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FORMULATION DEVELOPMENT AND IN-VITRO EVALUATION OF EXTENDED-RELEASE TABLETS CONTAINING TENATOPRAZOLE SODIUM

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Abstract:
The present study focuses on the formulation development and in-vitro evaluation of extended-release tablets containing Tenatoprazole Sodium, utilizing a combination of various polymers, including Carbopol, Hydroxypropyl Methylcellulose (HPMC), and Xanthan Gum. The aim was to achieve sustained and controlled drug release over a period of 12 hours, ensuring therapeutic efficacy with minimal dosing frequency. Different formulations were prepared by varying the concentrations of these polymers to optimize the drug release profile. In-vitro release studies were conducted, and the release pattern was evaluated using a standard dissolution test. Among all the formulations, formulation T2 exhibited the most favorable drug release profile, releasing 99.82% of Tenatoprazole Sodium over the 12-hour period. Based on its consistent and near-complete drug release, formulation T2 was considered the optimized formulation. The results demonstrate the potential of these polymer combinations to effectively control the release of Tenatoprazole Sodium and improve patient compliance in the treatment of gastrointestinal conditions.

Keywords: *Tenatoprazole Sodium , Extended release Tablets*

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1. INTRODUCTION:

The oral route is the most popular route used for administration of drugs, which is due in part to the ease of administration and to the fact that gastrointestinal physiology offers more flexibility in dosage form design than most other routes. The terms Sustained release, prolonged release, modified release, extended release or depot formulations are used to identify drug delivery systems that are designed to achieve or extend therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. [1,2]

There are several reasons for attractiveness of these dosage forms: provides increased bioavailability of drug product, reduction in the frequency of administration to prolong duration of effective blood levels, reduces the fluctuation of peak trough concentration and side effects and possibly improves the specific distribution of the drug. If one were to develop an ideal drugdelivery system, two pre-requisites would be required: Firstly single dose for the duration of treatment whether for days or weeks as with infection, diabetes orhypertension. Second it should deliver the active entity directly to the site of action minimizing the side effects.

There are certain considerations for the preparation of extended release formulations: If the active compound has a long half-life, it is sustained on its own, If the pharmacological activity of the active is not directly related to its blood levels, If the absorption of the drug involves an active transport and If the active compound has very short half-life then it would require a large amount of drug to maintain a prolonged effective dose. The above factors need serious review prior to design.[3]

Extended release formulations make the drug available over extended time period after oral administration. The extended release product will optimize therapeutic effect and safety of a drug at the same time improving the patient convenience and compliance. By incorporating the dose for 24 hrs into one tablet/capsule from which the drug is released slowly. This formulation helps to avoid the side effects associated with low and high concentrations. The ideal drug delivery system should show a constant zero-order release rate and maintain the constant plasma concentrations.

It is desirable to maintain a therapeutic blood concentration in order to achieve the desirable pharmacological effects. To maintain a narrow range of therapeutic blood concentration it is desirable to have a dosage form that can deliver the drug in a more sustainable or controlled way to achieve the desired results. Extended release tablets and capsules are commonly taken once or twice daily, compared with counterpart conventional forms that 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 drugs that promptly produces the desired therapeutic effect, followed by gradual release of additional amount of drugs to maintain this effect over a predetermined period. The sustained plasma drug levels provided by extended release products often eliminate the need for night dosing, which benefits not only the patient but the patient but the caregiver as well.[4]

Drawbacks of Conventional Dosage Form[5]

- ✓ Poor patient compliance, increased chances of missing the dose of a drug with short halflife for which frequent administration is necessary.
- ✓ The unavoidable fluctuations of drug concentration may lead to under medication or over medication.
- ✓ A typical peak-valley plasma concentration time profile is obtained which makes attainment of steady-state condition difficult.
- ✓ The fluctuations in drug levels may lead to precipitation of adverse effects especially of a drug with small Therapeutic Index (TI) whenever over medication occur.

Advantages of Extended Release Delivery System[6]

- ✓ The extended release formulations reduce dosing frequency of drugs.
- ✓ The extended release formulations may maintain therapeutic concentrations.
- ✓ Reduce the toxicity by slowing drug absorption.
- ✓ The use of these formulations avoids the high blood concentration.
- ✓ Extended release formulations have the potential to improve the patient compliance and convenience.
- ✓ Minimize the local and systemic side effects.
- ✓ Increase the stability by protecting the drug from hydrolysis or other degradative changes in gastrointestinal tract.
- ✓ Improvement in treatment efficacy.
- ✓ Minimize drug accumulation with chronic dosing.
- ✓ Improve the bioavailability of some drugs.
- ✓ Usage of less total drug.
- ✓ Improve the ability to provide special effects. For example, Morning relief of arthritis through bed time dosing.

Disadvantages of Extended Release Delivery System[6]

- ✓ Extended release formulation contains a higher drug load and thus any loss of integrity of the release characteristics of the dosage form.
- ✓ The larger size of extended release products may cause difficulties in ingestion or transit through gut.

- ✓ The release rates are affected by various factors such as food and the rate of transit through the gut.
- ✓ Some differences in the release rate from one dose to another dose but these have been minimized by modern formulations.
- ✓ High cost of preparation.
- ✓ Sometimes the target tissue will be exposed to constant amount of drug over extended period results in drug tolerance.

Rationale of Extended Drug Delivery[7]

The main objective to formulate an API in an extended drug delivery system is related to its pharmacokinetics parameters. An appropriate formulation can make the absorption, distribution, metabolism and elimination (ADME) profile of a drug much more favourable. This change of the ADME can have a profound impact on many aspects of the clinical use of the drug from patient compliance and convenience to its very efficacy, tolerance and safety parameters

MATERIALS AND METHODS:

Tenatoprazole Sodium Provided by SURA LABS, Dilsukhnagar, Hyderabad.
Carbopol Degussa India Ltd. (Mumbai, India).
HPMC Laser Chemicals, Ahmadabad, India.
Xanthan Gum Merck Specialities Pvt Ltd, Mumbai, India
Aerosil Merck Specialities Pvt Ltd, Mumbai, India

EQUIPMENTS

Weighing Balance Sartourious
Tablet Compression Machine (Multi station) Lab Press
Limited, India.
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

7. METHODOLOGY

7.1. Analytical method development:

7.1.1 Determination of Wavelength:

10mg of pure drug was dissolved in 10ml methanol (primary stock solution - 1000 µg/ml). From this primary stock solution 1 ml was pipette out into 10 ml volumetric flask and made it up to 10ml with the media (Secondary stock solution – 100µg/ml). From secondary stock solution again 1ml was taken it in to another volumetric flask and made it up to 10 ml with media (working solution - 10µg/ml). The working solution was taken for determining the wavelength.

7.1.2 Determination of Calibration Curve:

10mg of pure drug was dissolved in 10ml methanol (primary stock solution - 1000 µg/ml). From this primary stock solution 1 ml was pipette out into a 10 ml volumetric flask and made it up to 10 ml with the media (Secondary stock solution – 100µg/ml). From the secondary stock solution required concentrations were prepared (shown in Table 8.1 and 8.2) and those concentrations' absorbance were found out at required wavelength.

7.3. Formulation development of Tablets:

All the formulations were prepared by direct compression. The compositions of different formulations are given in Table 7.3.The tablets were prepared as per the procedure given below and aim is to prolong the release of Tenatoprazole Sodium. Total weight of the tablet was considered as 500mg.

Procedure:

1) Tenatoprazole Sodium 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.

Table 7.3: Formulation composition for tablets

INGREDIENTS (MG)	FORMULATION								
	T1	T2	T3	T4	T5	T6	T7	T8	T9
Tenatoprazole Sodium	40	40	40	40	40	40	40	40	40
Carbopol	20	40	60	-	-	-	-	-	-
HPMC	-	-	-	20	40	60	-	-	-
Xanthan Gum	-	-	-	-	-	-	20	40	60
Aerosil	10	10	10	10	10	10	10	10	10
Magnesium steareate	10	10	10	10	10	10	10	10	10
MCC	120	100	80	120	100	80	120	100	80
Total weight	200	200	200	200	200	200	200	200	200

8 RESULTS AND DISCUSSION:

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

8.1. Analytical Method

Graphs of Tenatoprazole Sodium were taken in 0.1N HCl and in pH 6.8 phosphate buffer at 260 nm and 265 nm respectively.

Table 8.1: Observations for graph of Tenatoprazole Sodium in 0.1N HCl (260nm)

Conc. [µg/ml]	Absorbance
0	0
10	0.107
20	0.213
30	0.331
40	0.439
50	0.547

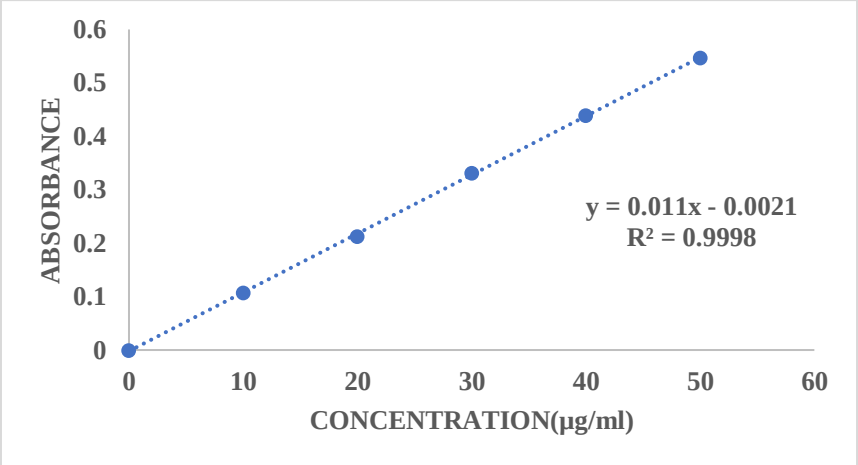

Figure 8.1: Standard graph of Tenatoprazole Sodium in 0.1N HCl

Table 8.2: Observations for graph of Tenatoprazole Sodium in pH 6.8 phosphate buffer (265nm)

Concentration [µg/ml]	Absorbance
0	0
10	0.142
20	0.271
30	0.402
40	0.527
50	0.662

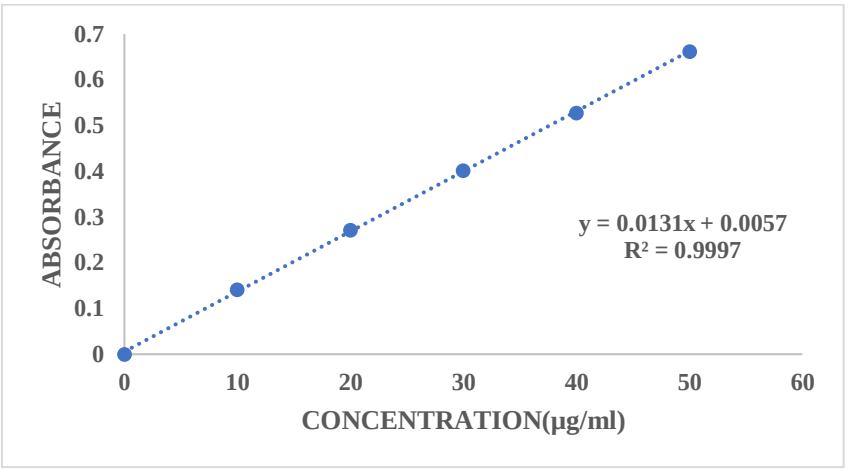

Figure 8.2: Standard graph of Tenatoprazole Sodium pH 6.8 phosphate buffer (265nm)

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
T1	27.51	0.33	0.38	13.157	1.15
T2	24.41	0.32	0.38	15.789	1.18
T3	29.72	0.31	0.37	16.216	1.19
T4	30.96	0.301	0.350	14.00	1.16
T5	28.47	0.286	0.342	16.37	1.19
T6	27.12	0.33	0.37	10.810	1.12
T7	26.85	0.31	0.38	18.42	1.22
T8	28.14	0.30	0.38	21.052	1.26
T9	27.38	0.32	0.41	21.95	1.28

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 0.31 to 0.301 (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 0.37 to 0.350 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 has shown the hausner ratio below 1.30 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 (%)
T1	198.31	3.47	0.26	1.87	98.67
T2	200.22	3.33	0.12	1.65	99.51
T3	201.08	3.56	0.47	1.93	100.38
T4	199.12	3.41	0.29	2.18	97.89
T5	197.45	3.67	0.33	2.08	98.76
T6	195.67	3.52	0.41	1.88	99.22
T7	199.83	3.83	0.26	1.94	99.39
T8	204.76	3.64	0.36	2.05	97.46
T9	201.51	3.39	0.27	2.26	98.62

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 Table 8.4. The average weight of the tablet is approximately in the range of 195.67 to 204.76 mg, so the permissible limit is ±7.5% (>200mg). The results of the test showed that, the tablet weights were within the pharmacopeia limit.

Hardness test:

The hardness of the three tablets of each batch was checked by using a Pfizer hardness tester and the data were shown in Table 8.4. The results showed that the hardness of the tablets was in the range of 3.33 to 3.83kg/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 1.65 to 2.26mm.

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 97.46 -100.38%.

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 Tenatoprazole Sodium tablets

TIME (H)	CUMULATIVE PERCENT DRUG DISSOLVED								
	T1	T2	T3	T4	T5	T6	T7	T8	T9
0	0	0	0	0	0	0	0	0	0
1	16.32	24.96	18.58	19.26	25.23	19.11	21.24	23.43	18.05
2	25.96	29.57	28.24	28.37	29.67	24.22	25.68	27.16	28.29
3	31.47	34.41	39.21	35.52	42.35	31.68	33.07	38.27	37.22
4	37.51	41.93	44.65	38.19	48.29	35.27	39.41	41.15	43.67
5	44.27	48.66	51.12	49.46	57.68	42.56	45.95	48.03	49.53
6	49.32	51.91	58.39	54.11	65.09	48.91	58.52	51.08	52.98
7	55.71	61.71	68.75	59.03	72.68	63.45	67.37	57.11	55.43
8	62.87	67.75	75.92	63.48	79.54	74.98	71.41	65.17	68.12
9	66.21	71.97	81.19	68.69	84.21	78.23	77.25	72.94	77.42
10	72.95	87.15	88.52	74.12	91.52	81.89	82.94	78.53	81.79
11	76.01	92.54	94.44	79.07	95.26	86.23	85.02	86.62	89.07
12	81.19	99.82	98.56	86.71	91.12	97.13	93.08	96.24	94.41

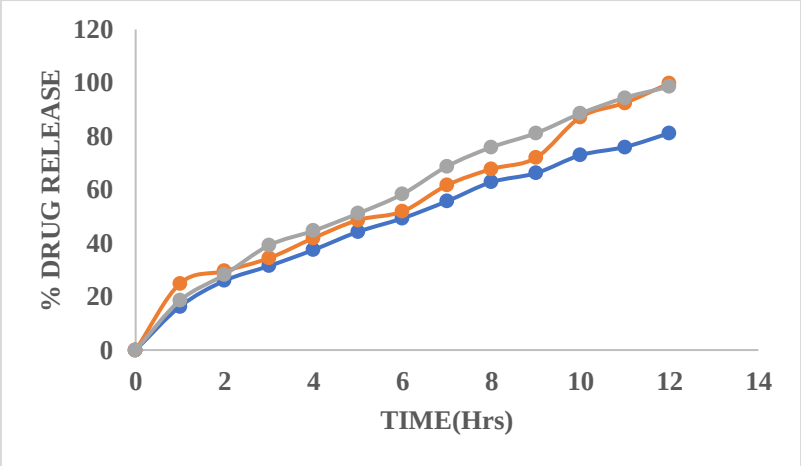

Fig 8.3: Dissolution profile of Tenatoprazole Sodium (T1, T2, T3 formulations)

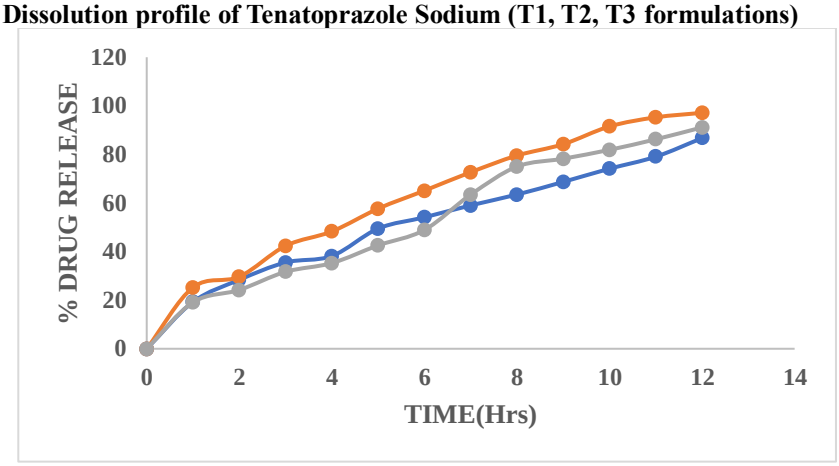

Fig8.4: Dissolution profile of Tenatoprazole Sodium (T4, T5, T6 formulations)

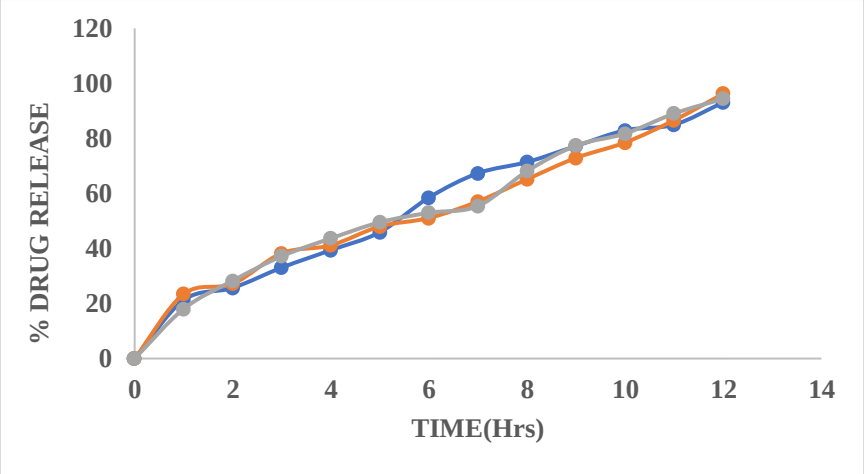

Fig 8.5: Dissolution profile of Tenatoprazole Sodium (T7, T8, T9 formulations)

Formulations prepared with Carbopol retarded the drug release in the concentration of 40mg (T2 Formulation) and showed the required release pattern i.e., retarded the drug release up to 12 hours and showed a maximum of 99.82 % in 12 hours with good retardation.

From the dissolution data, it was evident that the formulations prepared with different concentrations as 20, 40, and 60 mg polymer were retard the drug release up to the desired time period i.e., 12 hours.

Formulations prepared with HPMC retarded the drug release in the concentration of 60mg (T6 Formulation) and showed the required release pattern i.e., retarded the drug release up to 12 hours and showed a maximum of 97.13% in 12 hours with good retardation.

From the dissolution data, it was evident that the formulations prepared with different concentrations as 20, 40and 60mg polymer were retard the drug release up to the desired time period i.e., 12 hours.

Formulations prepared with Xanthan Gum retarded the drug release in the concentration of 40 mg (T8 Formulation) and showed the required release pattern i.e., retarded the drug release up to 12 hours and showed a maximum of 96.24 % in 12 hours with good retardation.

From the dissolution data, it was evident that the formulations prepared with different concentrations as 20, 40 and 60mg polymer were retard the drug release up to desired time period i.e., 12hours.

From the above results it was evident that the formulation T2 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 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.

Table 8.6: Release kinetics data 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
24.96	1	1.000	1.397	0.000	1.875	24.960	0.0401	-0.603	75.04	4.642	4.218	0.424
29.57	2	1.414	1.471	0.301	1.848	14.785	0.0338	-0.529	70.43	4.642	4.130	0.512
34.41	3	1.732	1.537	0.477	1.817	11.470	0.0291	-0.463	65.59	4.642	4.033	0.609
41.93	4	2.000	1.623	0.602	1.764	10.483	0.0238	-0.377	58.07	4.642	3.872	0.769
48.66	5	2.236	1.687	0.699	1.710	9.732	0.0206	-0.313	51.34	4.642	3.717	0.925
51.91	6	2.449	1.715	0.778	1.682	8.652	0.0193	-0.285	48.09	4.642	3.637	1.005
61.71	7	2.646	1.790	0.845	1.583	8.816	0.0162	-0.210	38.29	4.642	3.371	1.271
67.75	8	2.828	1.831	0.903	1.509	8.469	0.0148	-0.169	32.25	4.642	3.183	1.459
71.97	9	3.000	1.857	0.954	1.448	7.997	0.0139	-0.143	28.03	4.642	3.038	1.604
87.15	10	3.162	1.940	1.000	1.109	8.715	0.0115	-0.060	12.85	4.642	2.342	2.299
92.54	11	3.317	1.966	1.041	0.873	8.413	0.0108	-0.034	7.46	4.642	1.954	2.688
99.82	12	3.464	1.999	1.079	-0.745	8.318	0.0100	-0.001	0.18	4.642	0.565	4.077

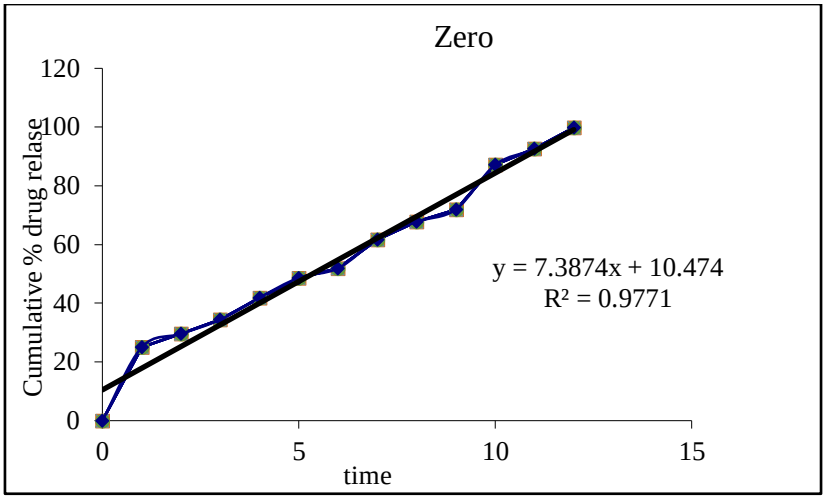

Fig 8.6 : Zero order release kinetics graph

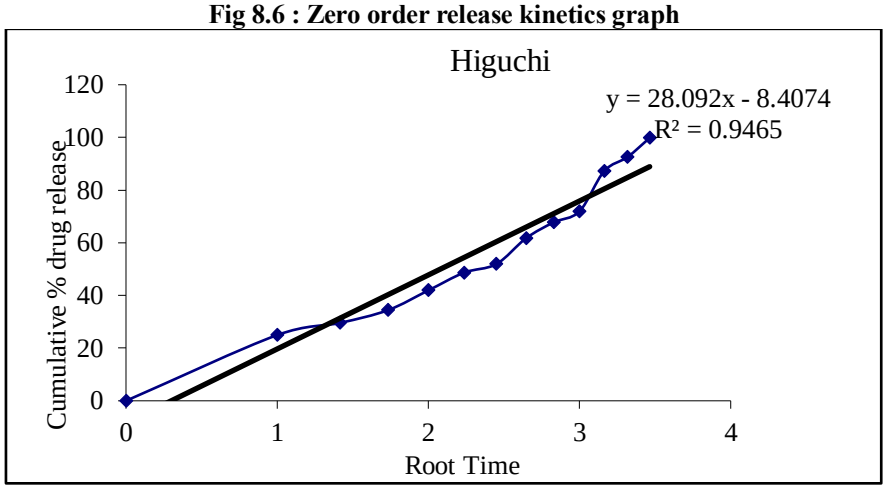

Fig 8.7: Higuchi release kinetics graph

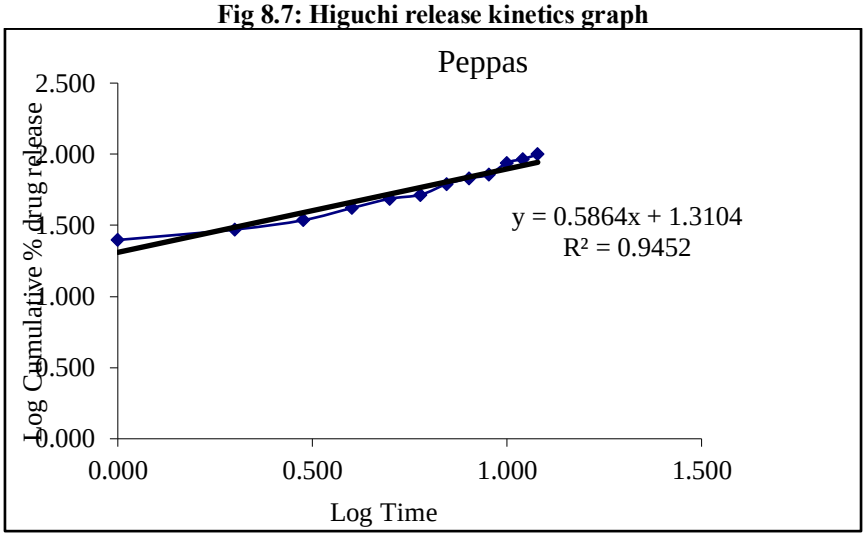

Fig 8.8: Kars Mayer Peppas graph

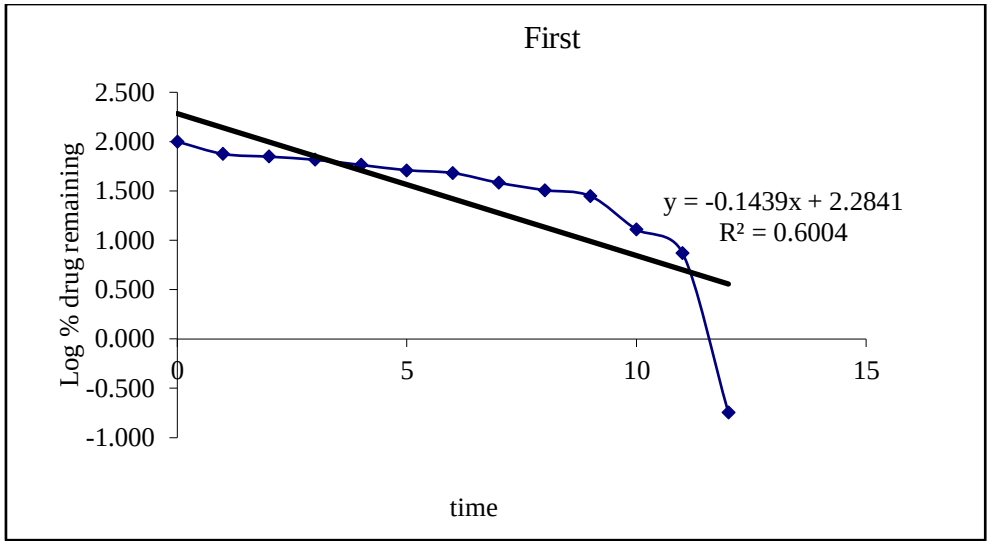

Fig 8.9: First order release kinetics graph

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

Drug – Excipient compatibility studies

Fourier Transform-Infrared Spectroscopy:

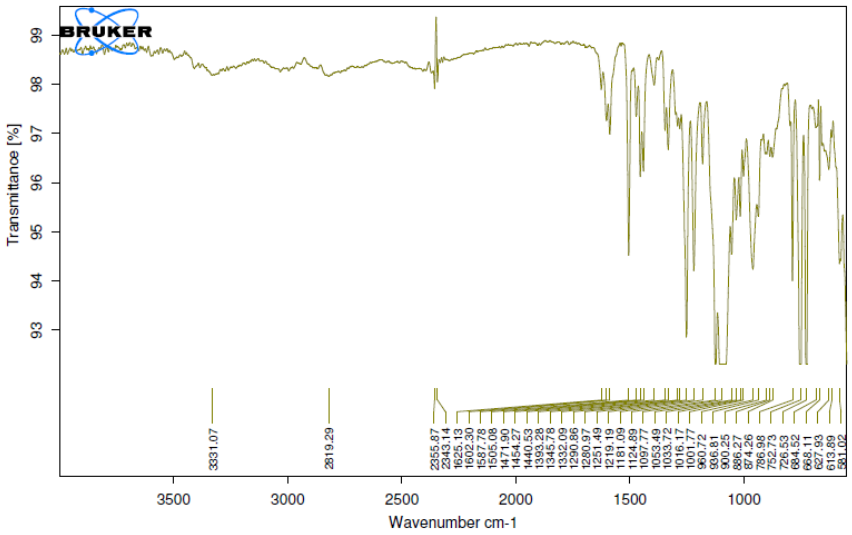

Figure 8.10: FT-IR Spectrum of pure drug

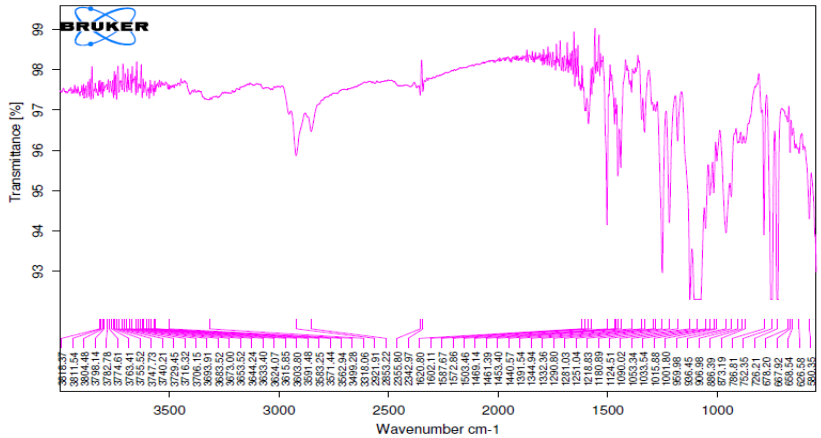

Figure 8.11: FT-IR Spectrum of Optimised Formulation

9. CONCLUSION:

In conclusion, the formulation and development of extended-release tablets containing Tenatoprazole sodium utilizing polymers such as Carbopol, HPMC, and Xanthan gum in various concentrations demonstrated promising results for controlled drug release. The combination of these polymers allowed for the modulation of the drug release rate, achieving the desired extended-release profile. The optimization of polymer concentrations played a crucial role in influencing the release kinetics, with higher concentrations of Carbopol and HPMC leading to a slower release, while Xanthan gum contributed to both controlled release and enhanced tablet . In vitro evaluation confirmed that the developed formulations maintained the therapeutic effectiveness of Tenatoprazole sodium over extended periods, minimizing fluctuations in drug plasma levels. The formulations exhibited good mechanical properties, uniformity in drug content under accelerated conditions, suggesting their potential for clinical use. Overall, the successful formulation of extended-release Tenatoprazole sodium tablets offers a promising approach for improving patient compliance and therapeutic outcomes by reducing the frequency of dosing while maintaining a consistent pharmacological effect.

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