INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Research Paper

Formulation And Evaluation of Gastro Retentive Floating Drug Delivery System of Gliclazide

Surendranath Betala*, Reshma Banu S, Ajay Kumar S. N., Dr. E. Gopinath

Shantha College of Pharmacy, Peresandra, Chickballapur (Dist.), Karnataka.

ARTICLE INFO

Published: 22 Aug 2026
Keywords:
Gliclazide, HPMC, Lag time, Buoyant, Disintegration
DOI:
10.5281/zenodo.22055378

ABSTRACT

A gastro retentive floating drug delivery system containing Gliclazide was prepared in the form of tablet and evaluated for its processing parameters and in vitro release behaviour. Gliclazide is a selective second-generation sulphonyl urea used in treatment of hyperglycemia and it absorbs rapidly and completely. However, its absorption is erratic in diabetic patient due to its impaired gastric motility or gastric emptying. To overcome these drawbacks, the present investigation was to develop a gastro retentive floating tablets of Gliclazide. Nine formulations consist of retardant materials such as hydroxy propyl methylcellulose K4M, K15M, and K100M. Sodium bicarbonate was used as a gas generating agent to reduce floating lag time and other release promoters. Tablets remained buoyant over 12 hours in the release medium, and the amount of sodium bicarbonate found to be significant for not only to remaining buoyant without causing disintegration of the tablet, but also to release of the drug in the acidic medium. Final F9 optimized formulation released approximately 94% drug in 12 hours in vitro, while the floating lag time was 31 sec and tablet remained floatable throughout all studies. In vitro gastro retentive study of tablets gave successful results by floating in gastric content over a period of 12 hours. The results of the current study clearly indicate, a promising potential of the Gliclazide floating system as an alternative to the conventional dosage form

INTRODUCTION

Oral route is the most convenient and extensively used route for drug administration. This route has high patient acceptability, primarily due to ease of administration. Over the years, oral dosage forms have become increasingly sophisticated with major role being played by controlled release drug delivery systems (CRDDS) release drug at predetermined rate.

Controlled Drug Delivery Systems[1,2,3]

***Corresponding Author:** Surendranath Betala
Address: *Shantha College of Pharmacy, Peresandra, Chickballapur (Dist.), Karnataka.*
Email ✉: surendrapharma05@gmail.com
Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Controlled drug delivery systems have been developed which are capable of controlling the rate of drug delivery, sustaining the duration of therapeutic activity or targeting the delivery of drug to a tissue.

Controlled drug delivery or modified drug delivery systems are conveniently divided into four categories.

1. Delayed release
2. Sustained release
3. Site-specific targeting
4. Receptor targeting

Gastro retentive Drug Delivery Systems

The development of oral CRDDS has been hindered by the inability to localize the system in the selected regions of the GIT. There has been considerable research over the last decade on the possibility of controlled and site-specific delivery to the GIT by controlling the gastro intestinal transit of orally administered dosage forms using Gastro Retentive Drug Delivery Systems (GRDDS). Such GRDDS possess the ability of retaining the drug in GIT particularly in the stomach for long periods.[4,5]

The idea of gastro retentive systems is to localize the drugs at specific region of GIT such as stomach in the body. Often the extent of drug absorption is limited by the residence time of the drug at absorption site. The transit time in GIT i.e., from the mouth to anus, varies from one person to another. It also depends upon the physical properties of the object ingested and the physiological conditions of the alimentary canal. In addition, the relatively brief G.I. transit time (8-12 hr) for most of the drugs impedes the formulation of once daily dosage form. Many drugs show poor bioavailability (BA) in the presence of intestinal metabolic enzymes like cytochrome P450 (CYP3A), abundantly present in the intestinal epithelium. Their activity decreases longitudinally along the small intestine, with levels rising slightly from the duodenum to the jejunum and declining in the ileum and colon. This non uniform distribution of CYP3A causes regional variability in the absorption of drugs that are the substrates of those enzymes.

The therapeutic window of many drugs is limited by their short circulating half-life and absorption via a defined segment of the intestine. Such pharmacokinetic limitations lead in many cases to frequent dosing of these medications to achieve the required therapeutic effect. This results in "pill burden" and consequently decreased patient compliance. The phenomenon of absorption via a limited part of the GI tract has been termed the "narrow absorption window" once the dosage form passes the absorption window, the drug will be neither bioavailable nor effective. In extreme cases, drugs that are insufficiently absorbed due to narrow absorption cannot be delivered entirely, and are either given by a parental route or the development of Novel Techniques or by GRDDS.[6,7,8]

A rational approach to enhance bioavailability and improve pharmacokinetic and pharmacodynamic profiles is to retain the drug reservoir above its absorption area, i.e., in the stomach and to release the drug in a controlled manner, so as to achieve a zero-order kinetics (i.e., "oral infusion") for a prolonged period of time. The need for gastro retentive dosage forms (GRDFs) has led to extensive efforts in both academia and industry towards the development of such drug delivery systems. GRDFs extend significantly the period of time over which the drugs may be released.

Various approaches have been pursued to increase the retention of an oral dosage form in the stomach. These systems include: Floating systems, bio adhesive systems, swelling and expanding systems, high density systems. Floating Drug Delivery System (FDDS) has a bulk density lower than gastric fluids and thus remain buoyant in the stomach for a prolonged period of time,

without affecting the gastric emptying rate. While the system is floating on the gastric contents, the drug is released slowly at a desired rate from the system. After the release of the drug, the residual system is emptied from the stomach. This, results in an increase in the GRT and a better control of the fluctuations in the plasma drug concentration.[9,10]

Formulation considerations for GRDDS[11,12,13]

1) It must show effective retention in the stomach to suit for the clinical demand.
2) It must be convenient for intake to facilitate the patient compliance.
3) It must have sufficient drug loading capacity,
4) It must control the drug release profile,
5) It must have full degradation and evacuation of the system once the drug release is completed.
6) It should not have effect on gastric motility including emptying pattern.
7) It should not have other local adverse effects.

MATERIALS AND METHODS

GLICLAZIDE

Gliclazide is an oral anti-hyperglycaemic agent used for the treatment of non-insulin-dependent diabetes mellitus (NIDDM). It belongs to the sulfonylurea class of insulin secretagogues, which act by stimulating β cells of the pancreas to release insulin. Sulfonylurea increase both basal insulin secretion and meal-stimulated insulin release. Medications in this class differ in their dose, rate of absorption, duration of action, route of elimination and binding site on their target pancreatic β cell receptor.

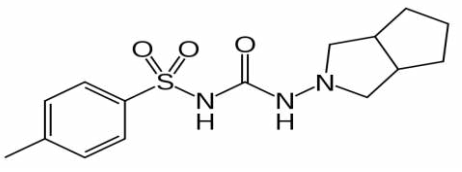

Fig no. 12: Structure of Glyclazide

Systemic (IUPAC) name:
(N-[[(Hexahydrocyclopenta[c]pyrol-2(1H) yl)amino]carbonyl]-4-methyl benzene sulphonamide)
Formula : $C_{15}H_{21}N_3O_3S$
Molecular weight : 323.412g/mol

Table No.1: Pharmacokinetic data

Bioavailability	Rapidly absorbed in man. Bioavailability is low and variable (approximately 5%) due to extensive first pass metabolism
Metabolism	Metabolized hepatically, primarily by oxidation by cytochrome P450 3A4 producing several hydroxylated derivatives and a pharmacologically active metabolite, 1-pyrimidinylpiperazine (1-PP).
Protein Binding	94% (approximately 70% bound to albumin, 30 % bound to alpha 1 -acid glycoprotein)
Half- Life	2-3 hours (although the action of a single dose is longer than the short half-life indicates much).
Elimination route	Metabolites and conjugates are eliminated primarily by the kidneys (60-70%) and also in the feces (10-20%).
Routes	Oral

Table No. 3: List of materials used in the study

SNO	INGREDIENTS	SUPPLIER
1.	Gliclazide	Yarrow Chem Products, Mumbai
2.	Hydroxy Propyl Methyl Cellulose	Colorcon, Goa
3.	Avicel PH102(MCC)	FMC Bio Polymers, Mumbai
4.	Sodium Bicarbonate	SD Fine Chemicals, Mumbai
5.	Magnesium Stearate	Evonik, Mumbai
6.	Talc	SD Fine Chemicals, Mumbai

Table No.4: List of equipment used for the study

S. No.	Name of the equipment	Model
1.	Electronic weighing balance	Eagle, Mumbai
2.	Friabilator	Roche Friabilator Electro lab, Mumbai
3.	Laboratory oven	DTC-00R
4.	Compression machine	Cmd (Cadmach)
6.	Tablet hardness tester	Pfizer Hardness Tester, Mumbai
7.	UV	Lab India UV 3000
8.	Dissolution apparatus	Electro Lab TDT-08L
9.	Vernier calipers	Cd-6" Cs

METHODOLOGY[14,15,16]

Construction of calibration curve of Gliclazide in 0.1N HCL:

Procedure:

Working standard: 100mg of Gliclazide was weighed and dissolved in 0.1N HCL and then made up to a volume of 100ml with0.1N HCL. **Dilution 1**: From the working standard solution 1ml was diluted to 10ml with 0.1NHcl.

from dilution 1, take 0.2, 0.4, 0.6, 0.8, 1.0ml of solution and was diluted up to mark in 10ml volumetric flask to obtain 2,4,6,8,10 µg/ml concentrated solutions. This solutions absorbance was noted at λ_{max242}

Formulation of gastro retentive floating tablets by direct compression method

Processing steps involved in direct compression method:

The floating tablets were prepared by following the General Methodology as given below:

1. All ingredients (Gliclazide + Avicel PH 102 + polymer) were weighing accurately and pass through #22 sieve, blend in a Poly Bag for 5 min, except magnesium stearate and talc.
2. Magnesium stearate & talc passed through # 40 Sieve and this is added to the above mass, then mix thoroughly to obtain uniform dry mass.

3. The obtained dry mass was punched in to tablets using single punch machine

Table No. 5: Quantities of ingredients used in formulation of tablets in mg

INGREDIENTS	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)	F7 (mg)	F8 (mg)	F9 (mg)
Gliclazide	60	60	60	60	60	60	60	60	60
HPMC K4 M	120	180	-	-	240	-	-	-	-
HPMC K15M	-	-	120	180	-	240	-	-	-
HPMC K100M	-	-	-	-	-	-	120	180	240
MCC 102	136	76	136	76	16	16	136	76	16
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2
$NaHCO_3$	30	30	30	30	30	30	30	30	30
Total weight	350	350	350	350	350	350	350	350	350

EVALUATION TESTS[17,18,19]

The formulated tablets were evaluated for the following Pre, post compression quality control studies & In vitro Buoyancy studies and dissolution studies

A) Pre Compression studies:

Angle of Repose: It is defined as the maximum angle possible between the surface of a pile of powder and the horizontal plane.

Angle of Repose of granules was determined by the funnel method. Accurately weighed powder blend was taken in the funnel. Height of the funnel was adjusted in such a way the tip of the funnel just touched the apex of the powder blend.

Powder blend was allowed to flow through the funnel freely on to the surface. Diameter of the powder cone was measured and angle of repose was calculated using the following equation.

$\theta = \tan^{-1} (h/r)$

Where:

θ = angle of repose

h = height in cms

r = radius in cms

The angle of repose has been used to characterize the flow properties of solids. It is a characteristic related to inter particulate friction or resistance to movement between particles.

2. Density:

Bulk density (BD): It is the ratio of total mass of powder to the bulk volume of powder Weigh accurately 25 g of granules, which was previously passed through 22 # sieve and transferred in 100 ml graduated cylinder. Carefully

a) level the powder without compacting, and read the unsettled apparent volume. Calculate the apparent bulk density in gm/ml by the following formula

Bulk density = weight of powder / Bulk volume.

$$D_b = \frac{M}{V_0}$$

M = mass of the powder

V_0 = bulk volume of the powder.

Tapped density (TD): It is the ratio of total mass of powder to the tapped volume of powder

Weigh accurately 25 g of granules, which was previously passed through 22# sieve and transferred in 100 ml graduated cylinder of tap density tester which was operated for fixed number of taps until the powder bed volume has

reached a minimum, thus was calculated by formula·

Tapped density = Weigh of powder / Tapped volume

Dt = $(M) / (V_f)$.

M = mass of the powder

V_f = tapped volume of the powder.

Carr's Index:

Compressibility index of the powder blend was determined by Carr's compressibility index. It is a simple test to evaluate the BD and TD of a powder and the rate at which it packed down. The formula for Carr's index is as below:

$$\textbf{Compressibility index} = 100 \times \frac{\text{Tapped density - Bulk density}}{\text{Tapped density}}$$

Hausner's Ratio:

Hausner's Ratio is a number that is correlated to the flow ability of a powder.

$$\textbf{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

Post compression studies:[20,21,22]

General appearance: The formulated tablets were assessed for its general appearance and observations were made for shape, color, texture and odor.

Average weight/Weight Variation: 20 tablets were selected and weighed collectively and individually. From the collective weight, average weight was calculated. Each tablet weight was then compared with average weight to assure whether it was within permissible limits or not. Not more than two of the individual weights deviated from the average weight by more than 7.5% for 300 mg tablets and none by more than double that percentage.

$$\textbf{Average weight} = \frac{\textbf{weight of 20 tablets}}{\textbf{20}}$$

$$\textbf{\%weight variation} = \frac{\textbf{average weight - weight of each tablet}}{\textbf{average weight}} \times 100$$

Thickness: Thickness of the tablets (n=3) was determined using a Vernier calipers

Hardness test: Hardness of the tablet was determined by using the Monsanto hardness tester (n=3) the lower plunger was placed in contact with the tablet and a zero reading was taken. The plunger was then forced against a spring by turning a threaded bolt until the tablet fractured. As the spring was compressed a pointer ride along a gauge in the barrel to indicate the force.

Friability test: This test is performed to evaluate the ability of tablets to withstand abrasion in packing, handling and transporting.

Initial weight of 20 tablets is taken and these are placed in the Friabilator, rotating at 25rpm for 4min.The difference in the weight is noted and expressed as percentage. It should be preferably between 0.5 to 1.0%.

$$\textbf{\%Friability} = [(W_1 - W_2)/W_1] \times 100$$

Where, W_1= weight of tablets before test, W_2 = weight of tablets after test

Assay Procedure: Weigh and finely powder not less than 20 tablets. Transfer an accurately weighed portion of the powder equivalent to about 10mg of model drug a 10 ml volumetric flask. Add approximately 6ml of 0.1N HCl and shake and sonicate for 10 min to complete the extraction. Dilute the methanol to volume and mix. Pipette 1ml aliquot into a 10ml volumetric flask, dilute with mobile phase to volume, mix and filter.. Calculate the quantity in mg of model drug Hydrochloride in the portion taken by the formula

Assay = test absorbance/standard absorbance*standard concentration/sample concentration*purity of drug/100*100

In vitro Buoyancy studies:[23,24]

The in vitro buoyancy was determined as per the method described by Rosa et al.

a. **Floating Lag Time (FLT):** A tablet was placed in a 100 ml beaker containing 0.1N HCl. The time required for the tablet to rise to the surface and float was determined as the Floating Lag Time (FLT).
b. **Total Floating Time (TFT):** A tablet was placed in a 100 ml beaker containing 0.1N HCl. The duration of time up to which the tablet constantly floats on the dissolution medium was noted as the Total Floating Time (TFT).
c. **Matrix integrity:** During the period of TFT the swelled matrix tablets were observed for integrity about 12 hrs.

In vitro Dissolution Study: 900 ml of 0.1N HCl was placed in the vessel and the USP-II apparatus (Paddle method) was assembled. The medium was allowed to equilibrate to temperature of 37^0C ± 0.5^0C. A tablet was placed in the vessel and was covered; the apparatus was operated up to 12 hrs. at 50 rpm. At definite time intervals, 5 ml of dissolution medium was withdrawn; filtered and again replaced with 5 ml of fresh medium to maintain sink conditions. Suitable dilutions were done with dissolution medium and were analyzed spectrophotometrically at λ_{max} =242 nm using a UV-spectrophotometer (Lab India).

Table No.6: Dissolution parameters

Parameter	Details
Dissolution apparatus	USP -Type II (paddle)
Medium	0.1N HCl.
Volume	900 ml
Speed	50 rpm
Temperature	37± 0.5 ºC
Sample volume withdrawn	5ml
Time points(hrs.)	1,2,4,6,8,10,12
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	242 nm

In vitro Release Kinetics Studies:[25,26]

The analysis of drug release mechanism from a pharmaceutical dosage form is important but complicated process and is practically evident in the case of matrix systems. The order of drug release from FDDS was described by using zero order kinetics or first order kinetics. The mechanism of drug release from FDDS was studied by using Higuchi equation and the Peppa's-Korsemeyer equation.

1. **Zero Order Release Kinetics:**

It defines a linear relationship between the fractions of drug released versus time.

$Q=k_0t$.

Where, Q is the fraction of drug released at time t and k_o is the zero order release rate constant. A plot of the fraction of drug released against time will be linear if the release obeys zero order release kinetics.

2. **First Order Release Kinetics:**

Wagner assuming that the exposed surface area of a tablet decreased exponentially with time during

dissolution process suggested that the drug release from most of the slow-release tablets could be described adequately by the first-order kinetics. The equation that describes first order kinetics is

$$\textbf{Log C= Log C}_o\textbf{-kt/2.303}$$

Where C is the amount of drug dissolved at time t,

C_o is the amount of drug dissolved at t=0 and
k is the first order rate constant.

A graph of log cumulative of log % drug remaining vs time yields a straight line will be linear if the release obeys the first order release kinetics.

1. **Higuchi equation:**

It defines a linear dependence of the active fraction released per unit of surface (Q) and the square root of time.

$$Q=K_2t^{1/2}$$

Where K_2 is release rate constant. A plot of the fraction of drug released against square root of time will be linear if the release obeys Higuchi equation. This equation describes drug release as a diffusion process based on the Fick's law, square root time dependent[20].

2. **Peppa's-Korsemeyer equation (Power Law):**

In order to define a model, which would represent a better fit for the formulation, dissolution data was further analyzed by Peppa's-Korsemeyer equation (Power Law).

$$Mt/ \mathbf{M}_\infty = K.t^n$$

Where, Mt is the amount of drug released at time t
M_α is the amount released at time α,
M_t/M_α is the fraction of drug released at time t,
K is the kinetic constant and n is the diffusion exponent.

To characterize the mechanism for both solvent penetration and drug release n can be used as abstracted. A plot between log drug releases up to 60% against log of time will be linear if the release obeys Peppa's-Korsemeyer equation and the slope of this plot represents "n" value[21].the kinetic data of the formulations were included.

Nature of release of the drug from the designed tablets was inferred based on the correlation coefficients obtained from the plots of the kinetic models. The data were processed for regression analysis using MS EXCEL

RESULTS AND DESCUSSIONS

DRUG AND EXCIPIENTS COMPATIBILITY STUDIES

The compatibility of Gliclazide with the excipients used in Gliclazide floating tablets are analyzed by IR studies. Compatibility of the drug with excipients are determined by preparing different ratios of drug and excipients, and then the mixtures are subjected for the IR studies immediately after mixing as well as after 1 month of mixing.

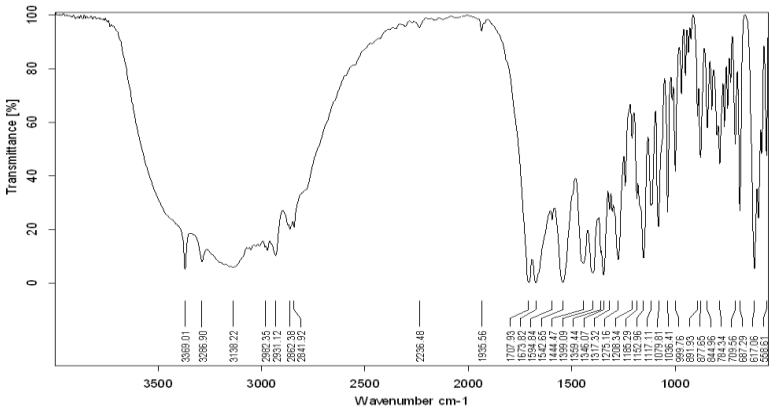

Fig.No.1: FTIR Spectra for Gliclazide

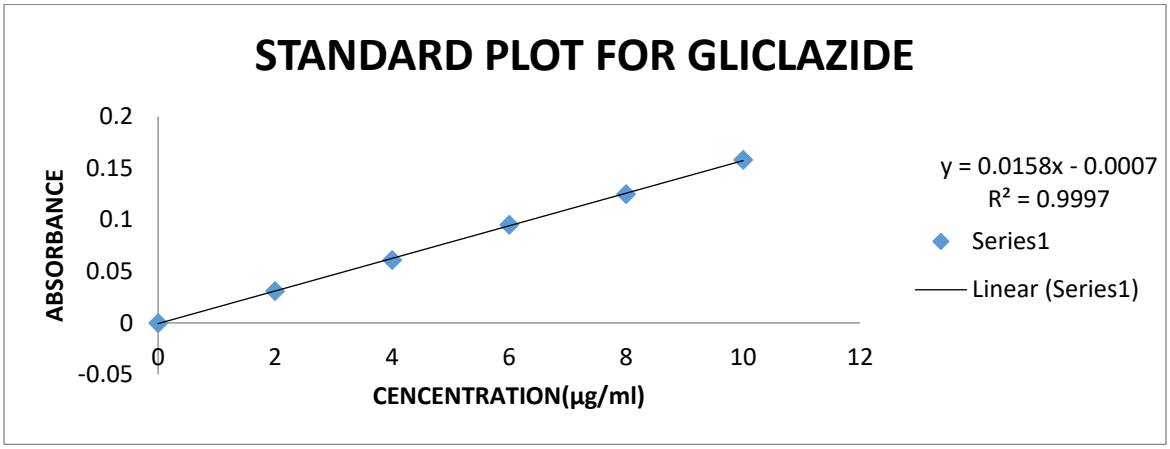

Figure No. 2: Standard calibration curve of Gliclazide in 0.1N HCl

Inference: The standard calibration curve of Gliclazide in 0.1N HCl showed good correlation with regression value of 0.999

Pre Compression studies

Table No. 7: Pre compression studies of Gliclazide Floating tablets

Formulations /tests	Bulk density	Tapped density	Angle of repose	Compressibility index	Hausner's ratio
F1	0.46±0.012	0.55±0.035	22.62±0.03	16.36±0.039	1.19±0.015
F2	0.59±0.02	0.68±0.07	22.29±0.019	13.04±0.023	1.15±0.011
F3	0.53±0.018	0.63±0.01	20.29±0.01	15.8±0.059	1.18±0.014
F4	0.47±0.012	0.59±0.018	28.23±0.06	20.3±0.01	1.25±0.02
F5	0.42±0.010	0.53±0.08	23.24±0.059	26.19±0.03	1.26±0.021
F6	0.48±0.013	0.57±0.01	27.4±0.04	14.04±0.042	1.14±0.010
F7	0.46±0.012	0.57±0.01	22.26±0.03	23.91±0.062	1.23±0.021
F8	0.44±0.011	0.53±0.08	23.62±0.042	20.45±0.061	1.2±0.02
F9	0.48±0.013	0.56±0.02	25.24±0.05	16.66±0.05	1.16±0.01

***n=3**

Inference: The blends prepared for dry granulation of tablets were evaluated for their flow properties; the results for the blends of compression tablets were shown in Table No.17

- The bulk density and the tapped density for all formulations were found to be dissimilar.
- The Carr's index and Hausner's ratio were found to be in the range of ≤ 26and 1.2 to 1.26 respectively, indicating good flow and compressibility of the blends.
- The angle of repose for all the formulations was found to be in the range of 20.29-28.23˚ which indicating good flow

Table No.8: Post compression studies of Gliclazide floating tablets

Formulations	Hardness (Kg/cm^2)	Friability (%)	Weight variation	Content uniformity
F1	5.433	0.568	pass	99.3
F2	5.283	0.531	pass	99.8
F3	5.016	0.488	pass	100.3
F4	6.0833	0.633	pass	99.6
F5	5.816	0.605	pass	100
F6	5.866	0.445	pass	100.16
F7	5.2	0.52	pass	100.3
F8	5.1	0.47	pass	100.6
F9	5.7	0.44	pass	100

Inference:

- The variation in weight was within the range of ±5% complying with pharmacopoeia specifications of USP.
- The hardness for different formulations was found to be between 5.0 to 6.0 kg/cm^2, indicating satisfactory mechanical strength
- The friability was < 1.0% W/W for all the formulations, which is an indication of good mechanical resistance of the tablet.
- The drug content was found to be within limits 99.3 to 100.6 %.

Table No. 9: In vitro Buoyancy Studies of Model drug floating tablets

Formulation Code	Floating lag time	Total floating time	Matrix Integrity up to 12 hrs.
F1	19 sec±0.32	Up to 4hrs	Eroding
F2	44 sec±0.35	Up to 6hrs	Eroding
F3	31 sec±0.32	Up to 12hrs	Non eroding
F4	19 sec±0.72	Up to 12hrs	Non eroding
F5	13sec±0.15	Up to 4 hrs	Eroding
F6	13sec±0.38	Up to 6hs	Eroding
F7	31sec±0.32	Up to 12hrs	Non eroding
F8	13 sec±0.38	Up to 5hrs	Eroding
F9	31sec±0.45	Up to 12hrs	Non eroding

n* = 3

Inference:

- The FLT was found to be within limits of < 45sec.
- The formulations having matrix integrity & TFT up to 12 hrs

INVITRO DISSOLUTION STUDIES OF GLICLAZIDE FLOATING TABLETS:

Table No.10: Dissolution parameters

Parameter	Details
Dissolution apparatus	USP -Type II (paddle)
Medium	0.1N HCl.
Volume	900 ml
Speed	50 rpm
Temperature	37± 0.5 ºC
Sample volume withdrawn	5ml
Time points(hrs)	1,2,4,6,8,10,12
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	242 nm

Note: 5 ml of sample was with draw at each time point & replace the same volume of 0.1N HCl.

Table No.11: *In vitro* Dissolution results of Formulation trails with HPMC K4M, HPMC K15M, HPMC K100M

Time in hrs.	%cumulative drug release								
	HPMC K4M			HPMC K15M			HPMC K100M		
	F1	F2	F5	F3	F4	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	**0**
0.5	33	28	25	25	21	18	23	19	**15**
1	45	41	39	33	29	25	31	27	**21**
2	68	61	54	46	36	32	42	31	**28**
3	83	76	67	59	49	41	61	43	**36**
4	95	89	79	68	63	58	72	64	**49**
6	99.4	93	91	81	79	68	85	73	**61**
8	_	99.8	97	96	84	81	91	89	**78**
10	_	_	100	99.2	97	96	96	95	**83**
12	_	_	_	_	99.9	98.9	99.2	99.4	**94**

Stability studies:

The accelerated stability study for the formulation at 40 ± 2 ^{0}C and 75 ± 5% RH., was conducted for 3 months, which includes the testing of parameters like identification of physical characters, identification by HPLC, average weight per tablet, water content, dissolution profile and Assay throughout the study period.

Table No. 12: Stability studies of Gliclazide floating tablets at 40 ± 2 ^{0}C and 75 ±5 RH

Characteristics tested	Specifications	Initial	1st Month	2nd Month	3rd Month
Description	White colored oval shaped film coated tablet with 'C' on one side	Complies	Complies	Complies	Complies
Identification By HPLC	The RT of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the standard preparation obtained as directed in the Assay.	Complies	Complies	Complies	Complies
Dissolution (%)	Not less than 60% of the drug should be released in 6 hrs.	60.2	60.5	60.7	61.0
Assay %	The tablet contains not less than 90.0% and not more than 110.0% of the stated amount of Gliclazide	98.0	98.2	98.6	98.6

The stability studies of optimized formulation of Gliclazide floating tablets were conducted according to the ICH guidelines. The formulations were withdrawn at suitable intervals (1,2 and 3 months) and analyzed visually for physical appearance and evaluated for different tests. The formulation showed no visual differences, complied with description. The formulation complied for identification test. The drug content remaining in the formulation at different intervals of time also complied with the specifications. From the above results, it can be concluded that the formulation of Gliclazide floating tablets is stable.

SUMMARY AND CONCLUSION

From the experimental data, it can be concluded that

- Floating Tablets of Glyclazide are formulated to increase gastric residence time and thereby improve its therapeutic efficacy.
- Higher the viscosity grade of the HPMC, greater the retarding rate of model drug and the order of Controlled release is: HPMC K100M >HPMC K15M>HPMC K4M
- HPMC K100M was respectively showed better Sustained drug release of Glyclazide.
- Synthetic polymers were showing more rate retarding drug release and matrix integrity; the order of better controlled release polymers are HPMC K100M >HPMC K15>HPMC K4M.
- When drug: polymer concentration increases the release rate decreases this is because of reason when the concentration of polymer increases the diffusion path length increases
- Formulated tablets showed satisfactory results for various Post compression evaluation parameters like: tablet thickness, hardness, weight variation, floating lag time, total floating time, content uniformity and *in vitro* drug release.
- Formulation F9 gave better-controlled drug release and floating properties in comparison to the other formulations.
- The release pattern of the F9 formulations was best fitted to Korsmeyer-Peppas model, Higuchi and first-order model.
- The most probable mechanism for the drug release pattern from the formulation was non-Fickian diffusion or anomalous diffusion.

REFERENCES

1. Yeol PG. Floating Drug Delivery System: Need and Development, Ind. Pharm Sci. 2005; 67: 265-272.
2. Shweta Arora. Floating Drug Delivery: A Review, AAPS Pharm Sci Tech, 2005; 47: 268-272.
3. Libo Yang. A New Intragastric Delivery System for the Treatment of Pylori associated with gastric ulcers, J. Cont. Rel., 1999; 34: 215-222.
4. Singh BN and Kim H. Floating drug delivery system an approach to control delivery via gastric retention, J. Cont. Rel., 2000; 63:235-259.
5. Choi BY and Park HJ. Preparation of alginate beads for floating drug delivery system: effect of CO2 gas forming agent. J Cont Rel., 2000; 25:488-491.
6. Timmermans J and Moes AJ. The cut off size for gastric emptying of dosage forms, J Pharm Sci. 1993; 82: 854.
7. Ichikawa M, Watanabe S and Miyake Y. A new multiple-unit oral floating dosage system: Preparation and in-vitro evaluation of floating and sustained-release characteristics. J Pharm Sci. 1991; 80:1062-1066.
8. Menon A, Wolfgang AR and Saks A. Development and evaluation of monolithic floating dosage form for Furosemide, Pharm. Sci.1994; 83: 239-245.
9. Ozdemir N, Ordu S and Ozkan Y. Studies of floating dosage forms of Furosemide: in-vitro and in vivo evaluations of bilayer tablet formulations, Drug Dev Ind Pharm., 2000; 26: 857-866.
10. Nur OA and Zhang JS. Captopril floating and/or bio adhesive tablets: design and release kinetics. Drug Dev Ind Pharm., 2000; 26:965-969.
11. Shah S, Quaqish R, Patel V, Amiji M. Evaluation of the factors influencing stomach specific delivery of antibacterial agents for Pylori infections. J Pharm Pharmaco. 1999; 51:667-672.
12. Hilton AK and Deasy BP, In vitro and in vivo evaluation of an oral sustained-release floating dosage form of Amoxicillin trihydrate. Int J Pharm. 1992; 86: 79-88.
13. Basak SC. Development and in vitro evaluation of oral matrix floating tablets formulation of Ciprofloxacin. Ind J Pharm Sci. 2004; 66: 313-316.
14. Hima Sankar K. Design and Biopharmaceutical evaluation of gastric floating drug delivery system of Metformin HCl. Ind J Pharm Edu Res.2006; 40:369-382.
15. Dave BS, Amin AF and Patel MM. Gastro retentive drug delivery system of ranitidine hydrochloride: formulation and in-vitro evaluation. AAPS Pharm Sci Tech. 2004; 5: 1-6.
16. Cooper J, Gunn C, Powder flow and compaction, In: Carter SJ, eds. Tutorial Pharmacy. New Delhi, India: CBS Publishers and Distributors; 1986; 211-233.
17. Lakade SH, Bhalekar MR, Formulation and Evaluation of Sustained release Matrix Tablet of Anti-Anginal Drug, Influence of Combination of Hydrophobic and Hydrophilic Matrix Former, Research J. Pharm. and Tech.2008;1: 410-413.
18. Higuchi T. Mechanism of Sustained-action medication. Theoretical Analysis of rate of release of solid drugs dispersed in solid matrices. J Pharm Sci. 1963; 51: 1145-1149.
19. Peppas NA. Analysis of Fickian and Non-Fickian drug release from polymers. Pharma Aceta.Helv, 1985; 60: 110-111.
20. Swati C. Jagdale, Formulation and Evaluation of Gastro retentive Drug Delivery System of Propranolol Hydrochloride. American

Association of Pharmaceutical Scientists. Vol. 10, No. 3, September 2009, 1071-1079.

21. Vobalaboina Venkateshwarlu, Dumpeti Janardhan, Meka Lingam, Chinnala Krishna Mohan: Formulation and In Vitro Evaluation of Gastro retentive Drug Delivery System for Ranitidine Hydrochloride. International Journal of Pharmaceutical Sciences and Nanotechnology, 2008; Vol 1.3:227-232.
22. Javed Ali, Formulation and Development of Floating Capsules of Celecoxib: In Vitro and In Vivo Evaluation AAPS Pharm SciTech 2007; 8 (4) Article 119. Javed Ali, Formulation and development of hydro dynamically balanced system for Metformin In-vitro and in vivo evaluation. European Journal of Pharmaceutics and Bio pharmaceutics 67 (2007) 196–201.
23. Kyriako's Kachrimanis, Solid dispersions in the development of a Nimodipine floating tablet formulation and optimization by artificial neural networks and genetic Programming. European Journal of Pharmaceutics and Biopharmaceutics 77 (2011) 122–131.
24. Mahesh D. Chavanpatil, Novel sustained release, swell able and bioadhesive gastro retentive drug delivery system for ofloxacin. International Journal of Pharmaceutics 316 (2006) 86–92.
25. Leopoldo Villafuerte-Robles, Sustained delivery of captopril from floating matrix tablets. International Journal of Pharmaceutics 362 (2008) 37–43.
26. Anilkumar j. Shinde, formulation and in vitro evaluation of sustained release floating tablet of cephalexin using hydrophilic polymers. International journal of pharmacy and pharmaceutical sciences. Vol 2, supple 2, 2010,58-65.
27. Vishal g. Karkhile: Formulation and evaluation of floating tablets of Furosemide, ijprd/2010/pub/arti/vov-1/issue-12/Feb./009,1-10.
28. Sanjay P. Boldhane, Bhanudas. Kuchekar, "Development and optimization of Metoprolol succinate gastro retentive drug delivery system, Actapharmceutica, Dec 2010, Vol.60 (4), P. 415-425.
29. A.I. Siddiqui, B.V. Bakde, K.K. Tappar: Floating Strategy for Low Absorption window Diltiazem Hydrochloride. International Journal of Pharmacy and Technology, 2011; Vol 3.1893-1903.
30. P Subash Chandra Bose, P Srikanth Reddy, Valluru Ravi, D Sarita, T M Pramod Kumar; formulation and evaluation of sustained release floating tablets of Diltiazem HCl using xanthan gum, RJPBCS, 2011, 2(2), 319-328.
31. Bagherwala, Dinesh Kumar Patidar, Pradeep Sharma; studies on formulation and evaluation of floating tablets of ciprofloxacin HCl, IJCP, 2010, 5(2),1-4.
32. RajaBenhar Dickson, Thakkar Hardik Rajeshbai, Paramasivam Sureshkumar, Jamsheer Assink, Adimoolam Senthi; formulation and evaluation of gastro retentive floating tablets of Glipizide, IJRAP, 2011, 2(3), 911-917.
33. Patel VM, Prajapati BG, Patel AK. Controlled release gastro retentive dosage form of verapamil hydrochloride. Int J Pharm Tech Res 2009; 1(2):215-21.
34. Jaimini M, Rana AC, Tanwar YS. Formulation and evaluation of famotidine floating tablets. Curr Drug Delivery 2007; 4(1):51-5.
35. Prabhu P, Harish NM, Guljar AM, Yadav B, Narayana CR, Satyanarayana D, Subrahmanyam EVS. Formulation and In Vitro Evaluation of Gastric Oral Floating Tablets of Glipizide. Indian J Pharm Educ. Res 2008; 42(2):174-83.

36. Deshmukh VN, Jadhav JK, Savarkar DM. Formulation and in vitro evaluation of theophylline anhydrous bioadhesive tablets. Asian J Pharm Sci 2009:54-8.
37. Rahman Z, Ali M, Khar R. Design and evaluation of bilayer floating tablets of captopril. Acta Pharm 2006; 56(1):49-57.
38. Gambhir MN, Ambade KW, Kurmi SD, Kadam VJ, Jadhav KR. Development and in vitro evaluation of an oral Floating matrix table formulation of Diltiazem hydrochloride. AAPS Pharm Sci Tech. 2007; 8: E1- E9.
39. Arza, Gonugunta CSR, Veerareddy PR. Formulation and evaluation of swell able and floating gastro retentive Ciprvenlafaxine HCl hydrochloride tablets. AAPS Pharm SciTech 2009; 10(1):220-6.
40. Prajapati ST, Patel LD, Patel DM. Gastric floating matrix tablets: Design and optimization using combination of polymers. Acta Pharm 2008; 58: 221-9.
41. Sungthongjeen S, Sriamorsak P, Puttipipatkhachorn S. Design and evaluation of floating multi-layer coated tablets based on gas formation. Eur. J Pharm Biopharm. 2008; 69(1):255-63.

HOW TO CITE: Surendranath Betala, Reshma Banu S, Ajay Kumar S. N., Dr. E. Gopinath. Formulation And Evaluation of Gastro Retentive Floating Drug Delivery System of Gliclazide, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 8, 3574-3588, https://doi.org/10.5281/zenodo.22055378