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A complete review on floating drug delivery system

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Abstract

The aim of writing this review on FDDS to focus on the system of floatation to attain gastric retention, or to attain desired concentration of drug in blood or tissues. Today's condition focus on the formulation of the FDDS. Effervescent FDDS release carbon dioxide gas, thus decreases the density of the system and remain floatable in stomach for a longer period of time and released the drug at slowly conveniently in order to improve bioavailability of drug. The study summarizes the application of the system, factors that affect floating system, mechanism, advantages, disadvantages and preparation.

Key words: FDDS, effervescent system, and non-effervescent system.

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Introduction

The most commonly used route is oral route which is used to receive more success because of its low cost therapy, patient compliance and administration is easy. About 50% or more than 50%of the drug delivery system available in market are oral drug delivery systems [1]. The solid oral dosage forms like capsule, tablet are having specific drug concentration in blood circulation. A problem with conventional sustained release dosage form is that the duration in stomach is unable to extend and cause fluctuations [2]. Gastric emptying of dosage form is an extremely variable process and resident stomach for a longer period of time than conventional dosage forms, but those are having physiological problems. Gastro retentive system remains in gastric environment for respective hours and hence prolonged the gastric retention time of

The drug. It improves the bioavailability and solubility of the drug and reduces the wastage of drug [3].

These systems are miserable systems that have enough buoyancy to float and remain buoyant in stomach without influencing the gastric emptying rate. These are hydro dynamically controlled systems and provide a continuous release of the drug. The buoyant systems have been developed on the foundation of granules, powders, capsules, tablets and hollow microspheres [4-5]. The human stomach is divided into 4 regions: fundus, body, intermediate and antrum (pylorus). The proximal part which is fundus and body collects the digestive gases [6], and antrum on the other hand holds the broken down food until the food is ready to be released in the small intestine. During fasting state an indigestive series of electrical events takes place which cycle both the stomach and intestine for every 2-3hrs, this is called as interdigestive myoelectric cycle or migrating myoelectric cycle (MMC) which is subdivided into four phases [4].

Types of floatation drug delivery system

Floating drug delivery system is of 2 types

1. **Effervescent systems**
2. **Non-effervescent systems**

1. **Effervescent systems**

These are matrix type systems which were prepared by using swelling polymers such as hydroxy-propyl methylcellulose or polysaccharides and also some effervescent components like citric acid, sodium bicarbonate, tartaric acid, calcium carbonate. The formulation of these have been done in such a way that when they get touched with acidic gastric content CO2 is released and gets entrapped in swollen hydro colloids

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which provides buoyancy to the dosage forms [7]. These systems subdivided into two categories:

A. Gas generating systems
- Floating capsule
- Floating pills

B. Volatile liquid
- Intra gastric osmotically controlled
- Gastrointestinal inflatable

2. **Non-effervescent systems**

This system based on the mechanism of polymers swelling or bio adhesion of polymer in GI traction mucosal layer. A model drug is prepared by extrusion method, a mixture of acetic acid and chitosan is evicted with the needle, then the evicted material is cut and dried. The chitosan hydrates floats in acidic media, the essential drug release will be obtained by altering the drug polymer ratio.

A. Alginated beads
B. Hollow microspheres
C. Ring capsule
D. Films
E. Magnetic system
F. Matrix layered tablets [7-8]

Advantages of FDDS

1. FDDS increases the first pass metabolism.
2. Floating dosage form will remain in the solution for longer time at alkaline pH
3. FDDS dosage forms are used for local actions in stomach e.g. Antacids
4. These are useful in diarrhea.
5. FDDS reduced the frequency of dosing.
6. FDDS reduced the fluctuations of plasma drug concentration [9-12].

Disadvantages of FDDS

1. FDDS are not attainable for the drugs having stability and solubility problems in gastric fluid.
2. Drugs like nifiedipine, propranol etc get absorbed easily throughout GIT are not be advisable candidate.
3. The major disadvantage of fdds is that they require an adequate high fluids in stomach.
4. The drugs which irritate the gastric mucosa are not suitable [13-19].

Mechanism of action of FDDS

The system floats on gastric contents (see in figure 3), the slow drug release with indispensable contents. The release is followed by removal of the residual system for the stomach. But, along with the suitable floating force (F), minimum levels of gastric contents are needed to allow attainment of buoyancy retention principle and also to keep dosage form buoyant over meal surface. To measure the kinetics of floating force, a novel apparatus is used for the calculation of resultant weight (RW) has been reported. Its operation composes measuring a force equivalent to F (with respect to time) which keeps the object submerged. Object floats better if the RW is on the higher positive side [20-22].

Factors affecting FDDS

Formulation factors

1. **Size of the tablet**

The phenomenon of floating retention in stomach depends on tablet size. The small tablet castaway from the stomach rapidly.

2. **Density of tablet**

A floating dose which are having less density than gastric fluid will float. Density of 1.0 g/ml of tablet is more effective.

3. **Viscosity of polymer**

Low viscosity polymers are initiated to be more useful in comparison of high viscosity polymers.

Idiosyncratic factors

1. **Gender**

Women have slower gastric emptying time in comparison to men.

2. **Age**

Lower gastric emptying time is frequent in elders than younger.

3. **Posture**

GRT will differ between upright and supine ambulant state of the patient. For the floating systems it absolutely was rumored that when subjects tract for 90 to 100 percent retention at 24 hrs as compared with the alternative shapes.

4. **Concomitant uptake of drugs**

Two or more drugs when taken or co-administered can influence the attainment of FDDS.

5. **Feeding regimen**

Gastric residence time enhance in presence of food which increase drug dissolution rate, gastric retention time/duration of about 4-10hours has been reported [23, 24].

Preparation Method of Tablets

1. **Direct Compression Method**

Involve compression of tablets directly from powdery material whereas not modifying the physical nature of the material. Carriers or direct compression must having good flow and compressible nature these properties are convey by predisposing these vehicles to spray drying, slugging or crystallization. The carriers used are di-calcium phosphate tri-hydrate, tri-calcium phosphate etc. The direct compression method will be used within the formulation of floating effervescent tablet and for all moisture sensitive products [25].

2. **Wet Granulation**

This method is generally used and the common method for preparation of tablets. The bubbling formulation of acid and carbonate are often granulated beside separately or as in a

combination with ethanol, water (possibly diluted with water), solvent or iso-propanol and other solvent. When granulating besides with solvents containing pure water or water, the bubbling reaction will start. The care must be taken of adequate control of the method. Vacuum processing is usually beneficial because of the ability which control the bubbling reaction and therefore the drying process [26].

3. **Dry Granulation**

   This process involves compaction of powder particles into compacts or large pieces which are later broken down into granules to produce granules and that can be further processed into dosage forms. When ingredients operated in tablet formulation is sensitive to moisture then slugging may be used. Slugging of the material is accomplished by using heavy-duty tableting equipment or with roller compaction [23-25].

Evaluation of FDDS [26-28]

Shape of tablet

FDDS tablets are examined under the magnifying lens for assessment of shape.

Tablet dimensions

The thickness and diameter of tablets are measured by venire calipers. The tablets are picked and thickness as well dimensions is measured.

Determination of weight variation

20 tablets are selected and then weighed individually, average weight is calculated and then weight variation is calculated.

Determination of hardness of tablets:

Pick 20 tablets randomly and measure the hardness with Monsanto hardness tester. If the hardness is as per standard then it has sufficient hardness.

Measurement of floating capacity:

- Three tablets are put in the flask
- Flask contains 400mL of 0.1 (N) HCl solutions.
- Now the time is noted down in min. when the tablet goes from bottom to the top of the flask.
- And when it constantly floats that time is also noted.
- Mean and standard deviation are calculated.

Measurement of density of formulation

- The density of tablet is calculated from volume and masses.
- The volume 'V' is calculated from height 'h' and radius 'r' of cylindrical tablet.

Determination of drug content

- Ten tablets are selected and transferred to 100mL volumetric flask filled up with 0.1N HCl.
- Stir and keep it for 2 hours.
- Take 1mL from volumetric flask and transfer it to the test tube.
- Sample are filtered, suitably diluted and analyzed in spectrophotometer.

***Invitro* dissolution study**

1. Place tablets in dissolution vessel.
2. 5mL sample is withdrawn at time interval of 1hr, 2hr, 3hr, 4hr, 5hr, 6hr, 8hr, 10hr, and 12hr.
3. The volume of dissolution medium is adjusted to 900mL.
4. The release studies were managed with "n" tablets and mean value are plotted versus time.
5. Samples are analyzed at maximum wavelength using UV visible spectrophotometer against a reagent blank.

Swelling study

- It is measured by weight gain/water uptake.
- Dimensional changes could be measured which tend to increase tablet diameter/thickness over time.
- % weight gain is measured in water uptake.

$$wv = (wt - wo) \times 100$$

Where,

wv = water uptake

wo= initial weight if dosage form

wt = weight of dosage form at time t

Application of FDDS

1. **Maximize bioavailability**

   Gastro retentive FDDS is applied for increasing the activity of the dosage type of drug to extended action bioavailability is maximized [29].

2. **Sustained released drug delivery**

   Oral Controlled Release formulations are come across with problems such as gastric residence time in GIT. These problems can be controlled with the HBS system which can remain in the stomach for the long periods and having bulk density <1 as a result they can float on the gastric contents. These systems are moderately larger in size and passing from the pyloric opening is proscribed.

3. **Minimize the absorption**

   These types of dosage form have less bioavailability specific site absorption from the upper part of the GIT, enhancing the absorption of dosage type 30.

4. **Site specific DDS**

   These systems are especially important for drugs that are specifically absorbed from the stomach or the proximal part of the small intestine. The controlled, slow delivery of the drug to stomach provides adequate local therapeutic levels and limits the systemic vulnerability to the drug. This decreases side effects that are caused by the drug in the blood circulation.

5. **Decrease the adverse activity of the colon**

Holding of the dosage type within the GRS (gastro retentive system), decrease the quantity of drug that arrives in the colon [28, 29, 30].

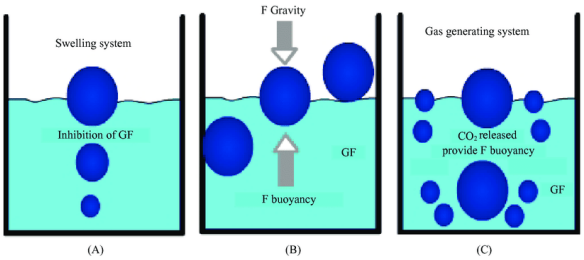

Figure 1: Mechanism of floating drug delivery system.

Table: 1 Marketed Preparation FDDS

Brand Name	Drug	Dosage form	Manufacturers
Cifran O.D	Ciprofloxacin	Tablet	Ranbaxy
Liquid Gavison	Mixture of alginates	Liquid	GlaxoSmithKlin
Madopar HBS	Levodopa and Benserazide	Capsule	Roche
Glumetza	Metformin Hydrochloride	Tablet	Depomed

Conclusion

The formulation of FDDS is a structured and prospective viewpoint for gastric retention of dosage forms to enhance bioavailability and also to attain control release of dosage forms. The most important benchmark which has to be looked into for the formulation of FDDS is that density of the dosage form should be less than that these dosage forms serves the most efficacious in the treatment of the disease correlated with the GIT and for extracting an extended action from a drug with a short half-life. Inspite of no. of difficulties to be worked out to attain extended gastric retention, a large no. of companies were focusing towards commercializing this technique. No. of economic products and patents issued in this field are perceptible of it.

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