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Research Article

Preparation and Evaluation of Oil Entrapped Gastro-Retentive Floating Gel Beads of Metoprolol Succinate as Antihypertensive

Mohit Vijay, Dr. Garvendra Singh Rathore *, Dr. Vinesh Kumar

Lal Bahadur Shastri College of Pharmacy, Jaipur, India

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For Correspondence:

Dr. Garvendra Singh Rathore, Lal Bahadur Shastri College of Pharmacy, Jaipur, India

Abstract

The objective of this study was to manufacture gastrointestinal-retentive floating liquid beads made of Metoprolol Succinate (MS). MS is a beta blocker antihypertensive medicine that is metabolized in the liver by first-pass action, which greatly decreases its availability throughout the body. This formulation was made to make the medicine more bioavailable by making it stay in the stomach for up to 12 hours longer. There were 24 different formulas made. These were split into four groups based on the type and amount of polymers utilized, with each group having six formulations. The emulsion gelation technique was employed to create these oil-encapsulated floating medication beads. We looked at a lot of things for each of the formulations we made, such as morphology, floating behavior, drug content, and in vitro % cumulative drug release (%CDR). The physicochemical characteristics of the generated microgel beads were deemed excellent. In vitro testing also showed that each of the prepared batches had good buoyancy. The benchmark was AstraZeneca's Toprol XL 25mg. We used different model-dependent release kinetics, like zero and first order, Higuchi, and Pappas models, to compare the chosen optimal formulation (SF4) with the ordinary marketed formulation. The results showed that the equation of Korsemeyer-Peppa fit the data best for the formulation SF4 (with R2 = 0.9952). This meant that the drug release followed a non-Fickian diffusion process.

Keywords: Metoprolol succinate, gastro retentive, FDDS, Sodium alginate, model dependent release kinetics

INTRODUCTION:

The fact that uniform absorption is not exhibited by all the medications across the entire gut or gastrointestinal tract (GIT) pose a significant barrier in oral controlled delivery of these drugs. Conventional controlled oral dose formulations exhibit two key challenges i.e. the erratic emptying time from gut (GET) and brief time of gastric retention (GRT). Medication system intended for gastro retentive delivery are deviced to have extended stay time in stomach/ gut. Thereby gradually releasing their content continuously in upper jejunum and duodenum part of GIT resulting in desired persistent effect [1–3]. An extended duration of stomach residence is especially desired for the drugs that are local acting, are particularly absorbed from the upper small intestine or stomach, are highly degradable in colonic condition or are poorly soluble in acidic pH of the gut [4].

Agent blocking adrenergic receptor, Metoprolol succinate (MS) is beta1selective [5]. Multiple dosing is necessary for MS to maintain the optimal systemic concentration that leads to the desired therapeutic effect, which in turn helps improve the patient's compliance. This is due to the observed half-life of roughly 3 to 4 hours for MS, which yields just 12% oral absolute susceptibility [6]. Additionally, MS is said to be especially accepted within the jejunum and duodenum parts of the gut, where it is tightly linked to the dose that is available [7]. Also, MS is extremely soluble at all physiological pH levels, using 157 mg per ml in 5.5 pH water alongside 183 mg per ml in 1.0 pH solution comprising HCl of strength 0.1 mol per lt [8]. This indicates that it is a suitable option for developing a gastro-retentive delivery system.

There are many ways to make a good delivery system that keeps the drug in the stomach. The most common method is to utilize floating forms that are filled with medications [9]. The bulk density of these floating delivery systems (FDDS) that carry drugs is much lower than that of the fluids in the stomach. So, they stay suspended above these liquids in the gastrointestinal tract for a long time without reducing down or changing how quickly they empty. During this time, the medications are slowly released in a controlled way at the right place. After the FDDS recently released all of the medicine, the rest is eliminated along with the emptying of the stomach. Consequently, the extended retention in the gastrointestinal tract regulates the fluctuations in the desired therapeutic dose of the active drug in plasma [10].

Srivastava, A.K. et al. produced matrix tablets using sodium carboxymethyl cellulose (CMC), guar gum, and

hydroxypropyl methylcellulose (HPMC) as polymers. They did this by looking at some of the studies that had already been done on the formulation and then examination of these gastro retentive systems. They created compositions using these polymers alone and in groups. They said that the medication stayed in the stomach longer, which made it more bioavailable [11]. In a similar way, Dave et al. and Chavanpatil et al. [12,13] each made an FDDS with psyllium husk and natural gum. They used HPMC to make the gel matrix. Chowdary K.P.R. created and studied a bio adhesive technique for controlled oral release in another study.

They used different polumers i.e. Ethyl cellulose, HPMC and Sodium CMC [14]. In similar line, Varshosaz and his group [15], formulated and assayed an effervescent FDDS system using several different polymers.

The research article details the development of a new formulation of floating gastro-retentive Metoprolol Succinate (MS) gel beads, which were assessed and compared with the commercially available equivalent for their controlled release efficacy. Five distinct polymers were utilized here, each at a different concentration. The final product was a system of several MS units that looked like a bunch of gel beads that released the pharmacological agent in a regulated way. Each little, free-flowing bead was its own delivery unit that could discharge MS without stopping during the planned dosing interval. The study has successfully developed a reliable multi-unit floating delivery dose of MS, incorporating the advantages of a single-unit floating system while mitigating its disadvantages, such as adherence or obstruction in the gastrointestinal tract [16,17].

EXPERIMENTAL:

Materials:

Reine Lifescience in Bharuch, Gujarat, India, sent us a sample of metoprolol succinate as a gift. Arora & Co. in Delhi, India, sold us sodium alginate and pectin. The Central Drug House (P) Ltd. in New Delhi, India, sold us other polymers. The other compounds utilized were all of laboratory grade.

Methods:

The substance obtained was identified and characterized via UV and FTIR spectroscopy. We also used common methods from pharmacopoeias to find the loss on air drying, melting point, solubility, and partition coefficient.

The calibration graph of Metoprolol succinate with phosphate buffer solution (pH 7.4) while water:

We made standard solutions that worked of MS pure sample with concentrations between 10 and 30 µg/ml by mixing the fundamental stock solutions in phosphate buffer solution with a pH of 7.4 and absolute water. Moreover, calibration curves were employed to ascertain the concentration of MS within the microspheres [18].

Study of drug-polymer compatibility:

To find out how likely it is that the excipients employed in the formulations will react with the active drug MS, compatibility tests were done. For this, we made separate physical mixes of the medicine and other excipients in a 1:1 ratio. The possible interaction between the drug and the excipients were studied by Infra-red spectroscopy between 1000 to 3500 cm^{-1}. The samples (10 mg per vials) were kept at 50°C for 15 days and in the same quantity immediate samples were taken and both compared for the compatibility.

Preparation of Floating gel beads of Metoprolol Succinate:

Various formulations were designed using sodium alginate along with soybean oil with different concentrations of 4 other polymers. The polymers used were Pectin, Agar, Guar gum, Gelatine. Total 24 formulations were formulated which were grouped into 4 categories, each having 6 formulations, depending on the polymer types and their concentrations. All the formulations were prepared by the emulsion gelation method. In this technique, polymer is dissolved in water with stirring. Then oil is added to the resulting polymer solution with continuous agitation to form an emulsion to which then the drug is added. This obtained homogenized solution mixture is then extruded into calcium chloride solution with gentle agitation at room temperature which results in the formation of drug loaded gel beads. The formed beads were filtered, washed and dried**.** Complete formulation design for 20ml of each formulation samples (made so with distilled water quantum sufficit or Q.S.) is shown in table 1 below.

Table 1: Different Formulation Design

Polymers	**Formulation number with Polymer Concentration (ml)**					
Pectin	F1 = 0.1	F2 = 0.2	F3 = 0.3	F4 = 0.05	F5 = 0.1	F6 = 0.15
Agar	F7 = 0.1	F8 = 0.2	F9 = 0.3	F10 = 0.05	F11 = 0.1	F12 = 0.15
Guar Gum	F13 = 0.1	F14 = 0.2	F15 = 0.3	F16 = 0.05	F17 = 0.1	F18 = 0.15
Gelatine	F19 = 0.1	F20 = 0.2	F21 = 0.3	F22 = 0.05	F23 = 0.1	F24 = 0.15
Ingredients	**Concentration in each of the above 24 Formulations (ml)**					
MS	1	1	1	1	1	1
Sodium Alginate	0.9 (in F1, F7, F13, F19)	0.8 (in F2, F8, F14, F20)	0.7 (in F3, F9, F15, F21)	0.45 (in F4, F10, F16, F22)	0.4 (in F5, F11, F17, F23)	0.35 (in F6, F12, F18, F24)
Soybean Oil	3	3	3	3	3	3
Distilled water	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.

Evaluation and Characterization of Floating Gel Beads Formulations:

Study of size and morphology of emulsion gel beads:

The diameter of beads was determined by screw gauge. For this purpose, 20 dried beads were randomly selected from each batch and the mean diameter was determined by screw gauge. The least count of screw gauge was 0.005 mm. Colour and shape of dried beads of each batch was also recorded.

How long emulsion gel beads float:

We put 10 gel bead samples in a beaker in 50 ml of 0.1 N HCl solutions. The temperature was kept at 370C. For 20 hours, the beads' floating time was watched. The test fluid was only regarded to exhibit buoyancy if all of the silicone beads were floating in it [19].

To find out how much medication was in the beads, 50 mg of them were measured and mixed in pastel mortar. The crushed component was mixed with 25 cc of phosphate buffer at a pH of 7.4. The amount of the solution was increased to 50 ml by adding mortar washings. The resulting mixture was shaken for five hours with a wrist action agitation machine and then left alone for 24 hours. After then, it was filtered. We used spectroscopy at 222 nm to test the filtrate. It was possible to find out how much medicine was in the capsules and how well they worked [20].

Studies on drug release:

We used a USP Type II dissolution devices (Electolab, E80) with 900 cc in phosphate buffer (PSB) at pH 7.4 along with water in it kept at 37±0.50C and swirled at 50 rpm to study how MS calcium alginate beads dissolved. Samples were taken at regular intervals and the dissolving media was changed. We used a UV spectrophotometer (UV-1700, Pharmaspec, Shimadzu) to find out what medicine was in these samples. The release research [21] only looked at batches with a lot of good drugs. Using a standard calibration curve, we figured out the cumulative % drug release.

Swelling studies:

We looked at how beads swelled. We only chose the batches that had a lot of drug in them and worked well at trapping it. Samples about drug-loaded beads were collected, weighed, and positioned within a wired basket of USP dissolving device. II. The beaker with 100 ml in 0.1 N HCl (pH 1.2) at 37°C held the basket with the beads. At set times, the beads were taken out and weighed. Then, the swelling ratio was computed using the following formula [22].:

Swelling ratio = weight of wet beads/weight of dried beads

Further Study:

Based on the results obtained from the 24 formulations above, 4 formulations were isolated to be taken for further evaluation. These were formulation number F4, F10, F16 and F23, now denoted as selected formulae (SF). Fresh formulation of the selected formulations was prepared and evaluated for above listed parameters.

Based on the results of these selected formulations, a Final Formulation (FF) was identified to be compared with the available marketed preparation (Toprol XL 25mg by AstraZeneca that serves as a extended release formulation) for evaluation parameters (such as release kinetics, similarity factor, and difference factor.

Kinetic Modeling:

The mechanism of Metoprolol succinate release from the floating gel beads was studied by fitting the dissolution data of optimized formulation in following methods of dependent and independent models.

Model Independent Methods

Model Independent approach included estimating the difference factor (f1) and similarity factor (f2)

$$f1 = \sum(\text{Rt-Tt}) / \sum Rt \times 100$$

A corresponding factor of 50 to 100 makes sure that two products are the same, while a distinction factor of 0 to 15 makes sure that two products are just slightly different [23].

$$f_2 = 50 \times \log\left\{\left[1 + \frac{1}{n}\sum_{t=1}^{n}(R_1 - T_1)^2\right]^{-5} \times 100\right\}$$

Model dependent Methods

The model dependent approach included

Zero Order Model: Qt = Qo + Kot

First Order Model: log C = log Co – Kt/2.303

Higuchi Model: Q = KH × t ½

Korsmeyer – Peppas Model: Q/ Qo = Ktn

Where, Ko to KH were release rate constants, Q/Qo was fraction of drug released at time t, K was a constant and n was diffusion constant that indicates general operating release mechanism. For Fickian (diffusion controlled), n ≤ 0.5; for non Fickian release, 'n' value is in between 0.5 to 1.0; for zero order release, n=1; for super case transport II, n > 1.040. Based on the slope and the r2 values obtained from the above models the mechanism of drug release was decided [24].

RESULTS AND DISCUSSION:

Physical characterization of the drug:

Metoprolol succinate had been white, odourless as well as bitter flavoring with ultraviolet (UV) absorption at 222 nm. Table 2 lists different characterization results under:

Table 2: Various Physical Characteristics Observed

S.no	Properties	Standard value	Observed value
1.	Physical Appearance	White crystalline powder	White crystalline powder
2.	% Loss on drying	NMT 0.2% w/w	0.11% w/w
3.	Melting point	132-134°C	131-133°C
4.	Solubility	Determined in water, alcohol, dichloromethane, acetone, diethyl ether and heptane.	freely soluble in water, soluble in methanol, sparingly soluble in ethanol, slightly soluble in dichloromethane and 2-propanol, insoluble in ethyl acetate, acetone, diethyl ether and heptane.
5.	Partition Coefficient	1.57	1.56

Standard measurements of Metoprolol succinate (MS): The average of the three samples made in phosphate buffer pH along with water (given in table 3) was used to build a curve for calibration at 222 nm. The conventional calibration curve in Fig. 1 has regression coefficient values of 0.997 and 0.995, a slope of 0.0288, and an intercept of 0.17. In the range of concentrations of 10 to 30 µg/ml, the curve was determined to be linear.

Table 3: Absorbance for different sample concentrations both in PSB and water

Concentration (mcg/ml)	Average Absorbance	
	PSB 7.4	Water
10	0.106	0.104
15	0.264	0.265
20	0.422	0.422
25	0.559	0.561
30	679	0.671

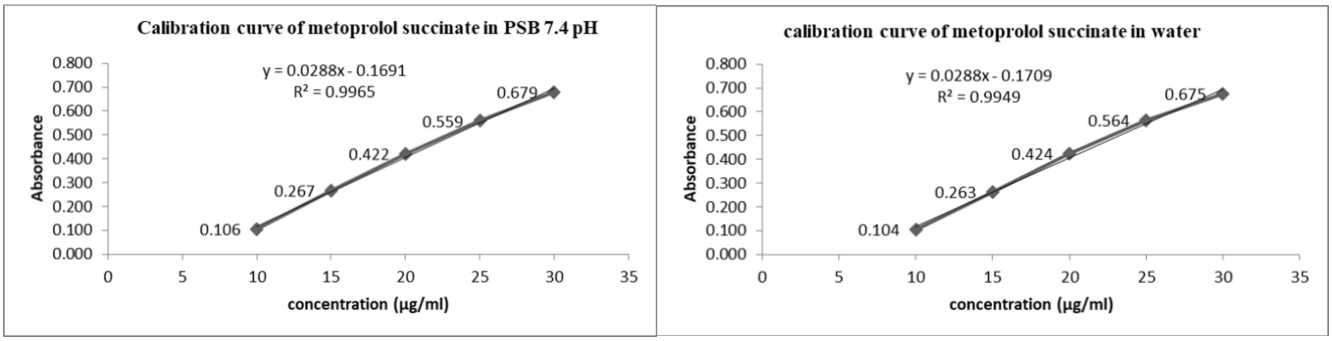

Figure 1 Standard Calibration Curve of MS

Study of drug-polymer compatibility:

We compared the FT-IR spectrum of the formulations to the FTIR spectrum of the pure medication right away and after 15 days at 500C. The peaks in the wavelengths of each formulation matched up with the peaks in the conventional pure drug spectrum. It did not demonstrate any clear interactions between the medication, MS, and different excipients. This means that the medicine works well with the other ingredients in the formulation, which means that there is no chemical reaction between the polymer components and the drug in the samples. Figures 2 to 7 show the spectra for the pure drug, the drug-excipients mixture, and the improved formulation.

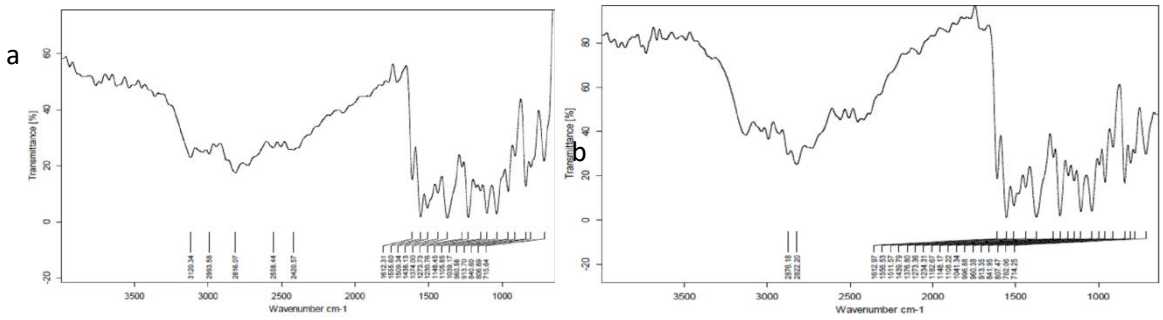

Figure 2: FTIR spectrum of Metoprolol succinate: a) Immediate b) After 15 days

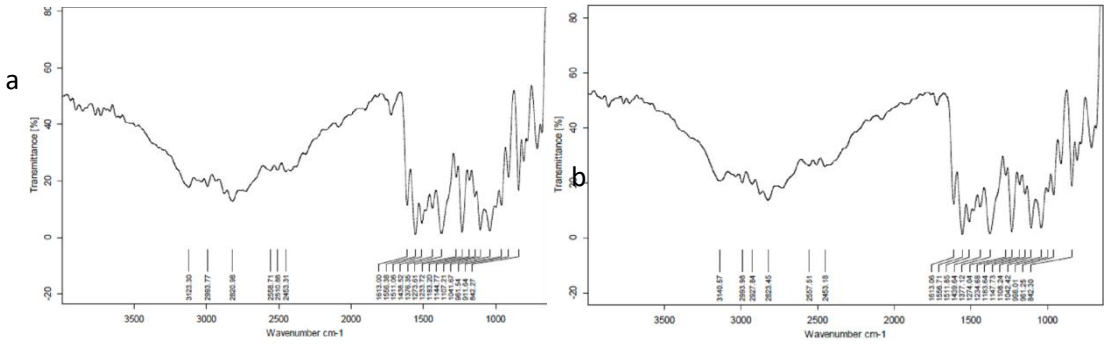

Figure 3: FTIR spectrum of Metoprolol succinate with Sodium alginate: a) Immediate b) After 15 days

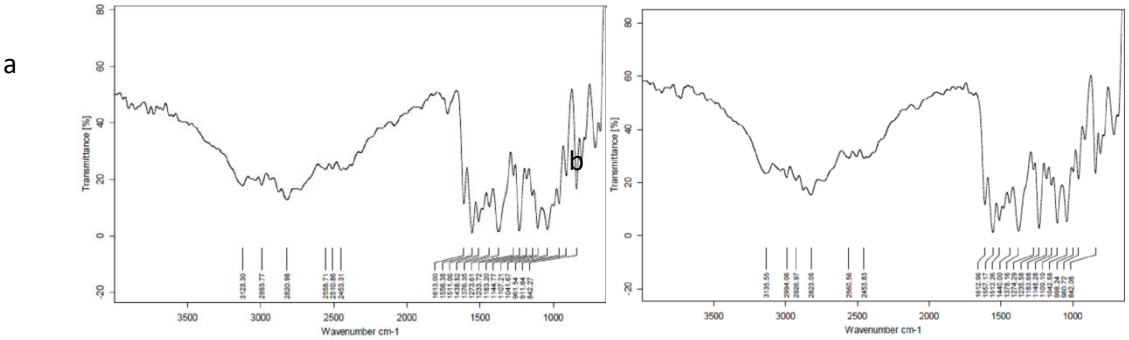

Figure 4: FTIR spectrum of Metoprolol succinate with Pectin: a) Immediate b) After 15 days

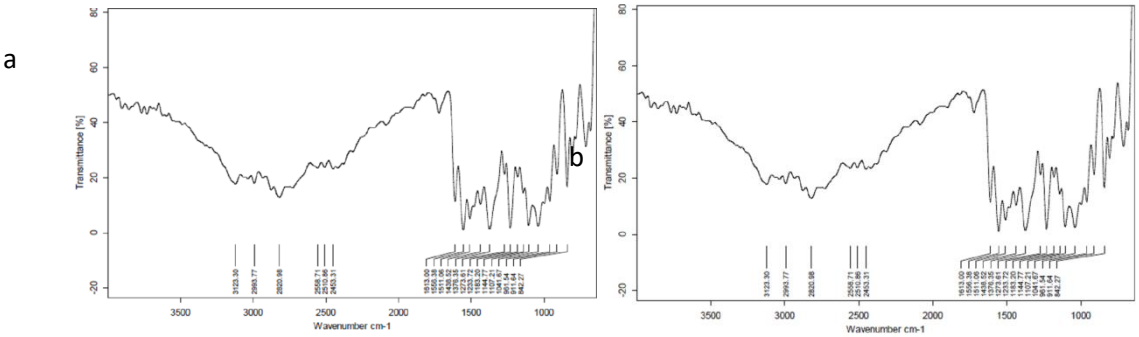

Figure 5: FTIR spectrum of Metoprolol succinate with Agar: a) Immediate b) After 15 days

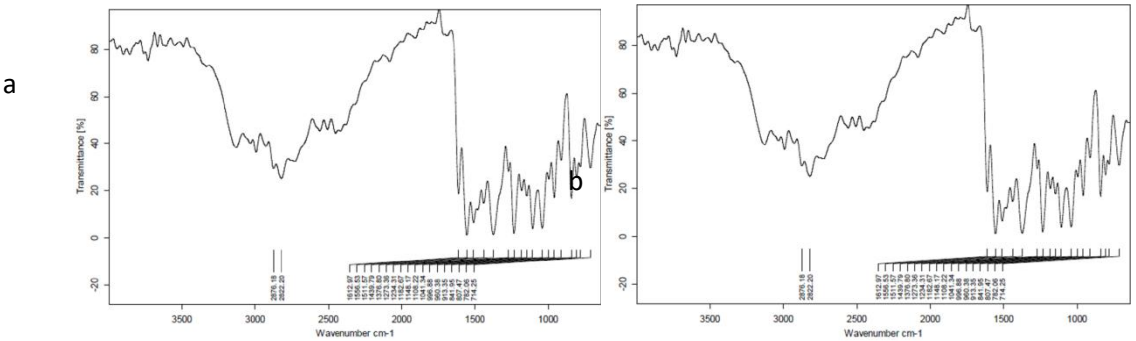

Figure 6: FTIR spectrum of Metoprolol succinate with Guar Gum: a) Immediate b) After 15 days

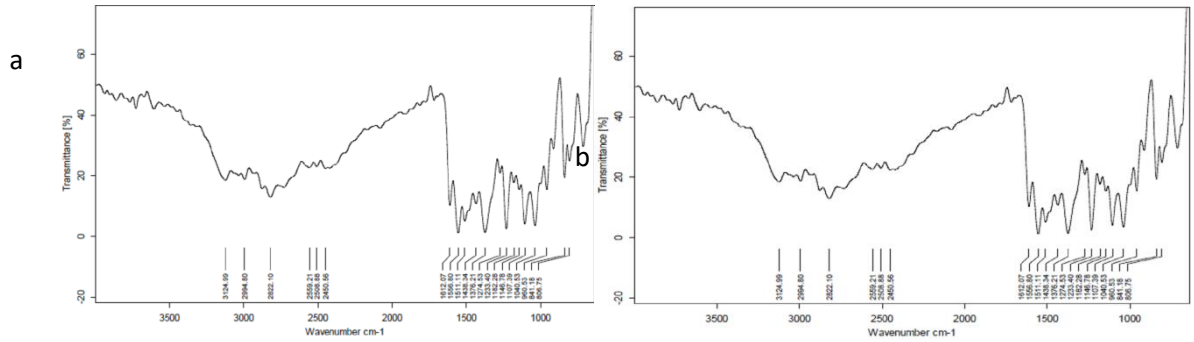

Figure 7: FTIR spectrum of Metoprolol succinate with Gelatine: a) Immediate b) After 15 days

Testing and Describing Flexible Gel Beads Formulations:

Every one of the formulations had spherical white foam beads that were all the same shape and size, ranging from 1.01 to 1.63 mm. The floating delay ranged between 1 and 130 minutes, with formulation F22 taking 1 to 2 minutes and formulation F13 taking 120 to 130 minutes. For all 24 formulations, the duration of floating duration was almost 10 hours. Formulation F4 had the most drug content, at 99.91%. All the other formulations likewise had a high score for medication content.

Drug Release in a Test Tube:

The cumulative release of drug of metoprolol succinate compound in PSB at pH 7.4 over 12 hours was 98.71%, and in water, it was 89.21% for formulation F4. This was the highest percentage among all 24 formulations. The dissolution investigation also indicated that PSB (pH 7.4) had the highest % accumulative drug release when compared to water.

This information led to the conclusion that the formulations F4, F10, F16, and F23 could be the best ones to explore further because they have the right Flag. Table 4 and Figure 8 demonstrate the comparison Cumulative Release profile of MS coming from those formulations over the course of 15 minutes to 12 hours.

Table 4: Comparative Cumulative Release profile of MS in Selected Formulations (SF)

Time(min.)	Cumulative Drug Release (%)			
	SF4	SF10	SF16	SF23
15	5.71	4.96	5.69	3.11
30	8.33	8.16	9.16	6.32
45	11.83	12.44	12.05	11.52
60	13.65	14.96	14.56	14.09
90	17.28	18.36	18.29	18.21
120	22.72	23.87	23.48	24.95
150	28.17	28.76	29.55	30.41
180	34.83	35.71	35.12	35.26
240	41.35	42.22	40.89	40.84
300	47.07	48.52	48.50	48.69
360	55.07	56.01	56.93	55.27
480	71.14	70.42	70.16	69.43
600	86.07	83.64	83.56	83.17
720	98.71	95.16	96.05	96.46

Swelling ratio:

The swelling ratio was recorded at different time points i.e. 0, 20, 40, 60, 80, 100, 120, 140, 160, 180 minutes. All the observations were taken and arranged in a plot to get an idea about the trend of swelling ratio with respect to time. F4 was found to have highest value of swelling ratio i.e. 1.37% among the 24 formulations. Results of swelling index are mentioned in table 5 and plot of % swelling index versus time (min) is depicted in Fig 9. Based on all the above observations, formulations F4, F10, F16, F23 were considered as selected formulation for further study.

Table 5: Swelling Index of the Selected Formulations at different times

	Time (min.)									
Batch code	0	20	40	60	80	100	120	140	160	180
SF4	0	1.28	1.25	1.23	1.23	1.24	1.24	1.24	1.24	1.24
SF10	0	1.17	1.15	1.16	1.15	1.15	1.15	1.15	1.15	1.15
SF16	0	1.19	1.15	1.15	1.14	1.18	1.18	1.18	1.18	1.18
SF23	0	1.13	1.12	1.12	1.12	1.12	1.12	1.12	1.11	1.11

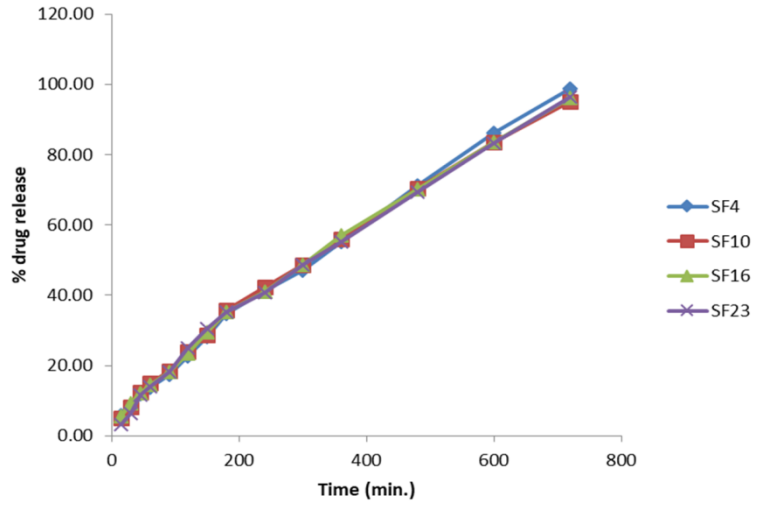

Figure 8: Comparative Release profile trend of metoprolol succinate from selected formulations

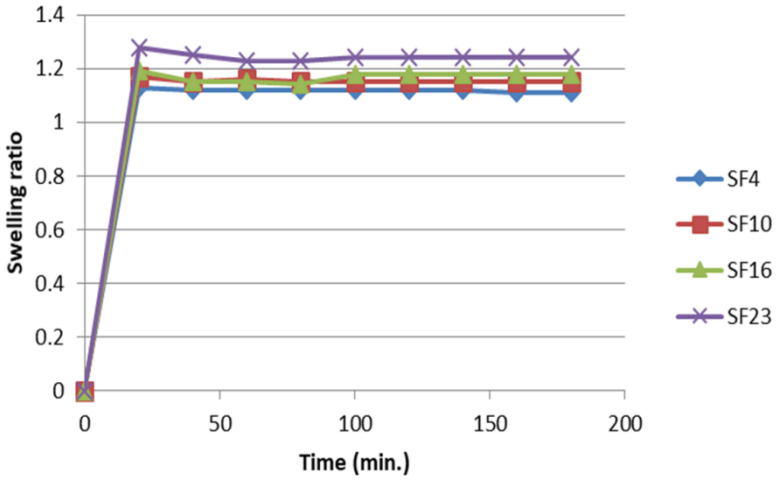

Figure 9: Swelling index versus time (min) of metoprolol succinate from selected formulations

A side-by-side analysis of the final formulations and Toprol XL:

The formulation that was sold had a medication concentration of 99.07%, which is quite good. The medicine was 91.12% eliminated in 12 hours, which implies that the formulation's release is stable. Figure 10 shows the plot of total percentage of drug release vs. time for the chosen final form (FF) and Toprol XL (MF).

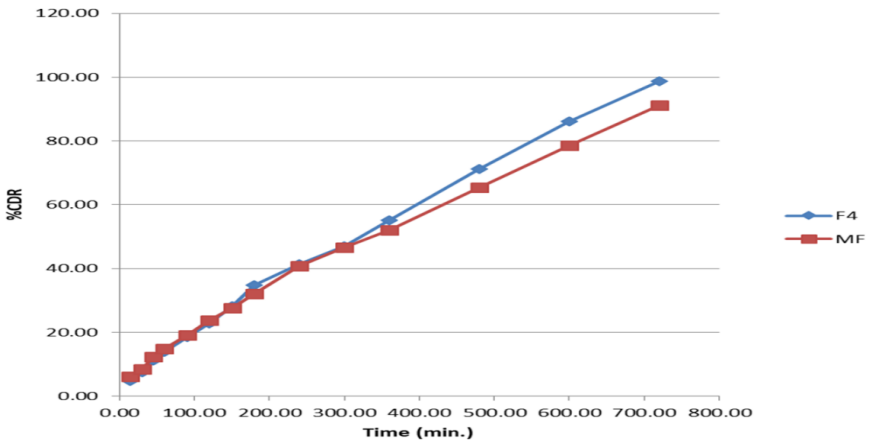

Figure 10: Cumulative percent drug release v/s time for FF and Toprol XL

In Vitro Drug Release Mathematical Kinetics Study Models:

Model Independent Methods

The Similarity factor result was found to be 51.09 for 15 min to 12 hrs. Thus it complies with the standard value. While Difference factor were found to be 2.17, less than 15.

Model dependent Methods

The data obtained from in vitro dissolution studies were fitted to zero-order, first-order, Higuchi, and Korsemeyer-Peppas equations. The dissolution data obtained were plotted as time versus cumulative % drug released for zero order kinetics, as time versus log cumulative % drug remaining for First order release kinetics, as square root of time versus cumulative % drug released for Higuchi model, and as log time versus log cumulative % drug released for Korsemeyer-Peppas model kinetics. The Release Kinetics of Final Formulation (FF) and the marketed formulation (MF) are compiled in table 6 and 7 under. The plot has been shown in figure 11 (for zero order kinetics), figure 12 (for first order kinetics), figure 13 (for Higuchi model) and in figure 14 (for Peppas model kinetics).

Table 6: Release Kinetics of Final Formulation (FF) and the marketed formulation (MF)

Time	Sq. rt time		Log time		%cdr		log % cdr		log % cdr remaining	
	FF	MF	FF	MF	FF	MF	FF	MF	FF	MF
15	3.8730	3.8730	1.1761	1.1761	5.71	6.23	0.7566	0.7947	1.9745	1.9720
30	5.4772	5.4772	1.4771	1.4771	8.33	8.47	0.9208	0.9277	1.9622	1.9616
45	6.7082	6.7082	1.6532	1.6532	11.83	12.24	1.0730	1.0878	1.9453	1.9433
60	7.7460	7.7460	1.7782	1.7782	13.65	14.86	1.1350	1.1719	1.9363	1.9302
90	9.4868	9.4868	1.9542	1.9542	17.28	19.04	1.2375	1.2796	1.9176	1.9083
120	10.9545	10.9545	2.0792	2.0792	22.72	23.71	1.3565	1.3749	1.8880	1.8825
150	12.2474	12.2474	2.1761	2.1761	28.17	27.56	1.4498	1.4403	1.8563	1.8600
180	13.4164	13.4164	2.2553	2.2553	34.83	32.02	1.5420	1.5054	1.8140	1.8324
240	15.4919	15.4919	2.3802	2.3802	41.35	40.78	1.6165	1.6104	1.7682	1.7725
300	17.3205	17.3205	2.4771	2.4771	47.07	46.62	1.6727	1.6686	1.7237	1.7274
360	18.9737	18.9737	2.5563	2.5563	55.07	52.03	1.7409	1.7163	1.6525	1.6809
480	21.9089	21.9089	2.6812	2.6812	71.14	65.35	1.8521	1.8152	1.4603	1.5397
600	24.4949	24.4949	2.7782	2.7782	86.07	78.56	1.9348	1.8952	1.1440	1.3311
720	26.8328	26.8328	2.8573	2.8573	98.71	91.12	1.9944	1.9596	0.1096	0.9484

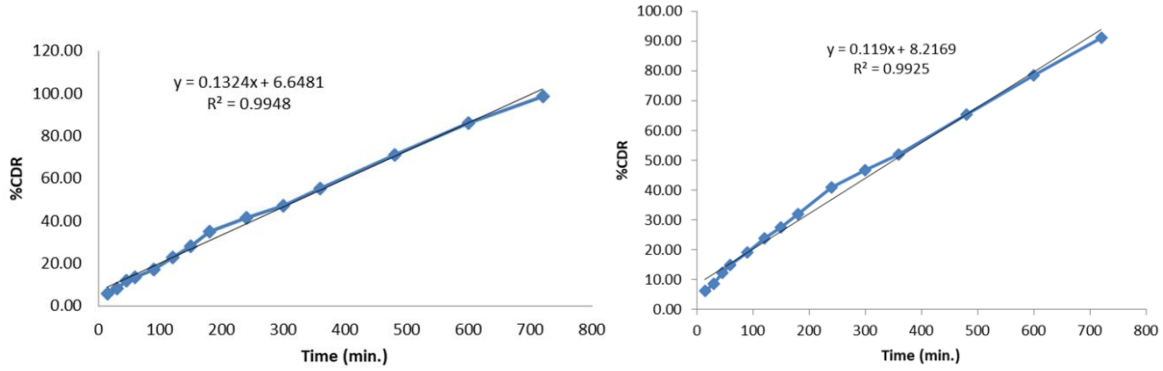

Figure 11: Zero Order Kinetic Graph of: a) FF b) MF

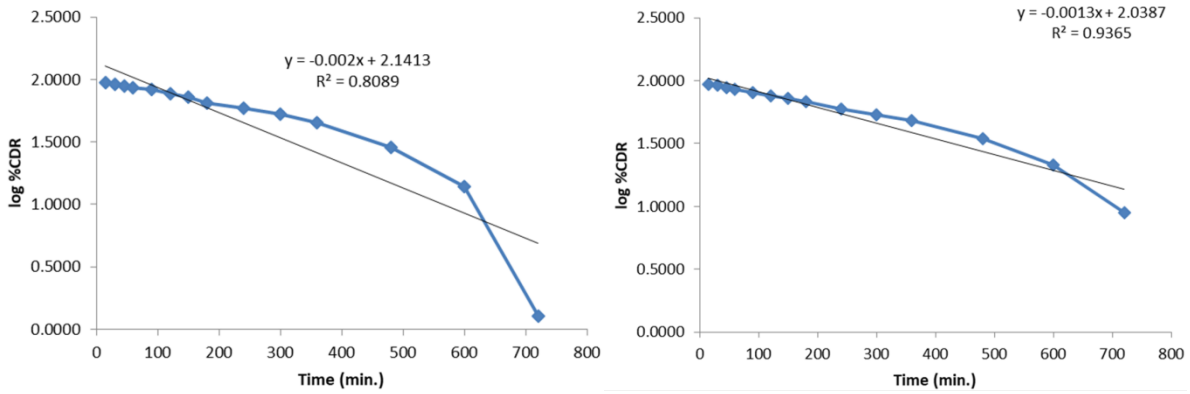

Figure 12: First Order Kinetic Graph of: a) FF b) MF

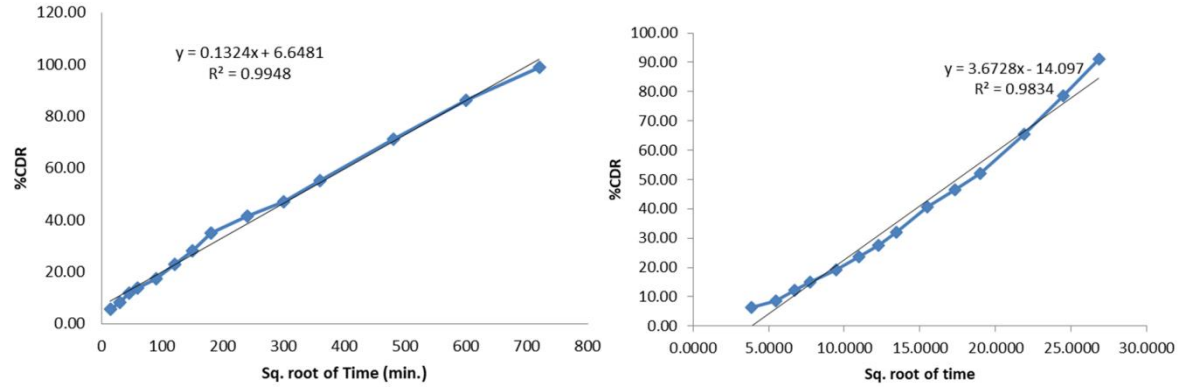

Figure 13: Higuchi equation Kinetic Graph of: a) FF b) MF

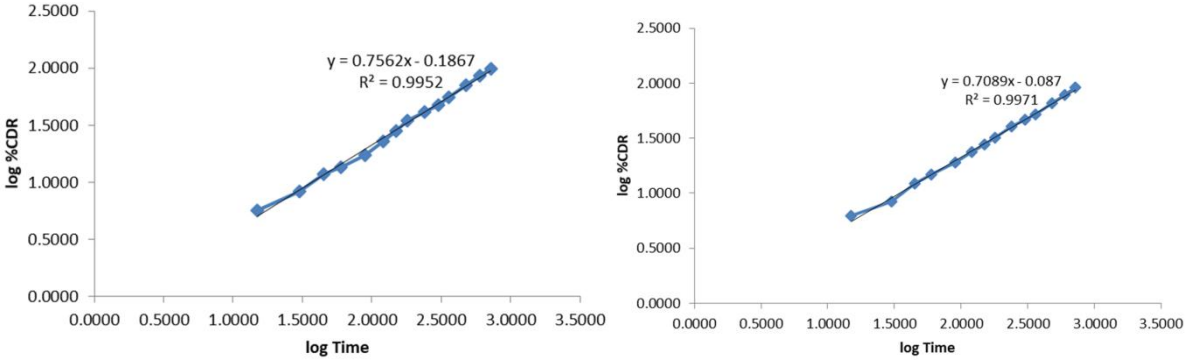

Figure 14: Korsmeyer peppas equation Kinetic Graph of: a) FF b) MF

Table 7: R^2 values of different models for FF and MF

Formulation	Model	R^2 value
Final	Zero order	0.994
	First order	0.808
	Higuchi equation	0.994
	Korsmeyer Peppas	0.995
Marketed	Zero order	0.992
	First order	0.936
	Higuchi equation	0.983
	Korsmeyer Peppas	0.997

R^2 i.e the determination coefficient indicates the best fitting among all the kinetic models that are considered in these kind of study. Here, in present study it was with the Peppas kinetic model, that highest coefficient of determination value (R^2 = 0.9952) was achieved for the formulations. Thus adherence to this kinetic model thereby suggested the conclusion that drug release mechanism followed diffusion which also has been reported as competent to gel based systems.

CONCLUSION:

The study aimed to enhance the oral bioavailability of metoprolol succinate by regulating and prolonging the release of the drug dosage. It made a remarkable effort in creating the floating gel particles as a component of FDDS. Additionally, it was determined to be consistent with the research profile of Toprol- XL, the commercially available extended-release version of MS. The experimental results of the FT-IR investigation indicate that there is no substantial shift in the absorbance peaks of the suspensions compared to the pure drug, hence confirming the medication's stability in gel beads. sodium alginate, cellulose, pectin, agar, guar gum, and gelatin are some of the polymers that can be used to make floating gel beads that are said to be biocompatible. All the formulations with the right amount of polymer showed the most medication release in 12 hours. As the percentages of polymers went up, the % accumulated release of MS went down a lot. The total number curve fitting into different mathematical models was determined to be good. The Final formulation (SF4) aligned most closely with the Peppas model, demonstrating the process of drug release and highlighting the role of diffusion in sustained drug release. So, the floating gel beads that were made could be a good option for an oral gastro retentive regulated delivery system for drugs since they keep the drug in the stomach longer and make it more available than other drug delivery systems. Moreover, additional stability tests may be conducted in conjunction with in vivo experiments to substantiate the notion.

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