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Research Article

**FORMULATION AND EVALUATION OF FLOATING
FENOVERINE TABLETS****Gulam Mehmood Afzal¹, Shahid Mohammed², Abdul Manan³, Ramya Sri. S⁴**^{1,2,3}Department of Pharmaceutics, Deccan School of Pharmacy, Darus Salam, Hyderabad,
Telangana- 500001, India⁴Department of Pharmacy, University College of Technology, Osmania University, Hyderabad,
Telangana- 500007, India**Abstract:**

Gastro-retentive dosage forms enable prolonged and continuous input of the drug to the upper parts of the gastrointestinal tract and improve the bioavailability of medications those are characterized by a narrow absorption window. The purpose of this research was to develop a novel gastro retentive drug delivery system based on direct compression method for sustained delivery of active agent to improve the bioavailability, reduce the number of doses and to increase patient compliance. Gastro retentive floating tablets of Fenoverine were prepared by direct compression method using altered concentrations of Carbopol, HPMC K 100 and Ethyl Cellulose as polymers. The prepared tablets of Fenoverine were evaluated tablet hardness, uniformity of weight, friability, uniformity of content, in vitro buoyancy test and in vitro dissolution study. All the compositions were resulted in adequate Pharmacopoeial limits. Compatibility studies was execution during FTIR shown that there was absence of probable chemical interaction between pure drug and excipients. The formulations were evaluated for various physical parameters, buoyancy studies, dissolution studies, dissolution parameters and drug released mechanisms. F5 formulation showed maximum floating time of 12 hours and gave slow and maximum drug release of Fenoverine spread over 12 hours. Finally the tablet formulations found to be economical and may overcome the draw backs associated with the drug during its absorption.

Key words: Fenoverine, Carbopol, HPMC K 100, Ethyl Cellulose and Floating Tablets.

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INTRODUCTION:

Oral delivery of drugs is the most preferable route of drug delivery. Oral route is considered most natural, uncomplicated, convenient and safe due to its ease of administration, patient compliance and flexibility in formulation and cost effective manufacturing process¹. Many of the drug delivery systems, available in the market are oral drug delivery type systems. Pharmaceutical products designed for oral delivery are mainly immediate release type or conventional drug delivery systems, which are designed for immediate release of drug for rapid absorption. These immediate release dosage forms have some limitations such as:

1. Drugs with short half-life require frequent administration, which increases chances of missing dose of drug leading to poor patient compliance.
2. A typical peak-valley plasma concentration-time profile is obtained which makes attainment of steady state condition difficult.
3. The unavoidable fluctuations in the drug concentration may lead to under medication or overmedication as the C_{ss} values fall or rise beyond the therapeutic range.
4. The fluctuating drug levels may lead to precipitation of adverse effects especially of a drug with small therapeutic index, whenever overmedication occurs.²

In order to overcome the drawbacks of conventional drug delivery systems, several technical advancements have led to the development of controlled drug delivery system that could revolutionize method of medication and provide a number of therapeutic benefits.³

Controlled Drug Delivery Systems:

Controlled drug delivery systems have been developed which are capable of controlling the rate of drug delivery, sustaining the duration of therapeutic activity and/or targeting the delivery of drug to a tissue.⁴

Controlled drug delivery or modified drug delivery systems are divided into four categories.

1. Delayed release
2. Sustained release
3. Site-specific targeting
4. Receptor targeting

More precisely, controlled delivery can be defined as:-

1. Sustained drug action at a predetermined rate by maintaining a relatively constant, effective drug level in the body with concomitant minimization of undesirable side effects.
2. Localized drug action by spatial placement of a controlled release system adjacent to or in the diseased tissue.
3. Targeted drug action by using carriers or chemical derivatives to deliver drug to a particular target cell type.
4. Provide physiologically/therapeutically based drug release system. In other words, the amount and the rate of drug release are determined by the physiological/ therapeutic needs of the body.⁵

MATERIALS AND METHODS:

Fenoverine Provided by SURA LABS, Dilsukhnagar, Hyderabad, Carbopol from Merck Specialities Pvt Ltd, HPMC K 100 from Merck Specialities Pvt Ltd, Ethyl Cellulose from Merck Specialities Pvt Ltd, Sodium bicarbonate from Merck Specialities Pvt Ltd, Citric acid from Merck Specialities Pvt Ltd, Aerosil from Merck Specialities Pvt Ltd, Mg Stearate from Merck Specialities Pvt Ltd, MCC from Merck Specialities Pvt Ltd.⁶

METHODS⁷**Drug – Excipient compatibility studies**

FORMULATION OF TABLETS:

Table 3: Formulation composition for Floating tablets

Ingredients (mg)	FORMULATION CHART								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Fenoverine	100	100	100	100	100	100	100	100	100
Carbopol	25	50	75	-	-	-	-	-	-
HPMC K 100	-	-	-	30	60	90	-	-	-
Ethyl Cellulose	-	-	-	-	-	-	50	100	150
Sodium bicarbonate	15	15	15	15	15	15	15	15	15
Citric acid	10	10	10	10	10	10	10	10	10
Aerosil	4	4	4	4	4	4	4	4	4
Mg Stearate	5	5	5	5	5	5	5	5	5
MCC	241	216	191	236	206	176	216	166	116
Total weight	400	400	400	400	400	400	400	400	400

All the quantities were in mg

RESULTS AND DISCUSSION 8:

Drug – Excipient compatibility studies

Fourier Transform-Infrared Spectroscopy:

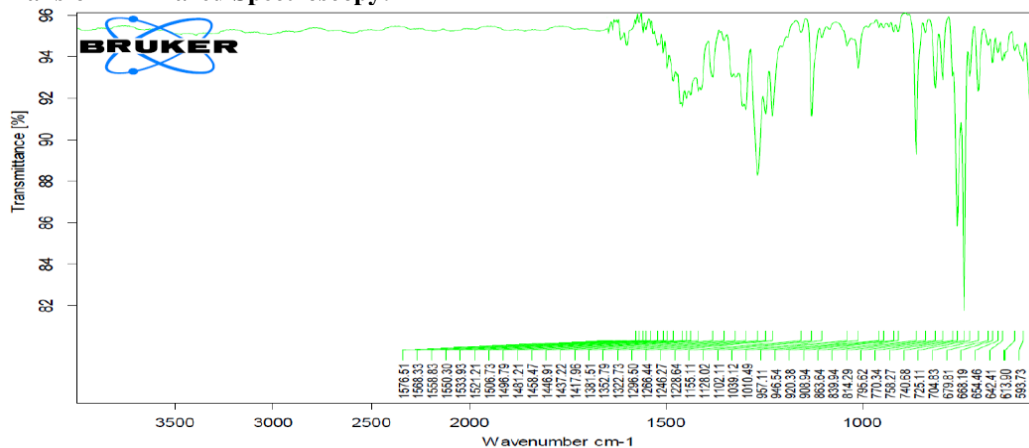


Figure 1: FTIR Spectrum of pure drug

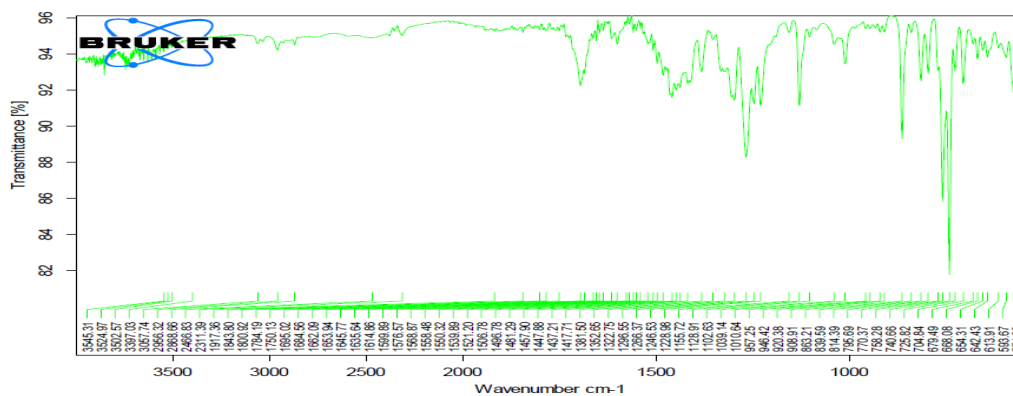


Fig 2 FTIR Spectrum of Drug and all excipients mixture

There was no disappearance of any characteristics peak in the FTIR spectrum of drug and the polymers used. This shows that there is no chemical interaction between the drug and the polymers used. The presence of peaks at the expected range confirms that the materials taken for the study are genuine and there were no possible interactions.

Fenoverine is also present in the physical mixture, which indicates that there is no interaction between drug and the polymers, which confirms the stability of the drug.

Analytical Method

A. Determination of absorption maxima

The standard curve is based on the spectrophotometry. The maximum absorption was observed at 258 nm.

B. calibration curve

Graphs of Fenoverine was taken in 0.1N HCL (pH 1.2)

Table no 5: Observations for graph of Fenoverine in 0.1N HCL

Conc [$\mu\text{g/mL}$]	Abs
0	0
5	0.137 \pm 0.04
10	0.264 \pm 0.05
15	0.387 \pm 0.07
20	0.511 \pm 0.09
25	0.627 \pm 0.03

All the values represent as mean \pm SD n=3

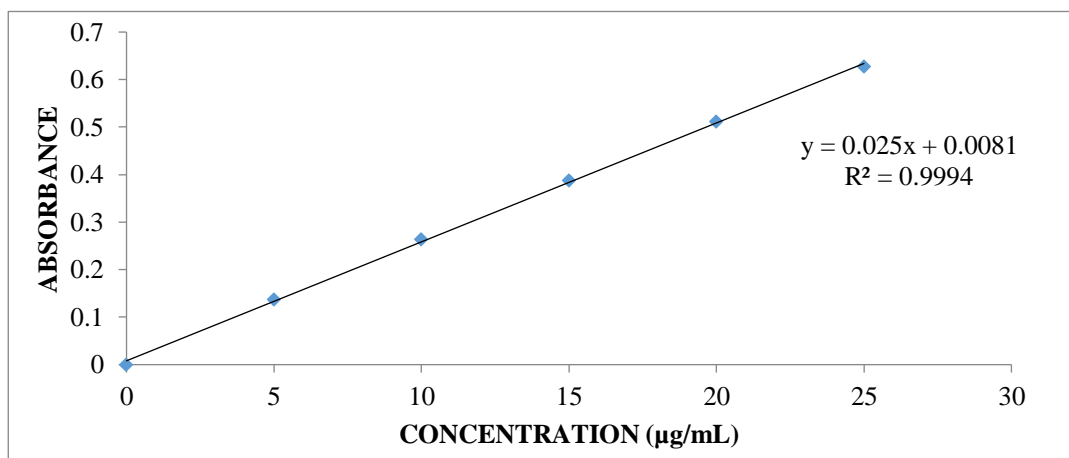


Fig 3 Standard graph of Fenoverine in 0.1N HCL

Standard graph of Fenoverine was plotted as per the procedure in experimental method and its linearity is shown in Table 5 and Fig 3. The standard graph of Fenoverine showed good linearity with R^2 of 0.999, which indicates that it obeys “Beer- Lamberts” law.

Preformulation parameters of powder blend:

Table 6: 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	18.8±1.13	0.38±0.03	0.43±0.05	11.6±0.10	1.13±0.03
F2	19.6±1.06	0.39±0.05	0.44±0.06	11.3±0.55	1.12±0.02
F3	19.4±0.95	0.42±0.07	0.47±0.02	10.6±0.09	1.11±0.05
F4	21.9±0.55	0.40±0.09	0.45±0.01	11.1±0.08	1.12±0.06
F5	17.5±0.96	0.41±0.05	0.46±0.07	10.8±0.11	1.12±0.09
F6	19.2±0.79	0.37±0.06	0.43±0.09	13.9±0.12	1.16±0.05
F7	19.5±1.15	0.38±0.07	0.46±0.05	17.3±0.22	1.21±0.07
F8	21.3±1.30	0.39±0.03	0.45±0.08	13.3±0.15	1.15±0.04
F9	20.1±1.22	0.41±0.02	0.45±0.03	8.8±0.09	1.09±0.02

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 0.37 to 0.42 (gm/ml) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.43 to 0.47 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 17.3 which show that the powder has good flow properties. All the formulations has shown the hausners ratio ranging between 1.09 to 1.21 indicating the powder has good flow properties.

Quality Control Parameters For tablets:

Tablet quality control tests such as weight variation, hardness, and friability, thickness, Drug content and drug release studies were performed for floating tablets.

Table 7: *In vitro* quality control parameters

Formulation codes	Average Weight (mg)	Weight Variation	Hardness (kg/cm ²)	Friability (%loss)	Thickness (mm)	Drug content (%)	Floating lag time (sec)	Total Floating Time(Hrs)
F1	399.32	Pass	5.1±0.24	0.36±0.04	5.21±0.02	98.62± 0.44	52	7
F2	400.12	Pass	4.6±0.39	0.54±0.03	5.69±0.04	99.35± 0.75	46	8
F3	398.91	Pass	4.1±0.48	0.41±0.01	5.72±0.09	100.01±0.92	38	10
F4	396.82	Pass	5.2±0.22	0.65±0.02	5.24±0.06	98.41± 0.44	49	9
F5	399.58	Pass	4.8±0.36	0.54±0.03	5.36±0.03	99.20± 0.92	21	10
F6	400.25	Pass	4.9±0.35	0.39±0.05	5.68±0.05	99.03±0.36	38	10
F7	399.31	Pass	5.3±0.46	0.57±0.06	5.76±0.07	98.16±0.81	35	5
F8	398.85	Pass	4.6±0.22	0.75±0.02	5.12±0.04	98.34±0.43	29	7
F9	397.42	Pass	5.4±0.25	0.34±0.01	5.53±0.06	99.16±0.75	25	9

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

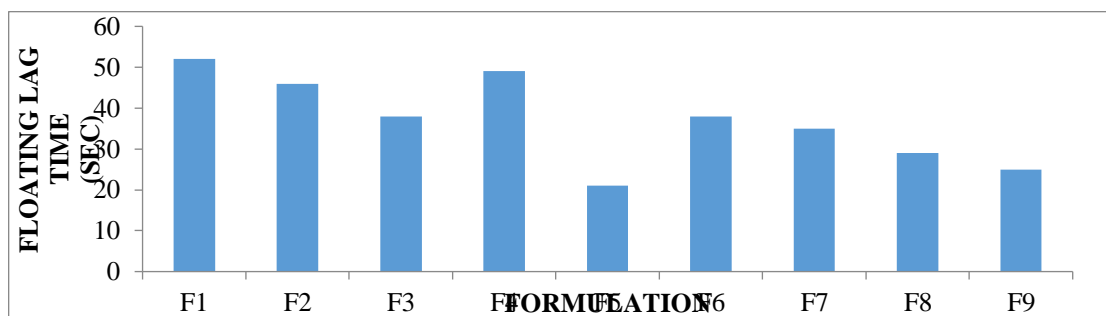


Figure 4: Floating lag time (sec)

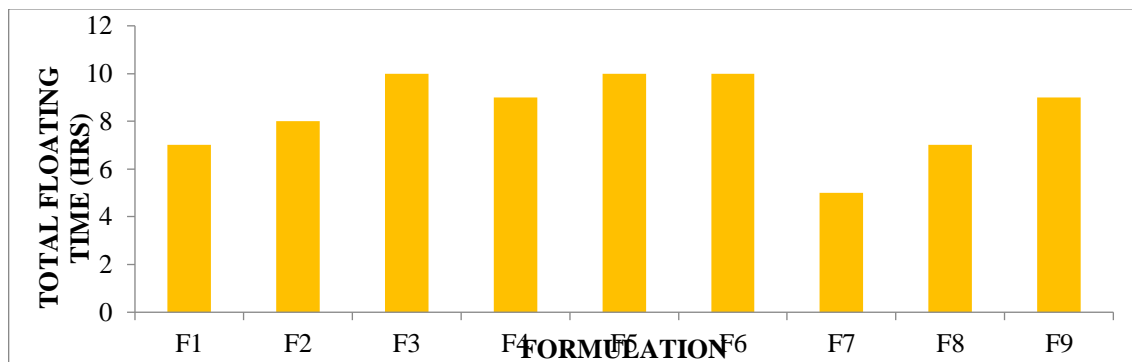


Figure 5: Total Floating Time (Hrs)

In Vitro Drug Release Studies

Table no 8: Dissolution data of Floating Tablets

Time	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	16.62±0.77	13.58±0.43	11.05±0.39	09.41±0.19	14.83±0.24	10.39±0.13	25.19±0.58	18.96±0.18	15.38±0.55
2	29.68±0.36	21.64±0.25	16.31±0.58	12.34±0.27	18.10±0.33	15.17±0.25	39.72±0.45	24.83±0.57	20.29±0.23
3	35.64±0.46	27.11±1.14	22.65±0.82	20.92±0.36	28.01±0.37	23.35±0.37	43.93±0.33	31.78±0.22	26.71±0.45
4	41.48±0.77	38.97±0.55	30.19±1.09	26.76±0.34	34.65±0.48	30.17±0.95	59.54±0.43	37.41±0.63	31.92±0.75
5	56.95±0.85	53.65±0.92	36.64±0.55	30.63±0.56	41.34±0.52	36.86±0.23	65.41±0.56	45.79±0.75	36.49±0.66
6	68.72±0.59	62.74±0.74	45.39±0.85	35.21±0.74	48.89±0.87	42.61±0.35	79.76±0.74	51.86±0.34	42.58±0.69
7	79.39±0.85	74.22±1.25	56.41±1.24	47.34±0.43	56.14±0.67	49.14±0.66	86.19±0.43	67.31±0.59	58.26±0.33
8	83.14±0.63	85.94±0.41	59.87±0.35	65.27±0.86	57.60±0.93	55.59±0.79	98.72±0.55	73.22±0.88	70.15±0.37
9	97.58±0.21	94.19±0.84	64.16±0.89	79.34±0.74	68.19±0.55	63.61±0.82	-	81.89±0.76	77.87±0.20
10	-	98.76±0.22	77.52±0.53	85.27±0.55	79.26±0.67	70.34±0.74	-	97.15±0.27	85.62±0.90
11	-	-	85.97±0.77	96.54±0.10	92.57±0.36	82.23±0.69	-	-	88.48±0.11
12	-	-	92.26±0.23	-	99.96±0.14	89.45±0.23	-	-	-

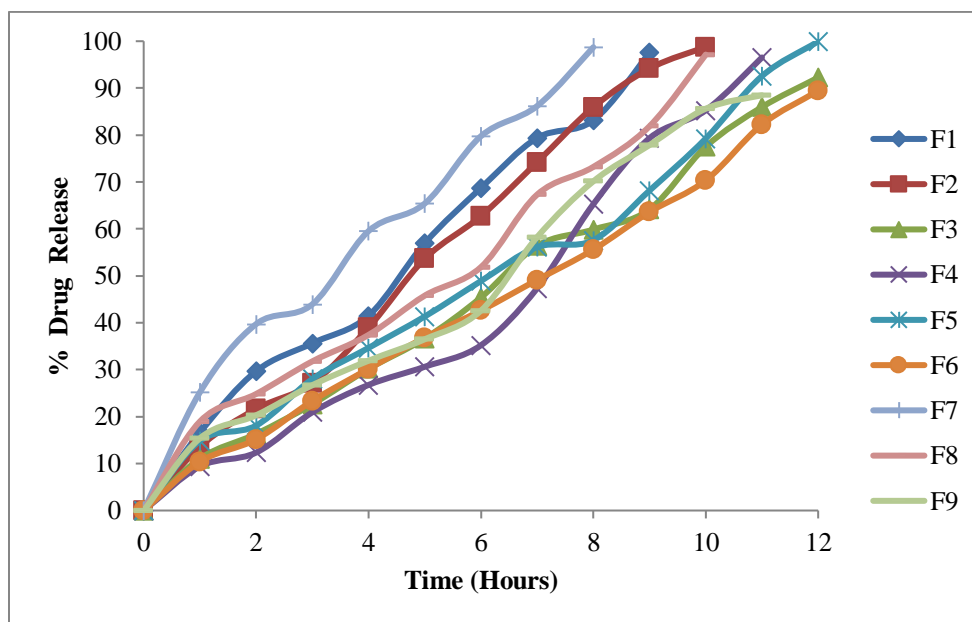


Fig:6 Dissolution data of Fenoverine Floating tablets

From the dissolution data it was evident that the formulations prepared with Carbopol as polymer were retarded the drug release more than 12 hours.

Whereas the formulations prepared with HPMC K 100 retarded the drug release up to 12 hours in the concentration 60 mg. In higher concentrations the polymer was unable to retard the drug release.

From the dissolution data, it was revealed that formulations prepared with Ethyl Cellulose retard the drug release up to 12 hrs.

Hence from the above dissolution data it was concluded that F5 formulation was considered as optimised formulation because good drug release (99.96%) in 12 hours.

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

Table No 9: Application kinetics for optimised formulation (F5)

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
14.83	1	1.000	1.171	0.000	1.930	14.830	0.0674	-0.829	85.17	4.642	4.400	0.242
18.1	2	1.414	1.258	0.301	1.913	9.050	0.0552	-0.742	81.9	4.642	4.343	0.299
28.01	3	1.732	1.447	0.477	1.857	9.337	0.0357	-0.553	71.99	4.642	4.160	0.482
34.65	4	2.000	1.540	0.602	1.815	8.663	0.0289	-0.460	65.35	4.642	4.028	0.614
41.34	5	2.236	1.616	0.699	1.768	8.268	0.0242	-0.384	58.66	4.642	3.886	0.756
48.89	6	2.449	1.689	0.778	1.709	8.148	0.0205	-0.311	51.11	4.642	3.711	0.930
56.14	7	2.646	1.749	0.845	1.642	8.020	0.0178	-0.251	43.86	4.642	3.527	1.115
57.6	8	2.828	1.760	0.903	1.627	7.200	0.0174	-0.240	42.4	4.642	3.487	1.155
68.19	9	3.000	1.834	0.954	1.503	7.577	0.0147	-0.166	31.81	4.642	3.169	1.473
79.26	10	3.162	1.899	1.000	1.317	7.926	0.0126	-0.101	20.74	4.642	2.747	1.894
92.57	11	3.317	1.966	1.041	0.871	8.415	0.0108	-0.034	7.43	4.642	1.951	2.690
99.96	12	3.464	2.000	1.079	-1.398	8.330	0.0100	0.000	0.04	4.642	0.342	4.300

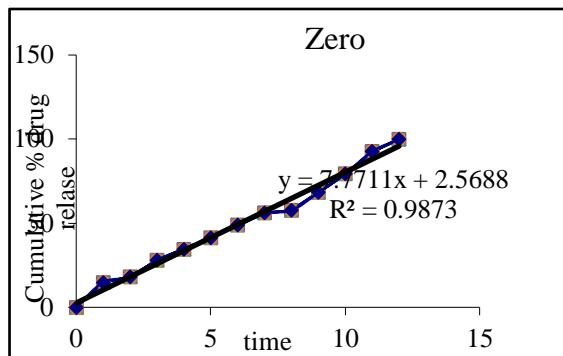


Fig no 10: Zero order release kinetics

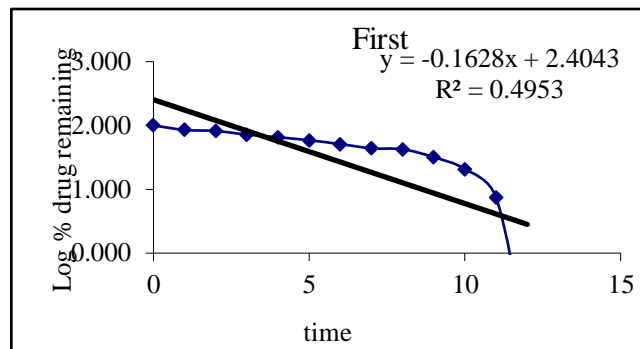


Fig 11: First order release kinetics

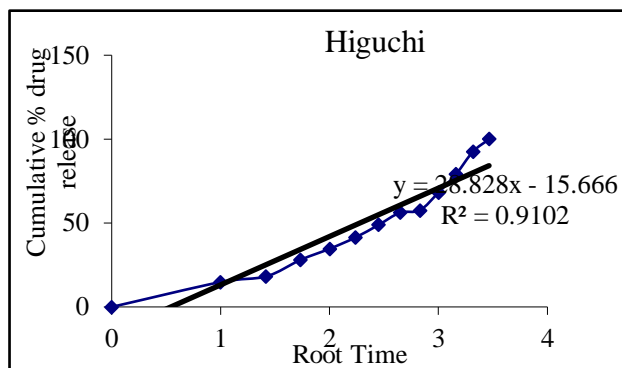


Fig no 12: Higuchi release kinetics

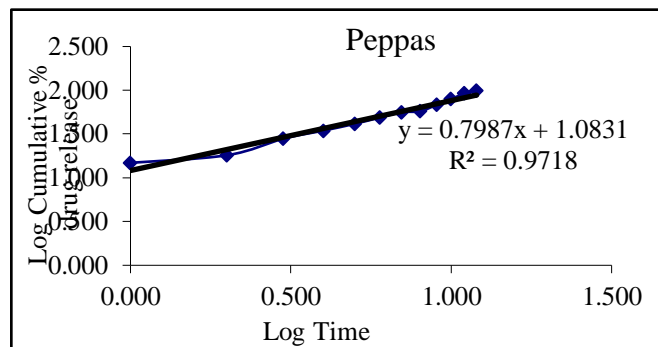


Fig 13: Kors mayer peppas release kinetics

Optimised formulation F5 was kept for release kinetic studies. From the above graphs it was evident that the formulation F5 was followed Zero order release kinetics and following Korsmeyer peppas mechanism with regression value of 0.971 and n value was found to be 0.798 which indicates it follows non fickian drug release pattern.

CONCLUSION;

This study discusses the preparation of effervescent floating tablet of Fenoverine. Fenoverine tablets were successfully prepared by direct compression method using different types of polymers Carbopol, HPMC K 100 and Ethyl Cellulose. The prepared tablets of Fenoverine were evaluated tablet hardness, uniformity of weight, friability, uniformity of content, *in vitro* buoyancy test and *in vitro* dissolution study. All the compositions were resulted in adequate Pharmacopoeial limits. Compatibility studies was execution during FTIR shown that there was absence of probable chemical interaction between pure drug and excipients. The varying concentration of gas generating agent and polymers was found to affect on *in-vitro* drug release and

floating lag time. *In vitro* drug release of floating gastro retentive tablet of Fenoverine shown that the formulation F5 was found to be the best formulation as it releases 99.96% Fenoverine in a controlled manner for an extended period of time (up to 12hrs). The release data was fitted to various mathematical models such as Higuchi, Korsmeyer-Peppas, First order and Zero order to evaluate the kinetics and mechanism of the drug release. The optimized formulation (F5) was followed Zero order release kinetics and following Korsmeyer peppas mechanism with regression value of 0.971 and n value was found to be 0.798 which indicates it follows non fickian drug release pattern.

Prepared floating tablets of Fenoverine may prove to be a potential candidate for safe and effective controlled drug delivery over an extended period of time for gastro retentive drug delivery system.

Floating tablets have emerged as the power full means of improving the bioavailability and providing sustained release and avoiding the adverse effects of many drugs. Floating tablets have proved to be potential approach for gastric retention. These systems have special advantage for the drug that is primarily absorbed from the upper part of GIT. So with an improved knowledge of formulation development aspect, physicochemical and pharmacological prospects of drug there is lot of future scope for designing of optimum floating drug delivery system.

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