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FORMULATION AND EVALUATION OF BEADS OF DICYCLOMINE HYDROCHLORIDE FOR GASTRORETENTIVE DRUG DELIVERY SYSTEM

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Abstract

Formulation of The main objective of this research work was to design, prepare and *in-vitro* evaluation of floating gastro retentive drug delivery system of dicyclomine hydrochloride. Sodium Alginate, Sodium Bicarbonate, Hydroxypropyl methylcellulose (HPMC) along with some other excipients. Floating gastro retentive drug delivery system alginate beads were prepared by the ionotropic gelation method and coded the formulations as F1 to F13 and F2 to F12 depending on the ratios of modified excipients. The beads are formed was stirred with a magnetic stirrer for ten minutes, to improve the mechanical strength of the beads and it was allowed to complete the reaction to produce gas inside the alginate beads. The formulated beads were filtered and washed with distilled water. The washed beads are then dried. The designed beads were subjected to various assessment parameters i.e. hardness test, friability test, drug content consistency and *In vitro* dissolution tests. The results obtained in this research work clearly showed a promising potential of gastroretentive drug delivery system of dicyclomine hydrochloride beads containing a specific ratio of HPMC. Sodium Bicarbonate and Sodium Alginate as a release rate controlling polymers for effective treatment of irritable bowel syndrome.

Keywords: GRDDS, Floating Drug Delivery System, Sustained Release Drug Delivery, Dicyclomine hydrochloride.

Introduction

The main goal of any drug delivery system is to achieve desired concentration of the drug in blood or tissue, which is nontoxic and therapeutically effective for a prolonged period [1]**.** An ideal dose regimen in the drug

therapy of any disease is the one which immediately attains the desired therapeutic concentration of the drug in plasma (or at the site of action) and maintain it constant for the entire duration of treatment [2,3].

The most important objectives of these new drug delivery systems are:

First, it would be single dose, which releases the active ingredient over an extended period of time. Second, it should deliver the active drug entity directly to the site of action, and minimizing or eliminating side effects. To overcome the limitations of conventional drug delivery system, gastro retentive drug delivery system have been developed [4]. Delayed gastric emptying promotes dissolution of the drugs, which are poorly soluble drugs and for the drugs that is majorly absorbed from stomach or proximal part of intestine [5]. Floating drug delivery systems with low density provide sufficient buoyancy to float over the gastric content. Floating drug delivery systems (FDDS) or hydro-dynamically balanced systems have a bulk density lower than gastric fluids and thus remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. It Improve the bioavailability and therapeutic efficacy of the drugs. [6]

Material and Method

Drug: Dicyclomine Hydrochloride [7].

Dicyclomine hydrochloride is a synthetic tertiary amine antispasmodic also known as dicycloverine hydrochloride, is an anticholinergic that blocks muscarinic receptors.

Preformulation Study

The following preformulation studies were carried out.

- **Identification**
- **Organoleptic property**
- **Melting point**
- **Loss of drying**
- **pH**
- **Analytical process development**
- **Solubility analysis**
- **Partition coefficient**
- **Drug excipient interaction study**

FTIR Study (Identification) [8]

The Infrared (IR) spectroscopy of the sample was carried out to ascertain identity of the drugs.

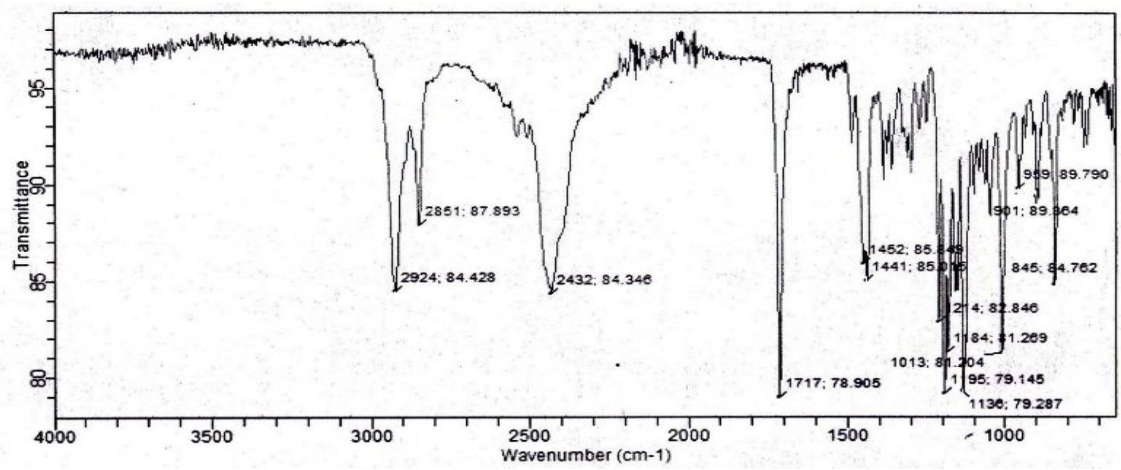


Fig.1: FTIR spectra of dicyclomine hydrochloride.

Table 1: Interpretation of FTIR spectra of drug [9, 10].

S. No.	Reported Peaks(cm-1)	Observed Peak (cm-1)	Inference
1	1250-1020	1136	C-N stretching
2	1300-1000	1184	C-O stretching
3	3000-2840	2924	C-H stretching
4	1725-1700	1717	C=O (ester)stretching

Organoleptic Properties of the Drug

Color: White

Odour: Odourless

Taste: Characteristic

MELTING POINT

Melting point of the drug dicyclomine hydrochloride was determined by capillary method using digital melting point apparatus (Labindia).

The average melting point found to be **173.6^0 C**

Table 2: Melting point data of dicyclomine hydrochloride

Channel No	M.P	Average
1.	**173**	
2.	**174**	**173.6**
3.	**174**	

LOSS ON DRYING (LOD)

1.0 g of the drug was weighed accurately. It was placed in oven at 105^{o}c for 4 hours, the drug was again weighed. Loss on drying was found to be less than 0.5%.

pH

It gives an indication of the nature of the drug, whether acidic or basic. Dissolve 0.5 gm in water and dilute to 50ml. The pH was determined with digital pH meter. The pH of drug was found to be **5.2.**

Analytical process Development

UV Scanning for λ max detection

To determine the wavelength of maximum absorbance (λmax) of dicyclomine hydrochloride for developing the analytical procedure for its spectrophotometric determinations, a solution of suitable concentration of the drug in water was scanned under the wavelength 200-400 nm in a UV-Visible Spectrophotometer using appropriate blank. The scanning diagram is given in Figure 2. The λmax was found to be 215 nm, which was used for spectrophotometric determination of dicyclomine hydrochloride in test samples.

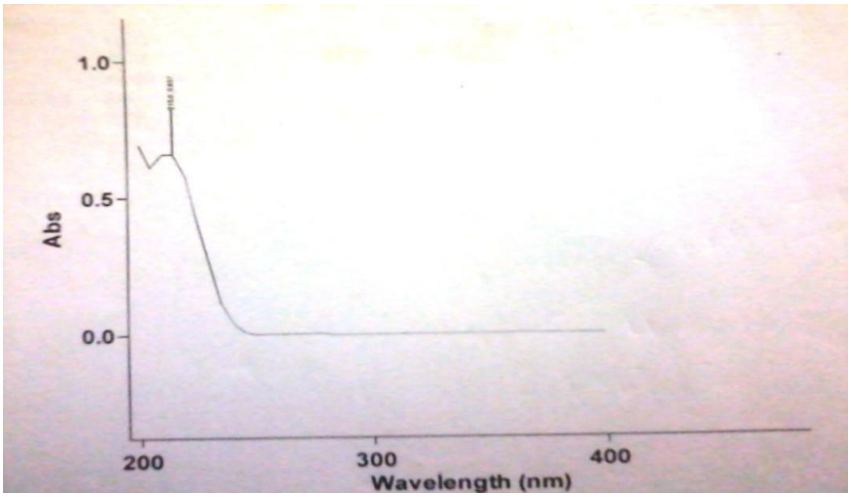


Fig.2: UV Scanning for λ max.

Preparation of Calibration Curve

For quick and accurate analysis of dicyclomine hydrochloride by spectrophotometric method at the determined λmax, an operating calibration curve or standard curve was prepared. A series of standard samples were prepared by using distilled water and 0.1N hcl of pH 1.2. The different concentration of drug taken and corresponding absorbance are plotted. The corresponding standard curve generated by linear regression analysis along with the mathematical equation representing the curve is given Figure.

Dicyclomine Hydrochloride in Distilled Water

Weigh accurately 100mg of dicyclomine hydrochloride was taken in a 100ml volumetric flask; sufficient amount of distilled water was added to make up the volume up to the mark (stock solution). 10 ml of stock solution was pipette out and transferred into another 100ml volumetric flask, then made up the volume up to the mark with distilled water. From that standard solution 1ml, 2ml, 4ml, 6ml, 8ml, and 10ml were withdrawn individually and in each case the volume was made up to 10ml. The absorbance of these solutions was measured spectrophotometrically at a suitable wavelength. The observed absorbance was plotted against concentration.

Table 3: Concentration Absorbance relationship of dicyclomine hydrochloride at 215 nm.

S.NO	Concentration (µg/ml)	Absorbance
1	10	0.049
2	20	0.1154
3	30	0.1725
4	40	0.2175
5	50	0.3298
6	60	0.3699
7	70	0.4383
8	80	0.4846
9	90	0.5488
10	100	0.6297

Fig. 3: Standard calibration curve of dicyclomine hydrochloride in distilled water.

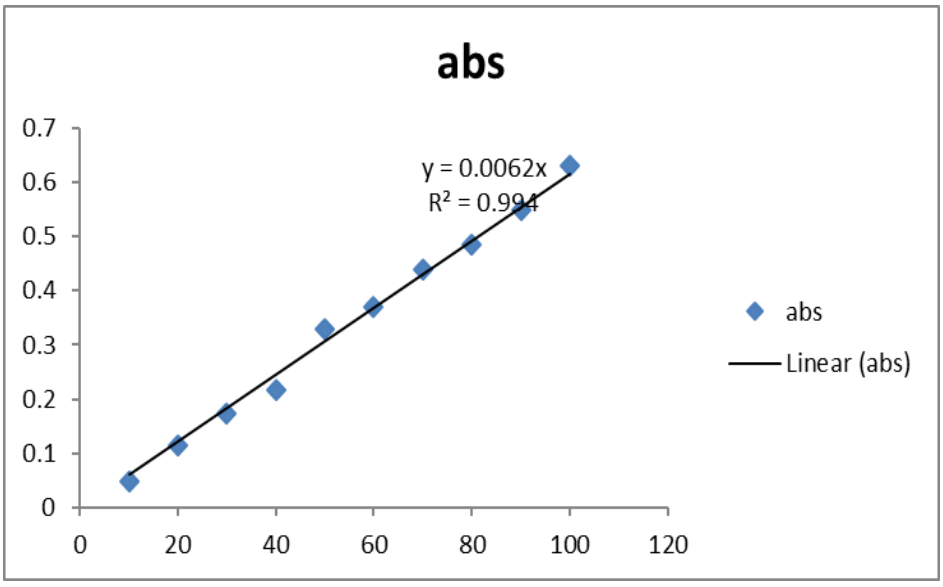


Table 4: Characteristic of calibration curves of dicyclomine.

S. No.	Parameters	Values
1.	λ_{max} (nm)	215
2.	Beer's law limit (µg/ml)	10 – 100
3.	Regression equation	y =0.006x
4.	Slope	0.006
5.	Correlation coefficient	0.994

Dicyclomine Hcl in 0.1N Hydrochloric Acid:

Measure accurately 8.5 ml of concentrated hydrochloric acid was taken in a 1000ml volumetric flask with the help of 10ml measuring cylinder. Sufficient amount of distilled water was added to make up the volume up to the mark. Weigh accurately 100mg of ciprofloxacin hydrochloride was taken in a 100ml volumetric flask; sufficient amount of prepared 0.1(N) HCl was added to make up the volume up to the mark (stock solution). 10 ml of stock solution was pipette out and transferred into another 100ml volumetric flask, then made up the volume up to the mark with0.1 (N) HCl (Standard solution). From that standard solution 1ml, 2ml, 4ml, 6ml, 8ml, and 10ml were withdrawn individually and in each case the volume was made up to 10ml. The absorbance of these solutions was measured spectrophotometrically at a suitable wavelength. The observed absorbance was plotted against concentration.

Table 5: Concentration- Absorbance Relationship of dicyclomine hydrochloride at 215 nm.

S.NO	Concentration (µg/ml)	Absorbance
1	10	0.0080
2	20	0.0173
3	30	0.0322
4	40	0..0529
5	50	0.0688
6	60	0.0744
7	70	0.0889
8	80	0.0950
9	90	0.1002
10	100	0.1221

Fig. 4: Standard calibration curve of dicyclomine hydrochloride in HCl.

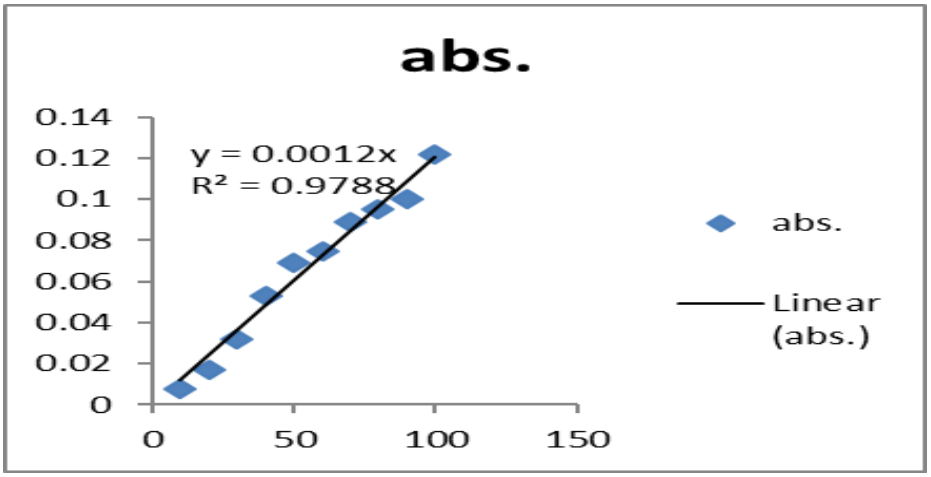


Table 6: Characteristic of calibration curves of dicyclomine hydrochloride.

S. No.	Parameters	Values
1.	λ_{max} (nm)	215
2.	Beer's law limit (µg/ml)	10 – 100
3.	Regression equation	y =0.001x
4.	Slope	0.001
5.	Correlation coefficient	0.978

Solubility Analysis

Solubility of dicyclomine hydrochloride was found in deferent solutions. It is a major step before development of a dosage form. Solubility determination of a drug is important because the first step of the drug in the body to come in the solution.

Solubility determine in deferent solvent by equilibrium method.

Table 7: Solubility of drug in various solvent.

Solvent	Solubility (mg/ml)
Water	39.233
Chloroform	34.366
0.1 N HCl	12.168

Partition Coefficient ($P_{O/W}$)

Partition Coefficient of the drug was determined by taking 20 mg drug in 40 ml mixture of n-octanol and water (20 ml each), in a 100 ml volumetric flask. The flask kept on Rotary flask shaker for 24 hours to equilibrate.

After which the two layers were separated using a separating funnel. After appropriate dilution, the aqueous phase was analyzed for dicyclomine hydrochloride against reagent blank solution on U.V. Spectrophotometer at λ_{max} 215 nm. Partition Coefficient was determined using the following formula.

Po/w = Concentration of drug in octanol / concentration of drug in water.

FTIR Study (drug +Excipient)

FT-IR study was carried out to identify any possible drug-polymer interaction. The peaks of pure drug and pure individual polymers were compared to the mixtures of the same and any significant shifting of the band was noted as the sign of interaction.

Fig. 5: FTIR spectra of dicyclomine hydrochloride with sod. Alginate.

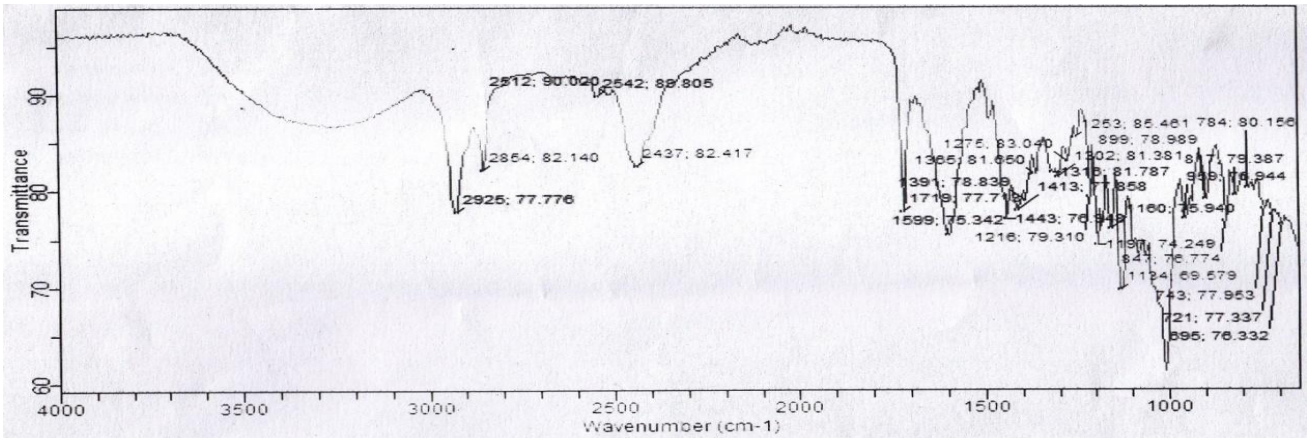


Fig. 6: FTIR spectra of dicyclomine hydrochloride with HPMC

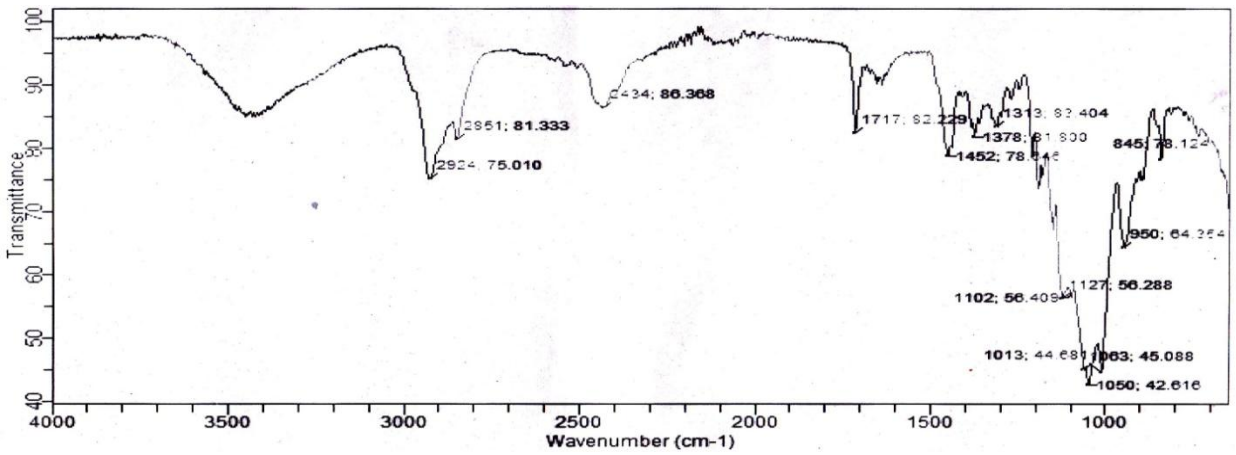
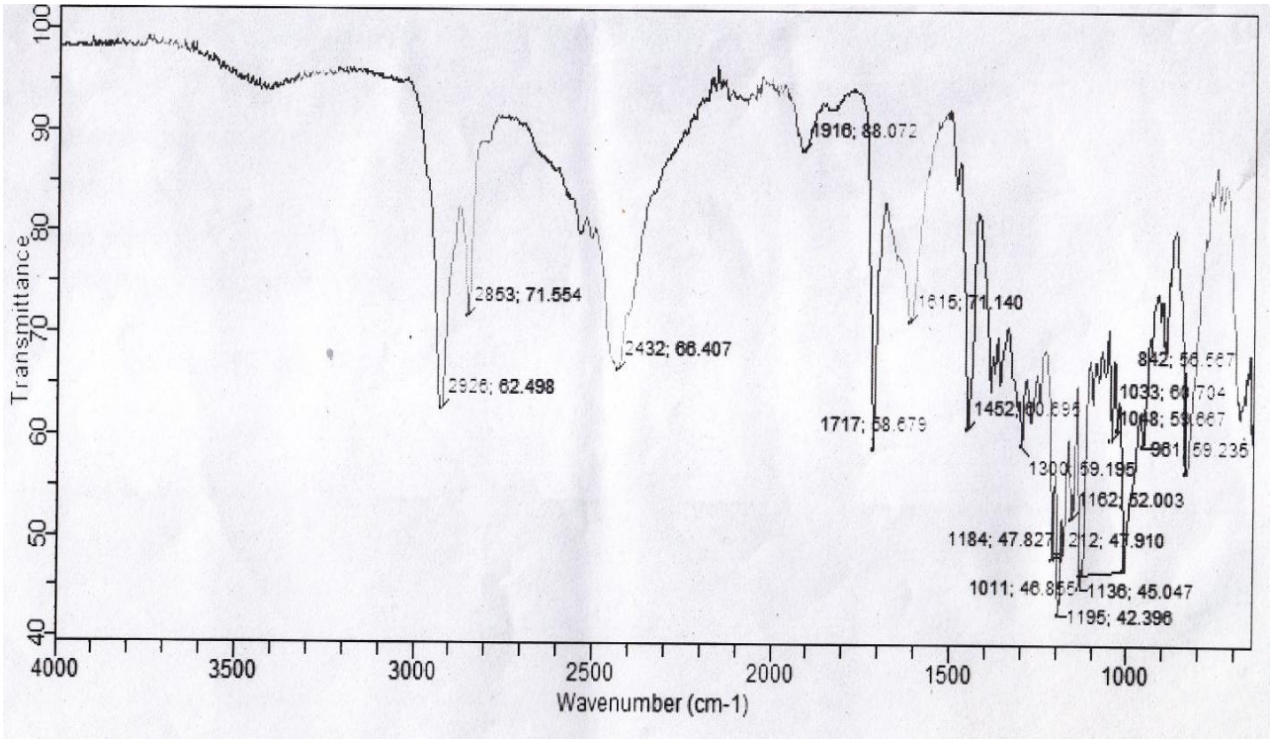


Fig.7: FTIR spectra of dicyclomine hydrochloride with sodium bi carbonate.



Inference

During preformulation study, FT-IR (Fourier Transform Infrared), Spectrophotometer was used to determine the compatibility in between drug and polymers. Study was carried out for the pure drug (dicyclomine hydrochloride) alone and in combination with polymer under study. FT-IR spectra of the samples are given in Figure.2.1, 2.5, 2.6 and 2.7. Major frequencies of functional groups of pure drug remained unchanged or no significant change in the presence of polymer. Hence, it seems that there is no major interaction between the drug and the polymers used in the study.

Formulation and Evaluation

Preparation of floating alginate beads (materials and method)

Drug: Dicyclomine hydrochloride was obtained as a gift sample from Penta Biotech Pvt. Ltd. Haridwar.

Excipient Used:

Sodium Alginate, HPMC, Sodium Bicarbonate, Calcium Chloride, Glacial Acetic Acid. [11]

Formulation Design:

Development of different ratios:

To determine the appropriate ratio different ratios of the components (sodium alginate, HPMC, and sodium bi carbonate) were test for their ability to form beads. Floating beads are prepared by either change in the ratio of sodium alginate and HPMC or change in the amount of sodium bi carbonate.

Table 8: Development of different ratios.

S. No.	Formulation	Sodium alginate	HPMC	Sodium Bicarbonate	Floating Ability
1	F1	900	100	50	-
2	F2	900	100	100	+
3	F3	900	100	200	++
4	F4	800	200	50	-
5	F5	800	200	100	+
6	F6	800	200	200	++
7	F7	700	300	50	-
8	F8	700	300	100	+
9	F9	700	300	200	++
10	F10	600	400	200	++
11	F11	500	500	200	++
12	F12	400	600	200	++
13	F13	300	700	200	…

Floating ability is the ability of the formulation float over the liquid medium. The formulations shows good floating ability was selected for further study. (- not floating, + floating, and ++ 100% floating). In formulation F13 beds are not formed.

Table 9: Formulation Composition of Different Batches

S. No.	Formulation	Drug	Sodium alginate	HPMC	Sodium Bicarbonate
1	F 2	120	900	100	100
2	F3	120	900	100	200
3	F5	120	800	200	100
4	F6	120	800	200	200
5	F8	120	700	300	100
6	F9	120	700	300	200
7	F10	120	600	400	200
8	F11	120	500	500	200
9	F12	120	400	600	200

Experimental Method

Calcium alginate beads were prepared by the ionotropic gelation method. In this method Different formulations (as shown In Table 9) of alginate beads of Dicyclomine hydrochloride were prepared. 120 mg Dicyclomine hydrochloride was dispersed in 20 ml of water. The resulting dispersion was added to the mixture containing the sodium alginate, HPMC and sodium bi carbonate in different concentration shown in the table 8 and 9 and mix gently. The resulting dispersion was dropped through a 26G syringe needle into 3%w/v of calcium chloride solution containing 10%v/v glacial acetic acid. The beads are formed was stirred with a magnetic stirrer for ten minutes, to improve the mechanical strength of the beads and it was allowed to complete the reaction to produce gas inside the alginate beads. The formulated beads were filtered and washed with distilled water. The washed beads are then dried.

Fig. 8: Prepared beads. Mixture (Sodium alginate/HPMC, gas-forming agent, Dicyclomine HCl).

Evaluation of Formulations

Determination of percentage yield

Percentage yield for the formulated beads was calculated from the following equation

Yield % = Weight of the beads / weight of drug + polymer weight x 100

Table 10: Percentage yield of the formulations.

S. No.	Formulations	TQ	AQ	% Yield
1	F2	1220	930	79.5033
2	F3	1320	1110	84.09091
3	F5	1220	870	75.64
4	F6	1320	1090	82.57576
5	F8	1220	970	79.70667
6	F9	1320	1100	83.33333
7	F10	1320	1080	81.81818
8	F11	1320	1000	75.75758
9	F12	1320	1070	81.06061

Floating Properties

50 mg beads were placed in 900 ml of 0.1 N HCl media. The floating properties of beads were evaluated in a dissolution vessel [USP Type II dissolution tester]. Paddle rotation speeds of 50 revolutions per minute were tested. Temperature was maintained at 37^0 C. The floating property of the samples was measured by visual observation.

Table 11: Floating property of the formulations

S. No.	Formulation	% Floating after 8 hours
1	F2	0
2	F3	40
3	F5	0
4	F6	40
5	F8	0
6	F9	60
7	F10	60
8	F11	80
9	F12	80

The formulation shown better duration and % of floating (8hrs) and they were selected for further study.

Determination of Entrapment efficiency

Accurately weighed quantities of approximately 50 mg of beads were crushed and 50 ml 0.1N HCl was added and shake the mixture in volumetric flask and make up the volume 100ml with 0.1 N HCl. Then filter the mixture and the liquid was assayed by UV-spectroscopy at 215 nm.

The entrapment efficiency was determined from the following equation = actual amount of drug (AQ)/theoretical amount of drug (TQ) x 100

Table 12: Drug entrapment efficiency of formulation.

S. No.	Formulation	% DEE
1	F3	92.62
2	F6	89.54
3	F9	96.14
4	F10	88.66
5	F11	95.04
6	F12	96.80

Determination *of In – Vitro* Dissolution Study

Dissolution study was carried out in USP –II type (paddle type) dissolution apparatus. Dissolution study was performed at 50 rpm in 900ml 0.1(N) HCL. 5ml of sample was withdrawn at a predetermined interval and the volume of Dissolution medium was maintained by adding same volume of dissolution medium. The absorption of withdrawn sample was measured spectrophotometrically with suitable dilution and the corresponding concentration was determined from the respective calibration curve.

Table 13: Percentage cumulative drug release for Formulation F3.

Time	Abs.	mcg/ml	mg/ml	mg/5ml	mg/900ml	C.R.	% C.R.
0	0	0	0	0	0	0	0
1	0.0008	0.8	0.0008	0.004	0.72	0.72	17.10214
2	0.0017	1.7	0.0017	0.0085	1.53	1.534	36.43705
3	0.0019	1.9	0.0019	0.0095	1.71	1.7185	40.81948
4	0.002	2	0.002	0.01	1.8	1.8095	42.981
5	0.0022	2.2	0.0022	0.011	1.98	1.99	47.26841
6	0.0029	2.9	0.0029	0.0145	2.61	2.621	62.25653
7	0.0032	3.2	0.0032	0.016	2.88	2.8945	68.75297
8	0.0035	3.5	0.0035	0.0175	3.15	3.166	75.2019

Fig. 9: Cumulative release data for formulation F3.

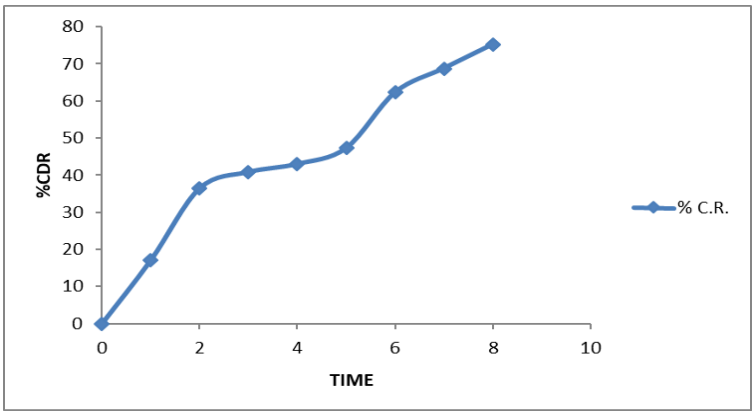


Table 14: Percentage cumulative drug release for Formulation F6.

Time	abs.	mcg/ml	mg/ml	mg/5ml	mg/900ml	C.R.	% C.R.
0	0	0	0	0	0	0	0
1	0.0007	0.7	0.0007	0.0035	0.63	0.63	15.47912
2	0.0013	1.3	0.0013	0.0065	1.17	1.1735	28.83292
3	0.0018	1.8	0.0018	0.009	1.62	1.6265	39.96314

4	0.0022	2.2	0.0022	0.011	1.98	1.989	48.86978
5	0.0029	2.9	0.0029	0.0145	2.61	2.621	64.39803
6	0.0031	3.1	0.0031	0.0155	2.79	2.8045	68.90663
7	0.0033	3.3	0.0033	0.0165	2.97	2.9855	73.35381
8	0.0035	3.5	0.0035	0.0175	3.15	3.1665	77.80098

Fig. 10: Cumulative release data for formulation F6.

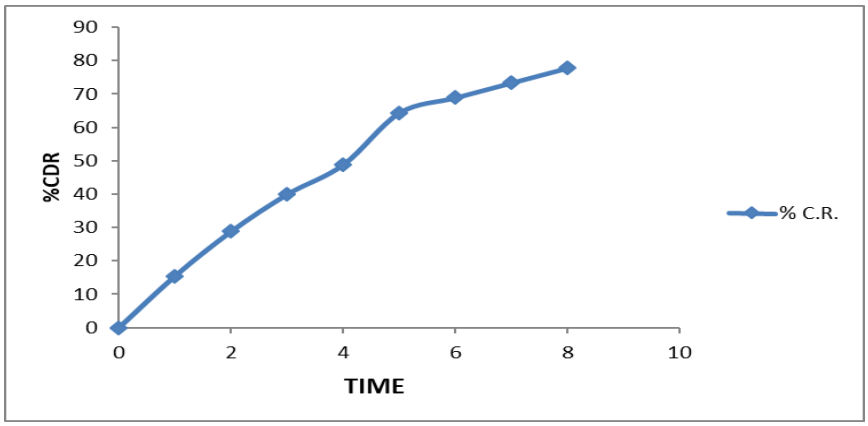


Table 15: Percentage cumulative drug release for Formulation F9.

Time	abs.	mcg/ml	mg/ml	mg/5ml	mg/900ml	C.R.	% C.R.
0	0	0	0	0	0	0	0
1	0.0009	0.9	0.0009	0.0045	0.81	0.81	19.90172
2	0.0019	1.9	0.0019	0.0095	1.71	1.7145	42.12531
3	0.0022	2.2	0.0022	0.011	1.98	1.9895	48.88206
4	0.0027	2.7	0.0027	0.0135	2.43	2.441	59.97543
5	0.003	3	0.003	0.015	2.7	2.7135	66.67076
6	0.0033	3.3	0.0033	0.0165	2.97	2.985	73.34152
7	0.0033	3.3	0.0033	0.0165	2.97	2.9865	73.37838
8	0.0035	3.5	0.0035	0.0175	3.15	3.1665	77.80098

Fig. 11: Cumulative release data for formulation F9.

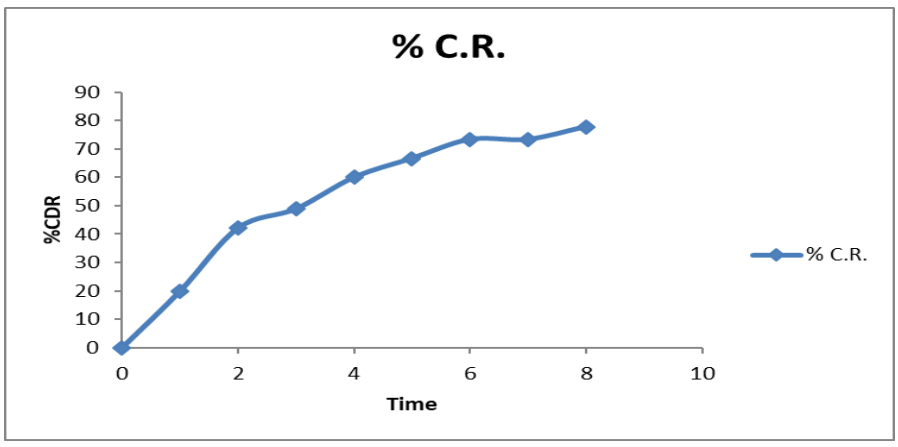


Table 16: Percentage cumulative drug release for Formulation F10.

Time	abs.	mcg/ml	mg/ml	mg/5ml	mg/900ml	C.R.	% C.R.
0	0	0	0	0	0	0	0
1	0.0011	1.1	0.0011	0.0055	0.99	0.99	24.32432
2	0.0017	1.7	0.0017	0.0085	1.53	1.5355	37.72727
3	0.0023	2.3	0.0023	0.0115	2.07	2.0785	51.0688
4	0.0024	2.4	0.0024	0.012	2.16	2.1715	53.35381
5	0.0029	2.9	0.0029	0.0145	2.61	2.622	64.4226
6	0.0032	3.2	0.0032	0.016	2.88	2.8945	71.11794
7	0.0035	3.5	0.0035	0.0175	3.15	3.166	77.7887
8	0.0037	3.7	0.0037	0.0185	3.33	3.3475	82.24816

Fig. 12: Cumulative release data for formulation F10.

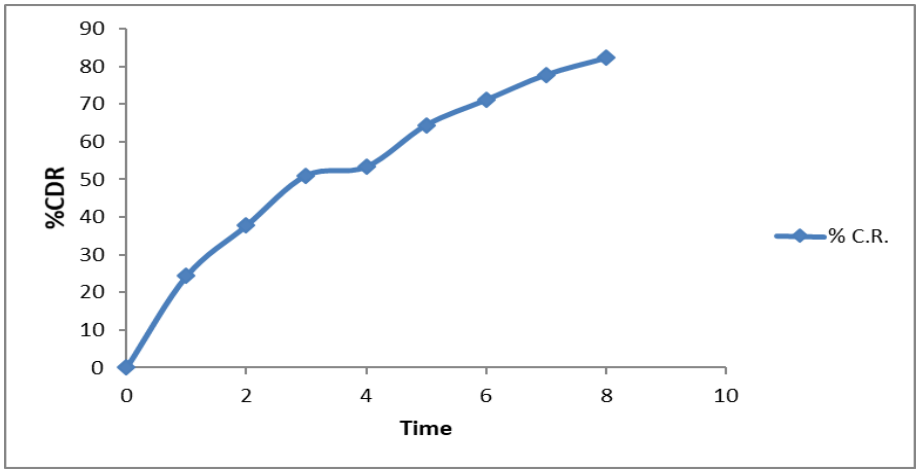


Table 17: Percentage cumulative drug release for Formulation F11.

Time	abs.	mcg/ml	mg/ml	mg/5ml	mg/900ml	C.R.	% C.R.
0	0	0	0	0	0	0	0
1	0.001	1	0.001	0.005	0.9	0.9	22.11302
2	0.0015	1.5	0.0015	0.0075	1.35	1.355	33.29238
3	0.0023	2.3	0.0023	0.0115	2.07	2.0775	51.04423
4	0.0029	2.9	0.0029	0.0145	2.61	2.6215	64.41032

5	0.0032	3.2	0.0032	0.016	2.88	2.8945	71.11794
6	0.0035	3.5	0.0035	0.0175	3.15	3.166	77.7887
7	0.0039	3.9	0.0039	0.0195	3.51	3.5275	86.67076
8	0.0042	4.2	0.0042	0.021	3.78	3.7995	93.35381

Fig. 13: Cumulative release data for formulation F11

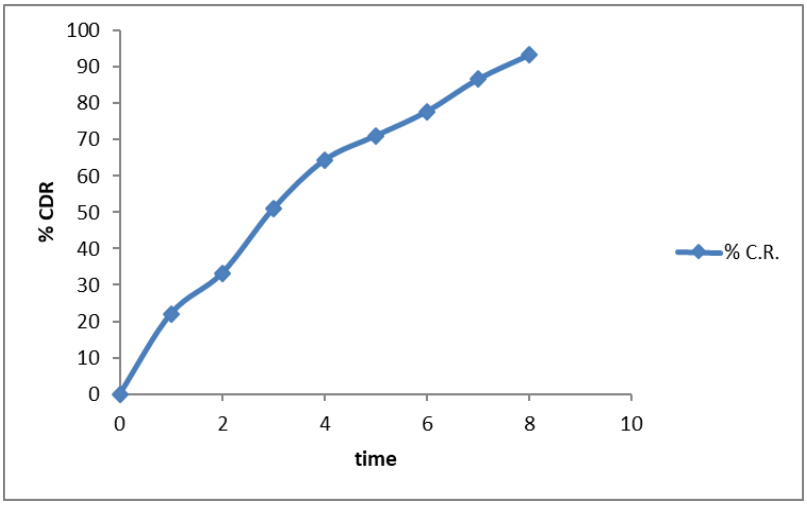
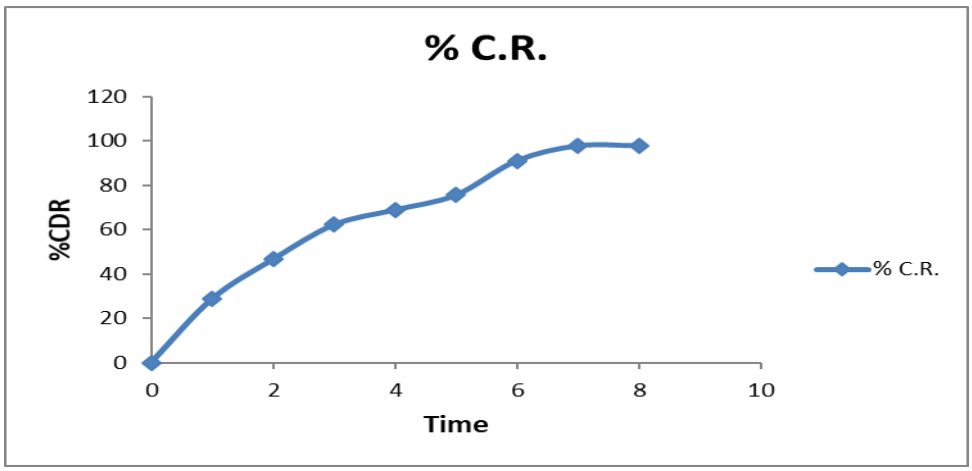


Table 18: Percentage cumulative drug release for Formulation F12.

Time	abs.	mcg/ml	mg/ml	mg/5ml	mg/900ml	C.R.	% C.R.
0	0	0	0	0	0	0	0
1	0.0013	1.3	0.0013	0.0065	1.17	1.17	28.74693
2	0.0021	2.1	0.0021	0.0105	1.89	1.8965	46.59705
3	0.0028	2.8	0.0028	0.014	2.52	2.5305	62.17445
4	0.0031	3.1	0.0031	0.0155	2.79	2.804	68.89435
5	0.0034	3.4	0.0034	0.017	3.06	3.0755	75.56511
6	0.0041	4.1	0.0041	0.0205	3.69	3.707	91.08108
7	0.0044	4.4	0.0044	0.022	3.96	3.9805	97.80098
8	0.0044	4.4	0.0044	0.022	3.96	3.982	97.83784

Fig. 14: Cumulative release data for formulation F12.



Statistical analysis

The results obtained were analyzed using a one-way ANOVA test and reported as the mean ± SD. Values ($p<0.05$) were considered statistically significant.

Result and Discussion

Preformulation study:

Table 19: Result of preformulation study.

S. No.	Property studied	Observation	Inference
1	Color	White	---
2	Analytical method	UV Visible spectroscopy λ_{max} at 215 nm, Slope: 0.006(water)and .001 (0.1NHCl)	Beer Lambert law followed good linearity $R^2 = 0.99$
3	Melting point	173.6^{o}c	Thermo stable
4	Loss on drying	Less than 0.5%	Within limit
5	Solubility(mg/ml)	Water : 39.233 0.1N HCl:12.168 Chloroform:34.366	Highly soluble in water and chloroform, soluble in 0.1N HCl
6	pH	5.2	Slightly acidic
7	Partition coefficient	0.84	Hydrophilic
8	IR spectroscopy	Principle peaks are shown.	Complies with monograph
9	Excipient compatibility	Principle peaks of drug shown.	No significant changes in peaks.

Evaluation of the prepared formulations:

All the nine formulation of floating beads of dicyclomine hydrochloride were prepared by using sodium alginate, HPMC, sodium bi carbonate, calcium chloride and glacial acetic acid. The beads are mainly prepared by the ionic gelation method. All the formulations were evaluated.

Table 20: Evaluation of the beads of Dicyclomine Hydrochloride.

Code	% yield	% floating	Drug entrapment efficiency
F2	79.5033	0	
F3	84.09091	40	92.62
F5	75.64	0	
F6	82.57576	40	89.54
F8	79.70667	0	
F9	83.33333	60	96.14
F10	81.81818	60	88.66
F11	75.75758	80	95.04
F12	81.06061	80	96.80

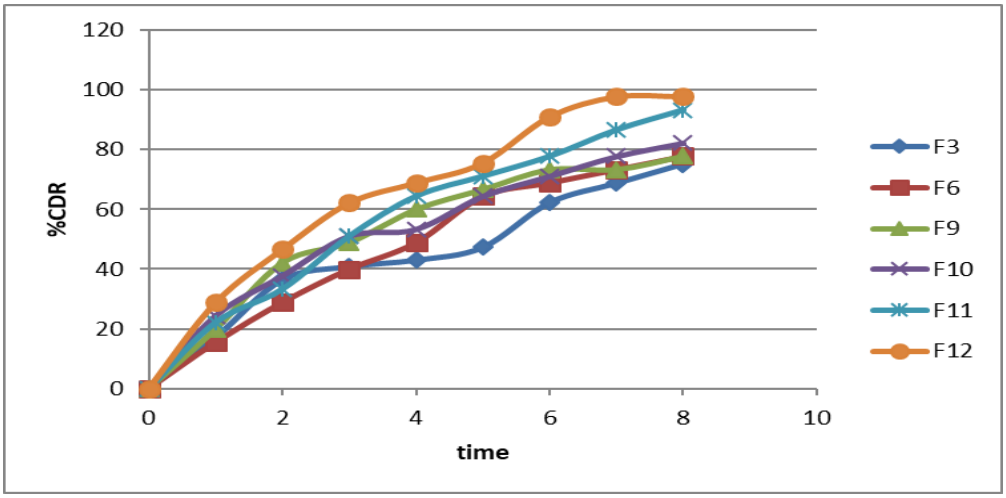
***In-vitro* drug release studies:**

Table 21: *In-vitro* drug release profile time vs. % cumulative release.

Time	F3	F6	F9	F10	F11	F12
0	0	0	0	0	0	0
1	17.10214 ±0.54	15.47912 ±0.71	19.90172 ±0.88	24.32432 ±0.76	22.11302 ±0.62	28.74693 ±0.58
2	36.43705 ±0.38	28.83292 ±0.68	42.12531 ±0.78	37.72727 ±0.72	33.29238 ±0.60	46.59705 ±0.55
3	40.81948 ±0.35	39.96314 ±0.66	48.88206 ±0.76	51.0688 ±0.65	51.04423 ±0.59	62.17445 ±0.48
4	42.981 ±0.36	48.86978 ±0.71	59.97543 ±0.77	53.35381 ±0.63	64.41032 ±0.56	68.89435 ±0.32
5	47.26841 ±0.38	64.39803 ±0.62	66.67076 ±0.68	64.4226 ±0.57	71.11794 ±0.44	75.56511 ±0.28
6	62.25653 ±0.22	68.90663 ±0.58	73.34152 ±0.75	71.11794 ±0.48	77.7887 ±0.33	91.08108 ±0.21
7	68.75297	73.35381	73.37838	77.7887 ±0.42	86.67076	97.80098

	±0.20	±0.54	±0.78		±0.36	±0.18
8	75.2019 ±0.19	77.80098 ±0.51	77.80098 ±0.82	82.24816 ±0.37	93.35381 ±0.22	97.83784 ±0.16

Fig. 15: Cumulative drug release data of formulations.



Discussion

The release of dicyclomine hydrochloride from the prepared formulations was analyzed by plotting the cumulative percent drug released vs. time as shown in Figure 15.

The percentage yield of all the formulations varies from 75% to 95% and percentage yield was found high (95.94%) in the formulation F1 shown in Table.4.2.

The *in-vitro* release study was carried out using 0.1NHCl. The drug release found 97.8 at the end of 8 hours. All the formulation under dissolution study show release of dicyclomine hydrochloride in sustain manner for a prolong period of time over 8 hours. It can be seen that the formulation F11 show 93 % cumulative drug release over the period of time of 8 hours and was the best formulation.

The different formulations of alginate beads are formulated and the percentage drug entrapments in the beads are calculated. The entrapment efficiency and drug content was studied and the results were found to be satisfactory varies between the 88.66-96.80%.

Conclusion

The Present study was carried out to develop the floating alginate beads of dicyclomine hydrochloride using sodium alginate, HPMC E5LV, sodium hydrogen carbonate, calcium chloride, and glacial acetic acid.

Six formulations F3, F6, F9, F10, F11 and F12 were found to be fulfilling all the criteria and feature required for a good floating formulation. All the evaluation tests were carried out for the preparations. The release

pattern of the drug from the formulations and the floating capability of formulations were found to be variable with the variation in the ratio of sodium alginate and HPMC, and the amount effervescent agents in the formulations. The project entitled and the result obtained herewith shows that the dicyclomine hydrochloride floating beads increase the gastric residence time as well as bioavailability and simultaneously decrease the dosing interval as well as dosing amount. In vivo studies need to be carried out before this product can be further developed.

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Conflicts of Interests: Authors have none to declare.

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