IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

FORMULATION AND EVALUTATION OF FLOATING DRUG LANSOPRAZOLE

Ms Payal Khandait[1]*, Dr Rajesh Mujariya[2], Dr Manjeet Singh[3]

*[1]Institute of Pharmaceutical Science & Research,
[2]Professor & Director, Institute of Pharmaceutical Science & Research,
[3]Associate Professor, Institute of Pharmaceutical Science & Research

Abstract:

Controlled release (CR) dosage forms have been extensively used to improve therapy with several important drugs. Incorporation of the drug in a controlled release gastroretentive dosage forms (CR-GRDF) which can remain in the gastric region for several hours would significantly prolong the gastric residence time of drugs and improve bioavailability, reduce drug waste, and enhance the solubility of drugs that are less soluble in high pH environment. Lansoprazole Floating Drug Delivery systems can be prepared by wet granulation method using HPMCK4M: Eudragit-RL100 polymer ratio and PVPK-30 as a binder, Sodium-bi-Carbonate: Citric acid as gas generating agent. The *In-vitro* dissolution profiles of all the prepared Lansoprazole floating drug delivery system formulations were found to extend the drug release over a period of 8 hours and the drug release rate decreased with increase in polymer concentration, it is concluded that formulation F5 (HPMCK4M: Eudragit-RL100) is the best formulation among all other formulations because it is showing very controlled release of drug from tablet formulation 99.26% of drug release in 8 hours, and floating lag time of 11seconds with a total floating time of 12 hours. concluded that the drug release from F5 (HPMCK4M: Eudragit-RL100) shows that, as HPMCK4M used in combination with Eudragit-RL100, the drug release of formulation is increases as compare to F1-F4 (HPMCK4M) & F6-F8(Eudragit-RL100: HPMCK4M). All the developed floating tablets floated up to 12 hour.

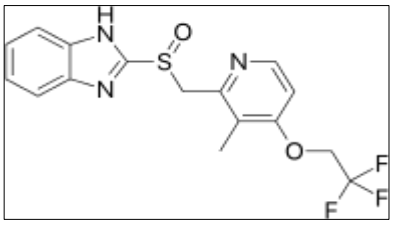
Keywords: Floating drug, Lansoprazole, Eudragit polymer, HPMCK4M,

INTRODUCTION

Oral delivery of drugs is by far the most preferable route of drug delivery due to the ease of administration, patient compliance and flexibility in formulation, etc. from immediate release to site-specific delivery, oral dosage forms have really progressed. However, it is a well accepted fact that it is difficult to predict the real in vivo time of release with solid, oral controlled release dosage form. Thus, drug absorption in the GI tract may be very short and highly variable in certain circumstances. It is evident from the recent scientific and patent literature that an increased interest in novel dosage form that are retained in the stomach for a prolonged and predictable period of time exist today in academic and industrial research group. 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. GRDFs extend significantly the period of time over which the drugs may be released. Thus, they not only prolonged dosing intervals, but also increase patient's compliance beyond the level of existing controlled release dosage forms.[1] This application is especially affective in delivery of sparingly soluble and insoluble drugs. It is known that, as the solubility of a drug decreases, the available for drug dissolution becomes less adequate and thus the transit time becomes a significant factor affecting drug absorption.[2] To address this, oral administration of sparingly soluble drugs is carried out frequently, often several times per day. 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. Many drugs categorized as once a day delivery have beendemonstrated to have sub optimal absorption due to dependence on the transit time of the dosage form, making traditional extended release development challenging. Therefore, a system designed for longer gastric retention ill extend the time within which drug absorption can occur in the small intestine. Certain types of drugs can benefit from using gastric retentive devices. These includes (a) drugs locally acting in the stomach

(b) drugs having a narrow absorption window in the stomach (c) that are unstable in the intestinal or colonic environments, (d) have low solubilityat high pH values[3].

DRUG PROFILE



LANSOPRAZOLE

Figure no . 1. (*RS*)-2-([3-methyl-4-(2,2,2-trifluoroethoxy)pyridin-2-yl]methylsulfinyl)-1*H*-benzo[*d*]imidazole

EXCIPIENTS PROFILE:

Most of the excipients selected are widely used in oral pharmaceutical formulations and are GRAS listed, sourced from reputed international manufacturers. All the excipients are from BSE-TSE free sources. A confirmation stating that excipients do not contain and are not derived from specified risk materials as defined in current commission directives was taken.[4]

Table no. 1 list of excipients

Excipients	**Function**
EUDRAGIT-RL100	Coating Polymer
HPMC	Binder
Citric Acid	Gas Generating Agent
Sodium Bicarbonate	Super Disintegrant
Magnesium Stearate	Lubricant
Talcum powder	Glidant

EXPERIMENTAL WORK:

MATERIALS USED

The Materials employed in the formulations and evaluations and thecorresponding suppliers were listed in the following Table No.2.

Table No.2: List of Materials Used

Sr. No	MATERIAl USED	SUPPLIER	ROLE OF MATERIALS
1.	Lansoprazole	Samar Chemicals, Nagpur	Antihypertensive agent
2.	Eudragit-RL100	Mahalakshmi chemicals, Hyderabad.	Matrix forming agent
3.	HPMC K4M	Mahalakshmi chemicals, Hyderabad.	Swelling agent
4.	PVP K-30	Mahalakshmi chemicals,	Binder
5.	Sodium-Bi-Carbonate	Samar Chemicals, Nagpur.	Gas generating agent
6.	Citric acid	Samar Chemicals, Nagpur.	Gas generating agent
7.	Lactose	Samar Chemicals, Nagpur.	Diluents
8.	Magnesium stearate	Samar Chemicals, Nagpur.	Lubricants
9.	Talc	Samar Chemicals, Nagpur.	Gliedent

EQUIPMENTS USED

Table No.3: List of Equipment Used

Sr. No.	Equipments/ Instruments	Manufacturer/Company Name
1.	Electronic Weighing Balance	Electronic balance, Shimandzu, Japan
2.	Sieves	Hicon sieves
3.	Hot air oven	Hicon
4.	Vernier calliper	Mutitoyo, Japan
5.	Hardness tester	Monsanto hardness tester
6.	Friability apparatus	Model-EF-2W,Electrolab
7.	Tablet compression machine	Fluid pack
8.	Dissolution Apparatus	Electrolab, DT (UST)

9.	U.V. Spectrophotometer	Shimadzu,U.V.1601.Spectrophotometer

EXPERIMENTAL DETAILS

PROCUREMENT OF PURE DRUG (LANSOPRAZOLE)[5]

The drug Lansoprazole was a gift sample from Samar Chemical, Nagpur.

CHARACTERIZATION OF PURE DRUG (LANSOPRAZOLE)

Pure Drug has been characterize by various parameters like Solubility, Identification by FT-IR, Melting range, Sulphated ash, Loss on drying, Heavy Metals and Assay.[6]

IDENTIFICATION OF PURE DRUG (LANSOPRAZOLE)

Pure drug has been identified by using technique of IR.

INFRA-RED SPECTROPHOTOMETRY

Apparatus

An infra-red spectrophotometer for recording the spectra in the infra-red region consists of an optical system. The means of measuring the quotient of the intensity of the transmitted light and the incident light.[6]

Preparation of sample: Triturate about 1 mg of the Lansoprazole with approximately 300 mg of dry, finely powdered potassium bromide IR. These quantities are usually suitable for a disc 13 mm in diameter. Grind the mixture thoroughly, spread it uniformly in a suitable die and compress under vacuum at a pressure of about 800 Mpa. Mount the resultant disc in a suitable holder in the spectrophotometer. Several factors, such as inadequate or excessive grinding, moisture or other impurities in the halide carrier, may give rise to unsatisfactory discs.[7]

METHOD OF PREAPRATION OF FLOATING TABLET BY WETGRANULATION METHOD

Floating Matrix Tablet of Antihypertensive Lansoprazole was prepared by Wet granulation method using Eudragit-RL100 and HPMCK4M as polymer. All the ingredients (except glidents and lubricant) and drug were accurately weighed and individually passed through Sieve No.60. Granulation was done with a solution of calculated quantity of PVP K-30 in sufficient Isopropyl alcohol.[8] The wet mass was passed through Sieve No.12/16 and dried at 45-55°C for 2 hours. Dried granules were passed through Sieve No.18/22 and mixed with magnesium stearate and talc and the blend thus obtained was compressed using a single stationcompression machine.[9]

Table No. 4: Formulation of Floating tablets

Sr. No.	Ingredients	HPMCK4M				Eudragit-RL100			
		F1	F2	F3	F4	F5	F6	F7	F8
1	Lansoprazole	30	30	30	30	30	30	30	30
2	HPMCK4M	100	100	100	120	80	80	80	80
3	Eudragit-RL100	--	--	--	--	50	40	30	20
4	PVP K-30	10	20	30	20	10	10	10	10
5	Sodium-Bi-Carbonate	50	50	50	50	50	50	50	50
6	Citric Acid	15	15	15	15	15	15	15	15
7	Lactose	85	75	65	55	55	65	75	85
8	Magnesium-stearate	5	5	5	5	5	5	5	5
9	Talc	5	5	5	5	5	5	5	5
	Total (mg)	300	300	300	300	300	300	300	300

Procedure for Evaluation of Tablets[10]:

The tablets were compressed using 8 mm diameter, round, biconcave punches on a Fluidpack multistation rotary tablet machine. The tablet weight was kept 400 mg and hardness between 2 – 5 kg/cm^2. Other parameters like size, thickness, shape, hardness, friability, weight variation were carried out.

Taste and Colour

The tablets of prepared formulations were observed for taste and colour.

Method:

Taste was observed by taste panels. Colour comparisons require that a sample be compared against some colour standard.

Thickness and Shape

Shape and thickness was measured using sliding Caliper scale.

Method:

Five or Ten tablets from each formulation were selected and their crown thickness was measured with a sliding Caliper scale. Shapes of the tablets were observed.

Hardness

Tablets require a certain amount of strength or hardness to withstand mechanical shocks of handling in manufacturing, packing and shipping.

Method:

The Monsanto hardness tester consists of a barrel containing a compressible spring held between two plungers. The lower plunger is placed in contact with the tablet and zero reading is taken. The upper plunger is then forced against a spring by turning threaded bolt until the tablets

break. As the spring is compressed, a pointer rides along a gauge in the barrel to indicate the force. The force of break is recorded and zero force reading is deducted from it.

Friability

Tablets were tested for friability using Roche Friabilator. This is important to know the mechanical strength of the tablet while handling.

Method:

Twenty tablets were weighed initially and transferred to the Friabilator. The instrument was set to 25 rpm for 100 rotations. The resulting tablets were reweighed and percentage loss was calculated using the formula.

Friability= (Initial weight – Final Weight) / Initial Weight ×100

Conventional compressed tablet that lose less than 0.5 to 1.0% was acceptable.

Weight Variation

Weight variation was measured to ensure that tablet contain proper amount of drug.

Method:

Weighed 20 tablets individually, calculated the average weight, and compared the individual tablet weights to the average. The tablets meet the test if not more than two tablets are outside the percentage limit and none of the tablet differs by more than two times the percentage limit. The weight variation tolerance for uncoated tablets differs depending on average weight of the tablets.

Floating properties

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 taken floating lag time.

Swelling index of formulations

When exposed to water or body fluids, the hydrophilic polymer matrix started to hydrate from the outer boundary towards the center forming a gel layer around the drug. The gelatinous swollen part of the matrix greatly influences the dissolution and diffusion of drug molecules through the polymer material into aqueous medium and provides a mechanism for controlled drug release.

IN-VITRO DISSOLUTION STUDY:

The development of dissolution methods for mouth dissolving tablet is comparable to the approach taken for conventional tablets, and is practically identical. Dissolution conditions for drugs listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent mouth dissolving tablet. Other media such as 0.1N HCl and buffers (pH - 4.5 and 6.8) should be evaluated for mouth dissolving tablet much in the same way as their ordinary tablet counter parts.

The USP 2 Paddle apparatus is used for this purpose which is the most suitable and common choice for orally-disintegrating tablets, with a paddle speed of 50 rpm commonly used. Typically the dissolution of mouth dissolving tablet is very fast when using USP monograph conditions; hence slower paddle speeds may be utilized to obtain a profile. The USP 1 Basket

apparatus may have certain applications but sometimes tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle where little or no effective stirring occurs, yielding irreproducible dissolution profiles.

Drug Relese Kinetic Model Fitting Study

The kinetic values obtained for formulation F1 to F8 were studied for model fitting study. The values of in vitro release were attempted to fit into various mathematical models. The value of n with regression coefficient for all the formulations.

STABILITY STUDY

The optimized Formulation was subjected to stability studied at 40ºC under humidity conditions (75%) for a period of four week. Samples were analysed for colour changes appearance, drug content and release characteristics.

5. RESULTS

CHARACTERIZATION OF PURE DRUG (Lansoprazole):-

Table 5: Characterization of pure drug.

Sr.No	Characterization	Specification	Result
1.	Description	White or brownish-white powder	A almost white powder
2.	Solubility	Freely soluble in dimethyl formamide, practically insoluble in water	Complies
3.	Identification by FT-IR	To match with working standard	Matches with the working standard
4.	Melting range	166^0C	Complies
5.	Sulphated ash	Not more than 0.1%	Complies
6.	Loss on drying	Not more than 0.5%	Complies
7.	Heavy Metals	20 ppm max	Complies
8.	Assay	Not less than 99.0% w/w and not more than 101.0%	Complies

Development of calibration curve of Lansoprazole

Preparation of 0.01 M Phosphate Buffer Preparation

7g of Potassium dihydrogen orthophosphaste was weighed accurately and dissolved in about 500 ml of distilled water and diluted with distilled water upto 1000 ml, and the pH was adjusted upto 6.8 with the sodium hydroxide solution and filtered through 0.45µ Whatmann filter paper. This buffer solution was used as diluent.

Preparation of standard stock solution and calibration curve:

Standard stock solution of Lansoprozole (100 µg /ml) was prepared by using 0.01 M Phosphate Buffer of pH 6.8 and aliquots of in the range of 15-90 µg /ml were prepared with the same solvent and scanned under spectrum mode for 200-400 nm wavelength range and a sharp peak was obtained at 298 nm. A calibration curve was plotted taking an absorbance on Y-axis against concentration of standard solution on X- axis.

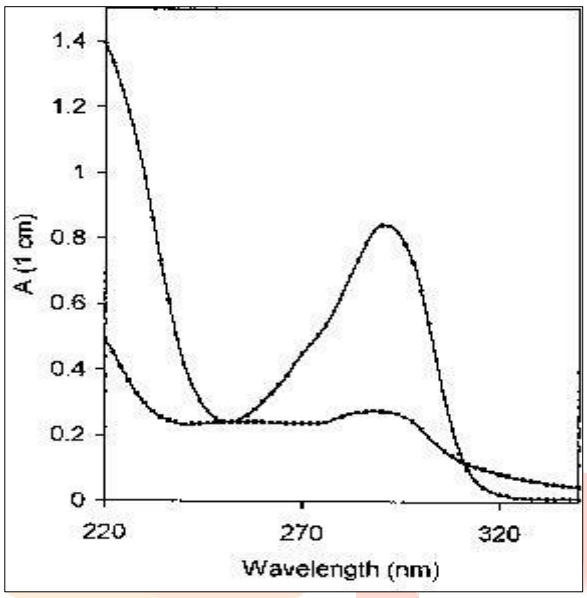


Fig. 4: Spectrum of Lansoprazole in 0.01 M Phosphate Buffer of pH 6.

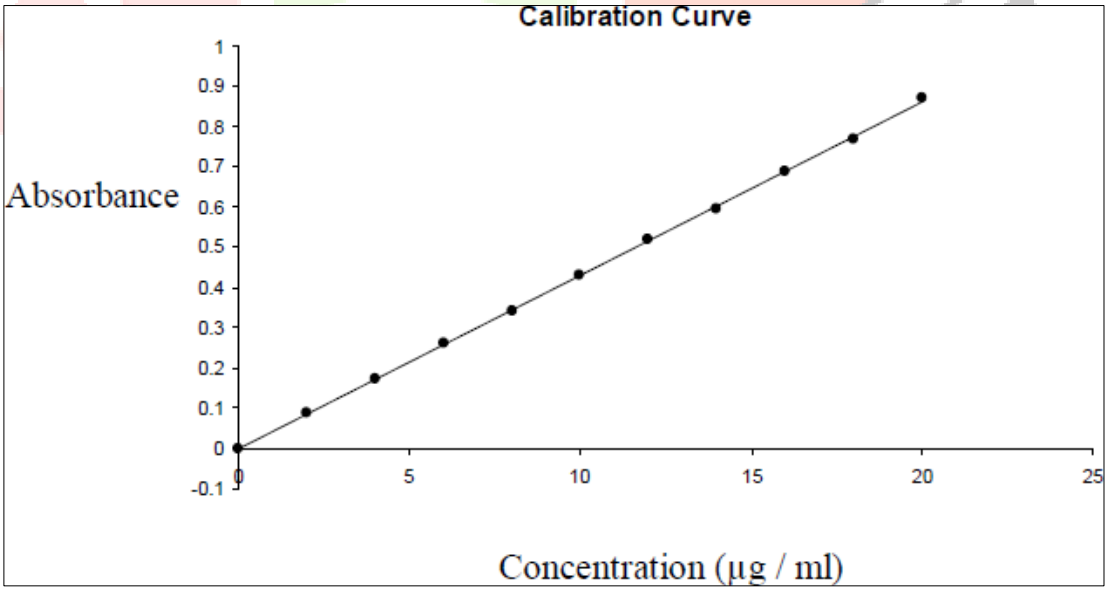


Fig. No. 5. calibration curve of Lansoprazole

FTIR COMPATIBILITY STUDIES OF LANSOPRAZOLE

The IR spectrum of pure drug and physical mixture of drug and polymers were studied. FTIR techniques have been used here to study the physical and chemical interaction between drug and excipients used. In the present study, it has been observed that there is no chemical interaction between Lansoprazole and the polymers used. From the following IR Spectra It was observed that there were no changes in these main peaks in IR spectra of mixture of drug and polymers, which show there were no physical interactions because of some bond formation between drug and polymers.

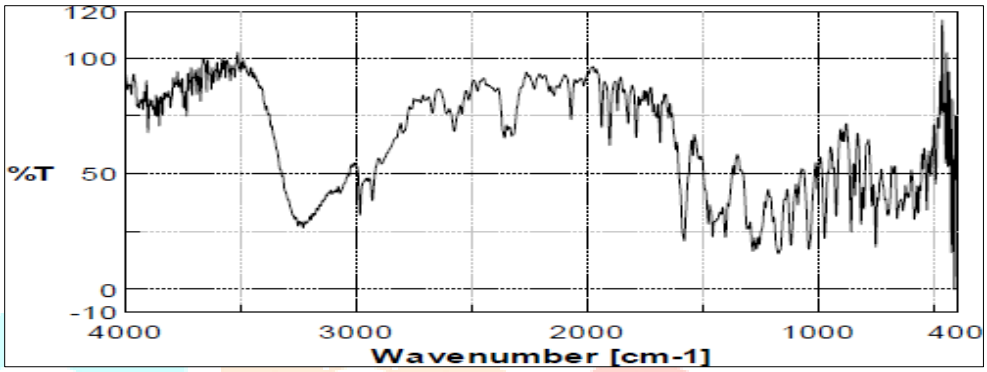


Fig. No. 6 IR Spectrum of Lansoprazole

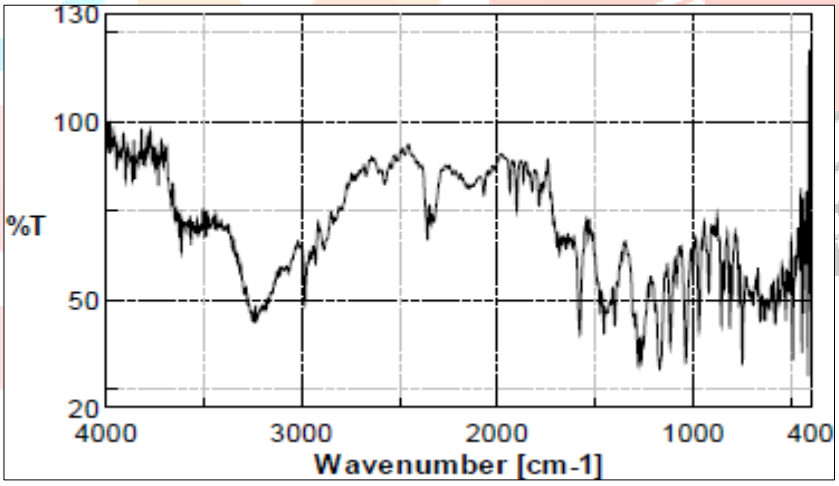


Figure 7: FTIR Spectrum Lansoprazole with PVP K-30

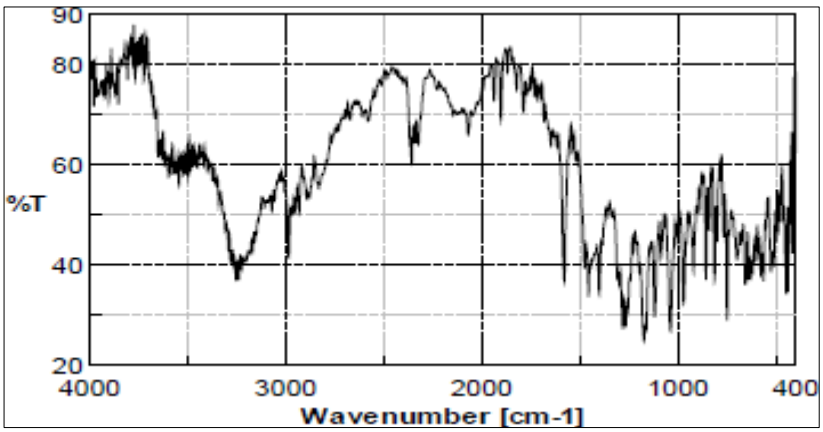


Figure 7: FTIR Spectrum Lansoprazole with HPMC

Evaluation of Tablet (Post-Formulation):-

Table No.6: Physical evaluation of formulated tablet batches

Batch	Thickness (mm)	Hardness (kg/cm^2) ±SD	Friability (%) ±SD	Weight Variation (mg) ±SD	Drug Content Uniformity (%)
F1	4.32±0.04	5.25±0.08	0.83±0.05	298±1.15	98.36±0.25
F2	4.35±0.01	4.35±0.14	0.53±0.06	300±2.08	98.40±0.30
F3	4.50±0.06	4.50±0.09	0.36±0.09	305 ±1.52	98.42±0.25
F4	4.35±0.04	4.50±0.11	0.53±0.04	300±1.52	98.50±0.25
F5	4.35±0.01	4.35±0.03	0.46±0.01	300±0.57	98.96±0.30
F6	4.32±0.02	4.50±0.12	0.76±0.02	298 ±2.0	98.74±0.17
F7	4.32±0.03	5.25±0.40	0.73±0.04	298±3.05	98.71±0.20
F8	4.50±0.02	5.25±0.17	0.39±0.09	305 ±0.57	98.70±0.17

Table No.7: Buoyancy studies of batches F1-F8

Batch	Buoyancy Lag Time (Sec)	Total Floating Time (Hr)
F1	13sec	>12
F2	14sec	>12
F3	15sec	>12
F4	12sec	>12
F5	11sec	>12
F6	13sec	>12
F7	12sec	>12
F8	13sec	>12

a) Initial stage of floating of tablet **b) After 11 sec floating of tablet**

Fig.No.7: Buoyancy studies of batch F5 tablet

c) After 11 sec floating of tablet

Swelling study

The swelling indexes of batches F1 to F8 are shown in Table No.18. Percentage water uptake was found to be increased on increasing the concentration of HPMCK4M: Eudragit-RL100 in the formulations and, hence, the water uptake capacity increases. Drug diffusion depends significantly on the water content of the tablet. This may be because the mobility of the polymer chains is very dependent on the water content of the system. In the case of high water

content, polymer chain relaxation takes place with volume expansion resulting in marked swelling of the system. Also, higher water content could lead to greater penetration of the gastric fluid into the tablet leading to faster carbon-di-oxide gas generation, thereby reducing the floating lag-time. Swelling study was performed on all Formulations for 8 hours.

Table No.8: Swelling index of Batches F1-F8

Time (hr)	SWELLING INDEX (%)							
	F1	F2	F3	F4	F5	F6	F7	F8
1h	18.10	17.06	19.21	22.2	28.68	24.39	26.03	21.09
2h	41.25	36.06	28.46	43.24	30.78	27.47	44.05	36.06
3h	40.66	41.49	36.06	38.21	36.73	42.03	45.73	49.55
4h	38.22	53.23	49.55	61.22	46.05	36.07	38.22	53.51
5h	31.32	51.70	52.55	59.19	65.07	40.22	34.30	39.12
6h	27.12	37.38	39.9	49.13	73.66	46.19	41.23	42.12
7h	22.21	31.14	37.38	41.23	53.61	36.22	38.24	36.22
8h	24.11	25.49	25.74	31.56	50.22	33.01	30.25	30.24

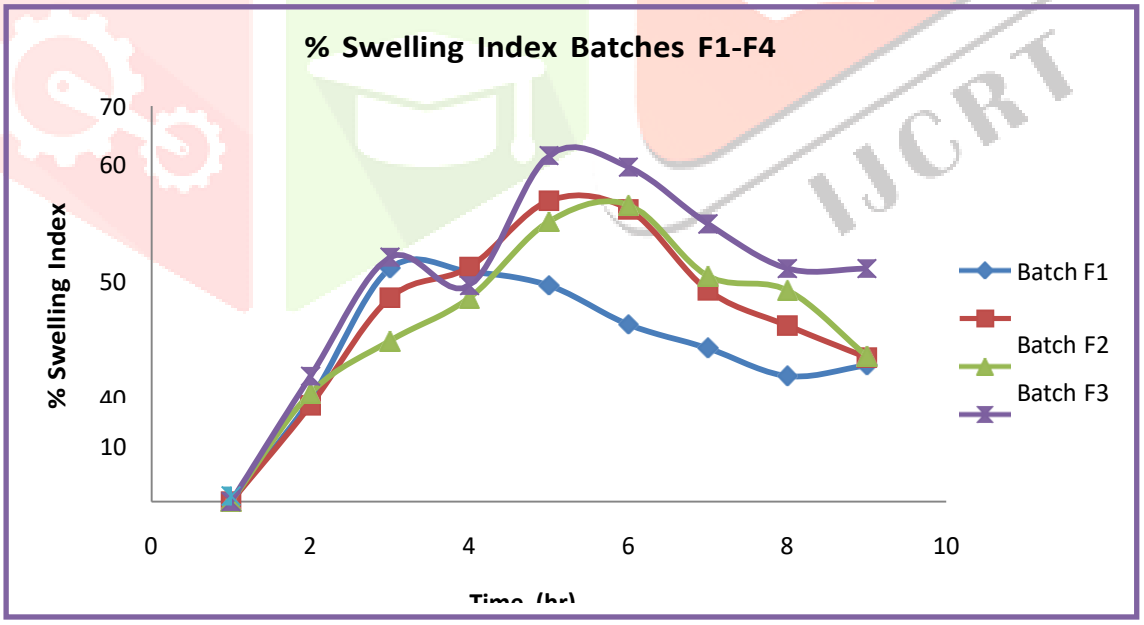


Fig.No.5: Relationship between Swelling Index & Time of batchesF1-F4.

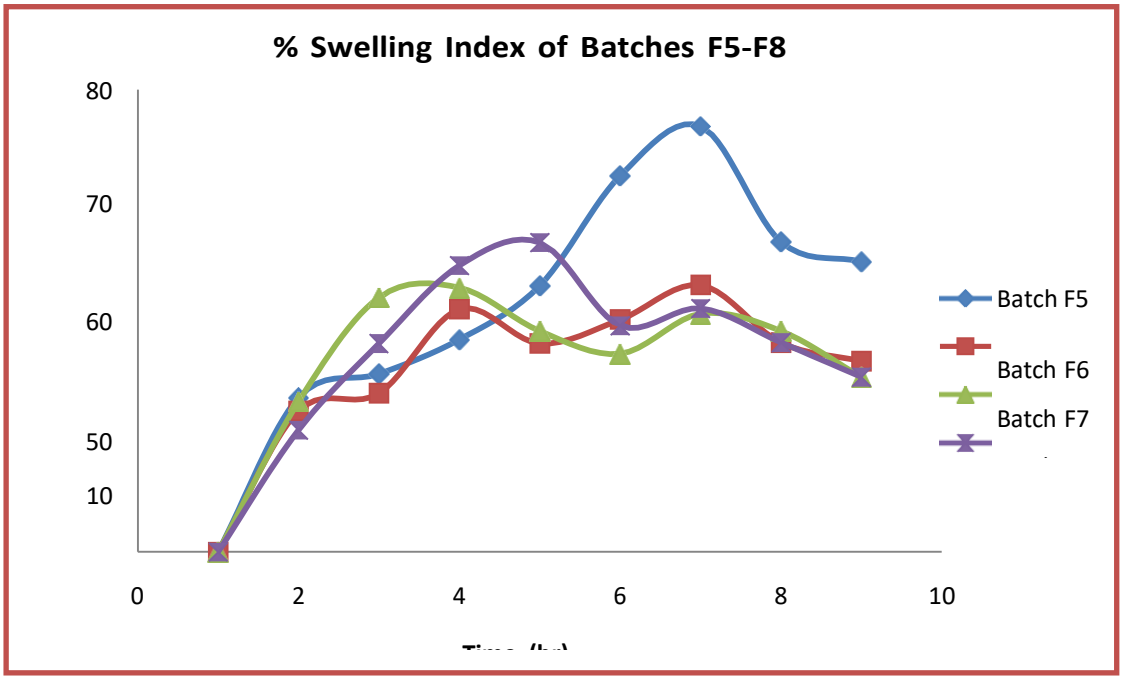


Fig.No.6: Relationship between Swelling Index & Time of batches F5-F8

Dissolution study (*In-vitro* Drug Release Study)

In-vitro drug release study of Lansoprazole tablets from each batches (F1 to F8) were carried out in 0.1N HCL having pH1.2 for 8 hours and the values are shown in Table No.19. The plot of graph %Cumulative drug release Vs Time (hr) was shown in Fig.No.16 & 17. From the *In-vitro* dissolution data it was found that the drug release study from formulations containing batches HPMCK4M: Eudragit-RL100 (F5-F8) extent of drug release than the batches containing HPMCK4M (F1-F4). The combination of HPMCK4M: Eudragit-RL100 provides a better option for control release action and improved bioavailability and the drug release formulation increases due to swelling properties of polymers.

Hydrophilic matrices immersed in water swell and eventually dissolve. When they are placed in water swelling starts and the tablet thickness increases. The polymer dissolves because of the chain disentanglement. As the polymers chain becomes more hydrated and the gel becomes more diluted, the disentanglement concentration may be reached and the polymer chain detach from a gellified matrix. Thus there is matrix undergoes simultaneously swelling, dissolution, and diffusion in to the bulk medium, resulting in a reduction of strength and erosion of the matrix. The addition of Eudragit-RL100: HPMCK4M shows the drug release rate decreased in the rank order-F5>F6>F7>F8. The drug release from F5 batch (HPMCK4M: Eudragit-RL100) ratio shows that, release of formulation is increases as compare to F1,F2,F3,F4 (HPMCK4M), & F5,F6,F7,F8 (Eudragit-RL100:HPMCK4M) This is because of the swelling properties of polymers.

Table No.9: *In-vitro* drug release study of Batches F1- F8

% OF DRUG RELEASE IN 0.1N HCL AT 1.2 Ph								
	HPMCK4M				Eudragit-RL100:HPMCK4M			
TIME (hr)	F1 ±S.D	F2 ±S.D	F3 ±S.D	F4 ±S.D	F5 ±S.D	F6 ±S.D	F7 ±S.D	F8 ±S.D
0h	00	00	00	00	00	00	00	00
1h	12.16 ±1.0	12.34 ±0.13	12.40 ±0.12	12.44 ±0.23	13.54 ±0.16	13.08 ±0.63	12.81 ±0.43	12.81 ±0.76
2h	30.46 ±0.84	31.56 ±0.35	31.47 ±0.64	30.46 ±0.89	31.11 ±0.53	31.47 ±0.45	30.10 ±0.45	28.44 ±0.98
3h	41.30 ±1.14	40.39 ±0.57	37.08 ±0.47	41.31 ±0.43	44.45 ±0.78	41.13 ±0.24	40.66 ±0.65	38.44 ±0.65
4h	51.11 ±1.13	51.02 ±0.79	51.09 ±0.88	54.79 ±0.75	55.46 ±0.34	48.72 ±0.54	51.11 ±0.32	48.78 ±0.76
5h	54.70 ±0.43	57.74 ±0.57	65.73 ±0.78	64.94 ±0.39	69.12 ±0.58	68.51 ±0.62	67.50 ±0.32	63.87 ±0.85
6h	67.25 ±1.33	69.29 ±0.95	77.33 ±0.56	78.10 ±0.48	79.68 ±0.62	77.00 ±0.75	75.51 ±0.23	77.85 ±0.41
7h	77.83 ±0.85	79.61 ±1.05	84.28 ±0.71	86.78 ±0.52	91.55 ±0.95	90.19 ±0.56	89.35 ±0.24	87.65 ±0.45
8h	91.79 ±1.03	93.67 ±0.13	95.83 ±0.60	96.89 ±0.33	99.26 ±0.32	98.75 ±0.76	97.44 ±0.43	97.38 ±0.56

% Drug release

All the values are expressed as mean ± SD=standard deviation (n=3)

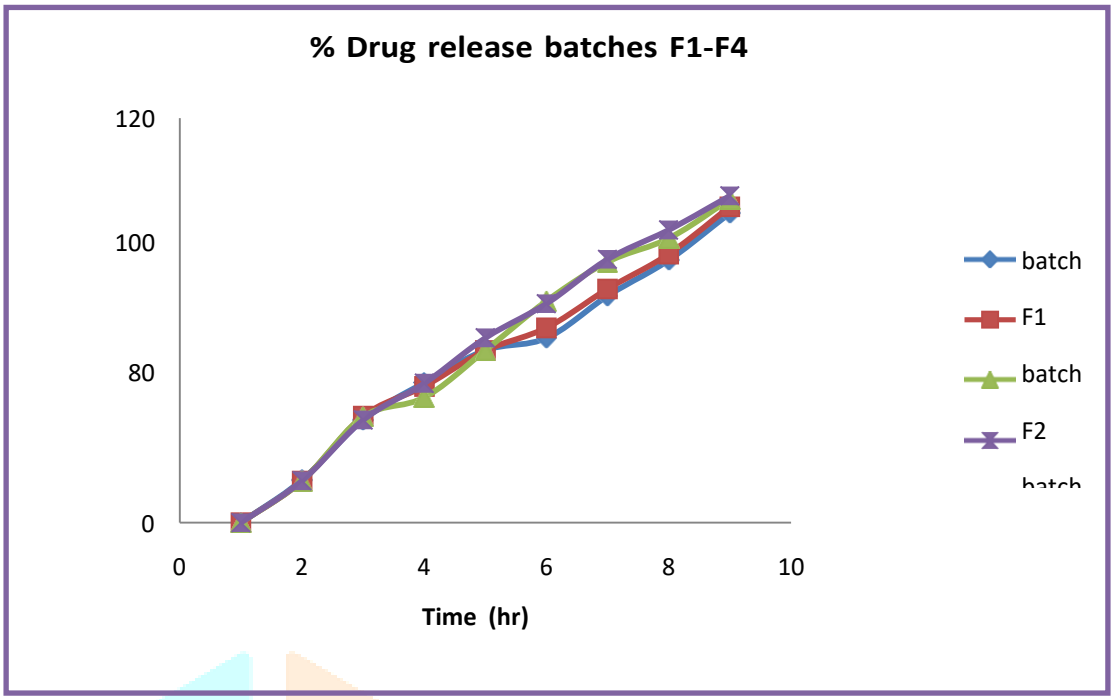


Fig.No.8: *In-vitro* Drug release study of Batches F1-F4

Drug Relese Kinetic Model Fitting Study

Zero Order Drug Release Kinetic

Table No.9: Zero order drug release kinetic data of batches F1-F8

% CUMULATIVE DRUG RELEASE								
TIME (hr)	**F1 ±S.D**	**F2 ±S.D**	**F3 ±S.D**	**F4 ±S.D**	**F5 ±S.D**	**F6 ±S.D**	**F7 ±S.D**	**F8 ±S.D**
0h	00	00	00	00	00	00	00	00
1h	12.16 ±1.0	12.34 ±0.13	12.40 ±0.12	12.44 ±0.23	13.54 ±0.16	13.08 ±0.63	12.81 ±0.43	12.81 ±0.76
2h	30.46 ±0.84	31.56 ±0.35	31.47 ±0.64	30.46 ±0.89	31.11 ±0.53	31.47 ±0.45	30.10 ±0.45	28.44 ±0.98
3h	41.30 ±1.14	40.39 ±0.57	37.08 ±0.47	41.31 ±0.43	44.45 ±0.78	41.13 ±0.24	40.66 ±0.65	38.44 ±0.65
4h	51.11 ±1.13	51.02 ±0.79	51.09 ±0.88	54.79 ±0.75	55.46 ±0.34	48.72 ±0.54	51.11 ±0.32	48.78 ±0.76
5h	54.70	57.74	65.73	64.94	69.12	68.51	67.50	63.87

	±0.43	±0.57	±0.78	±0.39	±0.58	±0.62	±0.32	±0.85
6h	67.25 ±1.33	69.29 ±0.95	77.33 ±0.56	78.10 ±0.48	79.68 ±0.62	77.00 ±0.75	75.51 ±0.23	77.85 ±0.41
7h	77.83 ±0.85	79.61 ±1.05	84.28 ±0.71	86.78 ±0.52	91.55 ±0.95	90.19 ±0.56	89.35 ±0.24	87.65 ±0.45
8h	91.79 ±1.03	93.67 ±0.13	95.83 ±0.60	96.89 ±0.33	99.26 ±0.32	98.75 ±0.76	97.44 ±0.43	97.38 ±0.56

All the values are expressed as mean ± SD and standard deviation (n=3).

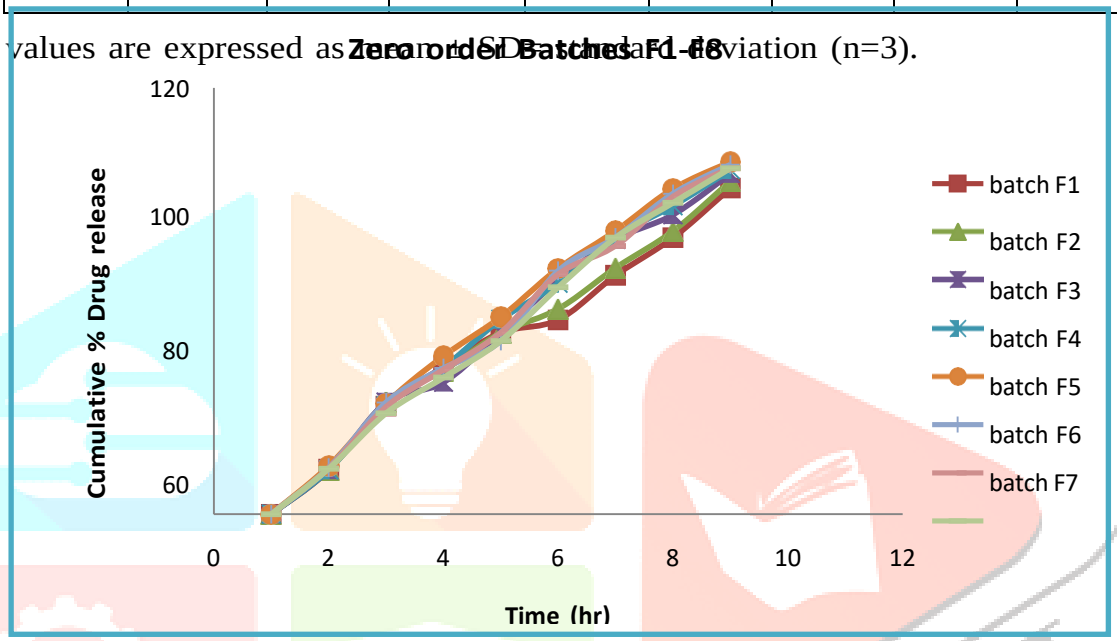


Fig.No.10: Zero order Kinetics for Formulations F1 to F8

Zero order release describes the release rate independent of drug concentration. The best fit with the highest determination r^2 coefficients was shown by both the zero order and peppas models in Fig No. 19 & 23.

Table No.10: Regression Coefficient data of Lansoprazole Floating Matrix Tablet of batches F1-F8

Batches	Zero order (R^2)	First order (R^2)	Matrix Higuchi (R^2)	Peppas(R^2)	Hixson Crowel (R^2)
F1	0.9898	0.9213	0.9552	0.9887	0.9680
F2	0.9923	0.9094	0.9550	0.9901	0.9647
F3	0.9955	0.9172	0.9436	0.9930	0.9672
F4	0.9956	0.9085	0.9496	0.9951	0.9670
F5	0.9946	0.8488	0.9538	0.9962	0.9513
F6	0.9943	0.8647	0.9408	0.9939	0.9428
F7	0.9950	0.8867	0.9430	0.9961	0.9509
F8	0.9971	0.8888	0.9976	0.9976	0.9516

Stability Study

The optimized Formulation was subjected to stability studied at 40ºC under humidity conditions (75%) for a period of four week. Samples were analysed for colour changes appearance, drug content and release characteristics. From the result it was observed that there was no significant change in physiochemical properties as well as in drug release profile even after storage at 40ºC for four week. It may be inferred that there was no degradation and change in the matrix system.

Table 11: Evaluation of formulation (F4) kept for stability at 40^0C / 75%RH

Parameter	0 week	1 week	2 weeks	3 weeks	4 weeks
Appearance	White	White	White	White	White
Thickness (mm)	4.16± 0.04	4.16± 0.04	4.16± 0.04	4.16± 0.04	4.16± 0.04
Hardness (Kg/cm2)	5.21± 0.03	5.17± 0.028	5.10± 0.021	5.07± 0.02	5.00± 0.015
Buoyancy Lag time (sec)	20	20	20	18	17
Duration of Floating	>12	>12	>12	>12	>12
Drug content (%)	99.9± 0.57	99.8± 0.99	98.7± 0.98	98.2± 0.95	98.2± 0.95

Table 12: In-vitro drug release study of formulation (F5) kept forstability at 40^0C / 75%RH:

Time (Hrs)	Cumulative % drug released (mean S.D.)				
	0 week	1 week	2 week	3 week	4 week
1	46.00±0.294	46.81±1.07	45.98±0.23	45.73±0.95	45.02±0.12
2	50.36±0.100	50.39±2.62	49.78±0.39	49.11±0.44	48.96±0.16
4	60.94±0.203	60.90±0.34	59.65±0.24	59.11±0.32	60.94±0.43
6	66.47±0.100	65.89±0.25	65.48±0.75	65.08±0.68	64.29±0.20
8	79.10±0.192	79.19±0.53	78.55±0.79	78.23±0.42	77.26±0.40
10	91.10±0.109	91.10±0.77	90.78±1.19	90.45±0.31	90.05±0.39
12	99.47±0.402	99.36±0.38	98.84±0.73	98.57±0.41	98.00±0.17

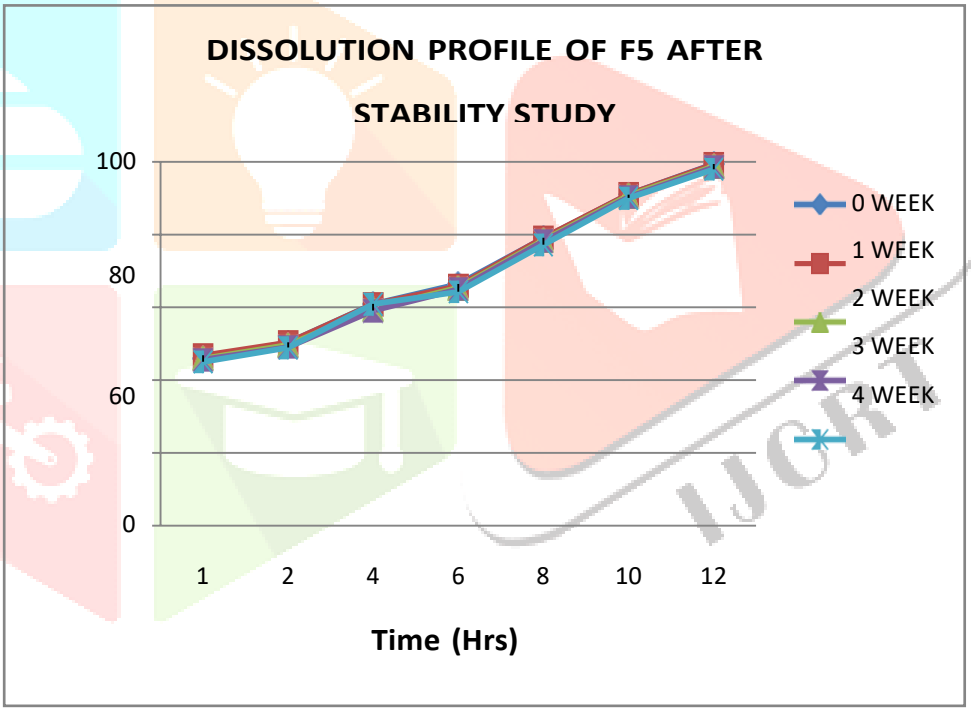


Figure 10: Comparative dissolution profile of formulation F5 before andafter stability study.

6. DISCUSSION:

The present study has been a satisfactory attempt, to formulate and evaluate floating tablet of Lansoprazole with a view of improving bioavailability and giving a controlled release of a drug,

7. CONCLUSION

1. In the current study indicates that the optimized Floating tablet of Lansoprazole, prepared using HPMCK4M: Eudragit-RL100 polymer ratio and PVPK-30 as a binder, Sodium-bi-Carbonate: Citric acid as gas generating agent, can successfully be employed as an oral controlled release drug delivery system.
2. High floating ability of the formulation is likely to increase its GI residence time, and eventually, improve the extent ofbioavailability.
3. Gastroretentive dosage form of Lansoprazole will reduce the frequency of administration of drug and helps to minimize dose of drug and side effects associated with the drug.

REFERENCES

1. Jain AK, Umashankar H, "A Review On Floating Drug Delivery System", *International Journal of Pharmaceutical Studies and Research,* Vol. 2, Issue 3, July-September, 2011, 01-06.
2. Narang N, "An Updated Review On: Floating Drug Delivery System (FDDS)", *Int J App Pharm,* 2011; 3(1): 17.
3. Pande SD, Vaidya PV, Gulhane PN, "Floating Drug Delivery System (Fdds): A New Way for Oral Drug Delivery System", *International Journal of Pharmaceutical and Clinical Science* 2013; 3(1): 1-13.
4. Nikita Dixit, "Floating Drug Delivery System", *Journal of Current Pharmaceutical Research*, 2011; 7 (1): 6-20.
5. Ratnaparkhi MP, Pawar SA, Somvanshi FU, Chaudhari SP, "Formulation And Development Of Floating Drug Delivery Of Itopride Hcl", *Journal of Drug Delivery & Therapeutics*; 2013, 3(4), 222-228.
6. Sharma N, Jain N, Sudhakar CK, Sanjay JAIN, "Formulation And Evaluation of Gastro Retentive Floating Tabletscontaining Cefpodoxime Proxetil Solid Dispersions", *International Journal of Current Pharmaceutical Research,* Vol 4, Issue 4, 2012, 82-87.
7. Thahera PD, Ashok, Latha K, Shailaja T, Nyamathulla S, Uhumwangho MU, "Formulation and evaluation of Norfloxacin gastro retentive drug delivery systems using natural polymers",*International Current Pharmaceutical Journal*, 2012, 1(7): 155-164.
8. Sheth NS, Mistry RB, "Formulation And Evaluation Of Floating Drug Delivery System", *International Journal of Pharma and Bio Sciences,* Vol 2, Issue 1, Jan – Mar 2011, 571-580.
9. Yadav SK, Kavita K, Tamizhamani T, "Formulation and Evaluation of Floating Tablets of RHCL Using Natural and Synthetic Polymers", *International Journal of PharmTech Research,* Vol.2, No.2, April-June 2010, pp 1513-1519.
10. Ravi Kumar, Patil MB, Patil SR, Paschapur MS, "Formulation and Evaluation of Effervescent Floating Tablet of Famotidine", *International Journal of PharmTech Research,* Vol.1, No.3, July-Sept 2009, pp 754-763.