2: Observations for graph of Trimetazidine Hcl in pH 6.8 phosphate buffer (235nm)

Concentration [µg/ml]	Absorbance
0	0
2	0.141
4	0.273
6	0.402
8	0.536
10	0.668

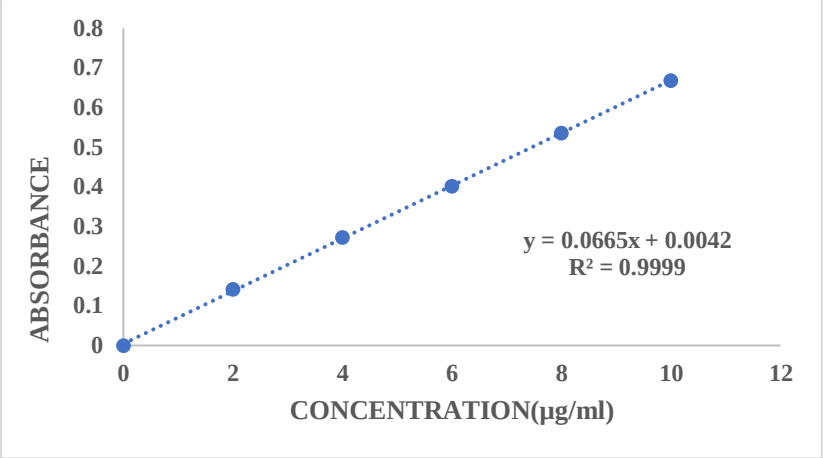

Figure 8.2: Standard graph of Trimetazidine Hcl pH 6.8 phosphate buffer (235nm)

8.3. Preformulation parameters of powder blend

Table 8.3: Pre-formulation parameters of Core blend

Formulation Code	Angle of Repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's Ratio
F1	28.23	0.47	0.55	14.54	1.17
F2	27.91	0.45	0.55	18.18	1.22
F3	26.71	0.46	0.55	16.36	1.19
F4	26.71	0.46	0.55	16.36	1.19
F5	28.23	0.47	0.55	14.54	1.17
F6	29.34	0.50	0.58	13.79	1.16
F7	26.78	0.41	0.50	18	1.21
F8	29.34	0.50	0.58	13.79	1.16
F9	26.78	0.41	0.50	18	1.21

Tablet powder blend was subjected to various pre-formulation parameters. The angle of repose values indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.41 to 0.50 (gm/cm^3) 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 to 0.58 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 18 which show that the powder has good flow properties. All the formulations have shown the Hausner ratio below 1.22 indicating the powder has good flow properties.

8.4. Quality Control Parameters For tablets:

Tablet quality control tests such as weight variation, hardness, and friability, thickness, and drug release studies in different media were performed on the compression coated tablet.

8.4. *In-vitro* quality control parameters for tablets

Formulation codes	Weight variation (mg)	Hardness (kg/cm^2)	Friability (%loss)	Thickness (mm)	Drug content (%)
F1	248.12	4.3	0.35	2.26	98.31
F2	250.08	4.0	0.41	2.14	99.34
F3	251.31	3.9	0.65	2.36	97.24
F4	247.22	4.2	0.44	2.15	98.10
F5	249.64	3.6	0.39	2.22	99.03
F6	252.88	4.0	0.55	2.82	97.42
F7	249.18	4.4	0.61	2.60	98.36
F8	247.39	4.5	0.59	2.13	99.25
F9	250.73	3.8	0.47	2.48	97.14

Weight variation test:
Tablets of each batch were subjected to weight variation test, difference in weight and percent deviation was calculated for each tablet and was shown in the Table 8.4. The average weight of the tablet is approximately in range of 247.22 to 251.31mg, so the permissible limit is ±7.5% (>300mg). The results of the test showed that, the tablet weights were within the pharmacopoeia limit.

Hardness test:
Hardness of the three tablets of each batch was checked by using Pfizer hardness tester and the data's were shown in Table 8.4. The results showed that the hardness of the tablets is in range of 3.6 - 4.5 kg/cm^2, which was within IP limits.

Thickness:
Thickness of three tablets of each batch was checked by using Micrometer and data shown in Table-8.4. The result showed that thickness of the tablet is raging from 2.13 to 2.82 mm.

Friability:
Tablets of each batch were evaluated for percentage friability and the data were shown in the Table 8.4. The average friability of all the formulations was less than 1% as per official requirement of IP indicating a good mechanical resistance of tablets.

Drug content:
Drug content studies were performed for the prepared formulations. From the drug content studies it was concluded that all the formulations were showing the % drug content values within 97.24 -99.34%.
All the parameters such as weight variation, friability, hardness, thickness and drug content were found to be within limits.

***8.5. In-vitro* drug release studies**

Table 8.5: Dissolution data of Trimetazidine Hcl tablets

TIME (H)	CUMULATIVE PERCENT DRUG DISSOLVED								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	29.91	28.63	24.66	25.36	22.63	18.25	19.52	25.97	22.22
2	42.56	37.72	35.48	32.67	33.82	26.54	34.15	36.53	29.37
3	49.11	42.53	42.14	38.73	41.22	31.57	38.05	44.33	34.07
4	55.09	53.65	57.53	48.86	46.41	37.64	47.42	54.74	44.24
5	62.75	66.71	59.92	55.96	54.56	48.68	53.22	61.67	51.68
6	69.08	73.67	69.87	65.08	62.68	52.57	58.79	71.58	65.04
7	74.22	79.29	75.25	68.94	68.03	58.01	64.03	82.65	73.35
8	78.53	85.07	82.63	74.05	76.26	62.88	69.45	86.75	75.93
9	86.24	89.88	87.61	83.24	85.17	71.63	76.41	88.62	81.56
10	92.87	92.41	91.86	90.01	92.02	78.81	79.27	91.44	89.95
11	96.78	97.66	93.44	94.89	95.65	88.61	85.04	95.57	92.68
12	98.44	99.32	98.18	98.52	97.27	95.24	91.75	95.05	97.83

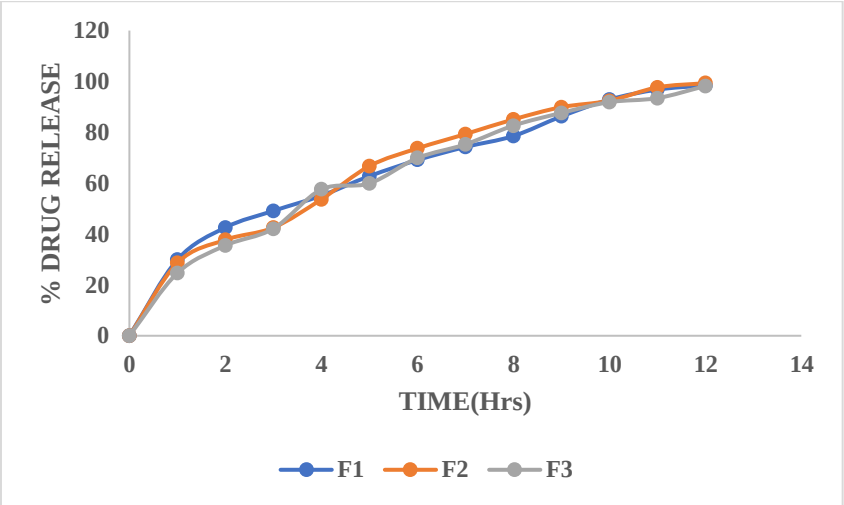

Fig 8.3: Dissolution profile of Trimetazidine Hcl (F1, F2, F3 formulations)

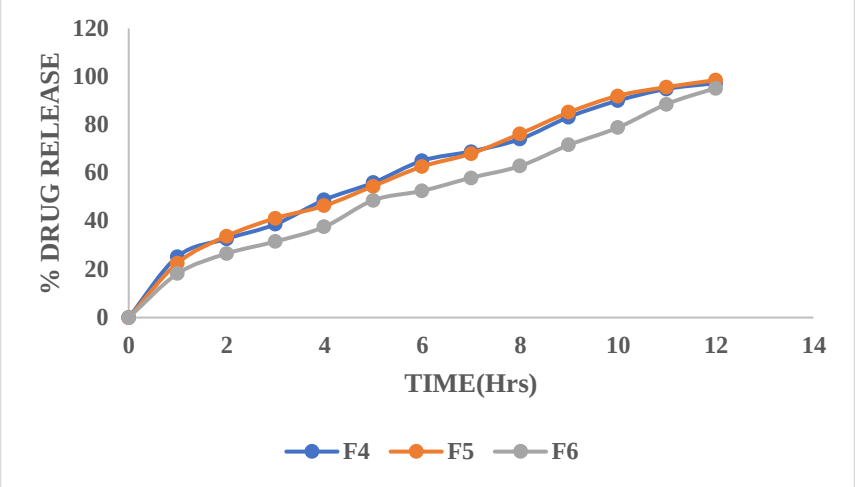

Fig8.4: Dissolution profile of Trimetazidine Hcl(F4, F5, F6 formulations)

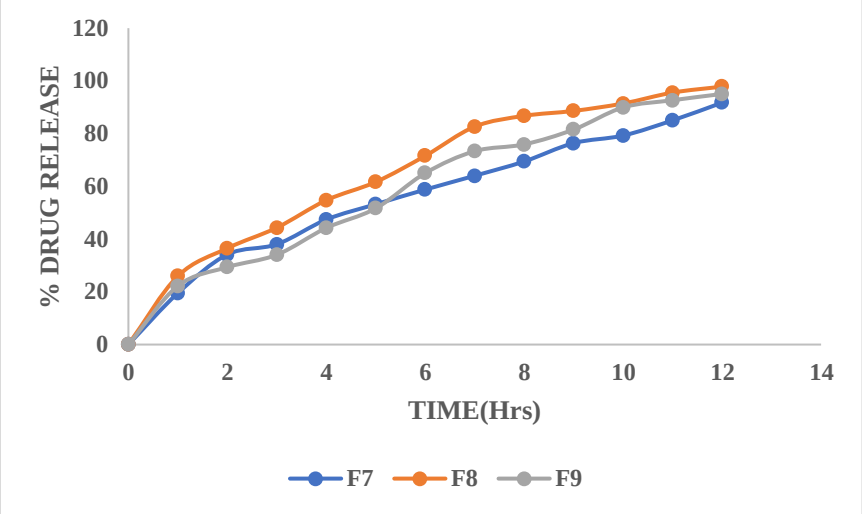

Fig 8.5: Dissolution profile of Trimetazidine Hcl(F7, F8, F9 formulations)

Formulations prepared with HPMC K100M retarded the drug release in the concentration of 60mg (F2 Formulation) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 99.32% in 12hours with good retardation.

From the dissolution data it was evident that the formulations prepared with different concentrations as 30, 60 and 90mg polymer were retard the drug release up to desired time period i.e., 12hours.

Formulations prepared with Carbopol 71 G retarded the drug release in the concentration of 30 mg (F4Formulation) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 98.52% in 12hours with good retardation.

From the dissolution data it was evident that the formulations prepared with different concentrations as 30, 60 and 90 mg polymer were retard the drug release up to desired time period i.e., 12 hours.

Formulations prepared with Eudragit RSPO retarded the drug release in the concentration of 90 mg (F9Formulation) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 97.83% in 12hours with good retardation.

From the dissolution data it was evident that the formulations prepared with different concentrations as 30, 60 and 90mg polymer were retard the drug release up to desired time period i.e., 12hours.
From the above results it was evident that the formulation F4 is best formulation with desired drug release pattern extended up to 12hours.

Application of Release Rate Kinetics to Dissolution Data:
Various models were tested for explaining the kinetics of drug release. To analyse 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.

Table 8.6: Release kinetics data for optimised formulation

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	%) REL	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
28.63	1	1.000	1.457	0.000	1.854	28.630	0.0349	-0.543	71.37	4.642	4.148	0.494
37.72	2	1.414	1.577	0.301	1.794	18.860	0.0265	-0.423	62.28	4.642	3.964	0.678
42.53	3	1.732	1.629	0.477	1.759	14.177	0.0235	-0.371	57.47	4.642	3.859	0.783
53.65	4	2.000	1.730	0.602	1.666	13.413	0.0186	-0.270	46.35	4.642	3.592	1.049
66.71	5	2.236	1.824	0.699	1.522	13.342	0.0150	-0.176	33.29	4.642	3.217	1.425
73.67	6	2.449	1.867	0.778	1.420	12.278	0.0136	-0.133	26.33	4.642	2.975	1.667
79.29	7	2.646	1.899	0.845	1.316	11.327	0.0126	-0.101	20.71	4.642	2.746	1.895
85.07	8	2.828	1.930	0.903	1.174	10.634	0.0118	-0.070	14.93	4.642	2.462	2.179
89.88	9	3.000	1.954	0.954	1.005	9.987	0.0111	-0.046	10.12	4.642	2.163	2.479
92.41	10	3.162	1.966	1.000	0.880	9.241	0.0108	-0.034	7.59	4.642	1.965	2.676
97.66	11	3.317	1.990	1.041	0.369	8.878	0.0102	-0.010	2.34	4.642	1.328	3.314
99.32	12	3.464	1.997	1.079	0.540	8.277	0.0101	-0.003	0.68	4.642	0.879	3.762

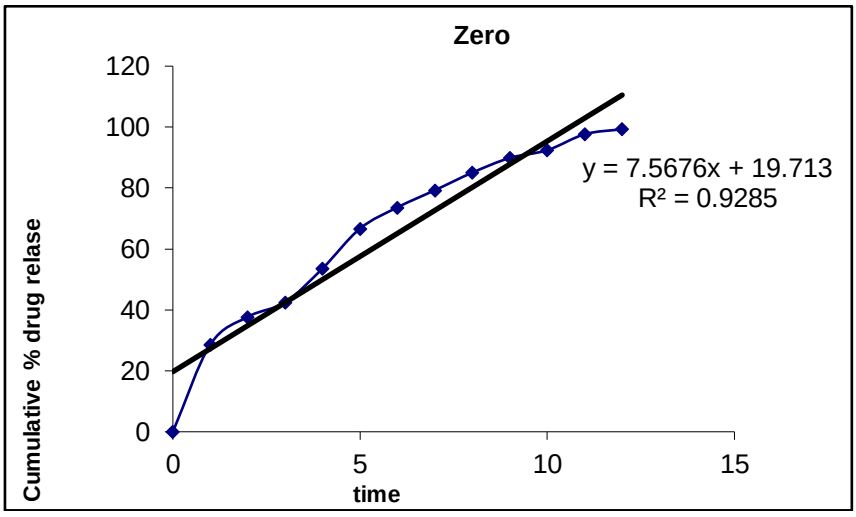

Fig 8.6 : Zero order release kinetics graph

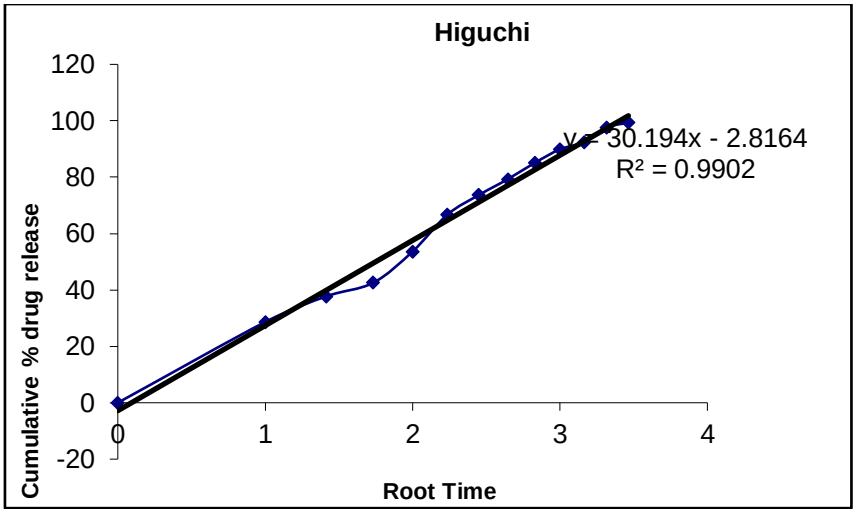

Fig 8.7 : Higuchi release kinetics graph

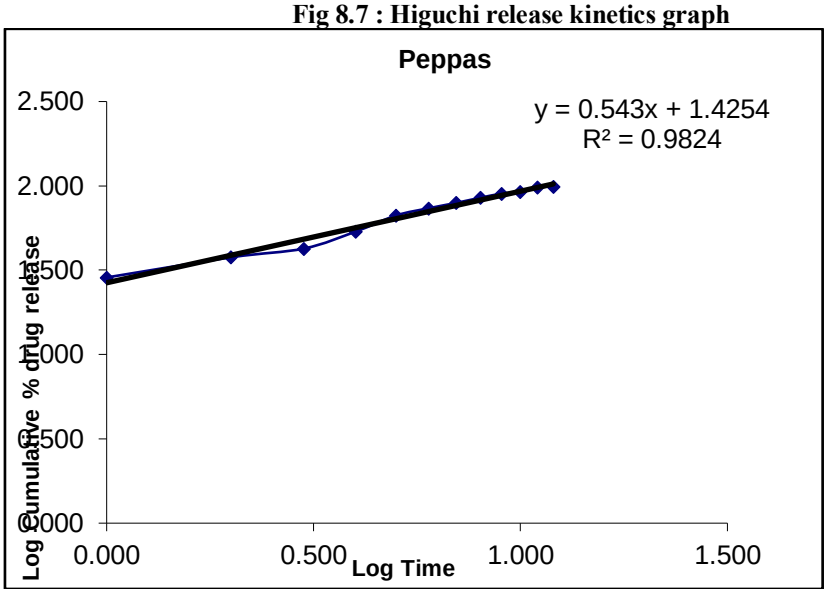

Fig 8.8: Kars mayer peppas graph

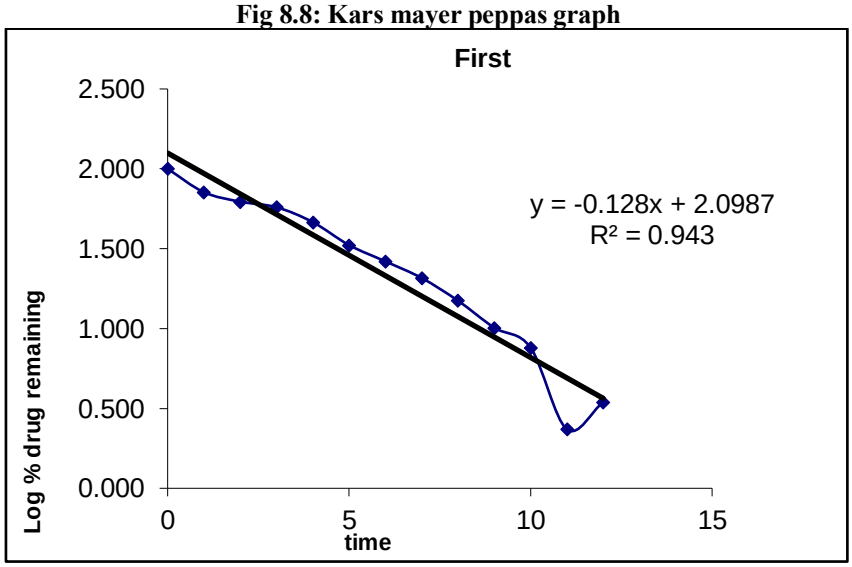

Fig 8.9: First order release kinetics graph

From the above graphs it was evident that the formulation F4 was followed First order release.

Drug – Excipient compatibility studies
Fourier Transform-Infrared Spectroscopy:

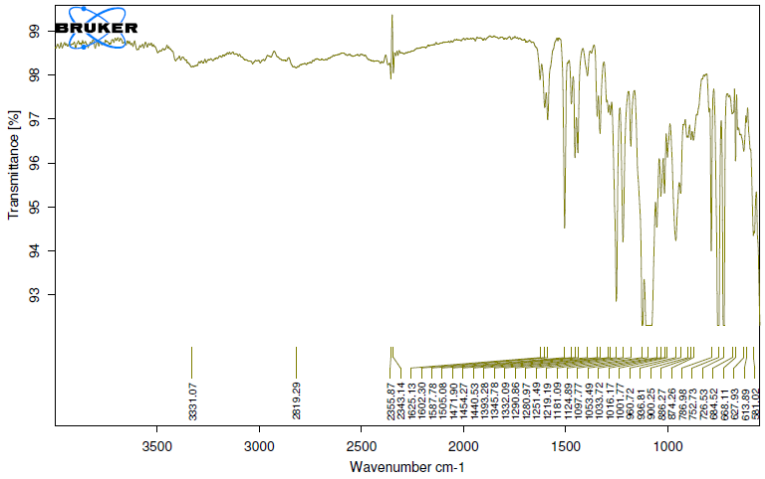

Figure 8.10: FT-IR Spectrum of pure drug

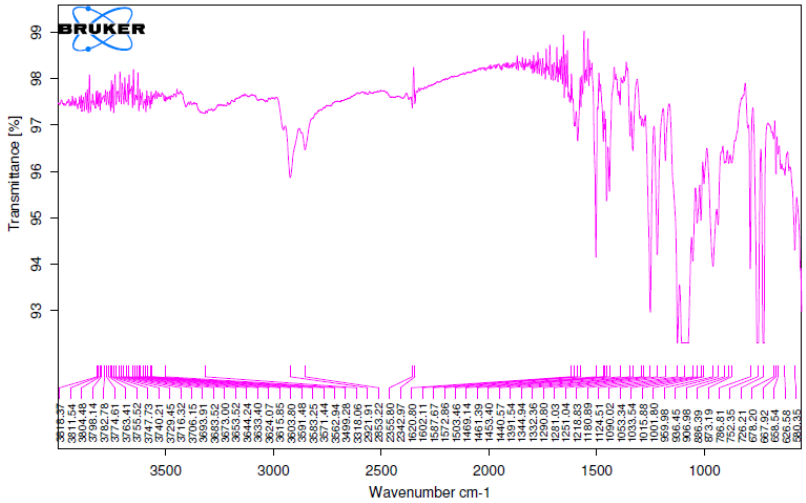

Figure 8.11: FT-IR Spectrum of Optimized Formulation

9. CONCLUSION:

The present study successfully demonstrated the formulation and evaluation of extended-release tablets of the anti-ischemic agent Trimetazidine HCl using suitable polymers. Various formulations were prepared and assessed for pre-compression and post-compression parameters, all of which were found to be within acceptable Pharmacopoeial limits, indicating good flow properties and tablet integrity. Among the developed formulations, the optimized batch showed a controlled and extended drug release profile up to 12 hours, achieving a cumulative drug release of over 99.32% of F2 Formulation there by complying with the desired therapeutic goal of maintaining prolonged plasma drug levels.

The in vitro drug release kinetics followed a controlled release mechanism, best fitting the Korsmeyer-Peppas model, indicating a combination of diffusion and erosion. Thus, the optimized formulation can effectively reduce the dosing frequency and improve patient compliance in the management of ischemic heart conditions.

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