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DESIGN, DEVELOPMENT AND EVALUATION OF GLIMEPIRIDE FLOATING BEAD TO IMPROVE THE SUSTAIN RELEASE OF DRUG

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ABSTRACT

The current work attempted to developed glimepiride floating beads made of sodium alginate and xanthan gum by ionotropic emulsifying gelation method was to evaluate their morphology, % of yield value, drug entrapment efficiency, drug content uniformity, in vitro floatation. In addition, *in vitro* drug release was performed. The different evaluated properties like morphological charecteristic, % of yield value, drug entrapment efficiency, drug content uniformity, in vitro floatation etc prove that rough surface to improve the drug release, good drug present due to better entrapment, excellent floatation to stability and developed the beads. Also the in vitro release of drug in all formulation (especially GB5) is more 12 hours in phosphate buffer (pH7.4). So, it was clearly stated that the formulation of glimepiride beads prepared by addition of suitable polymeric mixture, namely sodium alginate and xanthan gum with olive oil and Tween 80 by emulsifying ionotropic gelation method help to retain and sustain release the drug for prolong periods of time in the intestine.

KEYWORDS: Floating, Beads, Ionotropic, Gelation.

INTRODUCTION

The oral controlled release drug delivery have recently been of increasing interest in pharmaceutical field to achieve improved therapeutic advantages such as ease of doing administration, patient compliance and flexibility in formulation.[1] Over the past few decades, several oral control release drug delivery approaches being designed and developed, including floating systems that causes buoyancy in gastric fluid help to improve the pharmacotherapy.[2]

Many approaches have been reported in the literature for improved gastroretention for oral sustained release dosage forms viz. 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 limitations. For example, swelling and expanding systems may show a hazard of permanent retention in the desired site and muco- or bioadhesive systems may result in irritation of mucous layer due to high-localized concentration of the incorporated drugs,[6] which might have serious implications for the patient. Among various gastroretentive drug delivery approaches, floating drug delivery presents the most effective and rational protection against early and random times of gastric emptying. Floating dosage forms are designed to be remained buoyant on the gastric fluid because of its lower bulk density compared to that of the aqueous medium, thus retained in the stomach for several hours and the drug is slowly at a desired rate.[4,5] This results in an increased GRT and a better control of the fluctuation in plasma drug concentration and thus enhances the bioavailability. Floating drug delivery is of particular interest for drugs which[6-8] (a) act locally in the stomach; (b) are primarily absorbed in the stomach; (c) are poorly soluble at an alkaline pH; (d) have a narrow window of absorption; and (e) are unstable in the intestinal or colonic environment. The major requirements for floating drug delivery system including that it should release contents slowly to serve as a reservoir, it must maintain specific gravity lower than gastric contents (1.004 – 1.01 gm/cm^3), it must form a cohesive gel barrier.[8]

Floating has been achieved with the preparation of low-density dry solid systems e.g. inclusion of sponges, highly porous systems[5,6] or with systems, which decrease in density upon contact with gastric fluid contents based on the expansion 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]

Various attempts have been made to retain the floating dosage form in the stomach as a way of increasing the GRT due to their low bulk density than gastric fluid and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period. While the system is floating on the gastric contents, the drug is released slowly at the desired rate from the dosage form. After release of drug, the residual system is emptied from the stomach. This results in an increased GRT and a better control of the fluctuations in plasma drug concentration. However, besides a minimal gastric content needed to allow the proper achievement of the buoyancy retention principle, a minimal level of floating force (F) is also required to keep the dosage form reliably buoyant on the gastric content. To measure the floating force kinetics, a novel apparatus for determination of resultant weight has been reported in the literature. The apparatus operates by measuring continuously the force equivalent to F (as a function of time) that is required to maintain the submerged object. The object floats better if F 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 buoyancy capability variations[6-8]:

$$F = F_{buoyancy} - F_{gravity} = (Df - Ds)\, gv$$

(Where, F= total vertical force, Df = fluid density, Ds = object density, v = volume and g = acceleration due to gravity) Based on the mechanism of buoyancy, two distinctly different technologies, i.e. non-effervescent and effervescent systems have been utilized in the development of floating drug delivery systems.[3] Effervescent systems contain 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 (HBSs), Microballoons (Hollow microspheres) and Floating beads.[3,5,7]

Micro beads are nearly spherical, small with diameter of 0.5- 1000 μm. The solid and free-flowing particulate carriers containing dispersed drug particles either in solution or crystalline form allow a sustained release or multiple release profiles of treatment with various active agents without major side effects.[9] Additionally, the microbeads maintain functionality under physiological conditions; can incorporate drugs to deliver locally at high concentration, ensuring that therapeutic levels are reached at the target site while reducing the side effects by keeping systemic concentration low. The micro beads are produced from several polymers such as cationic polymers, e.g., chitosan, anionic polymers, e.g., sodium alginate, and binding components, e.g., gelatine, chondroitin sulfate, avidin in a predetermined ratio.[10]

Beads can provide sustained-release properties and a more uniform distribution of drugs within the gastrointestinal tract. Furthermore, the bioavailability of drugs formulated in beads has been enhanced. Numerous studies have been reported concerning the use of alginate beads as a controlled release carrier.[11] The advantages of micro beads including limiting fluctuation within therapeutic range, reducing side effects, decreasing dosing frequency, improving bioavailability and improving patient compliance. There are also different methods are available for formulation of beads including Ionotropic Gelation Method, External Gelation Method, Internal Gelation Method, Emulsion Gelation Method, Polyelectrolyte Complexation Method etc.[11]

Later there are also several polymers available in different categories like natural, synthetic, semi synthetic etc used to designing the different floating beads i.e., Cellulose derivatives: Methylcellulose, Ethylcellulose, Hydroxy-ethylcellulose, Hydroxyl propyl cellulose, Hydroxy propyl methylcellulose, Sodium carboxy methylcellulose; Poly (acrylic acid), Carbomers, olycarbophil, Poly (hydroxyethyl methylacrylate), Poly (vinyl alcohol), Sodium alginate; Guar gum, Xanthan gum, Lectin, pectin, gelatine, chitosan,[7,8,9,11] etc and also many drugs are used to designing microbeads for floating drug delivery system, mentioning some marketed product like Theophylline, Nifedipine, Norfloxacin, Zaltoprofen, Ibuprofen etc.[10]

In the present work, glimepiride (Glimepiride is widely used oral antidiabetic drug acts as a model drug in this research work belonging to the class of sulfonylurea in BCS-II category. It is commonly prescribed for the management of type 2 diabetes mellitus by stimulating insulin release from pancreatic beta cells. However, glimepiride has a relatively moderate to short biological half-life and its rapid metabolism and elimination can lead to the need for frequent dosing) floating beads made of sodium alginate and xanthan gum by ionotropic emulsifying gelation method was developed. These glimepiride beads were evaluated their morphology, % of yield value, drug entrapment efficiency, drug content uniformity, in vitro floatation. In addition, *in vitro* drug release was performed.

MATERIALS AND METHODS

Materials

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

Other materials were purchased from different sources like

Sodium alginate and xanthan gum: Sigma Aldrich, USA.

Calcium chloride Olive oil, Tween 80: Loba Chemie Pvt. Ltd., India

All other chemicals and reagents used were of analytical grade.

Formulation of floating beads of glimepiride

Floating bead containing Glimepiride was prepared by emulsifying ionotropic gelation method. Overall five batches were formulated using different ratios of sodium alginate and xanthan gum. Transfer the accurately weighed quantity of sodium alginate and xanthan gum in a clean beaker containing distilled water and stirred for 15 min. To this solution, add the required olive oil and stirred continuously for 30 min at 1000 rpm with addition of Tween 80 to form an emulsion. Add Glimepiride to the formed emulsion with continuous stirring for 15 min. This emulsion was extruded drop wise through a 20 gauge syringe needle into 100 ml of calculated concentration of calcium chloride solution; continuous stirred at 100 rpm until all the emulsion is extruded. Thus formed emulsion gel beads were allowed to stand in the solution for 60 min before being separated and washed with distilled water. The collected beads were dried in a tray dryer at 40°C and stored in a desiccators for further investigation.[12,19]

Table 1: Formula of different ingredients used to prepare glimepiride floating beads.

Ingredients	Formulation Code				
	GB1	GB2	GB3	GB4	GB5
Glimepiride (mg)	500	500	500	500	500
Sodium alginate (mg)	900	800	700	600	500
Xanthan gum (mg)	100	200	300	400	500
Olive oil (ml)	10	10	10	10	10
Tween 80 (%w/w)	0.25	0.25	0.25	0.25	0.25
Calcium Chloride (%w/v)	5	5	5	5	5
Water (ml)	100	100	100	100	100

Evaluation of morphological charecteristic

For the determination of morphological characteristic like theirs surface and size first, we take some beads in glass slide containing optical microscope and and visually inspect the surface morphology and the and diameter of the beads was determined by screw gauge[17] for this purpose, 20 dried bead were randomly selected from each batch and the mean diameter was determined by screw gauge. The least count of screw gauge was 0.005 mm. Colour and shape of dried beads of each batch was noted.[20]

Evaluation of % of yield value

The formulations' percentage yield was estimated as a % of the total amount of polymers and medication utilised to make the beads. The following formula was used to obtain the percentage yield.[21]

$$\text{Production yield (\%)} = \frac{\text{Total amount of prepared beads}}{\text{Amount of drug + total amount of polymers}} \text{ x100}$$

Evaluation of drug entrapment efficiency

By dissolving a known number of beads in methanol and vigorously shaking them on a Vortex mixer at room temperature, the amount of Glimepiride entrapped in the beads could be calculated. Spectrophotometric analysis was used to assess the amount of Glimepiride loaded in the beads. The loading efficiency percentage was obtained using the equation below.[22]

$$EE\,(\%) = \frac{(W_{total\,drug} - W_{free\,drug})}{W_{total\,drug}} \times 100\%$$

Evaluation of drug content uniformity

The drug content uniformity of beads was determined by using glass beaker in a magnetic stirrer. 100 mg of beads were placed in the beaker containing 500 ml of phosphate buffer (pH 7.4) 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 withdrown and check spectrophotomatrically after filtration with a suitable filter papers.[23]

Evaluation of in vitro floatation

The buoyant ability of beads was determined using dissolution apparatus type-II (Campbell Electronics, India). 100 mg of beads were placed in the dissolution vessel containing 500 ml of phosphate buffer (pH 7.4) maintained at 37 ± 0.5 ◦C for 12 h and the paddles were rotated at 1000 rpm. The floating ability of beads was measured by visual observation. The time taken to buoyant at the surface of dissolution medium (known as buoyant lag-time) and duration of floating were noted.[24]

Evaluation of in-vitro drug release study

The in vitro arrival of Glimepiride from the beads was investigated using a USP paddle disintegration apparatus (USP type-II). The disintegration medium was 900 ml of phosphate buffer solution (pH-7.4) at 37 0.5 °C and 100 rpm. At predetermined intervals (15 minutes, 30 minutes, 45 minutes, 60 minutes, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours, 8 hours, 12 hours,), an aliquot of 5 ml of the solution was removed and replaced with 5 ml of new dissolving media. Tests were spectrophotometrically estimated at 228 nm after filtration using a 0.45 m film channel (Millipore).[25,26]

Statistical analysis

All determined data are expressed as mean ± standard deviation (Here n = 3).

RESULTS AND DISCUSSION

Preparation of floating beads of of glimepiride

In generally floating beads was more reliable, economical, and easy to handling dosage system as compare to another system of those drugs having large extent absorbed in small intestine. Previously many similar works reported in this area (11, 12, 24, 26, 27-30), Here this beads was designed by addition of polymers sodium alginate and xanthan gum with suitable emulsifying ionotropic gellation method which help to floating the drug in intestine for long periods and sustain release the drug over a prolong periods of time to developed the system.

Morphological characteristic

The shape of beads varies from spherical to irregular shape with changing concentration and ratio of polymers and the colour of the beads were white creamy. The formulated beads were in the size range of 0.98 ± 0.23 to 1.31 ± 0.25mm which is shown in Table 2.

% of yield value

% of yield value was found to be satisfactory between 95 ± 0.07 to 98 ± 0.05 which demonstrates that beads were prepared by suitable composition of polymer and drug. The brief data of % of yield value is shown in Table 2.

Table 2: Size and % of yield value of glimepiride floating beads.

Formulation Code	Size (mm)	% of yield value
GB1	0.98 ± 0.23	95 ± 0.07
GB2	1.03 ± 0.13	97 ± 0.05
GB3	1.15 ± 0.34	96 ± 0.03
GB4	1.29 ± 0.38	98 ± 0.05
GB5	1.31 ± 0.25	97 ± 0.02

Drug entrapment efficiency

The drug entrapment efficiency (Showing Table 3) value range from 87.35 ± 0.34 to 88.77 ± 0.99 which help to maintain the maximum quantity of drugs are engulf within the beads and increase the drug content uniformity.

Drug content uniformity

The value of drug content uniformity is demonstrated in Table 3. The drug content of Glimepiride beads ranged from 89.05 ± 0.18 to 91.87 ± 0.46 which help to maintain the composition and proper release.

Table 3: Drug entrapment efficiency and content uniformity of glimepiride floating beads.

Formulation Code	Drug entrapment efficiency (%)	Drug content uniformity (%)
GB1	87.35 ± 0.34	89.05 ± 0.18
GB2	88.48 ± 0.45	90.68 ± 0.14
GB3	89.03 ± 0.57	90.03 ± 0.22
GB4	88.63 ± 0.62	91.43 ± 0.37
GB5	88.77 ± 0.99	91.87 ± 0.46

In vitro floatation

The percentage floating ability of all formulations is given in Table 4. It was found that all formulations' percentage floating ability was in a range of 86.05 ± 1.34 to 88.77 ± 1.89. These results explain that a significant effect on per cent drug content was observed with polymer concentration.

Table 4: In vitro floatation of glimepiride floating beads.

Formulation Code	In vitro floatation (%)
GB1	86.05 ± 1.34
GB2	87.48 ± 1.75
GB3	88.03 ± 1.57
GB4	87.63 ± 1.42
GB5	88.77 ± 1.89

In vitro drug release

In vitro release of glimepiride from floating beads has been given on Figure 2. All the formulation performs good release profile prepared through suitable composite polymer sodium alginate and xanthan gum with their proper ratio by the addition of olive oil with tween 80 as an emulsifying agent. These emulsifying ionotropic gelation method help to release the drug more than 12 hours because of sutable composition of polymer. Here all the formulation specially GB5 have better sustain release the drug because the quantity of sodium alginate and xanthan gum are equally 500 mg as compare to GB1, GB2, GB3 and GB4 due to its ratio changes.

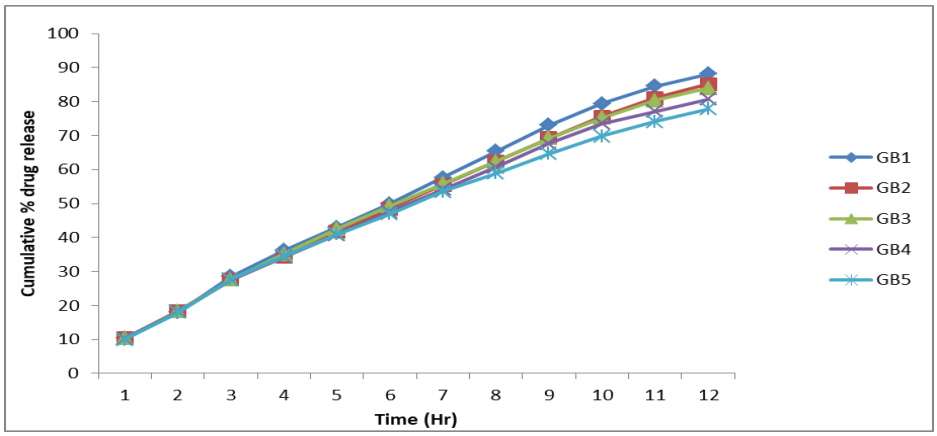

Figure 2: In vitro release of drug (glimepiride) from these floating beads.

CONCLUSION

In this research work, it was clearly stated that the formulation of glimepiride beads prepared by addition of suitable polymeric mixture, namely sodium alginate and xanthan gum with olive oil and Tween 80 by emulsifying ionotropic gelation method help to retain and sustain release the drug for prolong periods of time in the intestine. The different evaluated properties like morphological charecteristic, % of yield value, drug entrapment efficiency, drug content uniformity, in vitro floatation etc prove that rough surface to improve the drug release, good drug present due to better entrapment, excellent floatation to stability and developed the beads. Also the in vitro release of drug in all formulation (especially GB5) is more 12 hours in phosphate buffer (pH7.4). This is because proper the ratio of ratio of sodium alginate and xanthan gum. So this type of floating beads will be very useful in the future to other suitable characterized drugs which help to retain or holding and sustain release the drug over prolong periods of time.

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