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IN-VITRO CHARACTERIZATION AND EVALUATION OF GASTRORETENTIVE FLOATING HBS CAPSULES OF GLICLAZIDE FOR SUSTAINED DRUG RELEASE

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ABSTRACT

The present research work attempted to formulation, characterization and evaluation of gastroretentive floating HBS (Hydrodynamically Balance System) capsules of gliclazide for sustain drug release. These floating HBS capsules of gliclazide were formulated by using two suitable polymer cationic charge chitosan and anionic charge xanthan gum with the help of physical blending and filled in capsules. Different evaluation parameters like their weight uniformity, drug content uniformity, swelling index of all formulation showing good results to develop the system. *In-vitro* floatation and in-vitro drug release studies also prove that all these formulation specially formulation GFC4 showing better drug release which is more than 10 hours due to suitable ratio using polymeric blend as well as formation of polyelectrolyte complex between two opposite charge polymers. It is also confirmed that there are no more incompatibility produce between drug and polymers by the help of FTIR also help to develop

the system. So, these types of gastroretentive floating HBS capsules will be very effective for gastroretentive sustain drug release.

Keywords: Gastroretentive, Floating, HBS, FTIR

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INTRODUCTION

The oral control release delivery of drug has been recently increasing interest in pharmaceutical department to obtain improved therapeutic advantages such as ease of dosing administration, patient compliance and easy to formulate ([1]). Previously, several oral control release drug delivery system being designed and developed, including floating systems that causes buoyancy in gastric fluid help to improve the therapeutical response [(2)]. Many approaches have been mention for gastroretentive sustain release drug delivery system through floatation [(3),] bio or mucoadhesion [(4)], sedimentation [(5),] unfoldable, expandable, or swellable systems [(5),] super porous hydrogel systems [(6),] magnetic systems [(7),] etc. Every approach has its own demerits. For example, swelling and expanding systems showing a hazard of fixed retention in the located site and muco or bioadhesive systems may cause in irritation of mucous layer because of high-localized concentration of the incorporated drugs [(6),] which produce serious complication for the patient. Among various gastroretentive drug delivery systems floating delivery of drugs represent the most effective and rational protection against early and rapid times of gastric emptying. Floating drug delivery system are designed to be remained floated on the gastric content due to its lower bulk density differentiated to that of the aqueous medium, thus retained in the upper region of GI tract for several hours and the drug is gradually released at a desired rate [(4, 5).] This results in an increased gastric residence time and a advance control

of the fluctuation in plasma drug concentration and however increase the bioavailability. Floating delivery of drug is of particular interest for drugs which [6-8] (a) act locally in the upper GI region (b) are primarily absorbed in the stomach (c) are poorly soluble at an high alkaline pH (d) have a narrow window of absorption and (e) are unstable in the intestinal or colonic environment. The main needed for floating delivery of drugs including that it should release contents slowly to serve as a reservoir, it should maintain specific gravity lower than gastric contents (1.004 – 1.01 gm/cm^3), it should form a cohesive gel barrier [8]. Floatation has been completed with the preparation of low concentration solid systems e.g. inclusion of sponges, highly porous systems [5- 6] which decrease in density upon contact with gastric fluid contents based on the increase of swelling agents [7] or carbon dioxide generation [8]. In addition, the inherent low density can be provided by the entrapment of air (e.g. hollow chambers) [6] or by the incorporation of low density materials (e.g. fatty materials or oils, or foam materials) [5].

Many attempts have been design to retain the floating dosage form in the stomach as a way of increasing the Gastric Residence Time (GRT) due to their low bulk density than gastric fluid and so remain floated in the stomach without altering the Gastric Emptying Rate (GER) for a prolong periods of time. When the system is floating on the gastric contents the drug is released sustain over prolong periods of time from this dosage form. After release of drug the intact system is emptied from the stomach which increased gastric residence time (GRT) and a improve control of fluctuations in plasma drug concentration. Although besides a minimal gastric content required to allow the proper achievement of the floating retention principle, a minimal level of floating force (A) is also needed to keep the dosage form reliably floated on the gastric fluid. To measuring the floating force kinetics a novel instruments for determination of resultant weight has been previously reported. The apparatus use by measuring continuously the force equivalent to A (as a function of time) that is required to maintain the submerged object. The object floats well if A is on the higher positive side. This apparatus helps in optimizing floating drug delivery systems with respect to stability and durability of floating forces produced in order to prevent the drawbacks of unforeseeable intragastric floating capability variations [6-8]:

$A = A_{buoyancy} - A_{gravity} = (df - ds)\, vg$

(Where, A= total vertical force, df = fluid density, ds = object density, v = volume and g = acceleration due to gravity)

Based on the mechanism of floatation, two different technologies available, i.e. non-

effervescent systems and effervescent systems are used in the development of floating drug delivery systems [3]. Effervescent systems having gas generating systems including Intragastric single-layered floating tablets, Intragastric bi-layered floating tablets, Multiple-unit type of floating pills and Volatile liquid or vacuum containing systems including Intra gastric osmotically controlled floating delivery systems. Gas filled floating delivery systems. Non-effervescent systems contain hydrodynamically balanced systems (HBS), Microballoons (Hollow microspheres) and Floating beads [3, 5, 7]. Among these floating systems, HBS (hydrodynamically balanced systems) have showing a lot of importance in recent days to increase gastroretention, which improve absorption of drugs especially those are absorbed from stomach and small intestine or drugs such as weak bases, which dissolve better in the acid environment of the stomach [9]. These systems contain drugs with gel-forming hydrocolloids meant to remain buoyant for several hours in the stomach content. On contact with the gastric fluid, these systems form a water colloidal gel barrier around their surface and maintain a bulk density less than 1. They are mainly single-unit dosage forms, and usually composed of one or more gel-forming hydrophilic polymeric substances and an active pharmaceutical ingredient. Hydroxypropyl Methylcellulose (HPMC), Hydroxethyl Cellulose (HEC), Hydroxypropyl Cellulose (HPC), sodium Carboxymethyl Cellulose (NaCMC), polycarbophil, polyacrylate, polystyrene, Polyethylene Oxide (PEO), agar, carrageenans or alginic acid are commonly used excipients to develop these systems. The polymer is mixed with drugs and usually administered in the HBS capsules (10). When the capsule containing drug-hydrocolloid mixture is exposed to gastric fluid, the capsule shell dissolves and the mixture swells to form a gelatinous barrier. This imparts buoyancy in gastric juice for a long period due to its continuous erosion of the surface, which allows water penetration to the inner layers maintaining surface hydration and buoyancy to the dosage form [11].

In this present work, gliclazide gastroretentive floating HBS capsules prepared by chitosan and xanthan gum by physical blending method was developed. These gliclazide floating HBS capsules were evaluated their uniformity of weight, swelling activity, drug content consistency, *in-vitro* floatation; *in-vitro* drug release with kinetics and FTIR studies was performed.

MATERIALS AND METHODS

Materials

Gliclazide was a gift sample from Ajanta Pharma. Pvt. Ltd., India

Other materials were purchased from different sources like

Chitosan and xanthan gum: Sigma Aldrich, USA.

Talc, lactose, magnesium stearate: Loba Chemie Pvt. Ltd., India

All additional chemicals and reagents used were of analytical grade.

Methodology

Preparation of gliclazide Gastroretentive floating HBS capsule

Generally, gliclazide floating HBS capsules were prepared by simple mixing (Blending) of gliclazide with polymers like chitosan and xanthan gum with their required quantities, then mixing other excipients like lactose as a diluent, talc as a glidant and magnesium stearate as a lubricant with this drug-polymer mixture for some time. Finally, the mixture of gliclazide, chitosan, xanthan gum, lactose, talc and magnesium stearate carefully filled into 1-size hard gelatin capsules with special precautions for keeping the drug content and weight uniformity. The amount of different gliclazide floating HBS capsules is given in the following Table 1 [12-14, 16, 19].

Table 1: Formula of different ingredients used to prepare gliclazide gastroretentive floating HBS capsules

Formulation Code	Ingradients					
	Gliclazide (mg)	Chitosan (mg)	Xanthan gum (mg)	Lactose (mg)	Talc (mg)	Magnesium stearate (mg)
GFC1	100	25	125	138	2	10
GFC2	100	50	100	138	2	10
GFC3	100	75	75	138	2	10
GFC4	100	100	50	138	2	10
GFC5	100	125	25	138	2	10

Evaluation of the consistency of weight

For estimate of weight uniformity of prepared capsules by taking 20 capsules in each formulation and weighing them appropriately by using an analytical electronic balance that should help to determine the average or mean weight of these capsules. Then calculate the weight variation or % coefficient variation by using this formula [14-16].

% coefficient variation = standard deviation / mean or average weight × 100

Evaluation of Swelling Index

The produced capsules were immersed in an excess amount of simulated gastric fluid at a temperature of 37°C for a specified duration. Subsequently, a time interval the capsules were

promptly extracted and measured using an analytical balance. The swelling percentage of the beads was determined using the following formula [17, 18, 20].

% swelling = (swollen beads weight-dry beads weight)/ (dry beads weight) × 100

Evaluation of drug content uniformity

The drug content uniformity of floating capsules was determined by using glass beaker in a magnetic stirrer. Emptying 10 capsules from each formulation were placed in the beaker containing 500 ml simulated gastric fluid (pH 1.2) maintained at 37 ± 0.5 ◦C for 1 h and speed of this beaker containing magnetic stirrer at 500 rpm. After one hour sample was withdrawn and check spectrophotometrically at 230 nm after filtration with a suitable filter papers [12, 14, 17, 21 - 22].

Evaluation of *in-vitro* floatation

For evaluating the *in-vitro* floating ability of gliclazide floating HBS capsules, one capsule from each formulation was immersed in 500 ml of simulated gastric fluid (pH 1.2) in a glass beaker at a temperature of 37 ± 0.5 °C for the required time. Then, visually notice the capsule was floating/buoyant on simulated gastric fluid (pH 1.2) in particular duration of time and noted the time periods for expressing the floating periods of these capsules [14, 17, 23]

Evaluation of *in-vitro* drug release study

In-vitro drug release data of gliclazide floating HBS capsules in simulated gastric fluid (pH 1.2) was determined by using a dissolution instrument (USP type II) with a speed 50 rpm at 37 ± 0.5° temperatures. At first, one capsule of gliclazide was transferred to the simulated gastric fluid (pH 1.2) containing a basket rotational dissolution instrument. Then, at the intermediate time interval, 5 ml of the sample was withdrawn from the dissolution medium and the same quantity of fresh phosphate buffer (pH 7.4) was added to maintain sink conditions. Now this withdrawal sample from the dissolution medium was diluted and filtered by using Whatman filter paper, and the amount of gliclazide release was evaluated using a spectrophotometer (Double beam UV-VIS spectrophotometer) at a wavelength of 230 nm against a blank sample [17, 24, 25].

Evaluation of the kinetics data of in-vitro drug release

For the determination of *in-vitro* release kinetics mechanism of gliclazide floating HBS capsules, the in-vitro release data were fitted to mathematically curve-fitted kinetics models like zero order, first order, Higuchi, Korsmeyer-Peppas and Hickson-Crowell model. We observed the n value that will express the release mechanism of the drug. If the n value is less

than or equal to 0.5 then this is called ficken diffusion controlled release mechanism; if the value ranges between 0.5 to 1 then this is called non-ficken release mechanism and if the value is greater than or equal to 1 than it refers to case-II transport or release [17, 26].

Evaluation by Fourier Transform-Infrared Spectroscopy (FTIR)

Samples were tested as potassium bromide (IR-grade) pellets by an FTIR spectroscope instrument (Alpha-FTIR, Bruker Optics, Germany). The potassium bromide pellets containing samples were placed in the sample holder, individually. The spectral scanning was recorded over the range of 4000–500 cm^{-1} [12, 27].

Evaluated statistical analysis

All determined data are expressed as mean ± standard deviation (Here n = 5).

RESULTS AND DISCUSSION

Preparation of gliclazide gastroretentive floating HBS capsules

These HBS capsules of gastroretentive drug delivery show importance in recent days and especially those that are absorbed in the small intestine [12]. These capsules are floated due to the mixing of the drug with a colloidal gel-forming polymer that help to buoyancy in the gastric content for a long time. In past few decade there are, several work reported by taking of chitosan in stomach-specific drug delivery due to its gel forming nature as well as in stomach-specific or gastroretentive HBS systems. Also here I used xanthan gum as a very natural and economical polymer to reliability for compile with chitosan and produce more viscous to hydrate and float for release the drug for long periods of time and also important things in my previous reported work formation of polyelectrolyte complex for sustain release drug delivery between two opposite charge polymer low molecular mass chitosan cationic nature and carboxy methyl tamarind gum anionic nature [14, 17, 28-30].

So this HBS capsule of gliclazide will be prepared by physical blending of drug gliclazide and two oppositely charged hydrophilic polymers, chitosan and xanthan gum, by adding other excipients like lactose, talc and magnesium stearate as diluents, glidant and lubricating agent and this blend was encapsulated in a single unit 1 size empty hard gelatin capsule to improve the sustained release of gliclazide from these HBS capsules.

Uniformity of weight

Table 2 will represent the value of the weight uniformity of different capsules of gliclazide. All this formulation should follow the USP specification of the weight uniformity test. Coefficient

of variation to all formulation not more than 2.50 that's mean all formulation will be filled properly.

Table 2: Weight uniformity test of different floating HBS capsules of gliclazide

Formulation Code	Weight Uniformity	
	Mean Weight (gm)	Coefficient of Variation (%)
GFC1	493.15 ± 4.44	1.01
GFC2	499.65 ± 6.31	1.09
GFC3	494.15 ± 5.67	2.02
GFC4	497.45 ± 4.14	1.05
GFC5	495.20 ± 3.87	1.02

Swelling index

This swelling behaviour is primarily attributed to the addition of a polyelectrolyte complex formed by two opposite-charge polymers, which not only imparts buoyancy to the capsules but also contributes to their development. The swelling of HBS capsules enhances drug release by facilitating diffusion of the drug from the polymer matrix. The swelling percentage was calculated using the specified formula, with the GFC4 formulation exhibiting a swelling percentage of 82%, as shown in Table 3

Drug content uniformity

The value of drug content uniformity is demonstrated in Table 3. The drug content of Gliclazide HBS capsules ranged from 90.68 ± 0.14 to 92.43 ± 0.37, which helps to maintain the composition and proper release.

Table 3: Swelling index and drug content uniformity of gastroretentive floating HBS capsule of gliclazide

Formulation Code	Swelling index (%)	Drug content uniformity (%)
GFC1	78.35 ± 0.34	91.05 ± 0.18
GFC2	79.48 ± 0.45	90.68 ± 0.14
GFC3	80.03 ± 0.57	91.03 ± 0.22
GFC4	82.63 ± 0.62	92.43 ± 0.37
GFC5	81.77 ± 0.99	91.87 ± 0.46

***In-vitro* floatation**

The floating times for all formulations are given in Table 4. It was found that all formulations floated for not less than 10 hours. These results explain that a significant effect on per cent drug content was observed with polymer concentration.

Table 4: In-vitro floatation of gastroretentive floating HBS capsule of gliclazide

Formulation Code	***In-vitro* floatation time (Hr)**
GFC1	Not less than 10 hours
GFC2	Not less than 10 hours
GFC3	Not less than 10 hours
GFC4	Not less than 10 hours
GFC5	Not less than 10 hours

***In-vitro* drug release**

The *in-vitro* release of gliclazide from these capsules was analysed in simulated gastric fluid (pH 1.2) showing in Fig 2. Here all the formulations show good in-vitro drug release over a prolong periods of time, more than 10 hours. All these HBS capsules of gliclazide represent well-sustained release the drug. It is also noted that the *in-vitro* sustained release of the formulation will little bit increase slightly when the quantity of chitosan by taking appropriate ratio containing xanthan gum. Therefore, all formulations, especially GFC4, show better sustained release over prolonged periods of time (More than 10 hours). Here another important things to formation of electrolyte complexes by taking of two opposite charge polymers i.e. cationic chitosan and anionic xanthan gum that also improved the sustained release the drug

from different formulation.

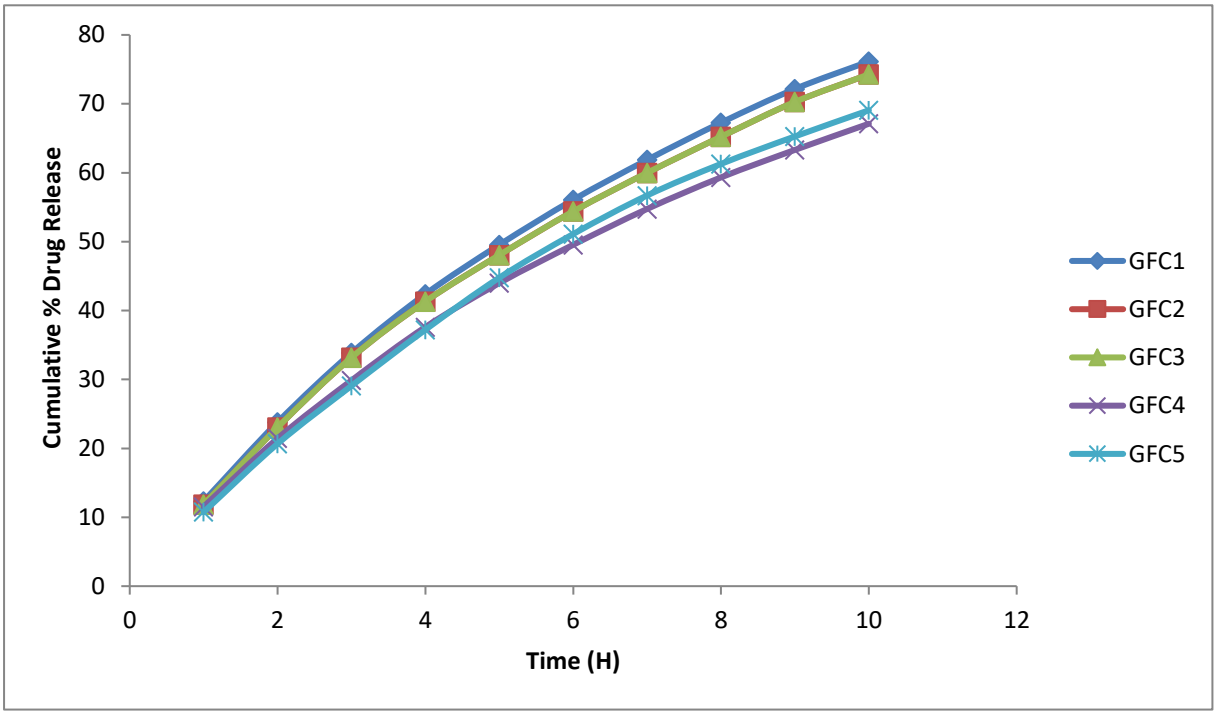

Figure 2: In-vitro release of gliclazide from these floating HBS capsules

In Table 5 represents the different curve fitting mathematical kinetics model. All the formulations of gliclazide floating HBS capsule will fit in the Korsmeyer-Peppas model (R^2 = 0.991 to 0.998). The release exponent (n) of all formulations was showing ranges within 0.77 to 0.79, referring to release mechanisms like non-Fickian or anomalous diffusion, indicating both controlled swelling and diffusion.

Table 5: In vitro release kinetics data of all formulations

Formulation Code	R^2 Value					n value
	Zero order	First order	Higuchi	Korsmeyer-peppes	Hickson-crowell	
GFC1	0.975	0.845	0.877	0.991	0.902	0.77
GFC2	0.974	0.843	0.876	0.998	0.901	0.78
GFC3	0.974	0.848	0.874	0.992	0.903	0.77
GFC4	0.975	0.853	0.889	0.993	0.906	0.79
GFC5	0.976	0.852	0.888	0.994	0.907	0.78

FTIR characterization

FTIR spectra of gliclazide, chitosan, xanthan gum and formulation GFC4 for the determination of drug-polymer interaction will be shown in Fig. 3. The FTIR spectrum of this formulation

will show different characteristic peaks due to the stretching and bending of the presence of different functional groups. This all type of peak compares to the drug and polymers, where there is no more interaction as well as chemical or physical incompatibilities occur in between the drug and polymer, which maintains the stability.

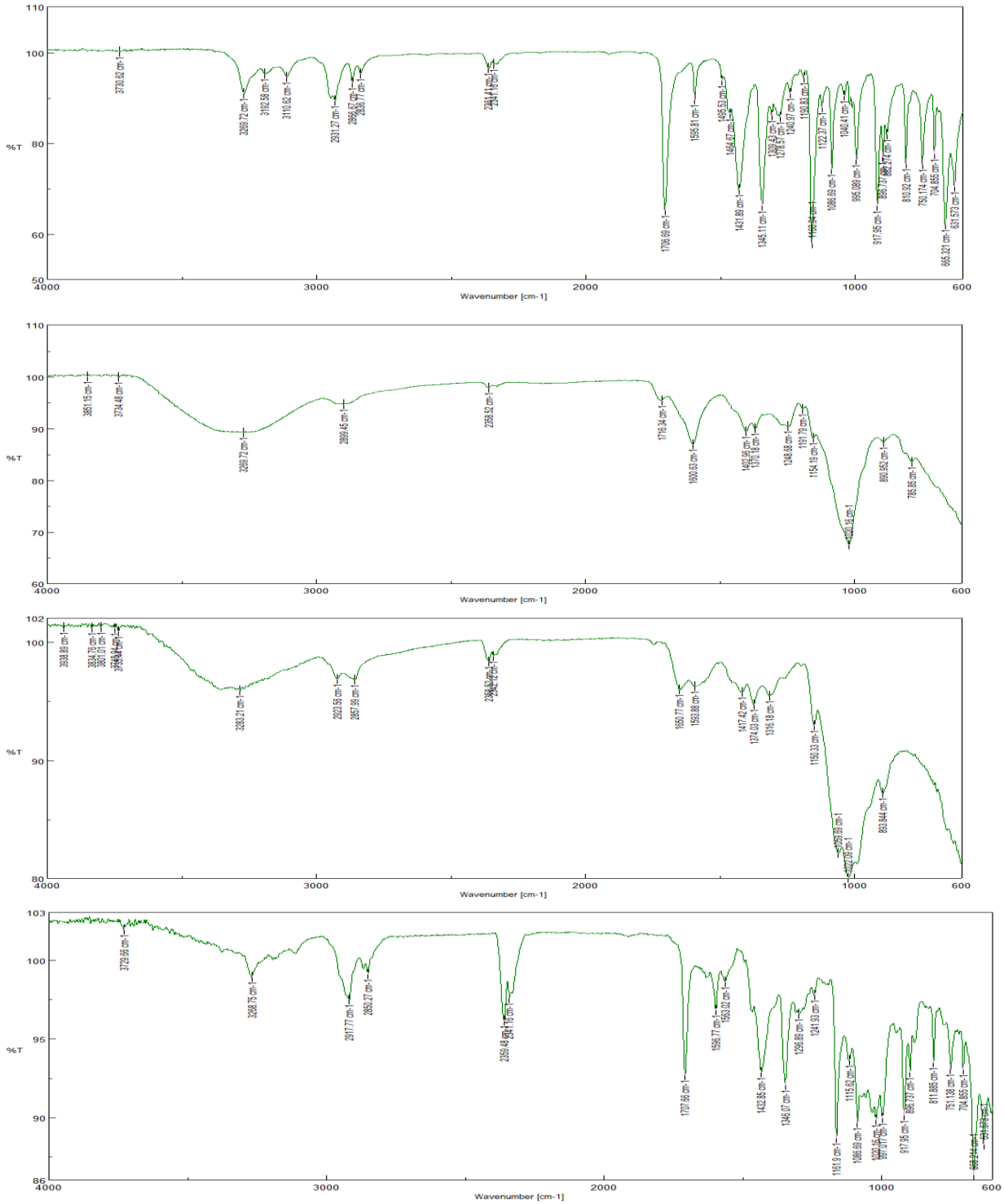

Figure 3: FTIR spectra of gliclazide, chitosan, xanthan gum and GFC4 HBS capsule

CONCLUSION

From this research work, it was concluded that the formulation of gastroretentive floating HBS capsules of gliclazide prepared by physical blending of two opposite charge hydrophilic gel-forming colloidal polymers, namely cationic chitosan and anionic xanthan gum (formation of electrolyte complex), helps to sustain the release of the drug. The different evaluated properties like uniformity of weight, drug content uniformity, swelling activity, *in-vitro* floatation prove that good drug present due to better mixing, excellent swelling and long floating retention to maintain the stability and developed the system. All these formulations show great sustained drug release *(in-vitro)* in simulated gastric fluid (pH: - 1.2) over more than 10 hours, although the GFC4 shows the best sustain among these. This is because the proper ratio of two opposite charge polymer and to form the polyelectrolyte complex. So this type of gastroretentive floating HBS capsules will be very useful in the future for other suitable characterised drugs which help to retain and sustain release of the drug over prolonged periods of time.

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AUTHOR CONTRIBUTIONS

Radheshyam Samanta: Conceptualization, formulation development, experimental work, data analysis, interpretation of results, and manuscript preparation.

Tamal Deb Goswami: Literature review, experimental assistance, data compilation, and manuscript editing.

Hrushikesh Behera: Formulation optimization, characterization studies, and data collection.

Ranjit Kumar Sutar: In-vitro evaluation studies, statistical analysis, and result interpretation.

Ashok Kumar Sethi: Research supervision, methodology validation, and critical review of the manuscript.

Pravati Deo: Scientific guidance, manuscript review, and technical support.

Bhabatarini Jena: Final manuscript review, proofreading, and approval of the final version.

All authors have read and approved the final manuscript.

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CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this manuscript.

DATA AVAILABILITY STATEMENT

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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