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Formulation and *in vitro* evaluation of ofloxacin as floating drug delivery system

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ABSTRACT

The present study outlines a systematic approach for designing and development of Ofloxacin floating tablets to enhance the bioavailability and therapeutic efficacy of the drug. Floating tablets of Ofloxacin have shown controlled release thereby proper duration of action at a particular site and are designed to prolong the gastric residence time after oral administration. Floating tablets of Ofloxacin were prepared employing different polymers like HPMC K100M, Karaya, Carbopol 934p and combination of HPMC K100M and Karaya gum along with sodium bicarbonate and citric acid as gas generating agent. The Floating tablets were evaluated for uniformity of weight, hardness, friability, drug content, in-vitro buoyancy, swelling index study, dissolution studies and stability studies. The effects of different concentrations of HPMC, Carbopol 934p and Karaya gum on drug release profile and floating properties were investigated. Comparable release profiles between the commercial product and the designed system were obtained. The model fitting showed that the optimized formulations (OH5, OHK3, OHKC1) followed Higuchi and Peppas model, which had a higher value of correlation coefficient (r). While tablet hardness had little or no effect on the release kinetics and was found to be a determining factor with regards to the buoyancy of the tablets.

Key words: Ofloxacin, gatroretentive, intragastric floating tablets, buoyancy studies, swelling studies.

INTRODUCTION

Oral route of administration is the most important and convenient route for drug delivery. The benefits of longterm delivery technology have not been fully realized for dosage forms designed for oral administration. This is mainly due to the fact that the extent of drug absorption from gastrointestinal tract is determined by gastrointestinal physiology; irrespective of the control release properties of the device prolonged gastric retention improves bioavailability [1].Gastric retentive dosage forms are designed to be retained in the stomach and prolong the gastric residence time of the drugs. Prolonged gastric retention improves bioavailability, reduces drug waste and improves solubility for drugs that are less soluble in a high pH environment [2]. Based on the mechanism of flotation, delivery systems can be classified in two types. Effervescent floating drug delivery system and non-effervescent floating drug delivery system it release the drug from floating drug delivery system. These systems when reached to stomach, carbondioxide is liberated by the acidity of gastric contents and is entrapped in the jellified Hydrocolloid. This is prepared by swellable polymers such as HPMC, sodium alginate, carbopol 940 and PVP K30 and various effervescent components like sodium bicarbonate and citric acid mixtures may be used [3].

Ofloxacin is a fluoroquinolone antibacterial agent which is highly effective against gram positive and gram negative bacteria [4]. Ofloxacin exhibits pH dependent solubility. The solubility of ofloxacin in water is 60 mg/ml at pH value ranging from 2 to 5, falls to 4 mg/ml at pH 7 (near isoelectric pH) [5]. Thus it is more soluble in acidic pH and slightly soluble at neutral or alkaline condition (intestinal environment). Hence, in the present study various natural polymers like guar gum, locust bean gum would be used either alone or in combination with synthetic polymer like HPMC K100M along with gas generating agent like sodium bicarbonate for the formulation of floating tablets of ofloxacin which would increase the bioavailability of ofloxacin and also to reduce frequency of administration, thereby improving patient compliance and therapeutic efficacy.

MATERIALS AND METHODS

2.1: Materials:

Ofloxacin was received as gift sample from Dr.reddy's laboratories Ltd, Hyderabad. HPMC K100M was obtained from Colorcon Asia Pvt. Ltd., Mumbai. Carbopol 934P and Gum karaya were Commercially procured from Yarrow chem. Products, Mumbai.All other chemicals were of analytical grade.

2.2: Preformulation studies

As per standard procedures, the preformulation studies including Compatibility study, Bulk density, Tapped density, Hausner's ratio and Angle of repose was performed for the crude drug, Ofloxacin.

2.3: Preparation of Floating tablets:

Floating tablets containing Ofloxacin were prepared by direct compression technique using varying concentrations of different grades of polymers with sodium bicarbonate and citric acid as gas generating agents.

All the powders were accurately weighed and passed through an 60 mesh sieve. Then, except Magnesium stearate and Talc all other ingredients were blended uniformly in double cone blender for 15 minutes. After sufficient mixing of drug as well as other components, Magnesium stearate and 1% Talc was added, as post lubricant, and further mixed for additional 2- 3 minutes. The blend was compressed into tablets having average weight of 550mg using clit-10 station mini press fitted with an 6mm round flat punches. The compositions of all formulations are given in table 1.

3. DETERMINATION OF PHYSICOCHEMICAL PARAMETERS

3.1: Hardness test

Monsanto hardness tester was used for the determination of hardness of tablets [6].

3.2: Friability

Twenty tablets were accurately weighed and placed in the friabilator (Roche's Friabilator) and operated for 100 revolutions. The tablets were dedusted and reweighed. The tablets that loose less than 1% weight were considered to be compliant.

3.3: Weight variation

20 tablets were selected randomly from the lot and weighed individually to check for weight variation [7].

3.4: Drug content:

Five tablets were powdered in a mortar. An accurately weighed quantity of powdered tablets(100 mg) was extracted with 0.1N HCl (pH 1.2 buffer) and the solution was filtered through 0.45µ membranes. Each extract was suitably diluted and analyzed spectrophotometrically at 294 nm.

3.5: In-vitro dissolution study

In-vitro release studies was carried out by using United States Pharmacopoeia (USP) 23 Dissolution Testing Apparatus II (Paddle method). The dissolution test was performed using 900 ml of 0.1N HCl (pH 1.2) at 37±0.5oC. 50 rpm was maintained, 5 ml of sample was withdrawn at predetermined time intervals for 24 hours and the same volume of the fresh medium was replaced. The absorbance of the withdrawn sample was measured spectrophotometrically at a wavelength of about 294 nm and cumulative percentage drug release was calculated using an equation obtained from a standard curve [8].

4. DETERMINATION OF FLOATING PARAMETER

4.1: *In-vitro* buoyancy test

The *in-vitro* buoyancy was determined by observing floating lag time, as per the method described by Rosa. The tablets were placed in a 100 ml beaker containing 0.1N HCl. The time required for the tablet to rise to the surface and float was considered as the floating lag time [9].

4.2: Swelling study

Swelling study of individual batch was carried out using USP dissolution apparatus-II (rotating paddle), in 900 ml of 0.1N HCl which is maintained at 37±0.5°C, rotated at 50 rpm. Weight of individual tablet was taken prior to the swelling study (W1). The tablet was kept in a basket. The tablet was removed every one hour interval up to 12 hour and excess water removed carefully using filter paper. The swollen tablets were re-weighed (W2); Percent hydration (swelling index) was calculated as shown in table 4 using following formula,

% Swelling Index = {(W2) – (W1)/ (W1)} x 100

Where
W1- initial weight of tablet,
W2- weight of the swollen tablet.

5. DRUG RELEASE KINETICS (Curve fitting analysis)

To analyze the mechanism of the drug release rate kinetics of the dosage form, the data obtained were fitted into zero order, first order Higuchi model and Korsmeyer's equation release models [10,11].

6. STABILITY STUDIES

To assess the drug and formulation stability, stability studies were done according to ICH guidelines [12]. The optimized formulation was subjected to stability study at 40 ± 2ºC and 75 ± 5% RH for 90 days. The samples were evaluated for physical changes, hardness, friability, drug content, buoyancy study and percentage drug release during the stability studies.

RESULTS AND DISCUSSION

Pre-compression parameters

Results of the pre-compression parameters performed on the blend for batch OH1 to OHKC2 are tabulated in Table 2.

The values for the angle of repose were found to be in the range of 25º.42´ to 27º.32´. This indicates good flow property of the powder blend. Compressibility index ranges between 11.20% and 14.87% indicating that the powder blend has the required flow property for wet granulation. Microscopic examinations of tablets from each formulation batches have showed cylindrical shape (oval) with no cracks. Hausner ratio was found to be in the range of 1.118 to 1.129.

Post-compression parameters

The formulated tablets were subjected for post- compressional evaluation such as thickness, hardness, weight variation, friability, drug content, *in vitro* buoyancy studies, swelling studies, *in vitro* dissolution studies, and stability studies.

Tablet thickness (n=3) were almost uniform in all the formulations and values for tablets ranged from 3.1±0.114 to 4.15±0.048mm. The hardness of all formulations was in the range of 5.5±0.3 to 5.8±0.2 kg/cm2, indicating satisfactory mechanical strength. The weight variation values of tablets ranged from 698±2.0 to 702±3.0 mg. All the tablets passed weight variation test as the % weight variation was within the Pharmacopoeias limits of ±7.5% of the weight. The friability values ranged from 0.12 to 0.20 %. All the values are below 1% indicating that the tablets of all formulations are having good compactness and showing enough resistance to the mechanical shock and abrasion. The percent drug content of tablets was found to be in between 248.2±0.5 to 251.9±0.2 % of ofloxacin, which was within the acceptable limits. Table 3 shows the results of physicochemical characters of ofloxacin tablets.

In vitro Buoyancy Studies

In vitro buoyancy of the tablets from each formulation (OH1 to OHCK2) was evaluated and the results are mentioned in Table 4. Where, the highest and lowest floating lag time (FLT) was observed with the formulation OHK1 and OC1 respectively.

Swelling index

The swelling index of the tablets from each formulation (OH1 to OHKC2) was evaluated and the results are mentioned in Table 5 and plot of % swelling index vs. time (hrs) is depicted in Figure 1 and 2. Where, the highest and lowest swelling was observed with the formulation OCH3 and OHK5 after 5 hrs respectively. The swelling index increases by increasing the contact time with pH 1.2 buffers as the polymer gradually absorbs buffer due to hydrophilic nature the polymer with resultant swelling.

In-vitro Dissolution Studies

In-vitro dissolution studies of all the formulations of ofloxacin were carried out in 0.1 N HCl. The study was performed for 24 hrs, and cumulative drug release was calculated at different time intervals. The *in-vitro* drug release profiles for the formulations (OH1-OHCK2) were tabulated in the table 6.

The plot of cumulative percentage drug release V/s time (hr) for formulations (OH1-OHCK2) were plotted and depicted in Figure 3,4,5,6 respectively. Effects of various ingredients and their concentration on drug release were studied. It was observed that the type of polymer influences the drug release pattern. As the amount of polymer in the tablet formulation increases, the drug release rate decreases and as the concentration of gas generating agent (NaHCO3) increases the drug release decreases in case of matrix tablets containing HPMC K100M as polymer and increases in tablets containing Carbopol 934P as polymer and at the same time floating lag time decreases.

Drug release kinetics

All the designed formulations of Ofloxacin displayed first order release kinetics. Log % undissolved vs Time plots for all the matrix tablet formulations were found to be linear with R^2 values in the range of 0.90 - 0.99.Amount of drug released vs square root of time plots for all the matrix tablet formulations were found to be linear with R^2 values in the range of 0.98 - 0.99.The release exponent (n) values for all the floating matrix tablet formulations were in the range of 0.5 – 0.8 which indicated the non-fickian mechanism of drug release from the dosage form. The log cumulative % drug released *s* log time plots were found to be linear with R^2 values in the range of 0.96 - 0.99.The formulations O1 containing HPMC K100M alone at a ratio of 1:1 with Ofloxacin, showed the controlled release of drug from the floating matrix tablet formulation upto 24 hours, following first order kinetics. The formulation OH5 containing HPMC K100M along with gas generating agent, showed minimal floating lag time and remained afloat throughout dissolution period, while extending the drug release upto 24 hours, following first order kinetics.The formulation OHK3 containing both HPMC K100M and GumKaraya along with gas generating agent, showed minimal floating lag time and remained afloat throughout dissolution period, while extending the drug release upto 24 hours, following first order kinetics.The formulation OHKC1 can be considered as a promising controlled release floating matrix tablet of Ofloxacin providing first order drug release over a period of 24hours, with minimum floating lag time of 15sec. The results were shown in table 7.

Stability studies

The formulations which showed good *in vitro* performance were subjected to accelerated stability studies. These studies were carried out by investigating the effect of temperature on the physical properties of tablets and chemical stability of matrix tablets containing drugs.The matrix tablet formulations OH5, OHK3, and OHKC1 were subjected to accelerated stability studies. The above said formulations were kept in petridishes after preparation and stored in thermostated oven at a temperature and relative humidity of 25 ± 2^0C, 60 ± 5% RH for 6 months and 40 ± 2^0C, 75 ± 5% RH for 6 months. The tablets were evaluated for physical parameters and drugs were analyzed for drug content uniformity by a known spectrophotometric method as described earlier. Further these were subjected to drug release studies as stated earlier. The results were shown in table 8.

Table 1: Composition of Various Ofloxacin Controlled Release Floating Matrix Formulations

Formulations	**OHKC2**	250	187.5	-	62.5	116.6	58.3	11	7	7	700
	OHKCI	250	187.5	-	62.5	93.3	46.6	46	7	7	700
	OHK5	250	187.5	-	62.5	175	-	11	7	7	700
	OHK4	250	187.5	-	62.5	140	-	46	7	7	700
	OHK3	250	187.5	-	62.5	105	-	81	7	7	700
	OHK2	250	187.5	-	62.5	70	-	116	7	7	700
	OHK1	250	187.5	-	62.5	35	-	151	7	7	700
	OC5	250	-	250	-	175	-	11	7	7	700
	OC4	250	-	250	-	140	-	46	7	7	700
	OC3	250	-	250	-	105	-	81	7	7	700
	OC2	250	-	250	-	70	-	116	7	7	700
	OC1	250	-	250	-	35	-	151	7	7	700
	OH5	250	250	-	-	175	-	11	7	7	700
	OH4	250	250	-	-	140	-	46	7	7	700
	OH3	250	250	-	-	105	-	81	7	7	700
	OH2	250	250	-	-	70	-	116	7	7	700
	OH1	250	250	-	-	35	-	151	7	7	700
Ingredients (mg/tab)		**Ofloxacin**	**HPMC K100M**	**Carbopol 934P**	**Gum Karaya**	**Sodium bicarbonate**	**Citric acid**	**MCC**	**Magnesium stearate**	**Talc**	**Total tablet weight (mg)**

Table 2: Pre-compression evaluation parameters

Formulation Batches	Angle of repose (θ)	Compressibility Index (%)	Hausner's ratio
OH1	25.76±0.05	12.37±0.024	1.129
OH2	26.40±0.07	14.24±0.019	1.120
OH3	27.32±0.09	11.20±0.027	1.127
OH4	26.54±0.13	12.75±0.017	1.129
OH5	25.69±0.03	11.78±0.014	1.128
OC1	25.42±0.05	14.87±0.017	1.129
OC2	26.85±0.02	13.68±0.014	1.120
OC3	27.01±0.03	12.37±0.024	1.127
OC4	25.76±0.05	14.24±0.019	1.129
OC5	26.94±0.02	14.20±0.022	1.120
OHK1	25.69±0.03	11.89±0.009	1.118
OHK2	25.42±0.05	14.87±0.017	1.121
OHK3	26.94±0.02	13.68±0.014	1.123
OHK4	25.69±0.03	12.37±0.024	1.118
OHK5	25.42±0.05	11.20±0.027	1.121
OHKC1	26.85±0.02	12.75±0.017	1.123
OHKC2	27.01±0.03	11.78±0.014	1.128

Table 3:Post-compression parameters

Formulation Batches	Hardness Kg/cm2 (n=3) Mean±SD	Weight Variation (mg) (n=20) Mean±SD	Friability (%) (n=10)	Drug Content (%) (n=3) Mean±SD
OH1	5.8±0.2	698±2.0	0.17	250.6±0.5
OH2	5.5±0.3	699±4.0	0.15	249.8±0.3
OH3	5.6±0.2	701±2.0	0.18	248.2±0.5
OH4	5.7±0.3	699±3.0	0.16	250.0±0.2
OH5	5.5±0.4	702±3.0	0.12	250.4±0.5
OC1	5.8±0.1	701±2.0	0.18	251.9±0.2
OC2	5.6±0.2	698±4.0	0.17	248.5±0.5
OC3	5.5±0.4	702±3.0	0.15	251.3±0.5
OC4	5.7±0.3	700±3.0	0.19	250.4±0.5
OC5	5.5±0.3	698±2.0	0.18	248.5±0.5
OHK1	5.8±0.2	699±4.0	0.14	251.3±0.5
OHK2	5.7±0.3	701±2.0	0.20	250.4±0.5
OHK3	5.5±0.3	702±3.0	0.16	251.9±0.2
OHK4	5.8±0.2	700±3.0	0.18	249.2±0.3
OHK5	5.5±0.4	699±3.0	0.14	251.9±0.2
OHKC1	5.8±0.1	702±3.0	0.20	249.2±0.3
OHKC2	5.6±0.2	698±2.0	0.14	249.8±0.5

Table 4: *In vitro* Buoyancy Studies

Formulation Batches	Floating lag Time (hrs.)	Total Floating Time (hrs.)
OH1	3hrs	>24hrs
OH2	1:25hrs	>24hrs
OH3	36mins	>24hrs
OH4	17mins	>24hrs
OH5	13mins	>24hrs
OC1	---	---
OC2	3hrs	>24hrs
OC3	2:40	>24hrs
OC4	1:30hrs	>24hrs
OC5	30min	>24hrs
OHK1	3:26hrs	>24hrs
OHK2	2:52hrs	>24hrs
OHK3	20min	>24hrs
OHK4	3min	>24hrs
OHK5	2min	>24hrs
OHKC1	12sec	>24hrs
OHKC2	8sec	>24hrs

Table 5: Percent Swelling Index

Formulation Batches	Time (hrs)						
	1	2	4	6	8	10	12
OH1	61.8	88.3	117.7	125.1	129.2	138.9	145.2
OH2	65.6	95.2	124.7	130.9	140.5	146.2	153.5
OH3	69.2	96.9	119.2	138.3	146.5	153.6	159.3
OH4	55.94	80.1	93.7	106.9	123.8	138.9	148.7
OH5	47.5	70.7	97.9	106.8	127.9	136.9	148.7
OHK1	51.9	73.5	105.7	111.3	114.3	121.7	127.6
OHK2	49.6	60.1	83.7	106.2	108.6	114.5	123.9
OHK3	41.3	64.4	94.3	108	116.5	124.1	125.8
OHK4	47.1	65.2	93.2	104.4	120.1	125.6	129.3
OHK5	60.4	67.7	86.5	102.9	118.3	123.5	128.9
OHKC1	50.3	61.3	76.8	109.5	119.6	125.3	138.4
OHKC2	49.8	60.2	75.6	105.5	115.6	123.6	132.5

Table 6:Drug Release Profile of Ofloxacin Controlled Release Floating Matrix Tablets

Cumulative % Drug Released	**OHKC2**	0	30.67	41.89	59.68	75.63	92.98	--	--	--	--	--
	OHKC1	0	21.62	32.45	46.67	58.91	70.68	82.31	94.39	--	--	--
	OHK5	0	3.412	18.34	31.21	39.98	46.23	52.67	58.5	69.99	82.56	94.12
	OHK4	0	9.34	21.34	34.67	43.67	51.34	58.78	67.34	76.56	87.67	98.78
	OHK3	0	15.12	26.78	38.34	47.56	56.45	64.45	71.34	79.67	90.65	--
	OHK2	0	19.81	29.81	43.45	50.34	59.98	67.7	76.56	83.45	94.67	--
	OHK1	0	21.45	32.45	46.34	54.89	66.5	71.12	77.45	86.78	98.78	--
	OC5	0	43.56	67.39	79.69	98.98	--	--	--	--	--	--
	OC4	0	40.62	64.56	81.56	98.36	--	--	--	--	--	--
	OC3	0	32.45	57.68	84.52	96.45	--	--	--	--	--	--
	OC2	0	29.1	51.23	73.27	87.88	98.78	--	--	--	--	--
	OC1	0	23.34	42.56	64.85	79.99	92.25	--	--	--	--	--
	OH5	0	6.47	12.12	26.34	37.23	45.56	53.34	59.98	66.56	75.12	88.45
	OH4	0	7.38	17.34	29.98	39.45	49.34	58.34	64.45	70.56	80.67	93.34
	OH3	0	11.78	19.6	34.56	45.34	54.56	61.98	70.12	77.34	87.34	98.98
	OH2	0	13.9	25.45	40.12	48.34	58.12	67.45	73.67	80.45	90.23	--
	OH1	0	18.23	30.34	46.12	57.34	65.34	72.39	79.12	84.56	96.54	--
Time (hrs)		**0**	**1**	**2**	**4**	**6**	**8**	**10**	**12**	**16**	**20**	**24**

Table 7: Pharmacokinetic Parameters of Controlled Release Floating Matrix tablets of ofaxacin

Formulation	Zero Order Constant		First Order Constant		Higuchi Constants		Peppas Constant	
	K_0	R^2	K_1 (h^{-1})	R^2	K_H ($mg.h^{1/2}$)	R^2	N	R^2
OH1	4.38	0.697	0.062	0.946	54.09	0.986	0.544	0.9855
OH2	4.27	0.786	0.046	0.990	53.90	0.991	0.612	0.985
OH3	3.88	0.843	0.067	0.816	54.50	0.996	0.666	0.990
OH4	3.71	0.876	0.043	0.934	52.68	0.994	0.759	0.976
OH5	3.56	0.900	0.035	0.968	51.04	0.994	0.817	0.817
OC1	11.05	0.888	0.136	0.981	91.67	0.995	0.653	0.987
OC2	11.60	0.831	0.233	0.902	92.12	0.988	0.578	0.980
OC3	15.50	0.846	0.253	0.980	108.52	0.977	0.611	0.973
OC4	10.81	0.87	0.246	0.994	111.23	0.972	0.701	0.991
OC5	10.15	0.847	0.263	0.983	120.36	0.968	0.612	0.982
OHK1	4.40	0.702	0.079	0.955	53.46	0.996	0.500	0.996
OHK2	4.29	0.744	0.056	0.961	52.55	0.996	0.516	0.997
OHK3	4.21	0.799	0.046	0.982	52.63	0.997	0.581	0.992
OHK4	3.89	0.868	0.065	0.922	54.60	0.998	0.697	0.978
OHK5	3.76	0.909	0.045	0.920	53.50	0.998	0.903	0.904
OHKC1	4.40	0.702	0.079	0.955	53.46	0.996	0.500	0.996
OHKC2	4.21	0.799	0.046	0.982	52.63	0.997	0.581	0.992

Table 8: Physical Parameters of Ofloxacine Matrix Tablets Formulations Before and After Storage at Different Conditions

Formulation	Storage Condition	Weight Uniformity (mg)	Hardness (Kg/cm^2)	Friability (%)	Drug Content (mg/tablet)
OH5	Before storage	702±3.0	5.5±0.3	0.12	250.4±0.2
	25±2^{0}C, 60±5% RH	702±3.0	5.5±0.3	0.12	250.3±0.2
	40±2^{0}C, 75±5% RH	702±3.0	5.5±0.3	0.11	249.4±0.2
OHK3	Before storage	700±4.0	5.8±0.3	0.18	249.3±0.4
	25±2^{0}C, 60±5% RH	700±4.0	5.8±0.3	0.18	249.3±0.4
	40±2^{0}C, 75±5% RH	700±4.0	5.8±0.3	0.18	248.3±0.4
OHKC1	Before storage	702±3.0	5.8±0.3	0.16	249.6±0.2
	25±2^{0}C, 60±5% RH	702±3.0	5.8±0.3	0.16	249.6±0.2
	40±2^{0}C, 75±5% RH	702±3.0	5.8±0.3	0.16	249.0±0.2

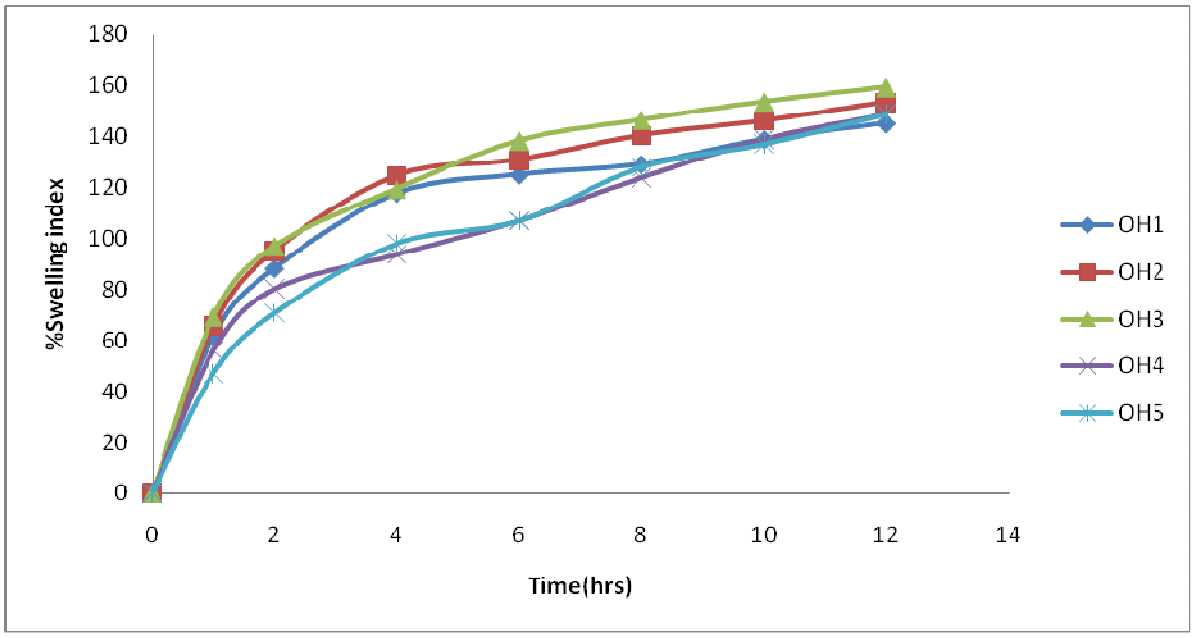

Fig 1: Percent Swelling Index of Controlled Release Floating Matrix Tablets of Ofloxacin

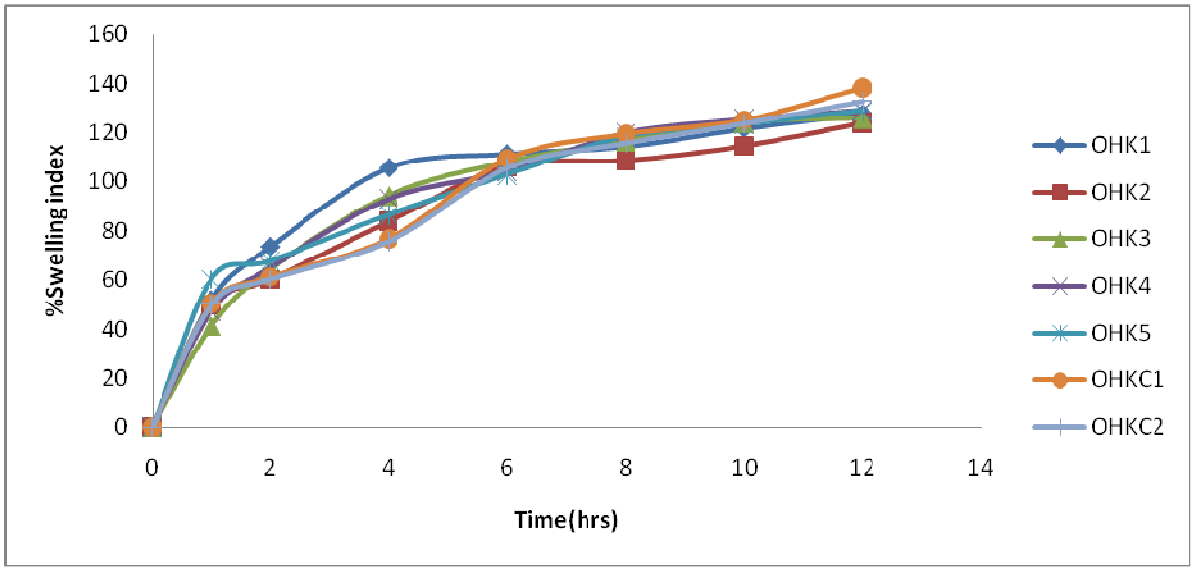

Fig 2: Percent Swelling Index of Controlled Release Floating Matrix Tablets of Ofloxacin

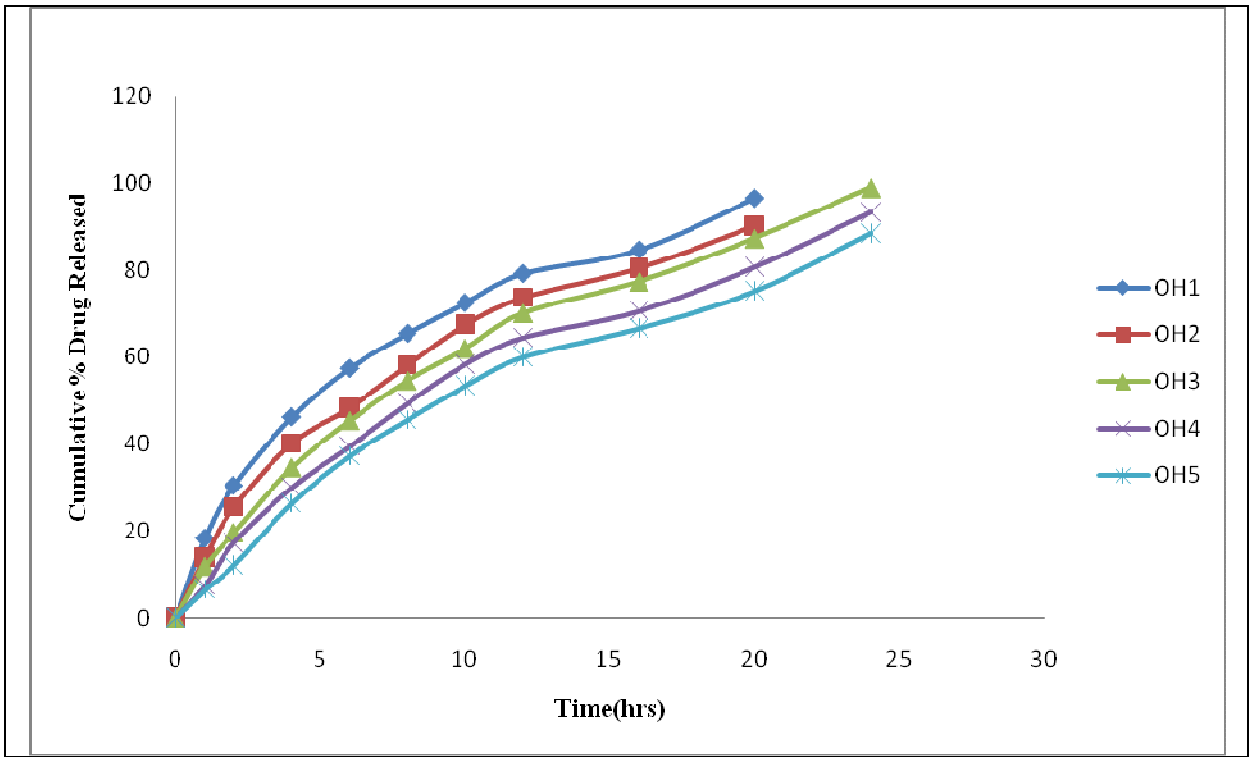

Fig 3 :*In vitro* Drug Released Profile of Formulations OH1 to OH5

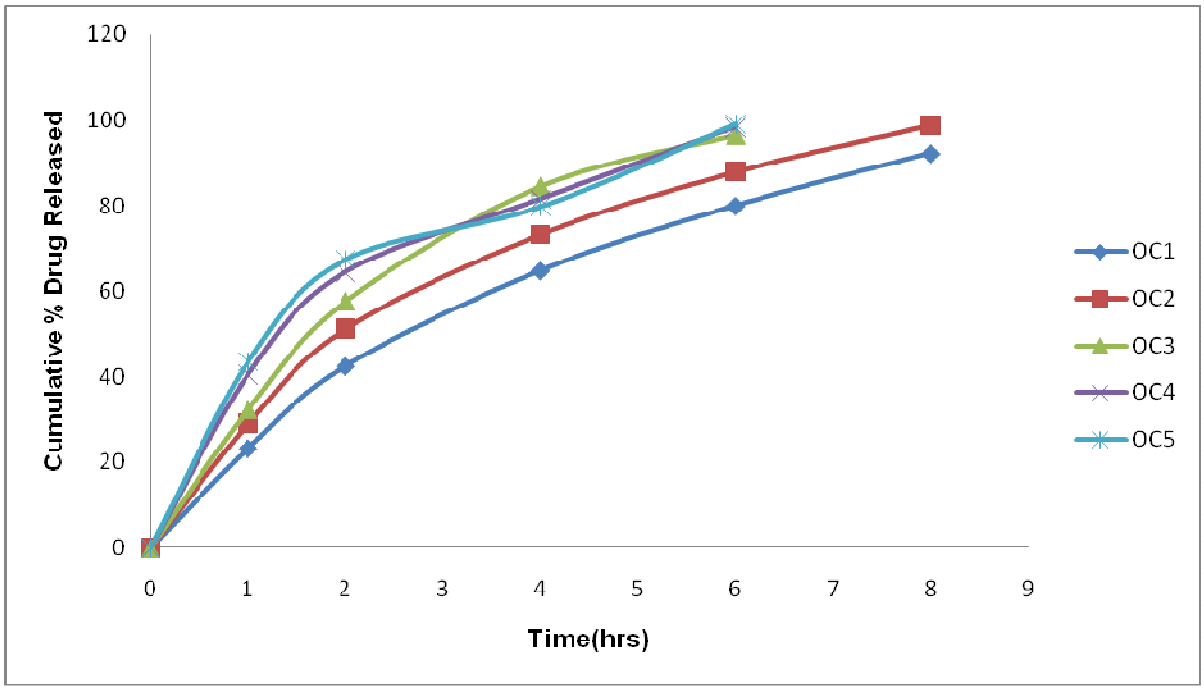

Fig 4:*In vitro* Drug Released Profile of Formulations OC1 to OC5

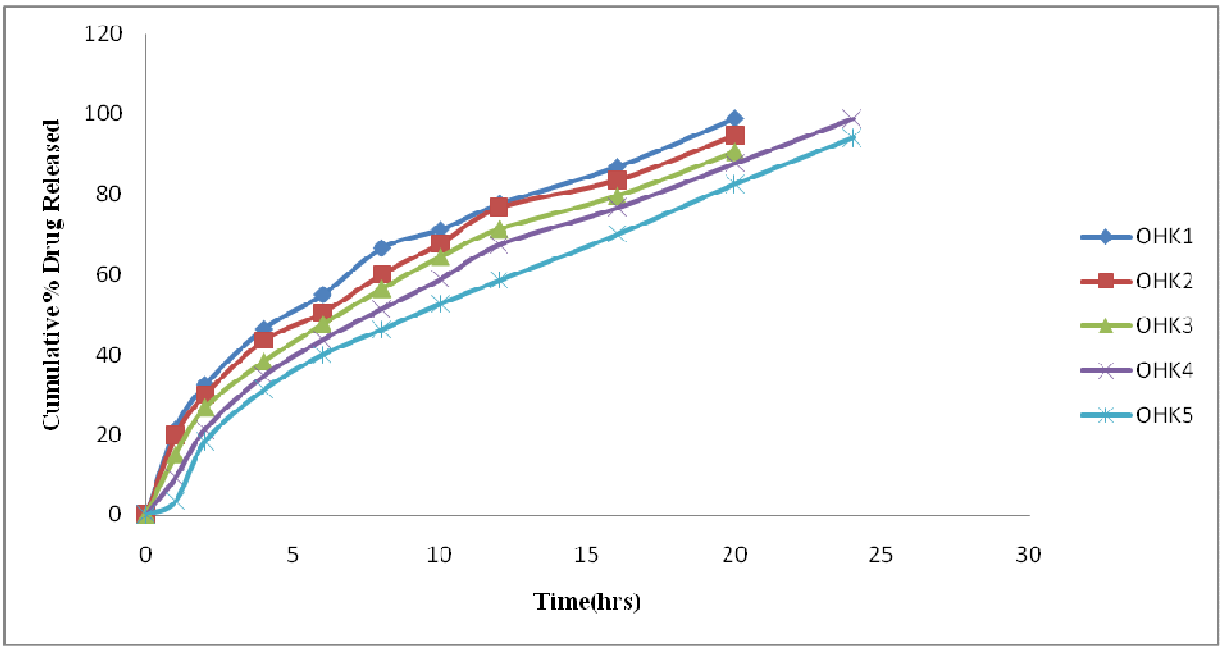

Fig 5:*In vitro* Drug Released Profile of Formulations OHK1 to OHK5

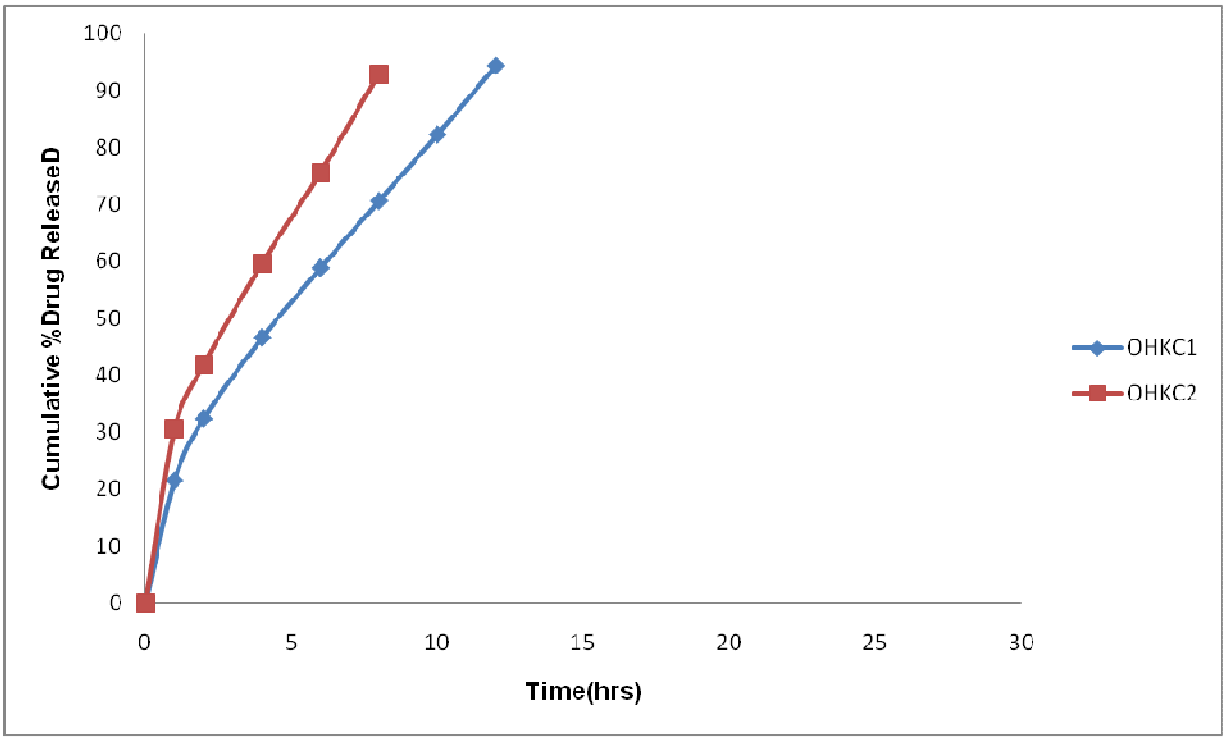

Fig 6:*In vitro* Drug Released Profile of Formulations OHKC1 to OHKC2

CONCLUSION

Gastroretentive floating drug delivery Systems offers a simple and practical approach to achieve increased gastric residence and to modify drug release profiles essential for controlled, site specific and localized drug action. Lower values of angle of repose below 30 indicates good flow properties of blends. All the prepared tablets were found to be of circular shape with no cracks. Friability and hardness were within the standard limits thus showing good mechanical strength of tablets. The drug content was well within the Pharmacopoeial limits indicating uniform distribution of drug within the controlled release gastroretentive dosage form. The formulation OHKC1 can be considered as a promising controlled release floating matrix tablet of Ofloxacin providing first order drug release over a period of 24hours, with minimum floating lag time of 15sec. The release exponent (n) values for all the floating matrix tablet formulations were in the range of 0.5 – 0.8 which indicated the non-fickian mechanism of drug release from the dosage form. The log cumulative % drug released *vs* log time plots were found to be linear with R^2 values in the range of 0.96 - 0.99. Short-term stability studies of optimized formulations OH5, OHK3 and OHKC1 indicate, that there are no significant changes in drug content and dissolution parameter values after 3 months storage at 40±2ºC.

REFERENCES

[1] Kumar M; Selvi R; Perumal P; Chandra Sekhar Y; Zakir. *International Journal of Innovative Pharmaceutical Research*, **2011**, 2(3),151-155.
[2] Sivabalan M; Vani T; Phaneendhar Reddy; Vasudevaiah; Anup Jose; Nigila G. *International Journal of Comprehensive Pharmacy*, **2011**; 2(1):1-4.
[3] Senthil A; Suresh Kumar P; Raju CH; Mohideen S. *International Journal of Biological and Pharmaceutical Researc*, **2010**, 1(2),108-113.
[4] Tang X; Cui Y; Zhang Y. *Int J Pharm*, **2008**, 360(1),47- 52.
[5] Block JH; Beale JM, editors. Wilson and Gisvold's textbook of organic medicinal and pharmaceutical chemistry. 11th ed. Philadelphia: Lippincott Williams and Wilkins; **2004**. p. 248.
[6] Sreenivas SA; Gadad AP. *Indian drugs*, **2006**, 43(1),35-38.

[7] Lachman L; Liberman HA; Kanig JL. The theory and practice of industrial pharmacy. 3rd ed. Varghese publication house; **1991**, 300.
[8] Gohel MC; Mehta PR; Dave PK; Bariya NH. *Dissolution tech,* **2005,** 11: 22-5.
[9] Rosa M; Zia H; Rhodes T. *Int J Pharm.,* **1994**, 105: 65-7.
[10] Higuchi T. *J Pharm Sci,* **1963**, 52: 1145-1149.
[11] Korsmeyer RW; Gunny R; Peppas NA. *Int J Pharm,* **1983**,15: 25-35.
[12] Cartensen J T. Drug Stability: Principle and Practices, Marcel Dakker, New Work, 2nd Ed, **1995**, p. 538-50.