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A Review on Floating Drug Delivery System

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ABSTRACT

Floating drug delivery frameworks improves the medication bioavailability and patient consistence by expanding the gastric living arrangement time and controlling the medication discharge. In ongoing decades, there have been various endeavors to beat the boundaries like short gastric living arrangement times and eccentric gastric discharging times. In this audit, the mechanical and research headways made in skimming frameworks are talked about. Later innovative and logical research has been committed to the improvement of rate controlled medication conveyance frameworks to conquer physiological difficulties, for example, short gastric living arrangement times and unusual gastric exhausting occasions. The drifting or hydro-powerfully controlled medication conveyance frameworks are helpful in such application. The present review addresses quickly about the skimming drug conveyance frameworks. This audit likewise outlines the in vitro procedures, in vivo examinations to assess the presentation and use of drifting frameworks, and utilizations of these frameworks. These frameworks are helpful to a few issues experienced during the advancement of a pharmaceutical dosage structure.

KEYWORDS: *Floating, Gastric Retention, Application, Evaluation*

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INTRODUCTION

The oral route is progressively being employed for the delivery of therapeutic agents as a result of the low value of the medical care and simple administration cause high levels of patient compliance.[1]Gastro long drug delivery systems ar the systems that are retained in the abdomen for a extended amount of time and thereby improve the bioavailability of drug that are preferentially absorbed from upper GIT.[2] Gastroretensive systems will stay within the stomachic region for many hours and thence considerably prolong the stomachic duration of medication. Prolonged stomachic retention improves bioavailability, reduces drug waste and improves solubility for medicine that ar less soluble during a high pH scale environment.[3] it's applications additionally for native drug delivery to the abdomen and proximal tiny intestines. Gastro retention helps to supply higher availableness of latest product with new therapeutic potentialities and substantial advantages for patients.[4] Prolonged stomachic retention improves bioavailability, reduces drug waste, and improves solubility for medicine that ar less soluble during a high pH scale environment.[5]

To formulate a successful stomach specific or gastro retentive drug delivery system, many approaches square measure currently utilized within the prolongation of the stomachic residence times (GRT) like hydrodynamic ally balanced systems (HBS) / floating drug delivery system, low density system, raft systems incorporating alginate gels, bioadhesive or mucoadhesive systems, high density systems, super porous hydro gels and magnetic systems.[6] Based on these approaches, classification of floating drug delivery systems (FDDS) has been represented intimately. In vivo/in vitro analysis of FDDS has been mentioned by scientists to assess the potency and application of such systems.[7]

STOMACH ANATOMY:

The basic operate of the abdomen is to method and transport food in little intestine.[8]The duration of food is tiny and largely proteins square measure digestible. Structurally the abdomen is split into 3 regions: structure, body, and pylorus.[9] The proximal half structure and body acts as a reservoir for undigested material, whereas the cavity is that the main website for commixture motions and act as a pump for viscus remotion by dynamic actions.[10]The average of pH scale in fasted healthy person is one.1± 0.15, once intake of food the pH scale could rise to levels within the three.0 to4.0 level thanks to the buffering capability of proteins. However, in fasted state, viscus secretion in girls is slightly below that of men.[11]

Migrating myoelectric cycle (MMC) is further divided in to four phases. They are:

1. Phase I (basal phase)
2. Phase II (preburst phase)
3. Phase III (burst phase)
4. Phase IV

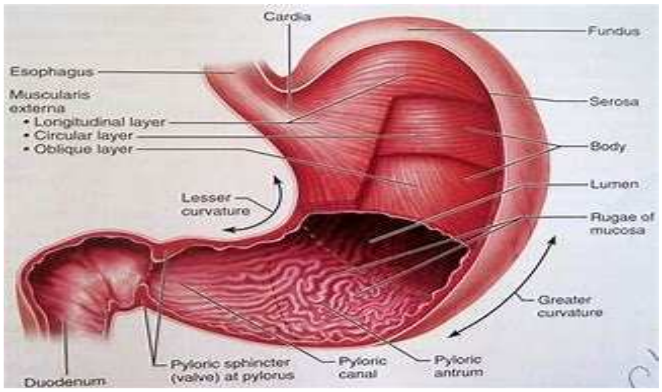

Fig. 1: Physiology of stomach

Gastric remotion happens in each the abstinence and fed states. throughout the abstinence state associate interdigestive series of electrical events crop up that cycle each through abdomen and gut each 2-3 hrs, that is named as repose biological process myloelectric cycle or migrating my electric cycle(MMC).[12]

Phase I- it's a quiescent amount lasting from thirty to 60minutes with no contractions.
Phase II- It consists of intermittent contractions that delicately increase in intensity because the section progresses, and it lasts regarding twenty to 40minutes. internal organ discharge of fluid and extremely tiny particles begins later during this phase.[13]

Phase III- this is often a brief amount of intense distal and proximal stomachic contractions (4– 5contractions per minute) lasting regarding ten to twenty minutes; these contractions, additionally referred to as house-keeper wave, sweep stomachic contents down the little Intestine.[14]

Phase IV- this is often a brief short-lived amount of regarding zero to5 minutes, and the contractions dissipate between the last a part of clinical test and quiescence of part I.[15]

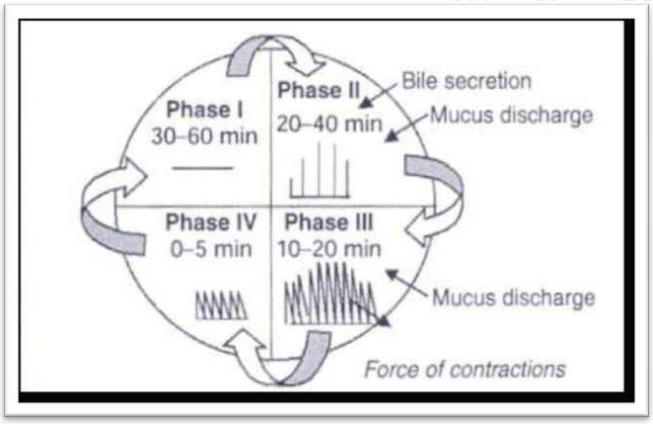

Fig 2: Motility pattern in gastrointestinal tract.[16]

Need For gastric Retention:
Drugs that are absorbed from the proximal a part of the canal (GIT). Drugs that are less soluble or are degraded by the alkalic pH they encounters at the lower a part of GIT.[17] Drugs that are absorbed due to variable internal organ evacuation time. Local or sustained drug delivery to the abdomen and proximal bowel to treat bound conditions.[18]

Approaches to Stomachic Retention:
Various approaches are pursued to extend the retention of Associate in Nursing oral dose type within the abdomen, for instance, bioadhesive approach during which the adhesive capability of some chemical compound with conjugated protein is closely applied to the animal tissue surface of abdomen. Alternative approach include: high density and rarity approach.[19]

1. High density approach:
For making ready such variety of formulations, the density of the pellets ought to be over the abdomen fluid. it might be a minimum of one.50 G/ml. during this kind, the drug will be coated or mixed with significant, nontoxic materials like sulfate, oxide, etc.[20]

2. **low density approach:Floating systems come back** below tenuity approach. during this approach, the density of pellets ought to be but one g/ml, thus on float the pellets or tablets within the internal organ fluid and, unleash the drug slowly for a extended amount of your time. this kind is additionally referred to as as Hydro dynamically balanced System (HBS). [21]

FACTORS AFFECTING GASTRIC RETENTION:
Factors affecting gastric emptying-
The most vital parameters touching stomachal remotion and, hence, the stomachal retention time of oral indefinite quantity forms include:

1. Density:GRT may be a operate of indefinite quantity kind buoyancy that's obsessed with the density.
2. Size: indefinite quantity kind units with a diameter of quite seven.5mm ar reportable to possess Associate in Nursing exaggerated GRT compared those with a diameter of nine.9mm.[22]
3. form of indefinite quantity kind: polyhedron and ring formed devices with a flexural modulus of forty eight and twenty two.5 kg pounds per area unit (KSI) ar reportable to possess higher GRT K ninetieth to 100% retention at twenty four hours compared with alternative shapes.[23]
4. single or multiple unit formulation:
   Multiple unit formulations show a a lot of inevitable unharness profile and insignificant impairing of performance thanks to failure of units, permit co-administration of units with totally different unharness profiles or containing incompatible substances and allow a bigger margin of safety against indefinite quantity kind failure compared with single unit indefinite quantity forms.[24]
5. Fed or Unfed state:Under fast conditions, the GI motility is characterised by periods of sturdy motor activity or the migrating myoelectric advanced (MMC) that happens each one.5 to two hours. The MMC sweeps undigested material from the abdomen and, if the temporal order of administration of the formulation coincides therewith of the MMC, the GRT of the unit is expected to be terribly short. However, within the fed state, MMC is delayed and GRT is is significantly longer.[25]
6. Nature of Meal – Feeding of inedible polymers or carboxylic acid salts will modification themotility pattern of the abdomen to a fed statethus decreasing the stomachal remotion rate and prolonging drug release.[26]
7. Caloric content – GRT is exaggerated by four to ten hours with a meal that's high in proteins andfats.
8. Frequency of Feed – The GRT will increase by over four hundred minutes once sequent meals aregiven

compared with one meal thanks to the low frequency of MMC.
9. Gender – Mean mobile GRT in males (3.4±0.6hours) is a smaller amount compared with their age and race matched feminine counterparts (4.6±1.2hours), no matter the load, height and body surface.
10. Age – senior individuals, particularly those over seventy, have a considerably longer GRT.
11. Concomitant Drug Administration –Anticholinergics like alkaloid and propantheline, opiates like antitussive and prokinetic agents like metoclopramide.[27]
12. Biological factors – polygenic disorder} and Crohn's disease, stress etc.
13. Posture – GRT will vary between supine and upright mobile states of the patient.

FLOATING DRUG DELIVERY SYSTEM:

Floating systems or hydrodynamic ally controlled systems area unit low-density systems that have decent buoyancy to float over the stomachal contents and stay buoyant within the abdomen while not touching the stomachic remotion rate for a protracted amount of your time differing kinds of floating medicine are effervescent and non-effervescent floating medicine. Effervescent systems embrace use of gas generating agents, carbonates like bicarbonate of soda and organic acid like acid and hydroxy acid gift within the formulation to provide CO2 gas, so reducing the density of system and creating it float on the stomachal fluid. These effervescent systems more classified into 2 varieties area unit Gas generating systems, Volatile liquid/vacuum systems.[28] The principle of buoyant preparation offers a straightforward and practical approach to attain enhanced stomachal continuance for the dose type and sustained drug release.[29] Based on the mechanism of buoyancy, 2 clearly totally different technologies are utilised in development of FDDS that are:

- **Effervescent System**

A. Gas generating system
B. Volatile liquid containing system

- **Non-effervescent system**

A. Colloidal gel barrier system.
B. Alginate beads.
C. Hollow microspheres / Microballons.
D. Intragastric Floating Drug Delivery Device / Microporous compartment system[30]

- **Effervescent System**

Effervescent systems include use of gas generating agents, carbonates (e.g. Na bicarbonate) and alternative organic acid (e.g. acid and salt acid) gift within the formulation to supply CO2 (CO2) gas, so reducing the density of system and creating it float on the gastric fluid. an alternate is that the incorporation of matrix containing portion of liquid, that manufacture gas that evaporate at body temperature.[31]
These effervescent systems more classified into2sorts.

A. Gas generating systems:

These are formulated by intimately mixing the CO2 generating agents and the drug within the matrix tablet. These have a bulk density lower than gastric fluids and therefore remain floating in the stomach unflattering the gastric emptying rate for a prolonged period.

B. Volatile liquid vacuum containing systems:

These systems is created to float within the abdomen owing to floatation chamber, which can be a vacuum or full of air or a harmless gas, whereas drug reservoir is encapsulated within a microporous compartment.[32]

- **Non Effervescent System**

This type of system, when swallowing, swells unrestrained via imbibitions of viscus fluid to associate extent that it prevents their exit from the abdomen. These systems could also be remarked because the 'plug-type systems' since they need a bent to stay lodged close to the pyloric valve. one in all the formulation strategies of such indefinite quantity forms involves the blending of drug with a gel, that swells involved with viscus fluid when oral administration and maintains a relative integrity of form and a bulk density of but one inside the outer jellylike barrier[33]. The air at bay by the swollen compound confers buoyancy to the current indefinite quantity forms. the foremost normally used excipient in non effervescent floating drug delivery system area unit gel forming or extremely swell able polysaccharide sort hydrocolloids, polysaccharides and matrix forming polymers like polyacrylate, polymethacrylate and polycarbonate. when oral administration these indefinite quantity kind swells involved with viscus fluid and attains a bulk density of < one. The air entrapped inside the swollen matrix imparts buoyancy to the indefinite quantity form.[34]

A. colloid Barrier Systems(Hydrodynamic Balanced Systems)

Such system contains drug with gel-forming hydrocolloids meant to stay buoyant on the abdomen content. This prolongs GRT and maximizes the number of drug that reaches its absorption web site within the resolution kind for prepared absorption, this technique incorporates a high level of1oradditional gel-forming extremely soluble polysaccharides ortmatter e.g.(HPMC),polysaccharides and matrix forming compound like polycarbophil, cinnamene and polyacrylate. On coming back within the contact with GI fluid, the matter within the system hydrates and forms a mixture gel barrier around its surface.[35]

B. Microporous Compartment Systems

This technology relies on the encapsulation of a drug reservoir within a Microporous compartment with pores on its high and bottom walls. The peripheral wall of the drug reservoir compartment is totally sealed to stop any direct contact of viscus surface with the unmelted drug. within the abdomen, the floatation chamber containing entrapped air causes the floatation chamber containing entrapped air causes the delivery system to float over the viscus content. viscus fluid enters through the aperture, dissolves the viscus fluid to associate extent that it forestall their exist from the drug and carrier the dissolved drug for continuous transport across the bowel for absorption .[36]

C. Floating small spheres/ Microballoons

Hallow microspheres square measure considers as most promising buoyant system as they're a lot of advantageous thanks to central sanctify area within the microsphere. sanctify microsphere is loaded with drug in their outer compound shelf were ready by a completely unique emulsion solvent Diffusion technique.[37]

D. Raft forming systems

Raft forming system have received a lot of attention for the delivery of antacid and drug Delivery for gastro infection and disorders on contact with viscus fluid a gel forming resolution swells and forms a viscous cohesive gel containing entrapped CO2 bubbles. that Forms raft layer on prime of viscus fluid that releases drug slowly in abdomen. (Often used For gastro reflux treatment.[38]

Advantages:

- Improved drug delivery
- Control within the quantity of drug to be delivered
- Have an area action on abdomen
- Minimize membrane irritation
- Simple administration
- Convenient instrumentality for producing
- Target/site specific drug delivery.[39]

Disadvantages:[39,40]

1. Floating systems don't seem to be possible for those medicine that have solubility or stability issues in stomachal fluids.
2. There area unit limitations to the pertinency of FDDS for medicine that area unit botheration tostomachal membrane.
3. one among the disadvantages of floating systems is that they need a sufficiently high level of fluids within the abdomen, so the drug dosages kind float in this and work expeditiously.
4. These systems additionally need the presence of food to delay their stomachal voidance.
5. medicine that cause irritation and lesion to stomachal membrane don't seem to be appropriate to be developed as floating drug delivery.

Drugs used Floating Drug Delivery system

Various medicine area unit employed in formulation of floating drug delivery system like acetylsalicylic acid, Griseofluvin, Ibuprofen, Verapamil, Nifedipine, Dipyridamol. These medicine area unit accustomed formulate floating microsphere.Diclofenic metallic element, nonsteroidal anti-inflammatory and glucocorticoid area unit usefull for floating granules. Tylenol, painkiller, ampicilline, Atenolol, Aspirine, carbonate, calcium blocker is appropriate for producing the floating tablets. Floating capsules area unit designed for Lasix, Misoprostol, Bendopa and propranolol.[41]

Polymers and other ingredient used in Floating Drug delivery System [42]

Polymers	Other ingredients
HPMC K4 M, HPMC 100, HPMC K15, HPMC 4000, Calcium alginate, Eudragit L-100, Eudragit S-100, propylene foam, polyethylene oxide, Sodium alginate, PVP, CMC, Chitosan, PVA, Polyethylene glycol, polycarbonate, HPC, Acrylic polymers	Inert fatty materials (5%-75%). These include fatty acids, Bee wax and long chain fatty alcohols. These are used to decrease the hydrophilic properties. Effervescent Agents. Sodium bicarbonate, Citric acid, tartaric acid, Di- SGC, CG. Release accelerants (5%-60%). Lactose, mannitol. Release retardants (5%-60%).Magnesium sterate, talc, Dicalcium phosphate. Buoyancy increasing agents. Ethyl cellulose Low Density material. PVP

APPLICATION OF FLOATING DRUG DELIVERY SYSTEM:

Floating drug delivery offers many applications for medication having poor bioavailability owing to the narrow absorption window within the higher apart of the epithelial duct. It retains the indefinite quantity type at the location of absorption and so enhances the bioavailability. These are summarized as:

1. Sustained Drug Delivery:

The generally downside of short stomachic duration encountered with associate oral atomic number 24 formulation thence are often overcome with these systems. HBS systems will stay within the abdomen for long amounts and thence will unleash the drug over a chronic period of your time. These systems have a bulk density of <1 as a results of that they'll float on the stomachic contents. These systems ar comparatively giant in size and spending from the opening gap is prohibited.[43] Eg.Sustained unleash floating capsules of nicardipine coordination compound were developed and were evaluated invivo. The formulation compared with commercially accessible MICARD capsules victimisation rabbits. Plasma concentration time curves showed a extended period for administration (16hours) within the sustained unleash floating capsules as compared with typical Microcapsules (8hours).

2. Site Specific Drug Delivery:

These systems are notably advantageous for medication that are specifically absorbed from abdomen or the proximal a part of the tiny viscus, Eg, diuretic drug and vitamin B2. Eg. diuretic drug is primarily absorbed from the abdomen followed by the small intestine. it's been rumored that a monolithic floating indefinite quantity type with prolonged stomachic duration was developed and also the bioavailability was enhanced. AUC obtained with the floating indefinite quantity was about one.8 times those of typical diuretic drug indefinite quantity form.[44]

3. Absorption Enhancement:

Drugs that have poor bioavailability as a result of site specific absorption from the higher a part of the channel area unit potential candidates to be developed as floating drug delivery systems, thereby rising their absorption. Eg. A significantly increase within the bioavailability of floating dose forms(42.9%) can be achieved as compared with commercially on the market dose type.[45]

4. Maintenance of constant blood level:

These systems give a straightforward manner of maintaining constant blood level with Associate in Nursing simple administration and higher patient compliance.[46]

EVALUATION OF STOMACH SPECIFIC FLOATING DEILIVERY SYSTEM:

1. Determination of floating lag time:

The basic mechanism behind floating was carbonate is present within the formulation as insoluble dispersion and have become soluble within the acidic medium. Released metal ions and carbonic acid gas, caused gelation of

compound and discharged gas get entrapped in gel matrix, that caused matrix system to float.[47]

2. Gelling Capacity:

The gelling capability made up our minds by placing10 cubic centimetre of solutionin a hundred cubic centimetre of stirred up stomachic fluid (pH 1.2) freshly ready and equilibrated at37 ± zero.5°C and visually assessing the gel formation and noting the time for gelation and therefore the time taken for the gel shaped to dissolve. totally different weights were assigned as per the gel integrity, weight and rate of formation of gel with respect to time.[48]

3. In Vitro Gelling Capacity:

To evaluate the formulations for their in-vitro gelling capability by visual technique, colored solutions of in place gel forming drug delivery system were ready. The in-vitro gelling capability of ready formulations was measured by putting 5 milliliter of the gelation resolution (0.1N HCl, pH 1.2) in a very fifteen milliliter salt glass tubing and maintained at 37±1ºC temperature.[49] One milliliter of coloured formulation resolution was added with the assistance of measuring system. The formulation was transferred in such some way that places the measuring system at surface of fluid in tubing and formulation was slowly free from the measuring system. because the resolution comes in touch with gelation resolution, it had been like a shot regenerate into stiff gel like structure.[50]The gelling capability of resolution was evaluated on the idea of stiffness of fashioned gel and fundamental measure that they fashioned gel remains intrinsically. Color was incorporate to allow visualised look to fashioned gel. The in-vitro gelling capability was ranked in 3 classes on the idea of gelation time and fundamental measure that they fashioned gel remains. (+) Gels once couple of minutes, spread rapidly (++) Gelation immediate remains for 12 hours (+++) Gelation immediate remains for over 12 hours.[51]

4. Measurement of water uptake by the gel:

The water uptakes by the gel of the chosen formulations of metal alginate were determined by a straightforward methodology. during this study the in place gel fashioned in forty milliliter of zero.1 N HCl (pH one.2) was used. From every formulation the gel portion from the zero.1 N HCl was separated and therefore the excess HCl resolution was obliterated with a paper. The initial weight of the gel taken was weighed and to the present gel ten milliliter of water was added and once each half-hour of the interval water was decanted and therefore the weight of the gel was recorded and therefore the distinction within the weight was calculated and reported.[53]

5. In Vitro Drug Release study:

The in vitro unharness rate of levetiracetam from sustained release in place gel was performed using USP equipment (model TDT-08L, Electro lab, Mumbai, India) fitted with paddle over disk (50 r/min) at 37± zero. 50C using five hundred cc of zero.1 N HCl as a dissolution medium. This speed was slow enough to avoid the breaking of gelled formulation and was maintaining the gentle agitation conditions believed to exist in vivo.[54]At the predetermined time intervals, five cc samples were withdrawn, filtered through a whatmann filter paper membrane filter, diluted, and assayed at given wavelength using a Shimadzu ultraviolet light 1800 double-beam spectrophotometer (Shimadzu, Kyoto, Japan). Accumulative share drug release (CPR) was calculated using an equation obtained from a standardization curve.

6. PH Measurement:

The pH was measured in each of the solution of Na alginate based in place solutions, using a mark digital PH meter at 27°C. [55]

7. Physical Appearance:

All the prepared in place gel was check for their clarity and also the type time required for gel formation duration of floating and type gel formed. The measurement of every information was in triplicate and average conclusion was taken.[56]

8. Determination of Drug Content:

Accurately, ten ml of in-situ gel from different batches (equivalent to 20 mg of metoclopramide HCL) were measured and transferred to ahundred milliliter of volumetric flask. to the current 50-70ml of zero.0.1N HCL was more and sonicated for thirty min. Volume was adjusted to a hundred millilitre. Complete dispersion of contents were ensured, visually and filtered using What man paper. From this answer, ten millilitre of sample was withdrawn and diluted to a hundred millilitre with zero.1 N HCL Contents of metoclopramide HCl determined spectrophotmeterically with using reference wavelength double beam UV-Visible photometer.[57]

CONCLUSION:

The floating drug delivery framework was set up in an exertion increment the gastric maintenance time of the measurements structure and to control tranquilize discharge. One of the most doable methodologies for accomplishing a delayed and unsurprising delved conveyance profiles in the gastrointestinal tract is to control the gastric living arrangement time, utilizing gastro-retentive dose frames that will furnish us with new and significant helpful alternatives. Coasting lattice tablets are intended to drag out the gastric living arrangement time after oral organization, at a specific site and controlling the arrival of medication particularly helpful for accomplishing controlled plasma level just as improving bioavailability. In spite of the fact that there are number of challenges to be worked out to accomplish delayed gastric maintenance, an enormous number of organizations are centering toward commercializing this system.

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