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RESEARCH ARTICLE

FORMULATION AND EVALUATION OF GASTRO RETENTIVE EFFERVESCENT FLOATING MATRIX TABLETS OF CEPHALEXIN

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ABSTRACT:

The present research work was an attempt to formulate and evaluate gastro retentive buoyant drug delivery system containing cephalexin in the form of tablets prepared by direct compression method by using the hydrophilic polymers such as HPMC K4M, HPMC K100M, Xanthan gum, Guar gum, Karaya gum, Sodium cmc and hydrophobic polymers (Ethyl cellulose) . Both grades of HPMC were used individually in different ratios and remaining polymers were used in combination with both HPMC polymers. Sodium bicarbonate & citric acid, MCC were also used. The prepared tablets were evaluated for their Pre & Post compression parameters such as weight variation, thickness, hardness, friability, drug content, swelling index, *in vitro* buoyancy, *in vitro* drug release studies. All formulations followed first order kinetics, showed good correlation in higuchi kinetics indicating drug release was predominantly diffusion controlled. When data was fitted to peppas slope values suggest that release followed non fickian diffusion.

Key Words: Cephalexin, HPMC K15M, HPMC K100M, Xanthan gum.

INTRODUCTION:

Oral drug delivery is the most widely utilized route of administration among all the routes that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage form. The objective of any drug delivery system is to afford a therapeutic amount of drug to the proper site of action in the body to attain promptly, and then maintain the desired drug concentration[1]. An ideal drug delivery system (DDS) should aid in the optimization of drug therapy by delivering an appropriate amount to the intended site and at a desired rate. Hence, the DDS should deliver the drug at a rate dictated by the needs of the body over the period of treatment.

Advances in oral controlled-release technology are attributed to the development of novel biocompatible and machineries that allow preparation of novel design dosage forms in a reproducible manner. The main oral drug-delivery approaches that have survived through the ages are as follows[2,3]:

- Coating technology using various polymers for coating tablets, nonpareil sugar beads, and granules
- Matrix systems made of swellable or nonswellable polymers
- Slowly eroding devices
- Osmotically controlled devices.

One of the most feasible approaches for achieving a prolonged and predictable drug delivery profile in the GI tract is to control the gastric residence time (GRT). Dosage form with a prolonged GRT, that is gastro retentive dosage forms (GRDFs), will provide us with new and important therapeutic options[4]. GRDFs extend significantly the period of time over which the drugs may be released. Thus, they not only prolong dosing intervals, but also increase patient's compliance beyond the level of existing controlled release dosage forms.

Gastric retention will provide advantages such as the delivery of drugs with narrow absorption window in the small intestinal region. Also, longer residence time in the stomach could be advantageous for local action in the upper part of the small intestine, for example treatment of peptic ulcer disease. Furthermore, improve bio availability is expected for drugs that are absorbed readily upon release in the GI tract. These drugs can be delivered ideally by slow release from the stomach[5].

Cephalexin is in a group of drugs called cephalosporin antibiotics and is used to fight bacteria in the body. It works by interfering with the bacteria's cell wall formation, causing it to rupture, and killing the bacteria[6,7,8]. It has good absorption in GIT, low pKa, which remained unionized in the stomach for better absorption and it has a half life of 0.5-1-2 hours. Cephalexin is used to treat infections caused by bacteria, including upper respiratory infections, ear infections, skin infections, and urinary tract infections[9,10,11].

The aim of the present study was not only preparing Cephalexin floating system but also to release the drug in the controlled manner, therefore the maximum drug release is maintained at desired site. The effect of different polymers and the effect of amount of polymers was investigated in the formulation to monitor the sustained release effect respectively.

MATERIALS & METHODS:

Materials: Cephalexin (drug) was obtained as a gift sample from A.P. drugs control office Hyd, india, remaining all the excipients were procured from SD Fine Chemicals Pvt. Limited.

Method: Direct compression method.

Preparation of floating tablets of cephalexin:

The composition of different formulations was shown in Table no.1. The powder mixture containing drug, controlled release polymers as per the formulae and MCC used as the diluent, sodium bicarbonate as effervescent agent were mixed thoroughly. The blend was lubricated with magnesium stearate for 3-5 mins and talc was added as glidant. The mixed blend was then compressed into tablets by direct compression method using 12 mm punches on a sixteen station rotary tablet punching machine.

Table 1: Formulation development of Cephalexin floating tablets:

Formulation (mg)	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8
Drug	250	250	250	250	250	250	250	250
HPMC K4M	100	125	150	100	100	100	100	100
Xanthan gum	---	---	---	50	---	---	---	---
Guar gum	---	---	---	---	50	---	---	---
Karaya gum	---	---	---	---	---	50	---	---
Sodium CMC	---	---	---	---	---	---	50	---
Ethyl cellulose	---	---	---	---	---	---	---	50
Sod.Bicarbonate	66	66	66	66	66	66	66	66
Citric acid	20	20	20	20	20	20	20	20
Talc	05	05	05	05	05	05	05	05
Mg. stearate	05	05	05	05	05	05	05	05
MCC	104	79	54	54	54	54	54	54

Formulation (mg)	F_9	F_{10}	F_{11}	F_{12}	F_{13}	F_{14}	F_{15}	F_{16}
Drug	250	250	250	250	250	250	250	250
HPMC K100 M	50	75	100	65	65	65	65	65
Xanthan gum	---	---	---	35	---	---	---	---
Guar gum	---	---	---	---	35	---	---	---
Karaya gum	---	---	---	---	---	35	---	---
Sodium CMC	---	---	---	---	---	---	35	---
Ethyl cellulose	---	---	---	---	---	---	---	35
Sod.Bicarbonate	66	66	66	66	66	66	66	66
Citric acid	20	20	20	20	20	20	20	20
Talc	05	05	05	05	05	05	05	05
Mg. stearate	05	05	05	05	05	05	05	05
MCC	154	129	104	104	104	104	104	104

Total Tablet weight in all formulation is 550 mg.

EVALUATION OF GRANULES: (PRE-COMPRESSION PARAMETERS)

Angle of Repose:

The angle of repose was determined by the funnel method. The accurately weighed powder was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touched the apex of the heap of the powder. The powder was allowed to flow through the funnel freely onto the surface. The diameter of the powder cone was measured.

The angle of repose was then calculated by measuring the height and radius of the heap of granules formed.

$$\tan \theta = h/r$$

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

Where, θ = angle of repose

h = height of the heap

r = radius of the heap

Bulk Density (BD):

An accurately weighed powder blend from each formula was lightly shaken to break any agglomerates formed and it was introduced in to a measuring cylinder. The volume occupied by the powder was measured which gave bulk volume. The loose bulk density (BD) of powder blends was determined using the following formula.

Bulk density = Total weight of powder / Total volume of powder

Tapped bulk density (TBD):

An accurately weighed powder blend from each formula was lightly shaken to break any agglomerates formed and it was introduced into a measuring cylinder. The measuring cylinder was tapped until no further change in volume was noted which gave the tapped volume. The tapped bulk densities (TBD) of powder blends were determined using the following formula.

Tapped bulk density = Total weight of powder / Total volume of tapped powder

Hausner's Ratio:

It indicates the flow properties of the powder and is measured by the ratio of tapped density to the bulk density

$$H = D_t / D_b$$

where H is the Hausner's ratio ,

Dt is the tapped density of the powder and D_b is the bulk density of the powder.

Hausner's ratio less than 1.25 indicates good flow while greater than 1.5 indicates poor flow.

CARR'S Compressibility Index: It is a simple index that can be determined on small quantities of powder. The compressibility indices of the formulation blends were determined using following Carr's compressibility index formula.

Carr's Compressibility Index (%) =

$$\frac{\text{Tapped bulk density} - \text{Bulk density}}{\text{Tapped bulk density}} \times 100$$

EVALUATION OF TABLETS: (POST COMPRESSION PARAMETERS)

The prepared tablets were evaluated for their parameters such as weight variation, thickness, hardness, friability, drug content, swelling index, *in vitro* buoyancy, *in vitro* drug release studies.

Weight Variation:

Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets were calculated. Then each batch passes the test for weight variation if not more than two of the individual tablet deviate from the average weight by more than the percentage.

Hardness:

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Monsanto hardness tester. It was expressed in kg/cm^2. Ten tablets of each formulation were randomly picked and hardness of the tablets was determined.

Friability: The Roche friability test apparatus was used to determine the friability of the Tablets. Ten pre-weighed Tablets were placed in the apparatus and was rotated at 25 rpm for 4 minutes and then the Tablets were reweighed. The percentage friability was calculated according to the following formula.

% friability was calculated as follows

$$\% \text{ Friability} = (W_1 - W_2) \times 100/W_1$$

Where W_1 = Initial weight of the 10 tablets.

W_2 = Final weight of the10 tablets after testing.

Friability values below 1.0% are generally acceptable.

Drug content (assay):

Ten tablets were taken and powdered. Powder equivalent to one tablet was taken and dissolved in 50 ml of 0.1N Hcl. The mixture was allowed to stand for 1 hr with intermittent sonication to ensure complete hydration of polymer and subsequent solubility of the drug. Then the volume was made up to 100ml. The mixture was filtered and 1ml of the filtrate was suitably diluted. The absorbance of solution was measured by using UV – Visible spectrophotometer (Elico, India) at 257 nm. Each measurement was carried out in triplicate and the average drug content in the floating tablet was calculated.

Swelling index: From each formulation, one tablet was weighed and placed in a beaker containing 200 ml of 0.1N Hcl buffer solution. After each hour the tablet was removed from beaker and weighed. The percentage weight gain by the tablet was caluculated by using the formula.

$$\%SI = \frac{W_t - W_0}{W_0} \times 100$$

%SI = Swelling index

W_t = weight of tablet at time t

W_0= weight of tablet before immersion.

***In vitro* floating lag time:**

The *in vitro* buoyancy was determined by floating lag time. The tablets were placed in a 100 ml beaker containing 0.1 N HCl. The media was kept in stagnant condition and the temperature was maintained at 37^0C. The time required for the tablet to rise to the surface and float was determined as floating lag time.

***In vitro* floating duration time:**

The floating capacity of the tablets was determined using USP dissolution apparatus II containing 900 ml of 0.1 N Hcl. The time interval between introduction of the tablet into the dissolution medium and its buoyancy to the dissolution medium was taken as buoyancy lag time and for which time the tablet constantly floats on the surface of the medium was observed visually and taken as floating duration.

***In vitro* Dissolution studies:**

The release of cephalexin from floating tablets was determined by using Dissolution type II test apparatus. The dissolution test was performed using 900 ml 0.1N Hcl solution at 37 ± 0.5^0C temperature and at 50 rpm. At specified time intervals, samples of 5ml were withdrawn at predetermined time intervals (1 to 12hrs) and the same volume was replaced with fresh medium to maintain the volume constant. The samples were filtered through Whattman filter paper and diluted to suitable concentration with 0.1N Hcl. The absorbance value of the diluted sample was analyzed by UV spectrophotometer at 257 nm. The percentage drug

release was calculated using an equation obtained from standard curve.

Drug release kinetics and mechanism [12,13,14,15]:

To analyze the mechanism of drug release from the formulation, the dissolution profile of all the batches were fitted to zero order, first order, Higuchi and Peppas models to ascertain the kinetic modelling of drug release.

Model	Equation
Zero order	$Q = K_0 t$
First order	$\text{Log } Q_t = \text{Log } Q_o + K_1 t / 2.303$
Korsmeyer-Peppas model	$Mt/M\infty = kt^n$
Higuichi	$Q = K_2 t^{1/2}$

Similarity Factor (f2) Analysis:

In vitro release profiles of floating tablets were compared with the theoretical release profile which was calculated earlier. The data were analyzed by the following formula.

$$f_2 = 50 \log \{[1+ (1/N) \sum (R_i - T_i)^2]^{-0.5} \times 100\}$$

Where N = number of time points,

Ri and Ti = dissolution of reference and test products at time i.

If f_2 is greater than 50 it is considered that 2 products share similar drug release behaviors.

Fourier Transform infrared (FTIR) Spectroscopic studies:

Fourier Transform Infrared spectrophotometer (FTIR) was used for infrared analysis of samples to intercept the interactions of drug with polymers and other ingredients. FTIR studies were conducted for characterization of drug in tablets. The floating tablets were compressed and powdered. The pelletized powder along with KBr was used for FTIR studies. The IR spectra were recorded using Fourier Transform Infrared Spectrophotometer. The samples were analyzed between the wave numbers 4000 and 400 cm^2 .

RESULT & DISCUSSION:

RESULTS:

Table 2: Results for Derived and Flow properties

Formulation Code	Derived properties		Flow properties		
	Bulk density (mean±SD)	Tapped density (mean±SD)	Angle of repose (mean±SD)	Carr's index (mean± SD)	Hausner's ratio (mean±SD)
F1	0.64±0.02	0.80±0.02	29.13±0.04	11.44±1.9	1.129±0.02
F2	0.65±0.02	0.78±0.03	27.31±0.03	13.22±1.9	1.126±0.03
F3	0.64±0.01	0.78±0.02	28.26±0.01	11.86±3.9	1.135±0.05
F4	0.63±0.08	0.77±0.05	28.28±1.50	14.48±1.8	1.105±0.02
F5	0.68±0.04	0.82±0.03	29.01±1.04	12.65±2.2	1.145±0.03
F6	0.64±0.03	0.79±0.02	26.87±2.0	9.32±3.16	1.103±0.04
F7	0.63±0.05	0.78±0.07	27.48±1.05	13.54±1.1	1.184±0.02
F8	0.67±0.08	0.81±0.02	28.15±1.53	11.69±3.6	1.126±0.05
F9	0.66±0.02	0.79±0.06	28.44±1.25	10.87±2.8	1.113±0.04
F10	0.62±0.06	0.75±0.08	27.57±0.82	14.21±1.1	1.165±0.01
F11	0.67±0.05	0.80±0.02	28.26±0.01	13.47±2.4	1.156±0.03
F12	0.65±0.02	0.79±0.02	29.01±1.04	14.23±3.2	1.154±0.02
F13	0.64±0.01	0.82±0.03	26.87±2.0	13.21±2.3	1.123±0.03
F14	0.68±0.04	0.78±0.02	27.48±1.05	9.32±3.1	1.156±0.03
F15	0.67±0.08	0.81±0.02	29.13±0.04	10.87±2.8	1.184±0.02
F16	0.66±0.02	0.75±0.08	28.15±.53	14.21±1.1	1.135±0.05

****** all values are expressed as mean± SD, n=3***

Table 3: Evaluation of physical parameters of the Tablets

Formulation code	Weight Variation(mg)	Hardness (Kg/cm^2)	Thickness (mm)	Fraibility (%)	Drug content (%)
F1	549.5±3.80	5.83±0.28	5.38±0.06	0.66±0.03	97.4±0.5
F2	549.4±2.79	6.66±0.28	5.27±0.12	0.79±0.04	100±2.5
F3	548.8±3.58	6.83±0.28	5.41±0.09	0.26±0.03	104.8±1.17
F4	550.5±3.02	6.0±0.5	5.28±0.09	0.40±0.05	104±0.2
F5	549.5±3.84	5.28±0.28	5.20±0.11	0.53±0.03	95.66±0.08
F6	550.4±2.71	6.5±0.5	5.28±0.12	0.94±0.01	99.14±1.02
F7	550.4±3.29	6.1±0.3	5.26±0.17	0.26±0.02	100.88±2.51
F8	548.9±4.40	6.1±0.7	5.28±0.12	0.60±0.04	100±2
F9	549.8±4.13	7.83±0.28	5.23±0.14	0.66±0.03	103.4±3.32
F10	548.8±3.52	7.5±0.61	5.25±0.14	0.40±0.05	101.7±0.01
F11	549.4±4.51	7.5±0.86	5.26±0.15	0.91±0.06	101.7±0.01
F12	550.5±3.83	7.66±0.28	5.22±0.17	0.39±0.94	104.36±1.0
F13	548.3±4.98	7.5±0.5	5.44±0.04	0.48±0.08	99.81±1.4
F14	549.1±2.51	7.7±0.7	5.36±0.04	0.41±0.03	100.26±0.8
F15	546.6±4.97	7.2±0.4	5.39±0.08	0.64±0.16	99.18±0.6
F16	548.8±4.31	7.66±0.28	5.26±0.09	0.36±0.03	97.53±1.3

Table 4: Floating time

Formulation code	Floating lag time (Sec)	Total floating time (hrs)
F1	45	>12 hrs
F2	45	>12 hrs
F3	55	>12 hrs
F4	65	>12 hrs
F5	65	>12 hrs
F6	70	>12 hrs
F7	70	>12 hrs
F8	85	>12 hrs
F9	45	>12 hrs
F10	45	>12 hrs
F11	50	>12 hrs
F12	60	>12 hrs
F13	65	>12 hrs
F14	75	>12 hrs
F15	70	>12 hrs
F16	90	>12 hrs

Table 5: Swelling index of cephalexin floating tablets

Formulation code	Swelling index (%)
F1	85.09
F2	92.92
F3	99.09
F4	100.9
F5	92.85
F6	87.9
F7	82.26
F8	81.47
F9	87.68
F10	91.5
F11	110.5
F12	95.06
F13	90.5
F14	106.5
F15	92.5
F16	88

Table 6: KINETICS DATA OF ALL FORMULATIONS

	ZERO ORDER KINETICS		FIRST ORDER KINETICS		HIGUCHI	PEPPAS	
CODE	R^2	K_0	R^2	K_1	R^2	R^2	n
F1	0.9015	11.43	0.9636	0.465	0.9974	0.9960	0.558
F2	0.9227	9.146	0.9677	0.327	0.9929	0.9977	0.591
F3	0.8893	8.10	0.9336	0.349	0.9630	0.9351	0.757
F4	0.9156	7.06	0.9708	0.231	0.9889	0.9632	0.566
F5	0.8894	7.855	0.9566	0.396	0.9857	0.9840	0.568
F6	0.8625	7.689	0.8998	0.325	0.964	0.9157	0.685
F7	0.9477	7.66	0.9730	0.168	0.9880	0.9934	0.592
F8	0.8884	6.67	0.9802	0.189	0.9942	0.9896	0.553
F9	0.905	11.13	0.9644	0.243	0.9847	0.9157	0.607
F10	0.9362	8.717	0.9419	0.193	0.9704	0.9924	0.798
F11	0.9193	7.989	0.9868	0.240	0.9584	0.9483	0.839
F12	0.9375	7.223	0.9911	0.196	0.9866	0.9889	0.596
F13	0.9093	7.779	0.9848	0.299	0.9876	0.9880	0.600
F14	0.935	7.507	0.9464	0.223	0.9801	0.9666	0.734
F15	0.9270	7.500	0.9886	0.103	0.9917	0.9833	0.632
F16	0.8856	7.05	0.9827	0.251	0.9854	0.9723	0.500

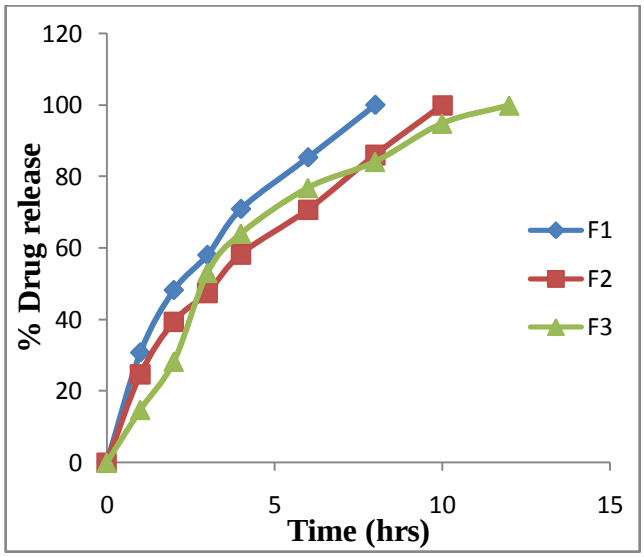

Fig 1: Comparison of dissolution profiles of F1, F2 & F3

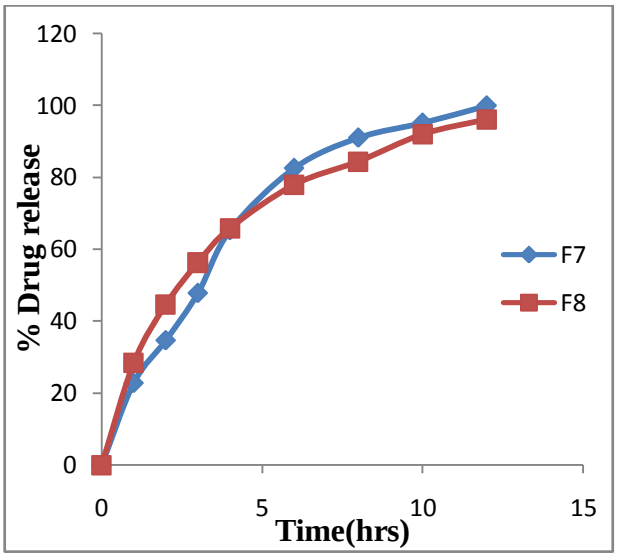

Fig 3: Comparison of dissolution profiles of F7 & F8

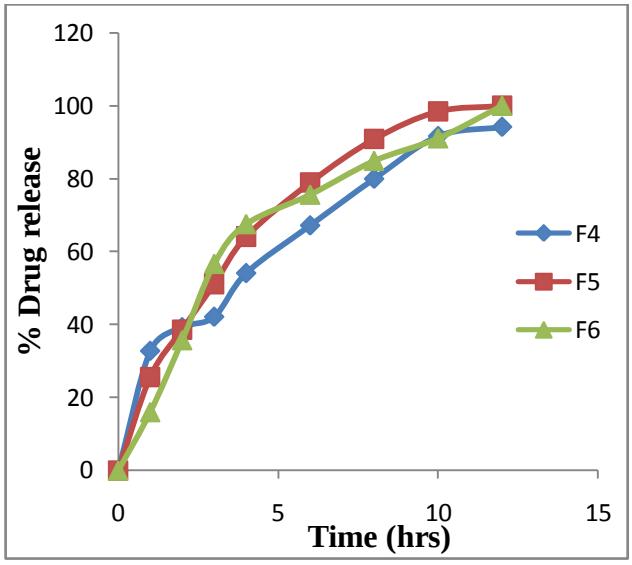

Fig 2: Comparison of dissolution profiles of F4, F5& F6

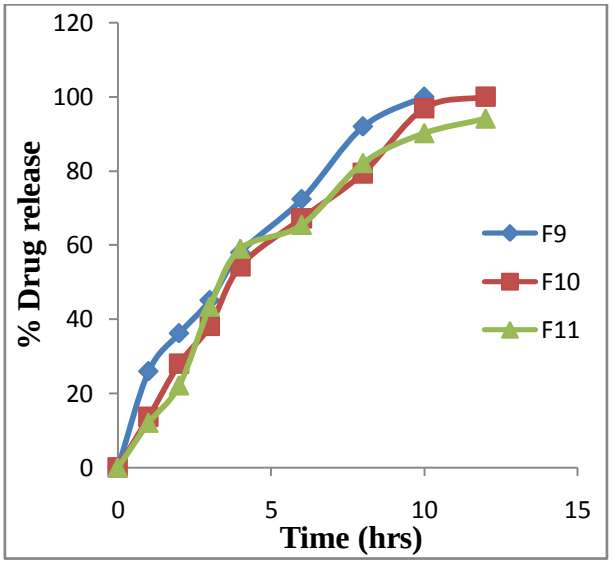

Fig 4: Comparison of dissolution profiles of F9, F10 & F11

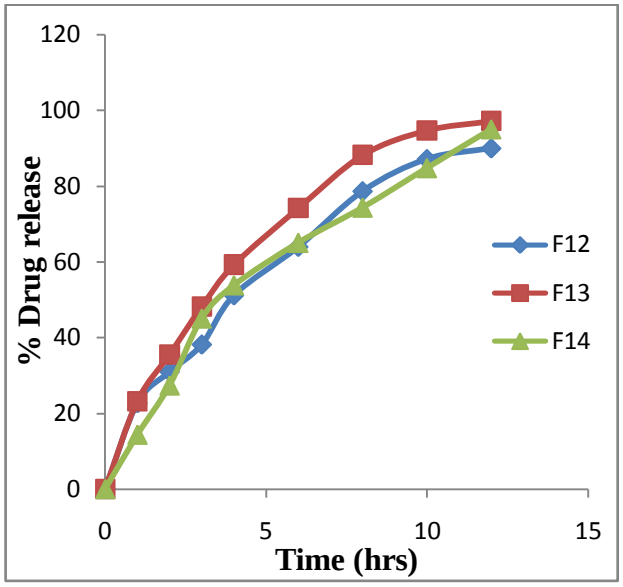

Fig 5: Comparison of dissolution profiles of F12, F13 & F14

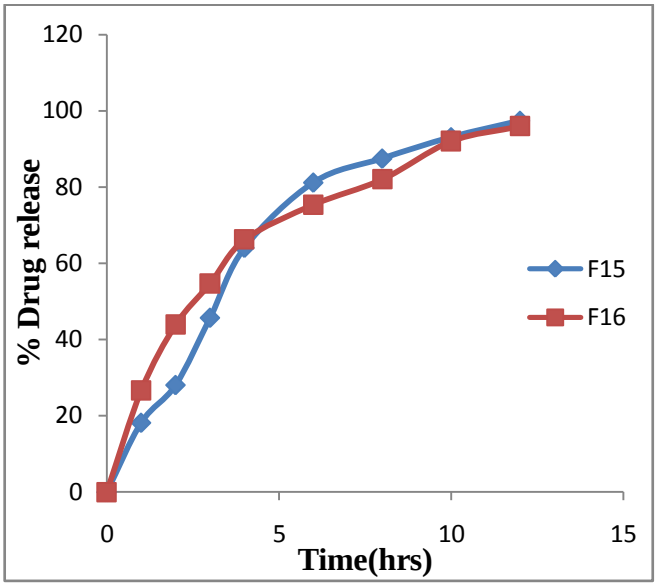

Fig 6: Comparison of dissolution profiles of F15 & F16

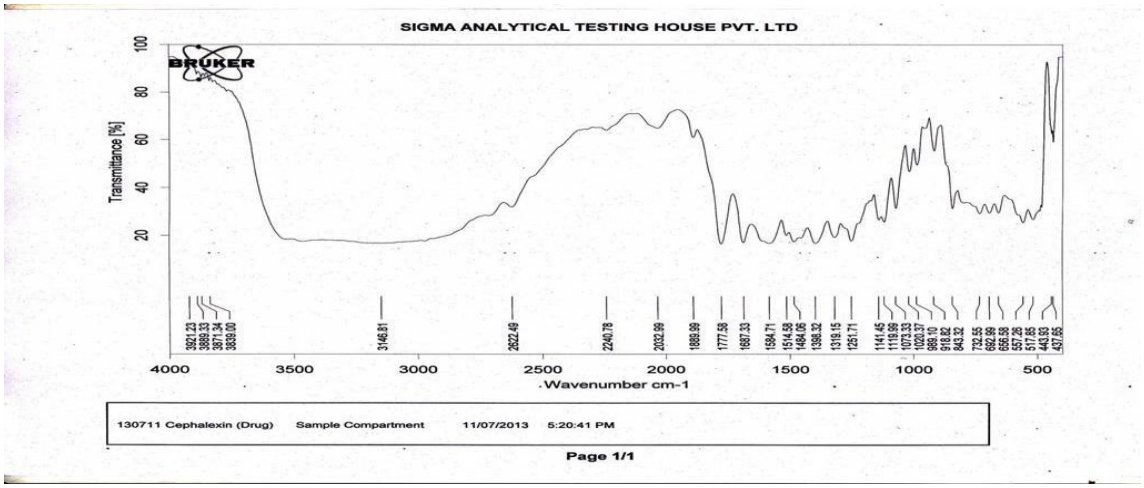

Fig 7: FTIR study of Cephalexin(drug).

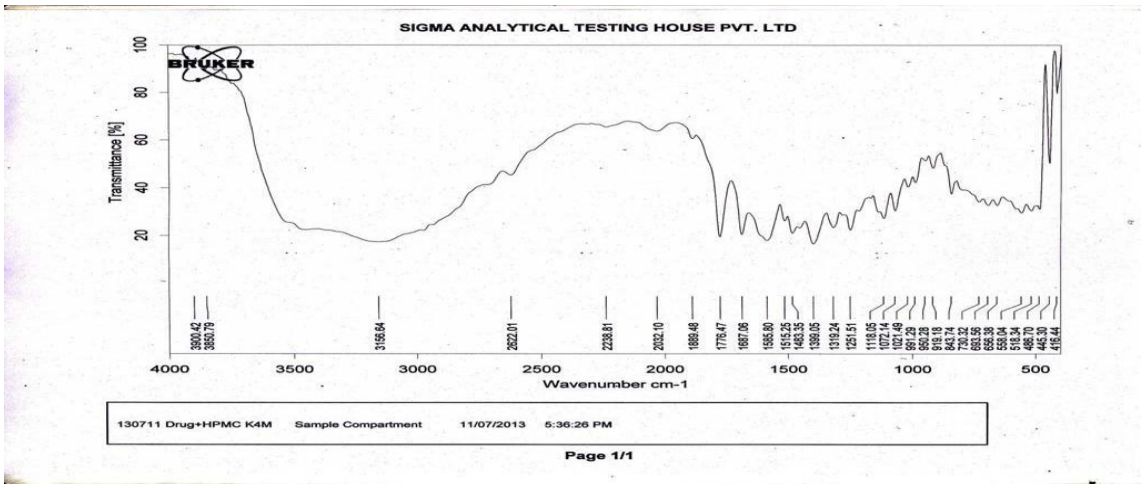

Fig 8: FTIR study of Cephalexin (drug) + HPMCK4M

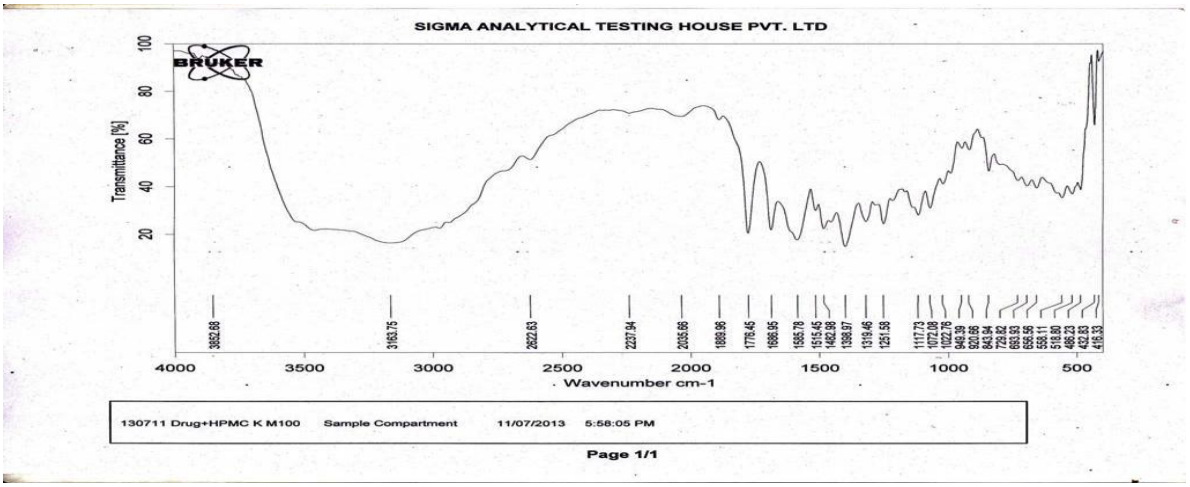

Fig 9: FTIR study of Cephalexin (drug)+ HPMCK100M.

DISCUSSION:

The absorption maximum was found to be 257 nm when scanned between 200 to 400 nm in 0.1 N HCl by the UV-Visible spectrophotometer. FTIR spectra revealed that there was no interaction between the drug and the polymers.

Standard graph of Cephalexin was performed in 0.1 N Hcl and graph showed a good linearity with an r^2 value of 0.999.

The Pre formulation studies were performed and the results were shown in the following table 2. Bulk density was found in the range of 0.62-0.68 g/cm^3 and the tapped density between 0.75-0.82 g/cm^3. Using these two density data compressibility index was calculated. The compressibility index was found between 9.32- 14.48 and the compressibility flowability correlation data indicated a fairly good flowability of the blend. Angle of repose was found to be in the range of 26.87- 29.13 indicating excellent flowability, hausner's ratio in range of 1.10- 1.16 indicating good flowability. The results were shown in table no.02

The tablets of different formulations were subjected to various evaluation tests such as weight variation, hardness, thickness, friability and drug content. In weight variation test, the pharmacopoeial limit of percentage deviation for the tablets of more than 324 mg is ±5 %. The average percentage deviation of all the formulations were found to be within the limits. The hardness ranged from 5.8± 0.28 to 7.83± 0.28 kg/cm^2 . The thickness of tablets ranged from 5.22± 0.17 to 5.44 ± 0.04 mm. The friability was below 1% for all the formulations, which is an indication of good mechanical resistance of the tablets. The drug content was found to be uniform in all formulations and ranged from 95.66 ± 0.08 to 104.8 ± 1.17. The values were shown in table no. 03.

The floating lag time was ranged from 45-90 sec and all the formulations showed good floating buoyancy time for more than 12 hrs. The results were shown in table no. 04.

Swelling index was performed for all the formulations (F1 to F16) up to 8 hours. The results of swelling index were shown in Table no. 05. The swelling index was calculated with respect to time. As time increases, the swelling index was increased because weight gain by tablet was increased proportionally with rate of hydration, later on, it decreased gradually due to dissolution of outermost gelled layer of tablet into dissolution medium.

From the above results it was concluded that swelling index increases as the concentration of polymer increased, it was also observed that the maximum swelling attained in 8 hr, afterwards polymer slowly started erosion in the medium.

In the present study, F11 formulation has shown maximum swelling index of 110.5%.

FTIR studies revealed that there was no interaction.

In Vitro dissolution studies of all the formulations were carried out in 0.1N HCl for 12hrs. All the floating formulations containing HPMC K4M (F1-F3) showed the drug release in controlled manner without changing their physical integrity in dissolution medium Formulations F1- F3 retarded the drug release as a function of polymer concentration. HPMC K4M, a hydrophilic polymer upon contact with aqueous fluid is able to form quite viscous gel, and hence retard the drug release from hydrophilic matrix. The percentage of drug release from the formulation F1 at the end of 8hrs is 100%. The percentage of drug release from the formulation F2 at the end of 10hrs is 99.95%. The percentage of drug release from the formulation F3 at the end of 12hrs is 99.92%. As the concentration of polymer is increased the release rate of drug was decreased . Theoretically speaking this behaviour is expected since more amount of polymer always delays the release. Formulations F4 to F6 retarded the drug release as a function of polymers concentration. The percentage of drug released from the formulations F4, F5 & F6 at the end of 12 hrs is 94.16, 100, 100 respectively. Formulations F7 & F8 also retarded the drug release as a function of polymers concentration. The percentage of drug released from the formulation F7& F8 at the end of 12 hrs is 100% & 96.12% respectively**.** All the floating formulations containing HPMC K100M (F9-F11) showed the drug release in controlled manner without changing their physical integrity in dissolution medium.

HPMC K100M, a hydrophilic polymer upon contact with aqueous fluid is able to form quite viscous gel, and hence retard the drug release from hydrophilic matrix. The maximum percentage of drug release from the formulation F9, F10 & F11 were 100% (10 hr), 100% (12 hr), and 94.16(12 hr) respectively. As the concentration of polymer is increased the release rate of drug was decreased. Theoretically speaking this behaviour is expected since more amount of polymer always delays the release. Formulations F12 to F14 retarded the drug release as a function of polymers concentration. The maximum percentage of drug released from the formulations F12, F13 & F14 at the end of 12 hrs is 90, 97.16 & 95.04 respectively. Formulations F15 & F16 also retarded the drug release as a function of polymers concentration. The percentage of drug released from the formulation F15& F16at the end of 12 hrs is 97.38% & 96 % respectively**.** .

The data obtained from *in vitro* dissolution studies were fitted to Zero order, first order, Higuchi and Korsemeyer peppas equation and the results are shown in Table no.06. The first order plots of all the formulations (F1-F16) were found to be fairly linear as indicated by their high regression values when compared with zero order plots, so all these formulations followed first order kinetics.

All the formulations (F1- F16) showed good correlation in Higuchi Kinetics, clearly indicating that the drug release mechanism was predominantly diffusion controlled. To confirm the exact mechanism of drug release from these tablets, the data were fitted to Korsemeyer equation. The slope values suggested that the release of cephalexin from formulations (F1- F16)followed non fickian diffusion (n>0.50).

CONCLUSION:

In conclusion, different swelling polymers such as HPMC K100M, HPMC K4M individually and in combination with, other polymers such as Xanthan gum, Guar gum, karaya gum, Sodium CMC and Ethyl cellulose can be successfully employed in the preparation of sustained release floating tablets of cephalexin. When compared to HPMC K4 M HPMC K100M showed more sustained action when used individually or in combination.The research study provided useful information for the scientists on formulation, characterization during development of controlled drug delivery systems of cephalexin using these polymers. The prepared formulations can be successfully commercialized after establishing the safety and efficacy in human volunteers.

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