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FORMULATION AND EVALUATION OF FLOATING TABLET OF METOPROLOL SUCCINATE WITH SYNTHETIC SUPERDISINTEGRANT

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ABSTRACT: The present work was designed to formulate floating tablet of Metoprolol Succinate with synthetic superdisintegrant as swelling agent. Various formulations of Metoprolol Succinate were prepared by direct compression method using the different concentrations of superdisintegrant ranging from 10% to 15%. The selected batches were evaluated for various parameter like weight variation, thickness, diameter, friability, floating lag time, duration of floating, water uptake, content uniformity, *in-vitro* drug release and *in-vitro* drug release kinetics. Formulations with Crosspovidone had showed better results than the Kyron T-314. The data obtained from the *in-vitro* dissolution studies of optimized batch **F5** was fitted in different models viz. zero order, first order, Korsemeyer-Peppas model, Higuchi model and Hixon-Crowell model. Drug release mechanism was found to be First order from optimized formulation. Further for getting the type of release mechanism the data was fitted as per the Korsemeyer-Peppas equation. The exponent value n was found in between 0.45 to 0.89. It indicates that the release of Metoprolol Succinate from developed floating tablets followed non-Fickian transport mechanism.

INTRODUCTION: Among all route of administration, oral route is most important and preferable route of administration for solid dosage form. Tablets are the most common solid dosage form, administered orally. Oral sustained drug delivery may be complicated by limited gastric residence time. Rapid gastrointestinal transit can prevent complete drug release in the absorption zone and reduce the efficacy of administered dose since the majority of drugs are absorbed in the stomach or the upper part of the small intestine.

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Dosage forms that can be retained in the stomach are called gastro retentive drug delivery systems (GRDDS) [1]. Gastro retentive floating drug delivery systems (GRFDDS) have a bulk density lower than that of gastric fluids and thus remain buoyant in the stomach without affecting gastric emptying rate for a prolonged period of time. While the system is floating on gastric contents, the drug is released slowly at a desired rate from the system [2].

After release of drug; the residual system is emptied from the stomach. This results in an increased GRT and a better control of the fluctuations in plasma drug concentration. The controlled gastric retention of solid dosage forms may be achieved by the mechanisms of mucoadhesion, flotation, sedimentation, expansion modified shape systems or by the simultaneous

administration of pharmacological agent that delay gastric emptying time [3, 4].

Approaches to increase the GRT include:

(i) Bio-adhesive delivery systems-which adhere to mucosal surfaces [5];

(ii) Swellable delivery systems-which increase in size after swelling and retard the passage through the pylorus and;

(iii) Density-controlled delivery systems-which either float or sink in gastric fluids.

Floating drug delivery is of particular interest for drugs which;

(a) Act locally in the stomach;

(b) Are primarily absorbed in the stomach;

(c) Are poorly soluble at an alkaline pH;

(d) Have a narrow window of absorption and;

(e) Are unstable in the intestinal or colonic environment [6].

Metoprolol succinate which is used in the treatment of hypertension, angina and arrhythmia has an absorption window and is mainly absorbed from the upper parts of GIT [7] and good stability in the acidic environment of the stomach makes it a suitable candidate to formulate in a GRDF [8]. More over its half-life of 3-7hrs, making repetitive dosing is necessary. Therefore a sustained drug delivery system that spends most of its time in acidic environment of stomach i.e., floating dosage form which improves the bioavailability is desirable [9].

The main objective of this study was to prepare floating drug delivery system of Metoprolol succinate by direct compression method. Superdisintegrant {Crosspovidone and Kyron T-314} having ranging from 10% to 15% are used as swelling inducers. Metoprolol succinate is water soluble drug. The various formulations were prepared with different concentration of swelling polymer and superdisintegrant. The various parameters like weight variation, thickness, diameter, friability, wetting time, water absorption ratio, content uniformity, *in vitro* dissolution drug release study, *in vitro* drug release kinetics of Floating tablet of Metoprolol succinate is investigated.

MATERIAL AND METHOD: Metoprolol succinate was a gift sample from MACLEOD'S Pharmaceutical limited Andheri (East) Mumbai, Carbopol P-971 and Kyron T-314 were gift sample from COREL Pharma Chem (Ahmedabad), $NaHCO_3$ was purchase from RANKEM (RFCL Limited, New Delhi), Magnesium Stearate was YARROW Chem product (Mumbai).

Formulation of Floating Tablet: Floating tablet of Metoprolol succinate was developed by direct compression method. The drug and excipient were weighed accurately for individual batch and passed through sieve no. 80. Drug, Crosspovidone, HPMC K-100, Carbopol 971-P, $NaHCO_3$, MCC and PVPk-30 were mixed in planetary mixture for about 10 min. The $NaHCO_3$ is previously heated at 105˚C for about 10min.The above mixture is the lubricated with talc and Magnesium stearate in a double cone blender for about 5min. Then tablet is compress in 16 station tablet compression machine using 10 mm bi-concave punches. The different compositions of various formulations were given in (**Table 1, Figure 1**)

TABLE 1: COMPOSITION OF VARIOUS FORMULATIONS

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug	50mg	50mg	50mg	50mg	50mg	50mg	50mg	50mg	50mg
Crosspovidone	17.5mg	**26.25mg**	**35mg**	17.5mg	17.5mg	17.5mg	17.5mg	17.5mg	17.5mg
HPMC K-100	25mg	25mg	25mg	**35mg**	**45mg**	25mg	25mg	25mg	25mg
Carbopol 971P	75mg	75mg	75mg	75mg	75mg	**50mg**	**100mg**	75mg	75mg
$NaHCO_3$	52.5mg	52.5mg	52.5mg	52.5mg	52.5mg	52.5mg	52.5mg	**35mg**	**43.75mg**
MCC	88mg	79.25mg	70.50mg	78mg	68mg	113mg	63mg	105.5mg	96.75mg
PVP k-30	35mg	35mg	35mg	35mg	35mg	35mg	35mg	35mg	35mg
Mg. stearate	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5
Talc	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5
Weight	**350**	**350**	**350**	**350**	**350**	**350**	**350**	**350**	**350**

Formulation of Floating Tablet:

FIGURE 1: FORMULATED TABLET

Evaluation of Formulated Floating Tablet: The prepared tablets can be evaluated for various parameters like thickness, diameter, buoyancy studies, duration of floating, weight variation, friability, content uniformity, water uptake study, *in vitro* dissolution drug release study and *in vitro* drug release kinetics [10, 11].

1. **Thickness:** The thickness of tablet is measured by electronic Vernier caliper. Tablet thickness should be controlled with in a ± 5% variation of a standard value. In addition, thickness must be controlled to facilitate packaging. The thickness in millimeters (mm) was measured individually for ten pre-weighed tablets using electronic Vernier caliper. The average thickness and standard deviation were reported.

2. **Diameter:** The diameter size and punch size of tablets depends on the die and punches selected for making the tablets. The diameter of tablet is measured by electronic Vernier caliper. The Diameter in millimeters (mm) was measured individually for ten pre-weighed tablets using electronic Vernier caliper. The average diameter and standard deviation were reported.

TABLE 2: THICKNESS AND DIAMETERS

S. No.	F1		F2		F3		F4		F5	
	D	T	D	T	D	T	D	T	D	T
1.	10.04	5.10	10.03	5.11	10.05	5.06	10.02	4.96	10.01	5.12
2.	10.00	5.12	10.01	5.10	10.03	5.05	10.03	5.06	10.04	5.09
3.	10.01	5.03	10.06	5.03	10.01	5.02	10.06	5.10	10.00	5.03
4.	10.02	4.99	10.05	5.00	10.02	5.01	10.11	5.01	10.01	5.99
5.	10.04	5.08	10.04	5.06	10.03	5.04	10.07	5.00	10.02	5.11
Mean ±S.D	**10.02±0.017**	**5.0 0.0**	**10.03± 0.019**	**5.06±0.046**	**10.02±0.014**	**5.03± 0.020**	**10.05±0.035**	**5.02±0.054**	**10.01±0.015**	**5.20± 0.405**

S. No.	F6		F7		F8		F9	
	D	T	D	T	D	T	D	T
1.	10.04	5.01	10.04	5.01	10.05	5.03	10.03	5.06
2.	10.02	5.08	10.02	5.00	10.03	5.01	10.01	5.10
3.	10.00	5.09	10.00	5.03	10.01	5.02	10.03	5.03
4.	10.03	5.00	10.02	5.09	10.01	5.00	10.02	5.01
5.	10.06	5.06	10.03	5.08	10.04	5.06	10.04	5.06
Mean ±S.D	**10.03±0.022**	**5.04±0.040**	**10.02±0.014**	**5.04±0.040**	**10.02±0.017**	**5.02±0.023**	**10.02±0.011**	**5.05±0.034**

3. **Buoyancy Studies:** *In vitro* buoyancy was determined by buoyancy lag time. The tablets were placed in a 100 ml beaker containing buffer. The time required for the tablet to rise to the surface and float was determined as floating lag time.

4. **Duration of Floating:** This can be determining by the maximum time for the tablet to float on surface. Test for buoyancy was performed in SGF-Simulated Gastric Fluid maintained at 37^{o}C.The time for which the dosage form continuously floats on the media is termed as floating time.

5. **Weight variation:** Twenty tablets were randomly selected and average weight was determined. Then individual tablets were weighed and percent deviation from the average was calculated.

6. **Friability:** Friability of the tablets was determined using Roche Friabilator (Electrolab, India) that is set at 25 rpm for 4 minutes dropping the tablets at a distance of 6 inches with pre-weighed sample of 20 tablets. Tablets were dusted using a soft muslin cloth and reweighed. The friability (F %) is given by the formula [12].

$$F\ \% = (1-W_0 / W) \times 100$$

Where, W_0 is weight of the tablets before the test and W is the weight of the tablets after test.

7. **Content uniformity:** 20 tablets were randomly selected and average weight was calculated and powdered in a glass mortar. Powder equivalent to 25mg of drug was weight and dissolved in 100ml of 0.1N HCl, filtered and drug content analyzed at spectrophotometrically at 224nm.

TABLE 3: FLOATING LAG TIME (BUOYANCY STUDIES) AND DURATION OF FLOATING

S. No.	F1		F2		F3		F4		F5	
	FL	DF	FL	DF	FL	DF	FL	DF	FL	DF
1.	2sec	12hr	2sec	12hr	6sec	12hr	3sec	12hr	2sec	12hr
2.	5sec	12hr	4sec	12hr	3sec	12hr	5sec	12hr	4sec	12hr
3.	7sec	12hr	3sec	12hr	3sec	12hr	3sec	12hr	5sec	12hr
4.	5sec	12hr	4sec	12hr	4sec	12hr	4sec	12hr	7sec	12hr
5.	8sec	12hr	6sec	24hr	2sec	12hr	3sec	12hr	3sec	12hr

S. No.	F6		F7		F8		F9	
	FL	DF	FL	DF	FL	DF	FL	DF
1.	3sec	12hr	8sec	12hr	2sec	12hr	3sec	12hr
2.	6sec	12hr	3sec	12hr	6sec	12hr	2sec	12hr
3.	3sec	12hr	5sec	12hr	3sec	12hr	6sec	12hr
4.	8sec	12hr	7sec	12hr	2sec	12hr	4sec	12hr
5.	2sec	12hr	3sec	12hr	4sec	12hr	5sec	12hr

TABLE 4: WEIGHT VARIATIONS, FRIABILITY AND DRUG CONTENT OF FORMULATED TABLET

Formulation	Avg. Weight of Tablet	Weight Variation	Friability (%)	% Drug Content
F1	348.6	Passed	0.67	96.33±1.33
F2	347.3	Passed	0.53	95.98±2.01
F3	349.7	Passed	0.44	97.74±1.30
F4	346.9	Passed	0.70	95.87±1.21
F5	350.1	Passed	0.58	96.88±1.48
F6	347.5	Passed	0.71	95.96±1.81
F7	349.1	Passed	0.69	96.80±2.62
F8	347.6	Passed	0.80	98.89±2.09
F9	348.4	Passed	0.47	95.10±1.49

8. **Water Uptake Study:** The swelling of the polymers can be measured by their ability to absorb water and swell. The water uptake study of the tablet was done using USP dissolution apparatus II. The medium used was distilled water, 900 ml rotated at 50 rpm. The medium was maintained at 37±0.5^{0}C throughout the study. After a selected time intervals, the tablets were withdrawn, blotted to remove excess water and weighed. Swelling characteristics of the tablets were expressed in terms of water uptake (WU) [13] as:

WU (%) = [(weight of the swollen tablet-initial weight of the tablet) / initial weight of the tablet] × 100

TABLE 5: WATER UPTAKE STUDY

Water Uptake Study		
Formulation	Average % swelling (n=3)	Std Dev.
F1	199.17	8.13
F2	245.24	6.82
F3	357.52	5.51
F4	249.59	4.04
F5	232.44	7.22
F6	185.82	4.02
F7	220.41	5.36
F8	202.95	4.51
F9	210.36	6.44

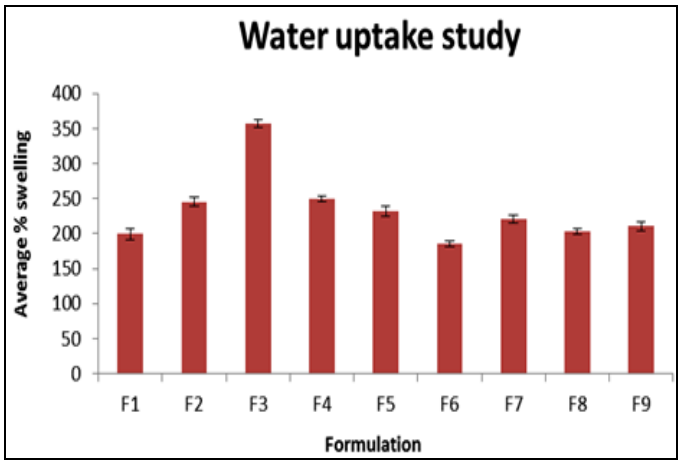


FIGURE 2: GRAPH OF WATER UPTAKE STUDY OF DIFFERENT FORMULATION

9. ***In-vitro* drug release study:** *In-vitro* drug release of Metoprolol succinate floating tablets was determined using USP Dissolution Apparatus II (Paddle type) (VEEGO). The dissolution test was performed using 900 ml of 0.1N HCl at 37˚C ± 0.5˚C. The speed of rotation of paddle was set at 50 rpm. 5 ml samples were withdrawn at time points of 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 360 min and same volume was replaced with fresh buffer media. Absorbance of solution was checked by UV spectrophotometer (Shimadzu-1700) at a wavelength 224nm and drug release was determined by standard curve [14].

a) ***In vitro* dissolution drug release kinetics:** In order to investigate the mechanism of release, the data were analyzed with the following mathematical models[15]: Zero order kinetic (1), first order kinetic (2), Higuchi Model (3).

$$Qt = Q^0 + K^0 t \quad \text{..... (1)}$$

$$\text{Log } Qt = \log Q^0 + K^1 t / 2.303 \quad \text{..... (2)}$$

$$Qt = K H. t 1/2 \quad \text{..... (3)}$$

The following plots were made: Qt vs. t (zero order kinetic model), log (Q^0 −Qt) vs. t (first order kinetic model) and Qt vs. t1/2 (Higuchi model), where Qt is the percentage of drug released at time t, Q^0 is the initial amount of drug present in the formulation and K^0, K^1 and KH are the constants of the equations13. Further, to confirm the mechanism of drug release, the first 60% of drug release was fitted in Korsemeyer and Peppas Release Model (4)

$$Mt / M\infty = K. tn \quad \text{..... (4)}$$

Where Mt / M∞ are the fraction of the drug release at time t, K is the rate constant and "n" is the release exponent. The value of "n" is used to characterize different release mechanisms and is calculated from the slope of the plot of log of fraction of drug released (Mt / M∞) vs. log of time.

TABLE 6: *IN-VITRO* % DRUG RELEASE

Time Interval	Percentage Drug Release of Different Formulation								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
30	11.25	16.88	7.74	14.87	9.3	8.4	6.6	7.7	10.77
60	13.01	23.71	12.54	15.83	16.64	24.67	10.77	10.61	13.05
90	17.20	30.59	14.07	21.86	19.69	36.24	14.39	14.44	18.89
120	21.86	33.43	17.75	24.75	21.86	49.90	17.68	18.87	21.62
150	26.04	44.68	21.46	28.85	29.65	60.00	21.16	21.46	28.61
180	30.86	55.35	24.91	33.83	32.07	65.17	25.96	25.10	34.56
210	33.35	65.01	32.39	36.40	34.80	68.15	34.75	31.59	38.90
240	37.21	71.16	35.68	42.27	37.93	70.40	37.53	34.80	41.15
270	40.90	76.56	37.09	43.56	40.74	74.30	40.02	37.21	45.87
300	45.65	81.02	40.71	46.93	43.72	74.07	40.99	41.71	47.98
330	47.03	85.67	45.89	48.85	47.01	76.10	42.59	44.78	50.45
360	52.34	91.05	**46.99**	50.44	49.74	78.01	48.74	47.87	52.33

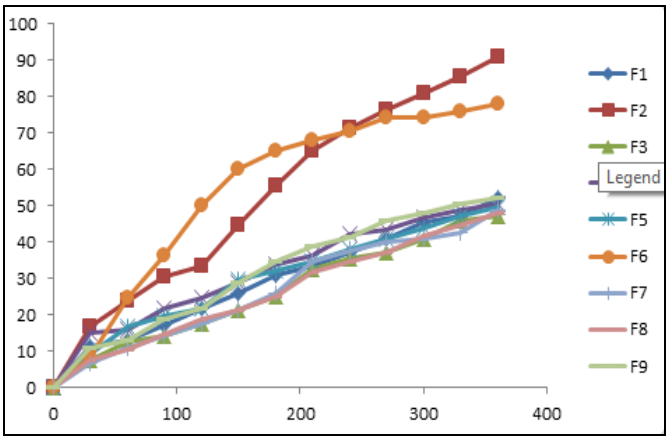
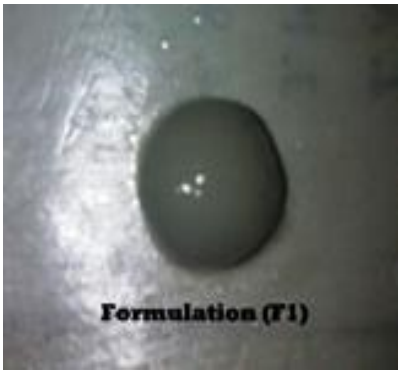


FIGURE 3: *IN-VITRO* DRUG RELEASE OF FORMULATION FROM F1 TO F9



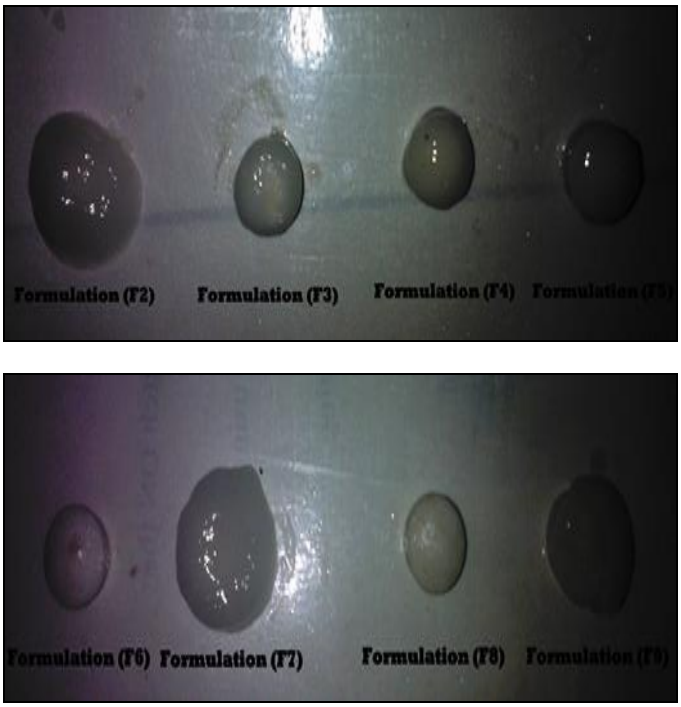


FIGURE 4: *IN-VITRO* DISSOLUTION EVIDENCES FROM FORMULATION F1 TO F9

TABLE 7: TABLE 7: INTERPRETATION OF DRUG RELEASE MECHANISM

Release exponent	Drug transport mechanism	Rate as a function of time
<0.45	Fickian	$t^{-0.5}$
0.45 < n< 0.89	Non -Fickian transport	t^{n-1}
0.89	Case II transport	Zero order release
Higher than 0.89	Super case II transport	t^{n-1}

TABLE 8: *IN-VITRO* DISSOLUTION DRUG RELEASE KINETICS

Formulation	Correlation – coefficient			Peppas equation		$T_{50\%}$	$T_{80\%}$	Best fit Model
	Zero order	First order	Higuchi	N	K			
F1	0.9866	0.9928	0.9076	0.6680	0.9805	6.0hr	12.2hr	Hix-Crowell
F2	0.9820	0.9820	0.9141	0.7294	1.0956	2.3hr	4.6hr	Hix-Crowell
F3	0.9886	0.9897	0.9119	0.7567	0.7599	6.5hr	13.1hr	Hix-Crowell
F4	0.9577	0.9846	0.9070	0.5575	1.3125	6.1hr	14.3hr	1st order
F5	**0.9672**	**0.9903**	**0.9125**	**0.6585**	**1.0138**	**6.2hr**	**12.6hr**	**Peppas**
F6	0.8594	0.9478	0.9391	0.8107	0.9147	2.4hr	6.2hr	1st order
F7	0.9801	0.9838	0.9192	0.8313	0.6427	3.1hr	5.5hr	Peppas
F8	0.9940	0.9945	0.9132	0.7786	0.7215	6.4hr	13.0hr	Hix-Crowell
F9	0.9739	0.9918	0.9156	0.7087	0.9026	5.5hr	9.0hr	1st order

The dissolution data was plotted in accordance with Zero order, First order and Higuchi kinetic and the drug release mechanism was evaluated by potting the data in accordance with Peppas equation. The best fit model was evaluated based on correlation coefficient (R^2) value for each formulation by using BIT-SOFT (software) and $T_{50\%}$ (time taken for $T_{50\%}$ dissolution as per best fit model) and $T_{80\%}$ (time taken for $T_{80\%}$ drug release as per best fit model) were obtained. The different models were showed in **Table 8**. The formulation F5 was selected as optimized formulation based on drug release data, floating lag time, duration of floating, friability, drug content and kinetic model fitting of drug release data.

The F5 formulation showed floating lag time of 4 sec (**Table 3**) and $T_{80\%}$ equivalent to 12.6 hrs (**Table 8**). Further it followed Korsemeyer Peppas-power law as show in table 8. The n- value was found to be 0.6595 which indicate non-Fickian diffusion type of release mechanism (**Table 7**).

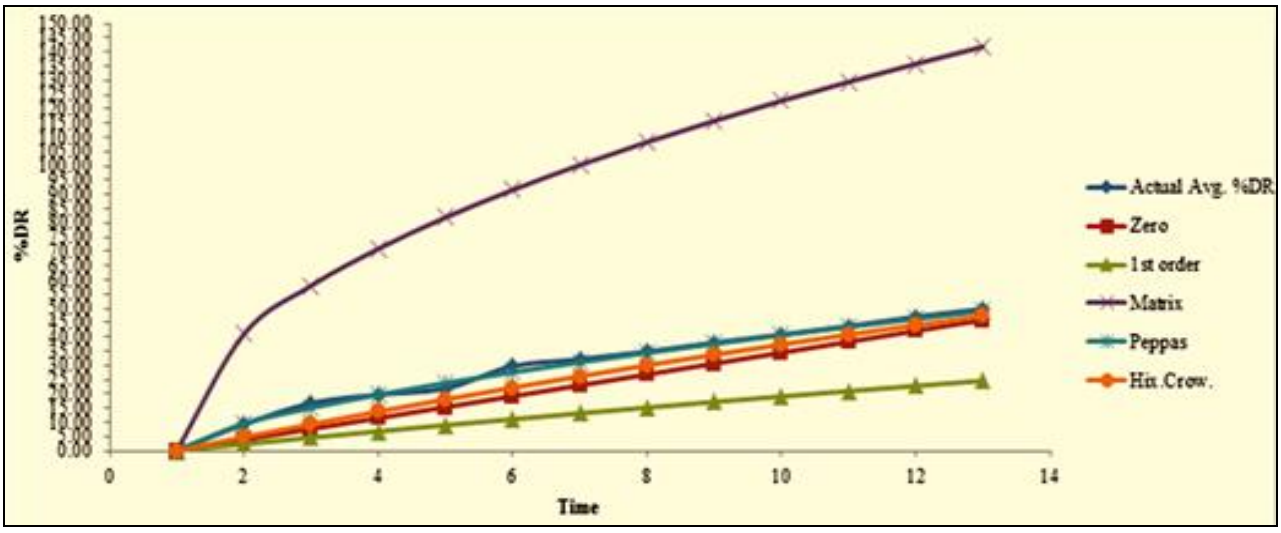


FIGURE 4: % CUMULATIVE DURG RELEASE FROM F5 FLOATING TABLET

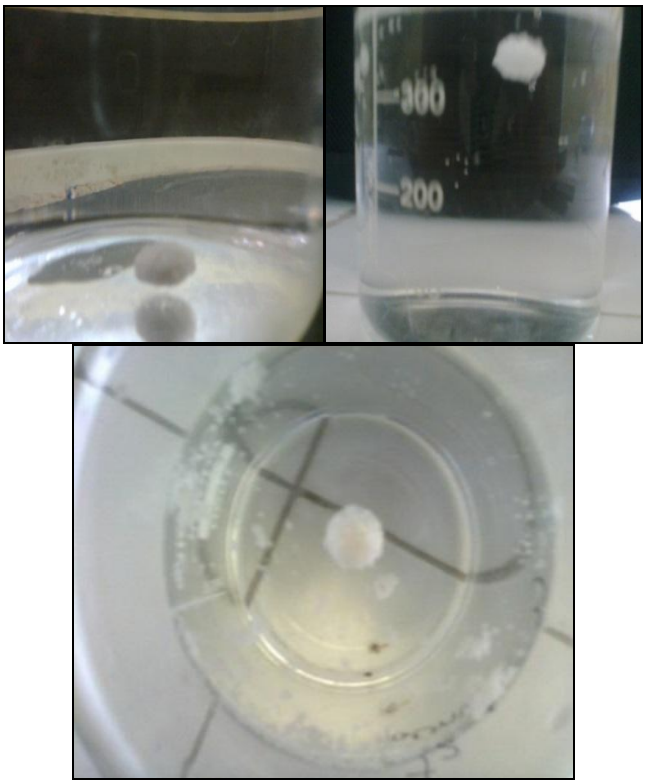


FIGURE 5: FLOATING EVIDENCES OF FORMULATED TABLET

RESULT AND DISCUSSION: All the formulations were found to maintain the physical integrity for desired time interval. Thickness was found to be in range of 5.02 ± 0.023 to 5.06 ± 0.053 mm and Diameter was found to be 10.01 ± 0.11 to 10.05 ± 0.054mm (**Table 2**: Thickness and Diameter). On set of floating was found to be 2 second to 8 second and duration of floating was found to be 12 hours for all formulations (**Table 3**: Floating lag time and Duration of floating and Figure 5 Floating evidences of formulated tablet). Formulations were evaluated for water uptake, the results revealed 199.17 ± 8.13 to 357.52 ± 5.51 % water uptakes (**Table 5**, Water Uptake Study and **Figure 2**: Graph of Water Uptake Study of Different Formulation).

The drug release study (**Table 6**: *In-vitro* % Drug Release and **Figure 3 and 4**, *In-vitro* drug release of formulation from F1 to F9 and Image Evidence) revealed that formulation F1, F2 and F3 where the concentration of swelling agent was increased from 17.5mg to 35mg, the drug release was decreased in F3 formulation as compared with F1 formulation at all the time points.

The F3 formulation showed 17.75% drug release in 2hr whereas F1 showed 21.86% drug released similarly F3, F2 and F3 formulation showed 52.34%, 91.05% and 46.99% drug release in 6 hrs. Further drug release from formulation F1 to F3 were also evaluated by applying one-way ANOVA Test (Kruskal-Watts one way Analysis of variance on point) which showed the difference in the mean value among the treatment groups are greater than would be expected by chance; there is a statistically significant difference (P=0.046). The decrease in the drug release in formulation F3 in comparison to F1 may be due to the increased in path length as the concentration of swelling agent became double in F3 as compared to F1. The increase in diffusion path length might decrease the drug release. The

formulation F4 and F5 were designed to check the effect of HPMC K-100 on drug release in comparisons to formulation F1. As the concentration of HPMC K-100 increased in F4 and F5 the drug release was partially decreased. The one way ANOVA test was applied to find out the statistically significant difference in drug release data. The result of ANOVA test in drug release profile of F1, F4 and F5 revealed that the difference in the mean value among the treatment group are not great enough to exclude the possibility that the difference is due to random sampling variability; there is not a statistically significant difference (P=0.913).

Formulation F6 and F7 were designed with varying concentration of Carbopol 971P. The formulation F1 contained 75mg of Carbopol 971P whereas formulation F7 contained 100mg of Carbopol 971P. The drug release data formulation F1, F6 and F7 revealed that drug released in 2hr was 21.86%, 49.9% and 17.68% respectively whereas drug release was 52.34%, 78.01% and 48.74% respectively in 6hr. The comparative drug release data showed that the drug release was decreased as the concentration of Carbopol 971P increased further. One way ANOVA was applied on drug release profile of F1, F6 and F7, which revealed that the differences in the group are greater than would be expected by chance; there is a statistically significant difference (P=0.03).

The formulation F8 and F9 were designed to check the effect of concentration of $NaHCO_3$ on drug release. The formulation F1, F8 and F9 were contained 52.5mg (15% concentration of total weight of tablet), 35mg (10%) and 43.75mg (12.5%) of $NaHCO_3$ respectively. The formulation F1, F8 and F9 showed 21.86%, 18.87% and 21.62% drug released in first 2hr respectively whereas 52.34%, 47.87% and 52.33% drug released respectively in 6hr. Further one way ANOVA was applied on drug release profile of F1, F8 and F9, which revealed that the differences in the group are greater than would be expected by chance; there is no statistically significant difference (P=0.705). .

Since the dosage form was floating type, the matrix tablet was fixed to the sinker and used for dissolution. During the dissolution process, the dosage forms were observed for its integrity. Even after 12 hours of drug release, the tablet remained intact, though in the gel form (Figure 4, *In-vitro* Dissolution Evidences)

CONCLUSION: Metoprolol succinate is used popularly for management of hypertension. It belongs to class I category in BCS classification system freely soluble & highly permeable. On the basis of analysis of data gathered from different formulations designed in our work we concluded that crosspovidone may be used as swelling inducer in combined matrix of HPMC K 100M and Carbopol 971P which sufficiently lowered the floating lag time. Further in present work, we optimized the ratios and conditions for sustained delivery of Metoprolol Succinate from floating matrix tablet of HPMC K 100M and Carbopol 971P using Crosspovidone as swelling inducer and sodium bi carbonate as gas generating agent.

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