Available online at www.scholarsresearchlibrary.com

Scholars Research Library

Der Pharmacia Lettre, 2016, 8 (14):12-22
(http://scholarsresearchlibrary.com/archive.html)

Scholars Research Library
ISSN 0975-5071
USA CODEN: DPLEB4

Formulation and Development of Stomach Specific Drug Delivery of Triprolidine Hydrochloride by Using Floating Alginate Beads

*** Darekar A. B.[1], Zope G. L.[1] and Saudagar R. B.[2]**

[1]*Department of Pharmaceutics, R. G. Sapkal College of Pharmacy, Anjaneri, Nashik-422213, Maharashtra, India*
[2]*Department of Pharmaceutical Chemistry, R. G. Sapkal College of Pharmacy, Anjaneri, Nashik-422213, Maharashtra, India*

ABSTRACT

Floating beads have been utilized to obtain prolonged and uniform release of drug in the stomach for development of once- daily formulation. The objective of this investigation was to develop intragastric floating drug delivery system of Triprolidine hydrochloride and also attempts were made to sustain the release of Triprolidine hydrochloride. Floating alginate beads of Triprolidine hydrochloride were prepared from sodium alginate solution containing gellan gum, methyl cellulose and corn oil by using ionotropic gelation method. These beads were evaluated for drug content, entrapment efficiency, floating duration, swelling index and in- vitro drug release. The floating time of beads was found excellent and they remain float for 12 hrs and also shows release characteristics for 12 hrs. Formulation F7 batch showed highest drug content, drug release and scanning electron microscopy revealed that the beads were spherical in shape with rough surface. The result demonstrated that oil entrapped gel beads can be used as floating drug delivery system for local as well as systemic drug delivery.

Key words: Floating drug delivery, Ionotropic gelation method, Triprolidine hydrochloride, Drug release, Drug entrapment efficiency

---

INTRODUCTION

Stomach Specific FDDS have a bulk density less than gastric fluids and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. While the system is floating on the gastric contents, the drug is released slowly at the desired rate from the system. After release of drug, the residual system is emptied from the stomach. This results in an increased GRT and a better control of fluctuations in plasma drug concentration. The floating sustained release dosage forms present most of the characteristics of hydrophilic matrices and are known as 'hydrodynamically balanced systems' ('HBS') since they are able to maintain their low apparent density ,while the polymer hydrates and builds a gelled barrier at the outer surface. The drug is released progressively from the swollen matrix, as in the case of conventional hydrophilic matrices. These forms are expected to remain buoyant (3- 4 hours) on the gastric contents without affecting the intrinsic rate of emptying because their bulk density is lower than that of the gastric contents. Among the different hydrocolloids recommended for floating formulations, cellulose ether polymers are most popular, especially hydroxypropylmethyl cellulose (HPMC). Fatty material with a bulk density lower than one may be added to the formulation to decrease the water intake rate and increase buoyancy.[1, 2] Gastric emptying of pharmaceuticals is highly variable and is dependent on the dosage form and the fed/fasted state of the stomach. Normal gastric residence times usually range between 5 mints and 2 hrs. In the fasted state the electrical activity in the stomach, the interdigestive myoelectric cycle or migrating myoelectric complex (MMC) governs the activity and, hence, the transit of dosage forms. [3, 4]

Oral administration is the most convenient and preferred means of any drug delivery to the systematic circulation.

Oral controlled release drug delivery have recently been of increasing interest in pharmaceutical field to achieve improved therapeutic advantages, such as ease of dosing administration, patient compliance and flexibility in formulation. Drugs that are easily absorbed from gastrointestinal tract (GIT) and have short half-lives are eliminated quickly from the systemic circulation. Frequent dosing of these drugs is required to achieve suitable therapeutic activity. To avoid this limitation, the development of oral sustained-controlled release formulations is an attempt to release the drug slowly into the gastrointestinal tract (GIT) and maintain an effective drug concentration in the systemic circulation for a long time. After oral administration, such a drug delivery would be retained in the stomach and release the drug in a controlled manner, so that the drug could be supplied continuously to its absorption sites in the gastrointestinal tract (GIT) These drug delivery systems suffer from mainly two adversities: the short gastric retention time (GRT) and unpredictable short gastric emptying time (GET), which can result in incomplete drug release from the dosage form in the absorption zone (stomach or upper part of small intestine) leading to diminished efficacy of administered dose. To formulate a site-specific orally administered controlled release dosage form, it is desirable to achieve a prolong gastric residence time by the drug delivery. Prolonged gastric retention improves bioavailability, increases the duration of drug release, reduces drug waste, and improves the drug solubility that are less soluble in a high pH environment . Also prolonged gastric retention time (GRT)in the stomach could be advantageous for local action in the upper part of the small intestine. [5]

MATERIALS AND METHODS

Materials

Triprolidine hydrochloride was obtained as a gift sample from Glenmark Pharmaceuticals Ltd. Nashik, Sodium alginate, Gellan gum, Methyl cellulose were obtained as gift sample from Research lab fine chem Industries, Mumbai; corn oil was purchased from Deve Herbs, New Delhi. The other chemicals and reagents used in the study were of analytical grade.

Methods

Ionotropic gelation method[6]

Ionotropic gelation technique was used to prepare the Triprolidine alginate sustained release beads. Nine different batches of beads were tried.

Following is the procedure for preparation of floating alginate beads:-

Step 1: Sodium alginate was dissolved in deionized water with continuous stirring.

Step 2: Then add different concentrations of gellan gum and methyl cellulose in the sodium alginate solution and stirred well.

Step 3: Accurately weighed 10 mg quantity of Triprolidine was uniformly dispersed in Polymer solution by using mechanical stirrer at 100rpm.

Step 4: Bubble free dispersion was dropped into 100ml of aqueous calcium chloride solution through a syringe with a needle of size no. 21 and stirred at 100rpm.

Step 5: After stirring for 15min the formed beads were separated by filtration, washed with distilled water and dried at RT for 24 hours.

Table 1: Formulation composition for floating alginate beads

Formulation code Ingredient(%)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Triprolidine Hydrochloride (mg)	10	10	10	10	10	10	10	10	10
Sodium alginate (%) (mg)	3	3	3	3	3	3	3	3	3
Gellan gum (%)	-	-	-	1	2	3	1	2	3
Methyl cellulose (%)	1	2	3	-	-	-	1	2	3
Corn oil (%)	20	20	20	20	20	20	20	20	20
Waterq.s. (ml)	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5

Evaluation of floating alginate beads

Percentage Yield[7]

The practical percentage yield was calculated from the weight of dried microcapsules recovered from each batch in relation to the sum of the initial weight of starting materials. The percentage yield was calculated using the following formula;

$$\text{Percentage Yield} = \frac{\text{Total mass of beads}}{\text{Total mass of raw materials}} \times 100$$

Measurement of micromeritic properties of floating beads[8]

The flow properties were investigated by measuring the angle of repose of drug loaded floating beads using fixed-base cone method. The height and diameter of the cone was measured and angle of repose was calculated by using the following formula. Each experiment was carried out in triplicate,

$$\tan\theta = \frac{h}{r}$$

Where, h is cone height and r is radius of circular base formed by the beads on the ground.

The bulk and tapped densities were measured in a 10ml graduated cylinder as a measure of pack ability of the floating beads. The sample contained in the measuring cylinder was tapped mechanically by means of constant velocity rotating cam. The initial bulk volume and final tapped volume were noted from which, their respective densities were calculated. Cylinder was tapped mechanically by means of constant velocity rotating cam. The initial bulk volume and final tapped volume were noted from which, their respective densities were calculated.

$$\text{Bulk density } (\rho_0) = \frac{M}{V_0}$$

$$\text{Tapped density } (\rho_0) = \frac{M}{V_t}$$

Hausner ratio of floating beads was determined by comparing the tapped density to the bulk density by using the equation

$$\text{Hausner ratio} = \frac{\text{Bulk}}{\text{Tapped}}$$

Cars index of floating beads was determined by using equation

$$\%\text{compressibility} = \text{Tapped} - \text{Bulk}/\text{Tapped} * 100$$

Swelling index [9]

Swell ability of the floating beads was determined by allowing the microcapsules to swell in the 0.1 N HCl. 10 mg of accurately weighed floating beads were immersed in little excess of 0.1 N HCl for 24 hours and washed thoroughly with deionized water and blotted with filter paper to remove excess surface liquid. The % swelling was arrived at using the following formula;

$$\text{Swelling Index} = Ws - Wo / Wo$$

Where,

Wo is the weight of beads before swelling and Ws is the weight of before after swelling.

Determination of drug content and drug entrapment efficiency [10]

50mg of beads were weight and crushed in a pastel mortar and the crushed material was dissolved in 100 ml of 0.1 N HCl. Stirred for 2 hrs. Then it was filtered. The filtered was assayed using UV-spectrophotometer (V-630, Shimadzu Co Ltd., Japan) at 289 nm after suitable dilution with 0.1N HCl. Percent drug content was determined using formula:

$$\%\ \text{Drug Content} = \frac{\text{Actual drug content}}{\text{Total drug amount taken}} \times 100$$

$$\%\text{Drug entrapment efficiency} = \frac{\text{Actual drug content}}{\text{Theoretical drug content}} \times 100$$

***In-vitro* floating duration [11]**

The *in-vitro* floating study was determined using USP dissolution apparatus II having 900 ml of Hydrochloric acid (pH1.2). The medium temperature was kept at 37^0C. The beads were placed in flask filled with 900 ml 0.1 N HCl solution. The floating time was observed for 12 hrs. The preparation was considered to have buoyancy in the test solution only when all the beads floated in it.

Floating lag time [11]
The floating lag time is defined as time taken by the beads to reach the top from bottom of the dissolution flask. The floating lag time is determined by visual inspectionUSP (Type II) dissolution test apparatus containing 900 ml of 0.1N Hydrochloric acid at 37^0C.

Surface characterization (SEM) [12]
Surface characterization of beads were examined with Scanning Electron Microscopy (SEM Diya laboratory Mumbai) beads were mounted on metal grids using double- sided tape and coated with gold under vaccum.

Determination of particle size determination [12]
Particle size determination by using optical microscope. The reason for this broad range particle size due to use in different concentration of drug and polymer, curing time of formulation also effect the particle size.

***In-vitro* drug release study[13]**
The release of Triprolidine Hydrochloride sustained release Floating beads was determined by using USP dissolution apparatus II. The dissolution medium used 900 ml of 0.1N Hydrochloric acid, and temperature was maintained at 37^0C and stirred at 50 rpm. A sample (5ml) of solution was withdrawn from the dissolution apparatus at 0min, 1hr, 2hrs, 3hrs, 4hrs, 5hrs,6hrs, 7hrs, 8hrs, 9hrs, 10hrs , 11hrs, 12hrsof dissolution. The samples were filtered through Whatmann filter paper and analyzed using UV method. Cumulative % of drug release was calculated and observed.

Best fit kinetic model for Optimized formulations [14]
The data obtained from study of diffusion kinetics of the optimized formulation was studied to obtain the best fit model. The best fitted model is the one which gives the highest R^2 value and least slope value.

Stability Studies [15]
Stability study of formulation which gave maximum dissolution rate was carried out to point out any visual physical or chemical change made in the formulation after storing it at elevated temperature and humidity conditions. The optimized formulation was store in amber colour bottle and stored at 40^0C ± 2^0C and 75% ± 5% RH for sixmonth. Floating alginate beads was analyzed for the drug content and drug release.

RESULT AND DISCUSSION

Appearance:
The developed formulation metal the prerequisite to become floating beads system, beads was floated instantaneously at the pH condition of stomach.

Fig 1. Formulated beads in floating condition

Percentage Yield
The percentage yield of prepared floating beads was found in ranges 30% to 64%.

Table 2. Result of percentage yield of prepared Floating alginate beads

Sr. no.	Batch code	Percentage yield
1	F1	40
2	F2	41.23
3	F3	41.51
4	F4	30.52
5	F5	35.01
6	F6	39.53
7	F7	63.57
8	F8	48.91
9	F9	58.55

Measurement of micromeritic properties of beads

Angle of repose, Bulk density, Tapped density &Hausner ratio

Beads were subjected for measurement of angle of repose by using fixed base cone method and results of test obtained are shown in table 19. Angle of repose value between 15- 25^0 and below indicates excellent flow property of the beads i.e. less or no interparticulate friction or resistance to movement between particles. From the Hausner ratio data it shows in the range of 1.0- 1.23 which concludes that it has good flow properties. Each value represents mean ± SD of three determinations.

Table 3: Micromeritic properties of beads

Sr. no.	Batch code	Angle of repose (θ ± SD)	Bulk density (gm/ml) ± S.D.	Tapped density (gm/ml) ± S.D.	Compressibilty Index (%)± S.D.	Hausner ratio ± S.D.
1	F1	21.80± 0.0024	0.1277± 0.0049	0.1379 ±0.0024	5.48 ±0.19	1.01 ±0.017
2	F2	18.77 ±0.0030	0.1308 ±0.0014	0.1355 ±0.0015	3.35 ±0.78	1.03 ±0.01
3	F3	19.79 ±0.0021	0.1270 ±0.0018	0.1291 ±0.0015	1.62 ±0.98	1.01 ±0.011
4	F4	19.79 ±0.0016	0.1398 ±0.0015	0.1451 ±0.0012	3.65 ±0.97	1.03 ±0.002
5	F5	18.77 ±0.0021	0.1312 ±0.0013	0.1358 ±0.0015	3.38 ±0.99	1.032 ±0.011
6	F6	19.90 ±0.0018	0.1275 ±0.0010	0.1303 ±0.0018	3.26 ±0.70	1.02 ±0.005
7	F7	17.74 ±0.0011	0.1341 ±0.0013	0.1475 ±0.0015	9.08 ±0.55	1.07 ±0.011
8	F8	18.77 ±0.0015	0.1435 ±0.0024	0.1478 ±0.0025	2.90 ±0.69	1.04 ±0.005
9	F9	18.26 ±0.0018	0.1508 ±0.0024	0.1552 ±0.0012	2.83 ±0.75	1.02 ±0.005

Degree of swelling

The swelling study of prepared floating beads was carried out in 0.1 N HCl. The results are presented in Table 4. The swelling of floating beads depends upon the concentration of polymers used. As the concentration increases, the swelling index increases.

Table 4: Swelling Index of floating beads

Sr. no.	Batch code	Swelling Index (%)
1	F1	31
2	F2	35
3	F3	50
4	F4	62
5	F5	75
6	F6	80
7	F7	95
8	F8	82
9	F9	90

Drug entrapment efficiency and Drug content

The drug entrapment efficiency of the sustained release beads was also studied and the values were found and given in Table 5. The maximum drug entrapment was found to be in F7 batch i.e. 98.13 ±0.15. Each value represents mean ± SD of three determinations

Table 5: Drug content and Drug Entrapment efficiency

Sr. no.	Batch code	Drug entrapment efficiency (%)	Drug content (%)
1	F1	91.7 ±0.17	91.7±0.27
2	F2	93.5 ±0.52	93.50±0.78
3	F3	92.5 ±0.20	92.58±0.35
4	F4	93.5±0.25	93.56±0.18
5	F5	94.9 ±0.15	94.94±0.17
6	F6	95.6±0.18	95.64±0.22
7	F7	98.1 ±0.12	98.13±0.15
8	F8	97.6±0.20	97.68±0.19
9	F9	96.7±0.19	96.7±0.25

In vitro floating duration

The in vitro floating study was determining dosing USP dissolution apparatus II having 900 ml of Hydrochloric acid (pH1.2). The medium temperature was kept at 37^0C. The beads were placed in flask filled with 900 ml 0.1 N HCl solution. The time the formulation to ok to emerge on theme dictum surface (floating lag time) and the time the formulation constantly floated on the dissolution medium surface (duration of floating) were note.

Table 6: Floating duration of formulation

Sr.No.	Batch	Floating time
1	F1	>12 hrs
2	F2	>12 hrs
3	F3	>12 hrs
4	F4	>12 hrs
5	F5	>12 hrs
6	F6	>12 hrs
7	F7	>12 hrs
8	F8	>12 hrs
9	F9	>12 hrs

Floating lag time

The floating lag time is defined as time taken by the beads to reach the top from bottom of the dissolution flask. The floating lag time is determined by visual inspection a USP (Type II) dissolution test apparatus containing 900 ml of 0.1N Hydrochloric acid at 37^0C.

Table 7: Floating lag time of formulation

Sr. No.	Batch	Lag time
1	F1	3 min
2	F2	3.5min
3	F3	7 min
4	F4	4.15 min
5	F5	4 min
6	F6	3 min
7	F7	2 min
8	F8	2.5 min
9	F9	4 min

Surface characterization

Surface characterization of beads were examined with Scanning Electron Microscopy (SEM Diya laboratory Mumbai) beads were mounted on metal grids using double- sided tape and coated with gold under vacuum.

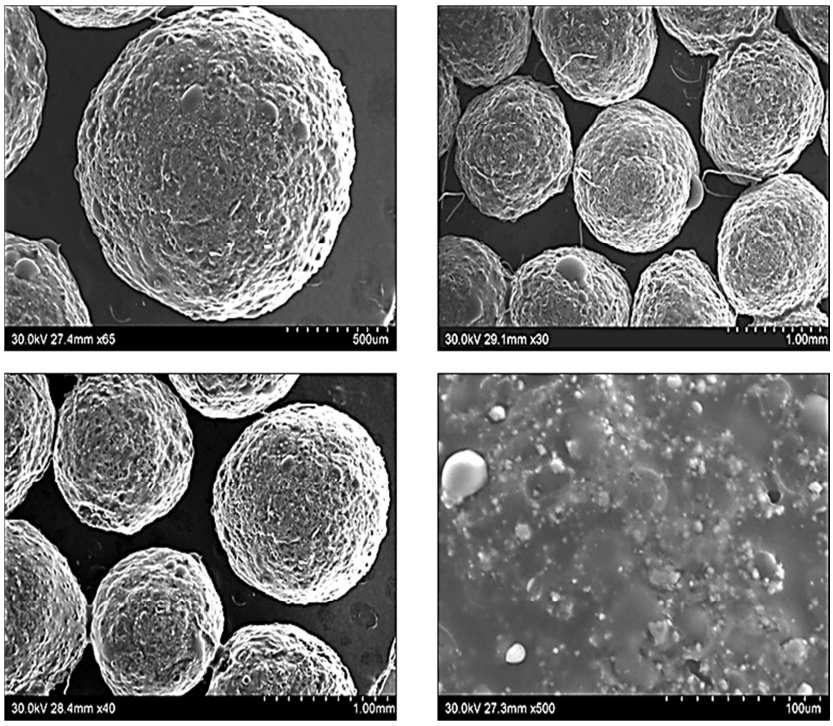

Fig.2: SEM study of floating alginate beads

The SEM photographs of beads show that beads are spherical shape with uniform texture and rough surface. The beads size in between 500 µm- 1mm. The SEM of floating alginates beads reveals that the beads are almost spherical and the matrix showed densely populated corn oil droplets, which provide floating property.

Particle size determination

The particle size of beads was determined by the dry state using the optical microscopy method.

Table 8: Particle size of formulation (n=3)

Sr.No.	Batch	Particle size (mm)
1	F1	1.28±0.010
2	F2	1.24±0.017
3	F3	1.41±0.015
4	F4	1.45±0.010
5	F5	1.35±0.015
6	F6	1.31± 0.007
7	F7	1.20± 0.026
8	F8	1.10± 0.027
9	F9	1.40±0.020

In-vitro release studies

The dissolution of sustained release beads was carried out. The results are shown in table 9. The study concludes that by increasing the concentration of polymer gives more sustaining effect.

Table 9: Dissolution rate of sustained release beads formulations

Time in hrs	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	**0**	0	0
1 hr	4.63± 0.007	5.2± 0.012	4.00± 0.008	6.33± 0.004	7.0± 0.024	6.22± 0.015	**9.0 ± 0.005**	7.4 ± 0.010	7.5 ± 0.014
2 hr	9.69± 0.012	12.6± 0.011	8.13± 0.004	14.1± 0.007	17.5± 0.020	11.70± 0.09	**16.1± 0.007**	14.2± 0.025	13.8± 0.008
3 hr	16.82± 0.018	18.9± 0.004	13.5± 0.007	18.7± 0.020	24.1± 0.014	18.95± 0.007	**25.2± 0.008**	19.0± 0.004	23.4± 0.008
4 hr	23.67± 0.011	28.1± 0.015	21.3± 0.009	23.4± 0.07	30.7± 0.005	26.69± 0.009	**34.0± 0.004**	30.7± 0.007	29.5± 0.015
5 hr	33.48± 0.023	35.3± 0.011	29.9± 0.005	29.5± 0.008	38.6± 0.015	36.62± 0.07	**43.9± 0.009**	39.0± 0.009	38.3± 0.010
6 hr	41.83± 0.008	41.6± 0.016	37.9± 0.010	40.0± 0.006	45.3± 0.014	44.24± 0.006	**51.7± 0.015**	46.5± 0.012	45.5± 0.009
7 hr	48.30± 0.022	50.1± 0.004	44.8± 0.004	46.1± 0.023	51.8± 0.018	52.04± 0.005	**58.4± 0.007**	55.4± 0.014	53.3± 0.005
8 hr	57.50± 0.009	58.5± 0.009	50.3± 0.020	52.2± 0.012	56.2± 0.022	58.83± 0.002	**67.0± 0.005**	62.5± 0.006	61.6± 0.020
9 hr	68.95± 0.019	65.9± 0.005	57.6± 0.07	59.9± 0.017	63.0± 0.016	65.35± 0.0010	**74.2± 0.005**	68.7± 0.013	68.4± 0.007
10 hr	74.92± 0.015	72.3± 0.007	63.7± 0.004	69.91± 0.016	68.0± 0.012	71.91± 0.005	**81.2± 0.006**	74.± 0.016	75.0± 0.010
11 hr	81.61 ±0.010	79.2± 0.019	71.3± 0.016	74.34± 0.018	73.9± 0.020	78.61± 0.010	**87.5± 0.004**	79.9± 0.020	79.0± 0.011
12 hr	85.57± 0.005	86.9± 0.010	79.3± 0.015	77.68± 0.007	80.7± 0.012	83.87± 0.004	**96.6± 0.009**	89.8± 0.017	87.3± 0.014

Maximum drug release shown by F7 batch. The data also suggests that beads are capable to produce line are drug release for longer period of time. Drug release profile of formulation F1 to F9 shown in Fig. 3 Dissolution profile of formulation F1 to F9 signified an extended drug release. Out of nine formulations maximum release after 12 hrs was found for F7 formulation.

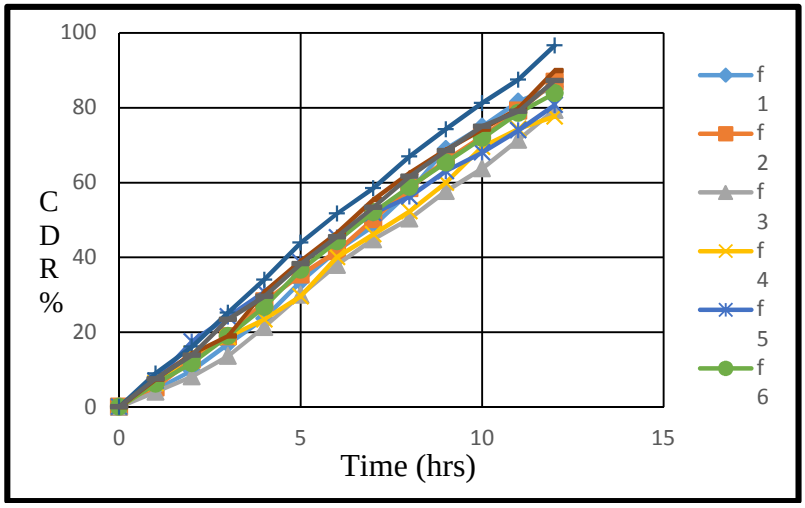

Fig.3: Drug release profile of all formulation F1-F9

DATA ANALYSIS

In order to investigate the mode of release from In-Stiegel data were analyzed with following mathematical model.

A. Zero-order kinetic

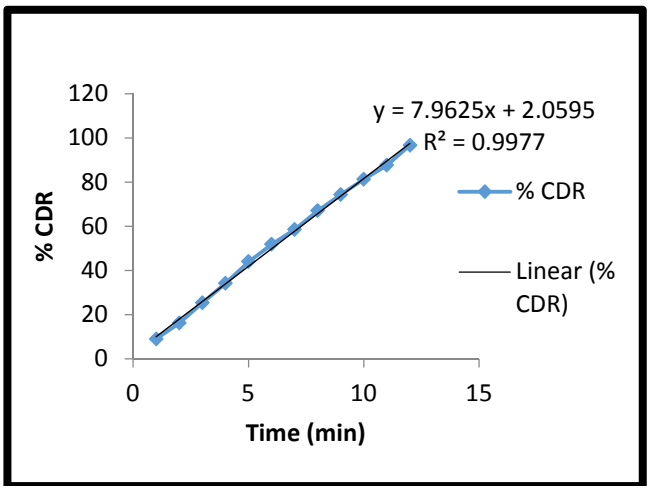

Fig.4: Zero order kinetic of formulation F7 batch

B. First-order kinetic

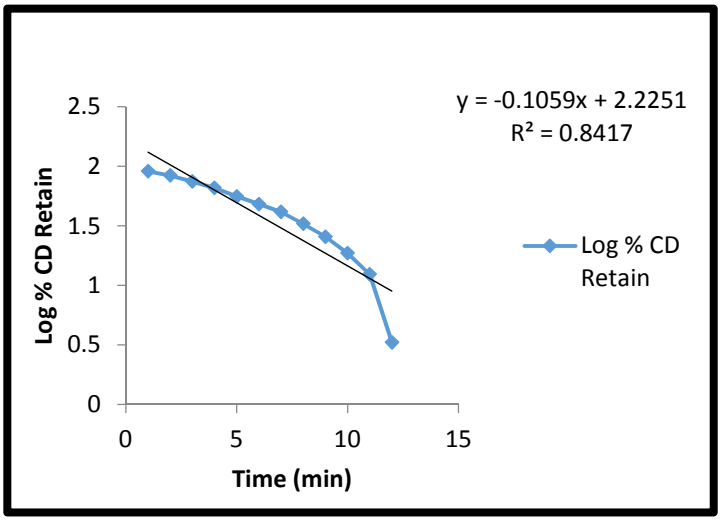

Fig.5: First order kinetic of formulation F7 batch

C. Higuchi equation

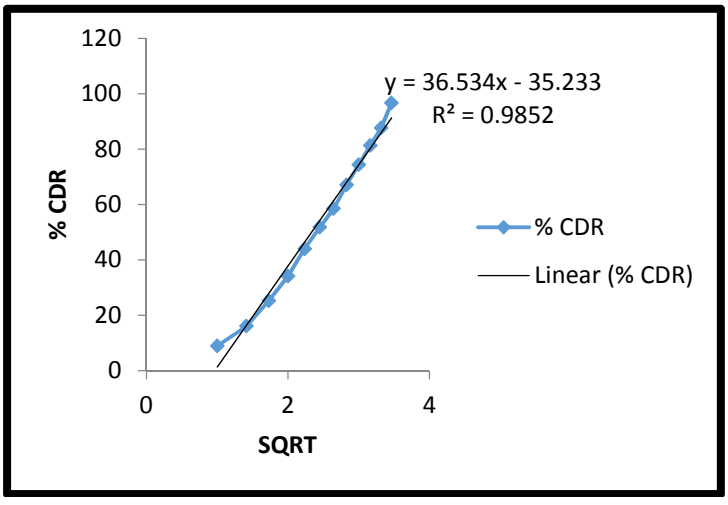

Fig.6: Higuchi Connors model of formulation F7 batch

D. Korsemayer-peppas equation

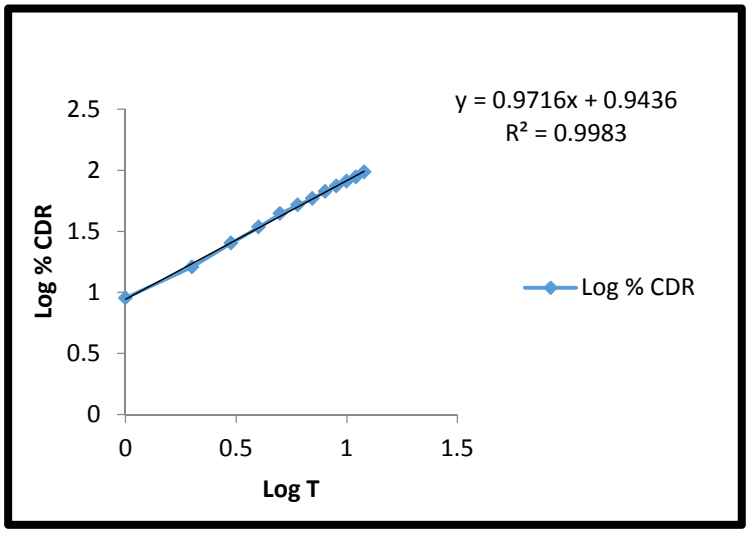

Fig.7: Korsemayer-peppas equation of formulation F7 batch

Table10: Drug release by using different models for F7 batch

Batch	Kinetic Model				
	Zero order	First order	Higuchi	Korsemayer-Peppas	
F7	R^2	R^2	R^2	R^2	n
	0.9977	0.8417	0.9852	0.9983	0.9716

The classical zero order release curve was found to be linear. The curves plotted according to first order and Higuchi model were also found to be linear. For the Korsemeyer-Peppas release curves R^2 was found to be ≥ 0.75 for all 9 formulations and n value was found to be ≥ 0.5 which indicates that all the formulations show anomalous (Non-Fiction release i.e. swell able matrix). The drug release occurs probably by diffusion and erosion and dissolution. From the above tables it is seen that the best fit model for formulation is Zero order kinetic, such type of model is applicable when sustained release dissolution mechanism are seen. The n values for all formulations are greater than 0.5 indicating anomalous or non-fiction diffusion

Data treatment

Drug release kinetic data of different formulation (F1-F9) are shown in Table 11.

Table11: The drug release kinetics data of different formulation (F1-F9)

Formulation Code	Zero order	First order	Higuchi connors	Korsemayer-peppas
	R^2	R^2	R^2	R^2
F1	0.9952	0.9474	0.9680	0.9975
F2	0.9993	0.9364	0.9774	0.9978
F3	0.9976	0.9512	0.9690	0.9959
F4	0.9944	0.9591	0.9644	0.9945
F5	0.9944	0.9723	0.9920	0.9910
F6	0.9965	0.9644	0.9817	0.9966
F7	0.9977	0.8417	0.9852	0.9983
F8	0.9949	0.9264	0.981045	0.9946
F9	0.9970	0.9504	0.9836	0.9979

STABILITY STUDIES:

The samples were withdrawn after 1, 3 and 6months and subjected to following tests as shown in Table 12.

Table12: Stability study

Test	Before	After		
	0 month	1 month	3 months	6 months
Drug content	98.13 ±0.15	98.13 ±0.10	98.12 ±0.10	98.12 ±0.015
Drug release	96.6± 0.009	96.6± 0.008	96.5± 0.009	96.5± 0.008
Floating lag time	2 min	2 min	2.03 min	2.03 min

CONCLUSION

Sodium alginate, gellan gum, methyl cellulose and corn oil is selected for preparation of Floating alginate beads. The identity of Triprolidine hydrochloride was confirmed by physical characteristics, spectrophotometric analysis such as UV Spectrophotometer, IR studies. The ionotropic gelation method was successfully utilized for formulation of floating alginate beads of Triprolidine hydrochloride. The adopted method for estimation of Triprolidine hydrochloride showed good linearity. The Floating alginate beads containing Triprolidine hydrochloride was prepared. The drug and polymers ratio are significant formulation factors which affected drug entrapment efficiency and sustained release of drug from beads. The effect of various process and formulation variables on Triprolidine hydrochloride was studied. The formulated floating beads have shown higher percentage of drug content, entrapment efficiency, floating lag time, floating duration, and % drug release in 0.1N Hydrochloric acid for 12 hrs. The concentration of gellan gum and methyl cellulose had significant impact on floating lag time. After the evaluation parameter of floating alginate beads, optimized formulation (F7) was selected because of better drug content, and sustained release of the drug. Optimized formulation (F7) was evaluated for stability study, floating lag time, floating duration, swelling study. The SEM of floating alginates beads reveals that the beads are almost spherical and the matrix showed densely populated corn oil droplets, which provide floating property. The rheological parameters like angle of repose and bulk density reflects better flow ability of floating alginate beads. Formulated floating beads of Triprolidine hydrochloride showed good swelling behavior. The optimized formulation showed best fit in Zero order kinetic.

CONCLUSION

Preformulation study of drug and polymer was done. Compatibility study between drug and polymers was done by IR studies and it was found that there is no chemical interaction between drug and polymers. Preparations of stomach specific floating beads by using polymers were done successfully. The sustained release study of prepared stomach specific floating beads of Triprolidine hydrochloride was done by *in- vitro* drug release. The evaluation study of prepared stomach specific floating beads of Triprolidine hydrochloride were done by using various parameters. Optimization study using 3^2 full factorial designs was done. The Stability study of prepared stomach specific floating beads was done. No significant change was observed in present drug release before and after stability studies carried out for 06 months of optimized batch (F7).The techniques employed were practically simple economic and can commercially exploited. From the present study we can conclude that this drug Triprolidine hydrochloride could be successfully formulated as floating beads.

REFERENCES

[1] SS Hardenia, A Jain, R Patel, A Kaushal, *Asian Journal of Pharmacy and Life science*, **2011**, 1, 3, 284- 293.
[2] LH Reddy, RH Murthy, *Crit. Rev. Ther. Drug Carr. Sys*,**2002**,19, 6, 553-585.
[3] Rajak P, *International Journal of Pharmacy and Pharmaceutical Science*,**2011**, 3, 4, 9- 16.
[4] RM Chandira, D Bhowmik, CB Jayakar,*International Journal of Pharmacy and Pharmaceutical Sciences*, **2010**, 2, 1, 53-65.
[5] A K Nayak, R M a j i , B D a s , *AsianJournalofPharmaceuticalandClinicalResearch*,**2010**,3, 1, 2-9.
[6] S Shashank, R Verma, VJ Negi, BS Chaudhary, A Verma, M Kumar, *Research Journal of Pharmaceutical, Biological and Chemical Sciences*, **2013**, 4, 2, 530-536
[7] 7)SMalviya,JPandepy, S Dwivedi, *International Journal of Pharmacy and Life Sciences*,**2013**, 4, 8, 2876-2884
[8] AR Dhole, PD Gaikwad, VH Bankar,SPPawar,*International Journal of Pharmaceutical Sciences Review and Research*, **2011**, 8, 2, 124-128
[9] M Yadav, D Chaudhary, B Shrivastava,*International Journal of Pharmaceutical Research and Bio-science*,**2014**, 3, 5, 114- 131.
[10] PNimase, G Vidyasagar,*Pelagia Research Library*, **2010**, 1, 1, 29-35
[11] MQ Ghareeb, Z Radhi, *International Journal of Pharmacy and Pharmaceutical Sciences*, **2014**, 6, 2, 456-460
[12] DA Khan, M Bajpai,*International Journal of Pharm Tech research*,**2011**, 3, 3, 1537-1546.
[13] RBera, B Mandal, M Bhowmik,HBera, S Dey, G Nandi, LK Ghosh,*Sci Pharm*, **2009**, 77, 669- 678.
[14] PMDandag,NDhople, AP Gadad, CK Pandey,VSMasthiholomath, *International Journal of Pharmaceutical Sciences and Nanotechnology*, **2003**, 6, 2269-2280
[15] RA Fursule, CH Patra, GB Patil, SB Kosalge, *International Journal of ChemTech Research*, **2009**, 1, 2, 162-167