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DESIGN AND OPTIMIZATION OF GASTRORETENTIVE FLOATING TABLETS FOR EPROSARTAN MESILATE

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ABSTRACT

The aim of the present research is to formulate and evaluate the gastroretentive floating tablets of antihypertensive drug, Eprosartan mesilate. Gastroretentive floating tablets (GRFT) were prepared by using a synthetic and natural polymers like hydroxyl propyl methyl cellulose in different grades (HPMC E15 and K15), Carbopol (934P and 940P), ethyl cellulose and natural polymers like guar gum, xanthan gum, karaya gum, chitosan and sodium alginate as release retarding polymers with sodium bicarbonate with citric acid as gas generating agent along with microcrystalline cellulose as diluent, talc and magnesium stearate as lubricant and glidant by direct compression method. The prepared tablets were evaluated for various pre-compression and post-compression parameters like thickness, hardness, weight variation, friability, *In vitro* buoyancy, swelling studies, *In vitro* dissolution studies and release mechanism studies. From the dissolution and buoyancy studies, E7 was selected as an optimized formulation. The optimized formulation followed zero order rate kinetics with non-Fickian diffusion mechanism. The final optimized formulation was performed with FTIR studies and observed no interaction between the drug and the polymers.

KEYWORDS

Gastroretentive floating tablets, Hydroxyl propyl methyl cellulose and Karaya gum.

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INTRODUCTION

Oral route of administration have gained popularity due to its several advantages like ease of administration, patient compliance and flexibility in formulation. To reduce the dosing frequency of conventional dosage forms researchers focus migrated to the formulation of controlled release dosage form which usage is restricted with the

physiological variations in gastric residence time from individuals to individuals. Gastroretentive technology is a better alternative to overcome this problem. Gastro retentive dosage form can be able to remain in the gastric region for several hours and hence significantly prolonging the gastric retention improves bioavailability, reduces drug waste, and improves solubility of drugs which are having least soluble at high pH environment. Hence Gastro retentive technology is most suitable for local drug delivery to the stomach and proximal small intestines.

The gastric retention of the dosage forms can be achieved by several methods such as floatation, mucoadhesion, swell able system, hydro dynamically balanced system, sedimentation, expansion modified shape systems, and so on. Among those many techniques, floating is the convenient and effective method for the gastric retention. Gastroretentive floating drug delivery systems (GRFDDS) can be buoyant in the gastric medium for prolonged period of time due to its lower bulk density compared to the gastric medium. While floating on the gastric contents, the drug will be continuously released at a desired rate from the dosage form and the GRT will be enhance. Due to increase in the GRT of the dosage form, more amount of the drug can be released in the gastric region, so that improves the bioavailability of the drug and also a better control of fluctuations in the plasma drug concentrations is achieved[1,2].

Eprosartan mesilate is an angiotensin II receptor antagonist used in the management of hypertension. Eprosartan is absorbed from the gastrointestinal tract with an absolute oral bioavailability of about 13%. The terminal elimination half life is about 5 to 9 hours[3]. The rationale for the development of gastroretentive drug delivery system is to prolong gastric residence time which reduces initial higher plasma concentrations of the drug so that dose related side effects can be minimized and also minimizing fluctuations in plasma drug concentration at steady state, reducing dosing frequency thereby improving therapeutic benefits. The aim of the present study is to develop floating tablets of Eprosartan mesilate with effervescent approach and compare the effectiveness of floating behavior of natural and synthetic polymers by direct compression method.

MATERIAL AND METHODS

Eprosartan mesilate was provided by Hetero Pharmaceutical, Hyderabad. HPMC (E15 and K15), Carbopol (934P and 940P), Ethyl cellulose, Guar gum, Xanthan gum, Karaya gum, Chitosan, Sodium alginate, sodium bicarbonate, citric acid, talc and magnesium stearate were obtained as gift samples from Granules India Pvt Ltd, Loba chemical Mumbai, Yarrow chemicals Ltd, Ranbaxy Research Laboratories, Merck Ltd Mumbai, Scientific Lab. All other reagents and chemicals were of analytical grade.

DEVELOPMENT OF GASTRORETENTIVE FLOATING TABLETS (GRFT) OF EPROSARTAN MESILATE

Floating tablets of Eprosartan mesilate were prepared by direct compression method according to the formula altering with respect to various parameters are shown below from Table No.1 to 3. Eprosartan mesilate was mixed with remaining excipients which were already passed through sieve no.60 seperately in a geometrical order except talc and magnesium stearate. Finally, talc and magnesium stearate were added and mixed well which was compressed into tablets using flat round punch in a 8-station tablet compression machine.

DETERMINATION OF λ MAX FOR EPROSARTAN MESILATE IN SIMULATED GASTRIC FLUID pH 1.2 (SGF)

About 100 mg of Eprosartan mesilate was accurately weighed into 100 ml volumetric flask and dissolved in small amount of simulated gastric fluid pH 1.2 which was then made upto 100 ml using the same. From this solution 20 ml was pipetted out and diluted to 100 ml in 100 ml volumetric flask using simulated gastric fluid pH 1.2. The above solution was scanned in the range of 200-400nm using Shimadzu ultra violet (UV)

spectrophotometer with simulated gastric fluid P^H 1.2 as blank solution. From the spectrum obtained, the λ max for Eprosartan mesilate in simulated gastric fluid P^H 1.2 was confirmed to be 233 nm.

Calibration curve for eprosartan mesilate in simulated gastric fluid pH 1.2 (SGF)

About 100 mg of Eprosartan mesilate was weighed accurately and taken in a 100 ml volumetric flask. Then it was dissolved in small amount of simulated gastric fluid pH 1.2 and the volume was made upto 100 ml with the same. Solutions ranging from 1 to 10µg/ml were prepared using simulated gastric fluid pH 1.2 separately and their absorbances were measured at λ max of 233 nm using UV spectrophotometer with simulated gastric fluid pH 1.2 as blank solution.

Drug excipient compatibility studies by fourier transform infra red (FTIR) spectroscopy[4]

The spectrums for Eprosartan mesilate alone and optimized formulation were recorded by FTIR spectroscopy (Perkin elmer) using potassium bromide disc method in the scanning range of 450 to 4000 cm^{-1} are shown in Figure No.1 and 2.

Evaluation of pre-compression parameters[5]

The powder blend of each formulation was subjected to evaluation of pre-compression parameters like bulk density, tapped density, carr's index and hausner's ratio. Bulk density of the powder blend was determined by introducing weighed amount of blend into 100 ml measuring cylinder without compacting which was carefully leveled and unsettled bulk volume, Vo was recorded. The bulk density was calculated using the formula, $\rho_b = M / Vo$ where ρ_b, M and Vo were bulk density, weight of sample and bulk volume of powder, respectively. The above blend was tapped for 500 times initially followed by an additional tap of 750 times until difference between succeeding measurement is less than 2 % and then tapped volume, V_f was measured, to the nearest graduated unit. The tapped density was calculated, in gm/ml, using the formula $\rho_{tap} = M / V_f$ where ρ_{tap}, M and V_f were tapped density, weight of sample and tapped volume of powder respectively. Carr's index and hausner's ratio were calculated from the formulas, Carr's Index = $100(\rho_{tap} - \rho_b) / \rho_{tap}$, and Hausner's Ratio = ρ_{tap} / ρ_b, where ρ_b and ρ_{tap} are bulk density and tapped density, respectively. Various pre-compression parameters of powder blend are tabulated in Table No.4.

Evaluation of post-compression parameters

The prepared tablets from each formulation were evaluated for various post-compression parameters like general appearance, thickness, weight variation, hardness, friability, *In vitro* buoyancy time, uniformity of drug content and *In vitro* release study. All the tablets were evaluated for its elegance[6]. Thickness of randomly selected tablets from each formulation was measured with vernier caliper[6]. Hardness of six tablets was measured using the Monsanto hardness tester[6]. The friability of a sample weight equal to 6.5 grams was dusted and placed in a Roche friabilator and operated for 100 revolutions which was then re-dusted and weighed. The Percentage loss was calculated using the formula, (initial weight-final weight/initial weight) x 100. Percentage loss should be within 0.5-1 % w/w[7]. Weight variation test was conducted with randomly selected twenty tablets from each formulation using Shimadzu electronic balance. The individual weight of each tablet was compared with the average weight and percentage deviation was calculated[8]. Swelling index (S.I) of the floating tablet was determined by immersing a weighed tablet in 900 ml of SGF pH 1.2 at room temperature and it was removed and weighed. S.I was calculated by the following equation, S.I (%) = (Final weight – Initial weight/initial weight) x 100. The S.I was determined for all the formulations[9]. *In vitro* buoyancy studies was carried out by placing randomly selected tablet from each formulation in beaker containing 100 ml SGF P^H 1.2 as a testing medium maintained at 37^0C. The time taken for the tablet to rise to the surface and float was taken as floating lag time (FLT). The duration of time the tablet constantly remained on the surface of medium was determined as the total floating time (TFT) (including floating lag time)[9]. The results for thickness, hardness, friability, weight variation,

swelling index, floating lag time and total floating time are shown in Table No.5 and 6.

Uniformity of drug content was performed for each formulation. Twenty tablets from each formulation were individually weighed and pulverized to a fine powder and amount of powder equivalent to average weight was dissolved in 100 ml of SGF pH 1.2. The solution was filtered through 0.45µ membrane filter, diluted suitably and the absorbance of resulted solution was measured spectrophotometrically at 233 nm for Eprosartan mesilate using SGF pH 1.2 as blank. The drug content was determined from standard calibration curve[9]. The results for drug content are shown in Table No.6.

In vitro dissolution studies of the floating tablets of Eprosartan mesilate were performed in USP Type-II dissolution apparatus (Lab India Disso 2000) employing a paddle stirrer revolved at 50 rpm using 900 ml of SGF pH 1.2 at 37°C ± 0.5°C as dissolution medium for 6 tablets from each formulation. About 10 ml of sample was withdrawn for 10 hours at each time interval and replaced immediately with equal volume of fresh medium in apparatus. The samples collected were filtered and their absorbances were measured at 233 nm for Eprosartan mesilate using SGF pH 1.2 as blank in UV spectrophotometer[9]. The results for *In vitro* dissolution studies for all formulations are shown in Table No.7 and Figure No.3.

Kinetic model had described drug dissolution from solid dosage form where the dissolved amount of drug is a function of test time. In order to study the exact mechanism of drug release from the tablets, drug release data was analyzed according to zero order, first order, Higuchi square root, Korsmeyer-Peppas model. The criteria for selecting the most appropriate model was choosen on the basis of goodness of fit test.

Zero order equation: % drug released = kt
where k is constant and t is time

First order equation: Log % drug released = kt/2.303
where k is constant and t is time

Korsmeyer - Peppas equation: $M_t / M_\infty = kt^n$

where M_t / M_∞ represents the fraction of drug release at time t, k is the release rate constant and n is the diffusion coefficient. (or)

Log drug released = log k + n log t where n is release exponent

Higuchi equation: % drug released = $kt^{0.5}$

The order of drug release from matrix systems was described by using zero order kinetics or first orders kinetics. The mechanism of drug release from matrix systems was studied by using Higuchi or erosion equation. The 'n' value is obtained as a slope for different batches of matrix tablets by plotting log percent drug dissolved against log time. If the value of n = 0.45 indicates Fickian (case I) release; >0.45 but <0.89 for non-Fickian (anomalous) release; and > 0.89 indicates super case II transport. Case II generally refers to the erosion of the polymeric chain and non-Fickian diffusion refers to a combination of both diffusion and erosion mechanism from the controlled drug release tablets[9,10]. The various plots of kinetic studies for *in vitro* dissolution data for optimized formulations of floating tablet of Eprosartan mesilate (E7) are shown from Figure No.4 to 7.

RESULTS AND DISCUSSION

In pre-formulation studies, drug - excipient compatibility were determined by comparing fourier transform infra red spectrum for pure drug with optimized formulation of floating tablet of Eprosartan mesilate both are shown in Figure No.1 and 2 and found that there was no appearance or disappearance of major peaks in drug like NH stretching (3371), carboxylic acid (2924), C=C aromatic stretching (1639) and C-N vibration (1049) concluded that there was no chemical interaction between drug and excipients.

In the formulation development of floating tablet of Eprosartan mesilate, three steps were followed like in first set of trial, formulations were prepared with various synthetic (HPMC (E15 and K15), Carbopol (934P and 940P) and Ethyl cellulose) and natural polymers (Guar gum, Xanthan gum, Karaya gum, Chitosan and Sodium alginate) in same concentration (10% w/w of total tablet weight) without effervescent agent to find the effect of

polymer on swelling index of floating tablet. In second set of trial, formulations were prepared with same concentration of karaya gum with varying concentrations of effervescent agent (sodium bicarbonate only) keeping concentration of citric acid constant to find the effect of effervescent agent on *In vitro* buoyancy studies especially floating lag time. In third set of trial, formulations were prepared with eight polymers and they were evaluated to find the effect of polymer on total floating time, drug contant and *In vitro* release studies.

From the results of pre-compression parameters tabulated in Table No.4, it was concluded that powder blends of all formulations exhibited excellent flow properties. From the results of post-compression parameters tabulated in Table No.5, to find the effect of various polymers on swelling index (trial I), formulation containing ethyl cellulose and sodium were omitted for next trials due to their low swelling index (F3 and F9) than formulations containing other polymers. From the results tabulated in Table No.5, to find the effect of effervescent agent on floating lag time, it was revealed that formulation containing highest ratio of sodium bicarbonate with citric acid (5:2) showed lowest floating lag time of 1 sec than other formulations with various ratios of 1:2, 2:2, 3:2 and 4:2, which concluded that increase in concentration of sodium bicarbonate gradually reduces the floating lag time due to fastest evolution of carbon dioxide by interaction of sodium bicarbonate with citric acid forms hollow space inside the tablet reduces the density of the tablet less than the density of gastric fluid allows to float immediately. From the results tabulated in Table No.6, to find the effect of polymer on total floating time and *In vitro* release studies, it was revealed that formulation containing karaya gum (E7) floated for long time in simulated gastric fluid pH 1.2 than other formulations and further confirmed by sustained release of drug from E7 till 10 hours follows zero order non-fickian diffusion controlled confirmed by kinetic plots of dissolution data are shown from Figure No.4 to 7.

Physical evaluation of blend was done by determining bulk density, tapped density, compressibility index and hausner ratio. From the results, the flow property of all formulation was found to be excellent.

Table No.1: Effect of polymer on swelling index

S.No	Name of the ingredients in a tablet/ Formulation Code	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1	Eprosartan mesilate*	360	360	360	360	360	360	360	360	360	360
2	Carbopol 934P	50	-	-	-	-	-	-	-	-	-
3	HPMC E 15	-	50	-	-	-	-	-	-	-	-
4	Ethyl cellulose	-	-	50	-	-	-	-	-	-	-
5	HPMC K15	-	-	-	50	-	-	-	-	-	-
6	Carbopol 940P	-	-	-	-	50	-	-	-	-	-
7	Guar gum	-	-	-	-	-	50	-	-	-	-
8	Xanthan gum	-	-	-	-	-	-	50	-	-	-
9	Karaya gum	-	-	-	-	-	-	-	50	-	-
10	Sodium alginate	-	-	-	-	-	-	-	-	50	-
11	Chitosan	-	-	-	-	-	-	-	-	-	50
12	Microcrystalline cellulose	75	75	75	75	75	75	75	75	75	75
13	Talc	10	10	10	10	10	10	10	10	10	10
14	Magnesium stearate	5	5	5	5	5	5	5	5	5	5
15	Total	500	500	500	500	500	500	500	500	500	500

* 1.2 mg of Eprosartan mesilate is equivalent to 1 mg of Eprosartan

* All the ingrediants are expressed in mg/tablet

Table No.2: Effect of effervescent agent on *in vitro* buoyancy studies

S.No	Name of the ingredients in a tablet/ Formulation Code	F11	F12	F13	F14	F15
1	Eprosartan mesilate*	360	360	360	360	360
2	Karaya gum	50	50	50	50	50
3	Sodium bicarbonate	5	10	15	20	25
4	Citric acid	10	10	10	10	10
5	Microcrystalline cellulose	60	55	50	45	40
6	Talc	10	10	10	10	10
7	Magnesium stearate	5	5	5	5	5
8	Total	500	500	500	500	500

* 1.2 mg of Eprosartan mesilate is equivalent to 1 mg of Eprosartan

* All the ingrediants are expressed in mg/tablet

Table No.3: Development of floating tablets of Eprosartan mesilate

S.No	Name of the ingredients in a tablet/ Formulation Code	E1	E2	E3	E4	E5	E6	E7	E8
1	Eprosartan mesilate*	360	360	360	360	360	360	360	360
2	Carbopol 934P	50	-	-	-	-	-	-	-
3	HPMC E 15	-	50	-	-	-	-	-	-
4	HPMC K15	-	-	50	-	-	-	-	-
5	Carbopol 940P	-	-	-	50	-	-	-	-
6	Guar gum	-	-	-	-	50	-	-	-
7	Xanthan gum	-	-	-	-	-	50	-	-
8	Karaya gum	-	-	-	-	-	-	50	-
9	Chitosan	-	-	-	-	-	-	-	50
10	Sodium bicarbonate	25	25	25	25	25	25	25	25
11	Citric acid	10	10	10	10	10	10	10	10
12	Microcrystalline cellulose	40	40	40	40	40	40	40	40
13	Talc	10	10	10	10	10	10	10	10
14	Magnesium stearate	5	5	5	5	5	5	5	5
15	Total	500	500	500	500	500	500	500	500

* 1.2 mg of Eprosartan mesilate is equivalent to 1 mg of Eprosartan

* All the ingrediants are expressed in mg/tablet

Pre-compression parameters of blend

Table No.4: Pre-compression parameters of blend of Eprosartan mesilate

S.No	Formulation Code	Bulk Density (g/ml)	Tapped density (g/ml)	Carr's Compressibility index (%)	Hausner ratio
1	F 1	0.660	0.722	8.59	1.09
2	F 2	0.4189	0.4505	7.01	1.08
3	F 3	0.676	0.716	5.59	1.06
4	F 4	0.720	0.791	8.98	1.10
5	F 5	0.688	0.794	10.12	1.12
6	F 6	0.4436	0.4929	10	1.11
7	F 7	0.671	0.710	5.49	1.06
8	F 8	0.740	0.823	10.09	1.11
9	F 9	0.4528	0.4922	8	1.09
10	F10	0.466	0.5065	7.99	1.09
11	F11	0.714	0.789	9.50	1.11
12	F12	0.4684	0.5091	7.99	1.09
13	F13	0.681	0.750	9.20	1.10
14	F14	0.4414	0.4904	9.99	1.11
15	F15	0.736	0.810	9.14	1.10
16	E1	0.691	0.731	9.12	1.06
17	E2	0.4428	0.4795	7.65	1.08
18	E3	0.720	0.791	8.97	1.10
19	E4	0.4702	0.5111	8	1.09
20	E5	0.736	0.810	9.14	1.10
21	E6	0.4634	0.5037	8	1.09
22	E7	0.721	0.818	11.85	1.13
23	E8	0.4252	0.4724	9.99	1.11

Post compression parameters of floating tablets of Eprosartan mesilate

Table No.5: Evaluation of floating tablets of Eprosartan mesilate

S.No	Formulation code	Thickness (mm) (n=6) Avg ± S.D	Hardeness (kg/cm^2) (n=6) Avg ± S.D	Friability (%) (n=20)	Weight variation (mg) (n=20) Avg ± S.D	Swelling index (%)Avg ± S.D	Floating lag time (FLT) (Sec)	Total floating time (TFT) (h)
1	F1	3 ± 0	5.20 ± 0.16	0.2888	0.595 ± 0.008	72	-	-
2	F2	3.03 ± 0.008	5.18 ± 0.18	0.30	0.596 ± 0.003	86	-	-
3	F3	3 ± 0	4.90 ± 0.11	0.45	0.596 ± 0.003	46	-	-
4	F4	2.78 ± 0.004	5.20 ± 0.20	0.34	0.595 ± 0.008	88	-	-
5	F5	2.72 ± 0.004	4.76 ± 0.12	0.54	0.597 ± 0.004	79	-	-
6	F6	3 ±0	4.84 ± 0.18	0.23	0.594 ± 0.008	86	-	-
7	F7	2.97 ± 0.005	4.90 ± 0.11	0.25	0.595 ± 0.26	87	-	-
8	F8	2.8 ± 0.004	4.76 ± 0.14	0.56	0.594 ± 0.008	92	-	-
9	F9	2.82 ± 0.004	5.06 ± 0.21	0.16	0.598 ± 0.005	62	-	-
10	F10	2.8 ± 0.005	4.76 ± 0.14	0.52	0.596 ± 0.003	80	-	-
11	F11	3 ± 0	4.90 ± 0.11	0.19	0.595 ± 0.006	-	8	-
12	F12	2.97 ± 0.005	4.86 ± 0.14	0.18	0.596 ± 0.18	-	6	-
13	F13	3± 0	5.18± 0.18	0.48	0.595 ± 0.008	-	5	-

Table No.6: Evaluation of floating tablets of Eprosartan mesilate

S.No	Formulation Code	Thickness (mm) (n = 6) Avg ± S.D	Hardness (kg/cm^2) (n = 6) Avg ± S.D	Friability (%) (n = 20)	Weight variation (mg) (n = 20) Avg ± S.D	Floating lag time (FLT) (sec)	Total floating time TFT) (min)	Drug content (mg)
1	E 1	2.97 ± 0.005			0.595 ± 0.008	1	270	91.77
2	E 2	3 ± 0			0.594 ± 0.008	1	340	88.2
3	E 3	2.82 ± 0.004			0.596 ± 0.003	1	315	90.25
4	E 4	2.97 ± 0.005	4.91 ± 0.11	0.22	0.595 ± 0.26	1	260	86.49
5	E 5	2.78 ± 0.004	4.89 ± 0.18	0.16	0.594 ± 0.008	1	320	86.32
6	E 6	2.97 ± 0.005	4.88 ± 0.13	0.32	0.593 ± 0.005	1	390	90.14
7	E 7	2.8 ± 0.004	4.71 ± 0.19	0.31	0.595 ± 0.008	1	580	93.14
8	E 8	2.82 ± 0.004	4.94 ± 0.12	0.26	0.595 ± 0.26	1	450	89.90

Table No.7: *In vitro* dissolution studies data for floating tablets of Eprosartan mesilate

S.No	Time (min)	% Drug released							
		E1	**E2**	**E3**	**E4**	**E5**	**E6**	**E7**	**E8**
1	0	0	0	0	0	0	0	0	0
2	5	16.54	17.14	15.29	18.28	11.61	11.24	2.58	4.72
3	10	28.24	28.91	21.67	22.32	24.19	24.91	7.48	10.96
4	30	36.32	36.27	31.28	34.17	35.29	35.64	13.27	21.24
5	60	48.65	41.78	47.35	59.41	48.61	46.14	25..60	32.62
6	90	56.87	49.45	56.27	71.56	54.73	58.91	32.69	41.24
7	120	65.62	58.27	68.62	78.81	60.81	62.27	41.09	51.33
8	180	71.36	65.34	72.41	84.67	72.14	75.69	48.33	59.71
9	240	84.27	78.54	85.21	90.65	84.27	81.42	55.24	67.36
10	300	92.68	84.82	92.32		91.84	88.13	64.54	72.96
11	360		89.65				92.54	72.57	80.02
12	420							79.68	86.27
13	480							84.48	94.68
14	540							89.76	
15	570							93.24	
16	600							98.47	

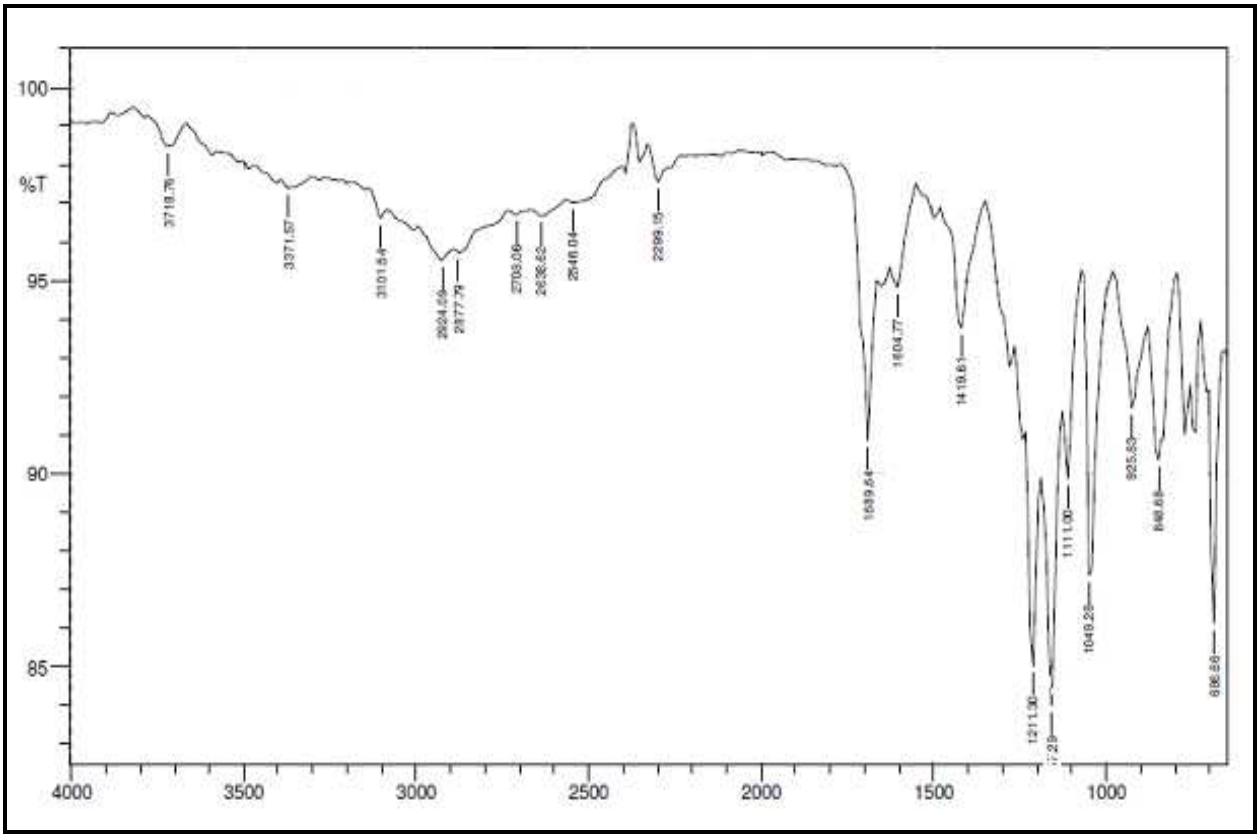

Figure No.1: FTIR spectrum of Eprosartan mesilate

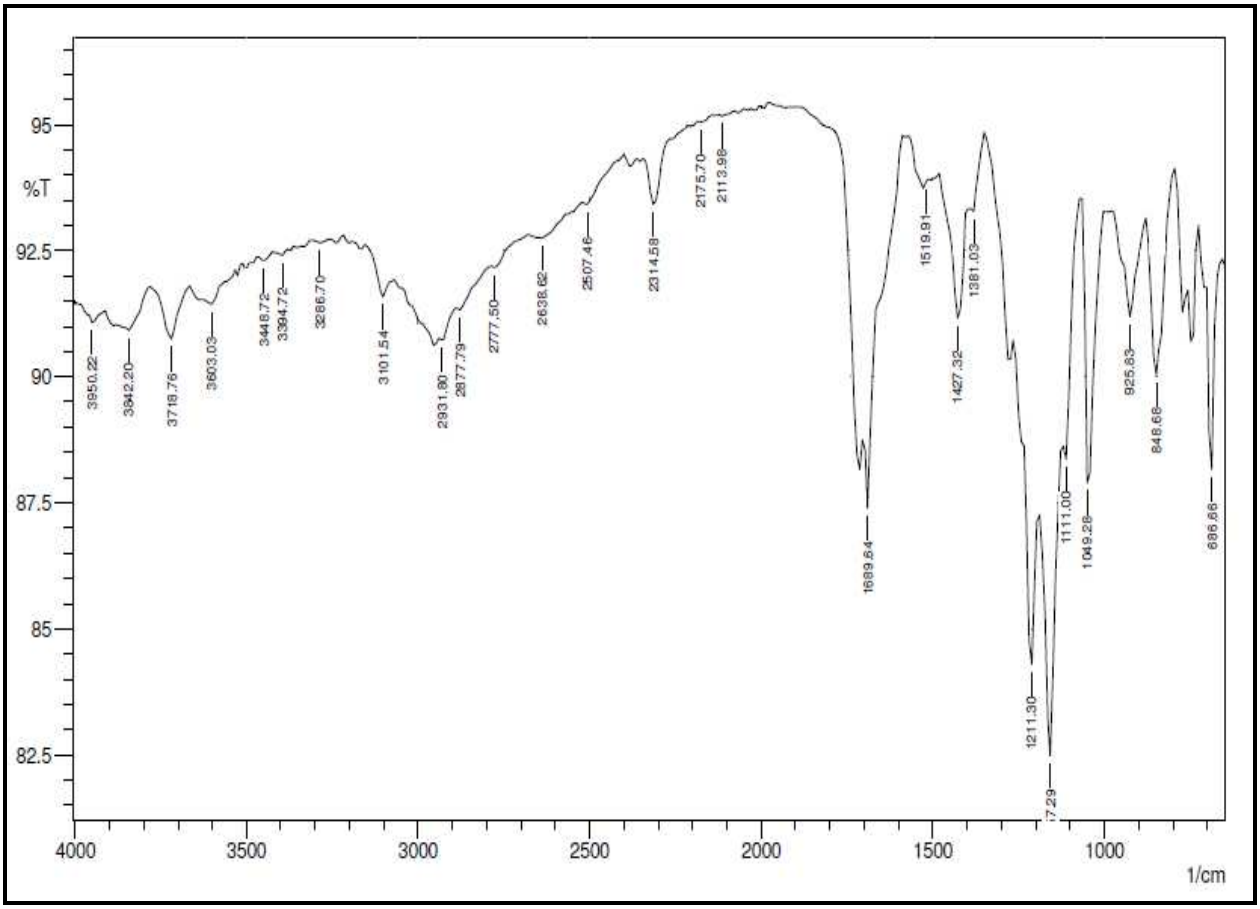

Figure No.2: FTIR spectrum of optimized formulation of Eprosartan mesilate

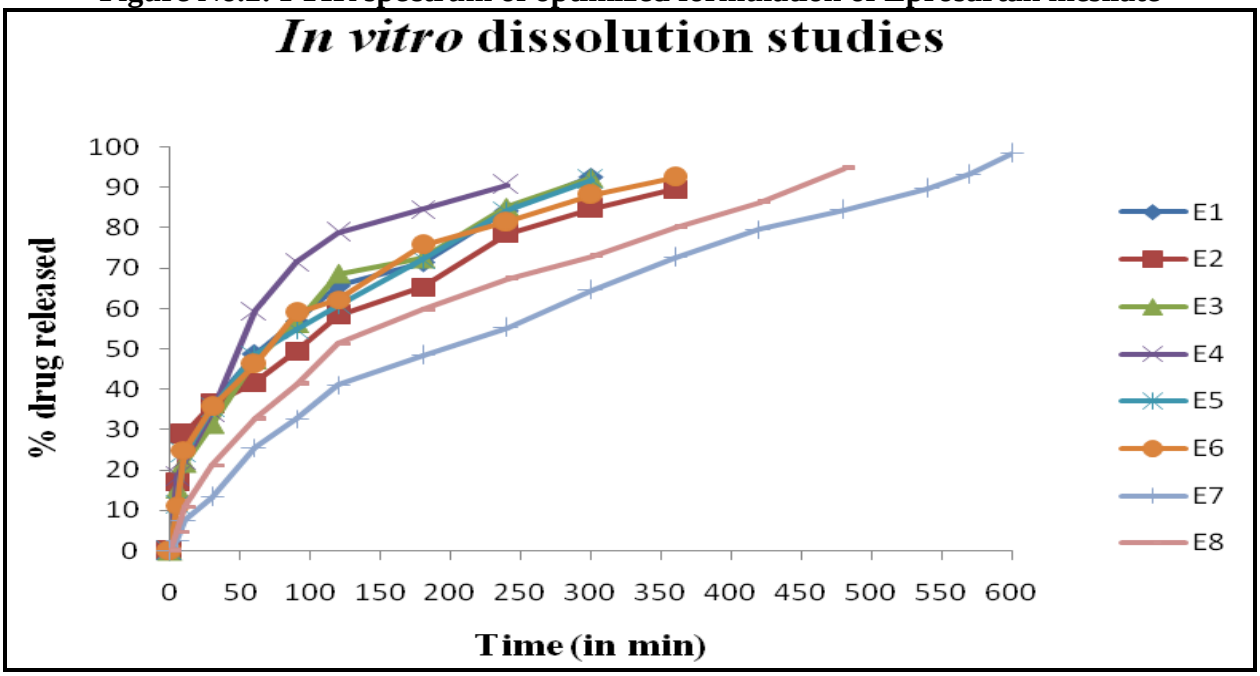

Figure No.3*: In vitro* dissolution profile for floating tablet of Eprosartan mesilate

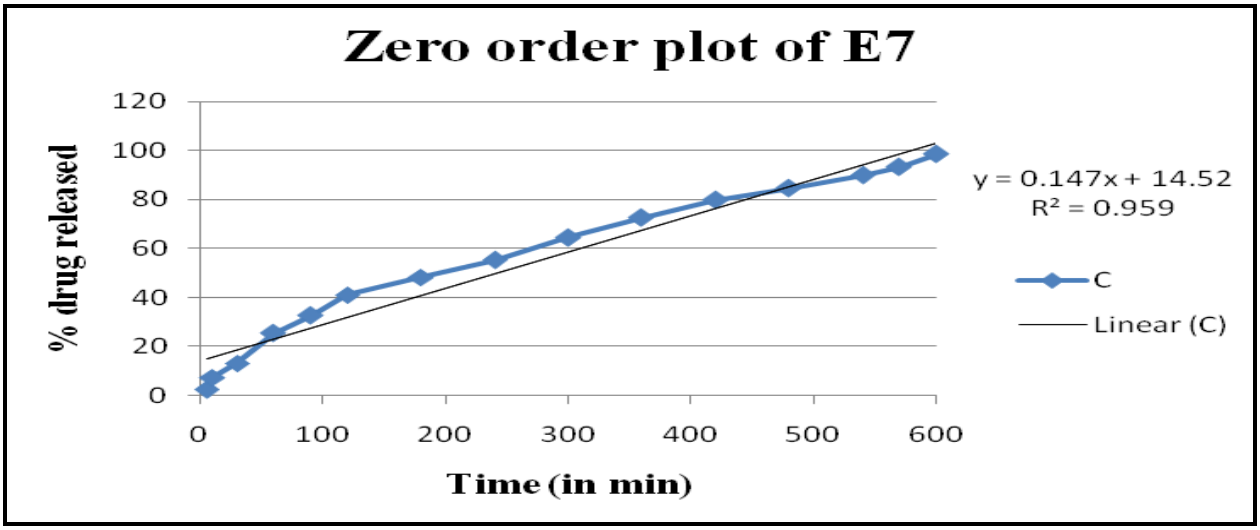

Figure No.4: Zero order plot for optimized formulation of floating tablet of Eprosartan mesilate (E7)

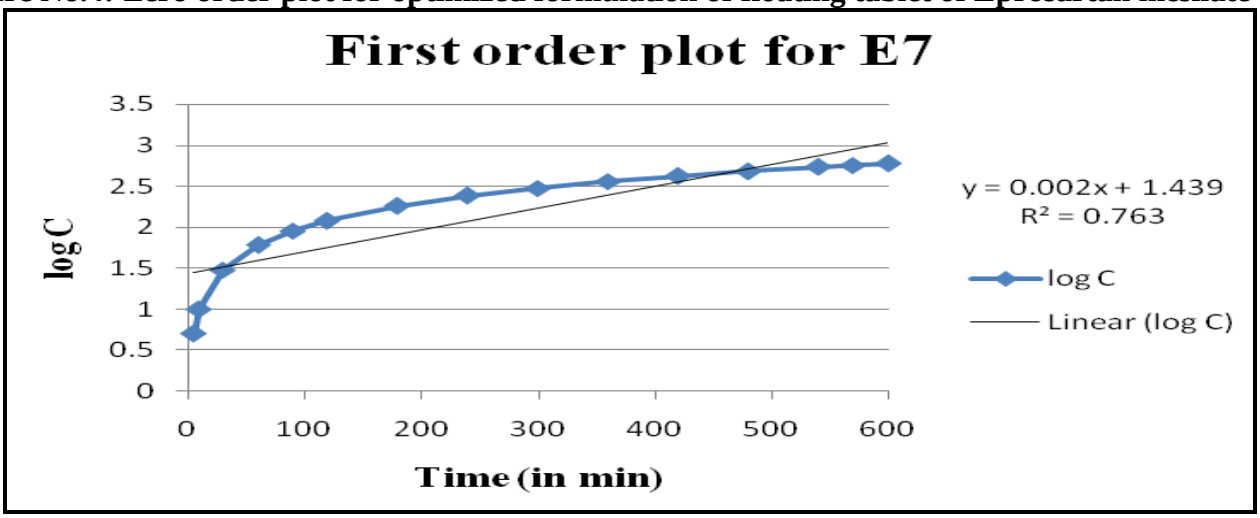

Figure No.5: First order plot for optimized formulation of floating tablet of Eprosartan mesilate (E7)

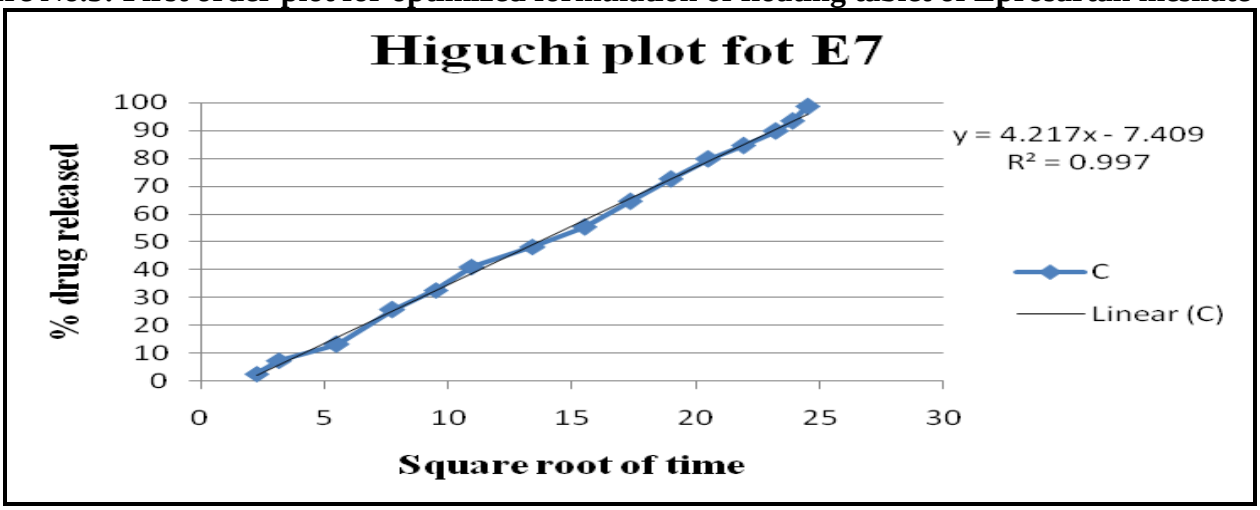

Figure No.6: Higuchi plot for optimized formulation of floating tablet of Eprosartan mesilate (E7)

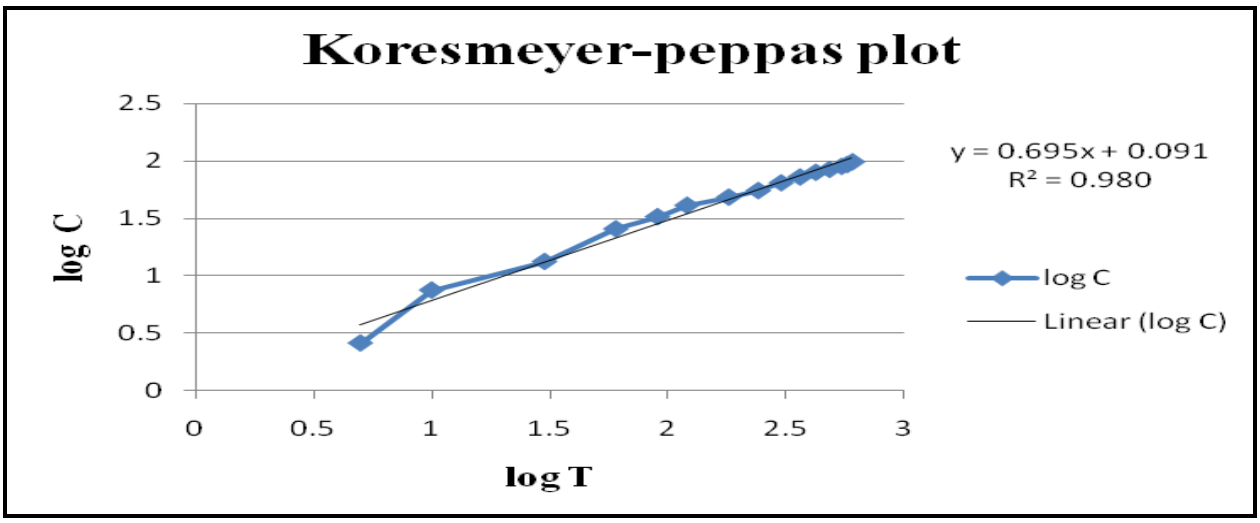

Figure No.7: Koresmeyer peppas plot for optimized formulation of floating tablet of Eprosartan mesilate (E7)

CONCLUSION

In the present study, and attempt was made to develop the floating tablet of Eprosartan mesilate by effervescent approach comparing various synthetic and natural polymers concluded that formulation containing karaya gum with highest ratio of effervescent agent (E7) was the best formulation with least floating lag time, highest total floating time with sustained drug release follows zero order non-fickian diffusion than other formulations along with its biocompatible, less side effects than synthetic polymer makes karaya gum as an promising nature polymer for sustained release dosage forms. The principle of buoyant offers simple and practical approach to achieve increased gastric residence time for sustained drug release. The most important criteria for the production of FDDS is density of system should be less than that of gastric fluid. It can be concluded that these dosage forms serve the best in the treatment of diseases related to GIT and for prolonging the action of drug with short half life.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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