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Floating Drug Delivery System – A Review

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Abstract: *The principal objective behind the writing of this article on the floating drug delivery system (FDDS) was to systematize the recent literature with the core process of floatation in acquiring gastric retention. The novel methodologies in FDDS include approaches to design a single unit and multiple-unit floating systems, the physiological and formulation variability affecting gastric retention along with the use of recently invented and developed polymers. FDDS is the drug delivery system that floats immediately upon contact with gastric fluids present promising approaches for increasing the bioavailability of drugs with absorption windows in the upper small intestine. However immediate floating can only be achieved if the density of them device is low at the very beginning. This review also summarizes the in vitro techniques, in vivo studies to evaluate the performance and application of floating systems. Floating dosage forms can be delivered in conventional forms like tablets, capsules with the addition of suitable ingredients along with the gas generating agent. This review also throws light on some approaches to prepare a floating system, evaluation methods and characterization for FDDS pharmaceutical dosage form and also it's classification and different techniques used in developing floating dosage forms along with current and novel advancements.*

Keywords: Floating Drug Delivery System, single unit and multiple unit floating system, In vitro and in vivo evaluation, Novel advancements

I. INTRODUCTION

1.1 Floating Drug Delivery System

Oral administration is the most convenient mode of drug delivery and is associated with superior patient compliance as compared to other modes of drug intake. However, oral administration has only limited use for important drugs, from various pharmacological categories, that have poor oral bioavailability due to incomplete absorption and/or degradation in the gastrointestinal (GI) tract. Some of these drugs are characterized by a narrow absorption window (NAW) at the upper part of the gastrointestinal. Gastric emptying of dosage forms is an extremely variable process and ability to prolong and control emptying time is a valuable asset for dosage forms, which reside in the stomach for a longer period of time than conventional dosage forms.

1.2 Gastro Retentive Drug Delivery Devices

These are primarily controlled release drug delivery systems, which gets retained for longer period of time in stomach, thus helping in absorption of drug for the intended duration of time, which in turn improves bioavailability by reducing drug wastage, and improving solubility of drugs that are less soluble at high pH environment. It also helps in achieving local delivery of drug in the stomach and proximal small intestine. G.R.D.D devices can be useful for the spatial and temporal delivery of many drugs. Ideal candidates for gastro retentive drug delivery systems:

- Drug which act locally in the stomach.
- Drugs which get primarily absorbed in the stomach.
- Drugs which are poorly soluble at alkaline ph.
- Drugs with a narrow therapeutic window of absorption.
- Drugs which are absorbed rapidly from GI tract.
- Drugs that degrade in the colon.

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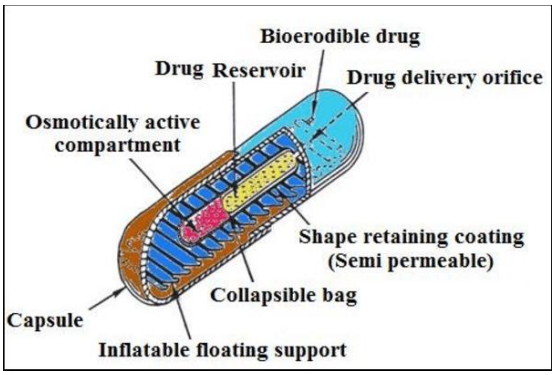

Floating drug delivery systems (FDDS) have a bulk density less than gastric fluids and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. While the system is floating on the gastric contents, the drug is released slowly at the desired rate from the system. 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 surface. To measure the floating force kinetics, a novel apparatus for determination of resultant weight has been reported in the literature. Te apparatus operates by measuring continuously the force equivalent to F (as a function of time) that is required to maintain the submerged object. Te object floats better if F on the higher positive side. This apparatus helps in optimizing FDDS with respect to stability and durability of floating forces produced in order to prevent the drawbacks of unforeseeable Intragastric buoyancy capability variations.

1.3 Classification of the Floating Mechanism

Floating drug delivery systems (NDDS) are characterized based on two varieties of preparation variables: effervescent and Non-effervescent system such as

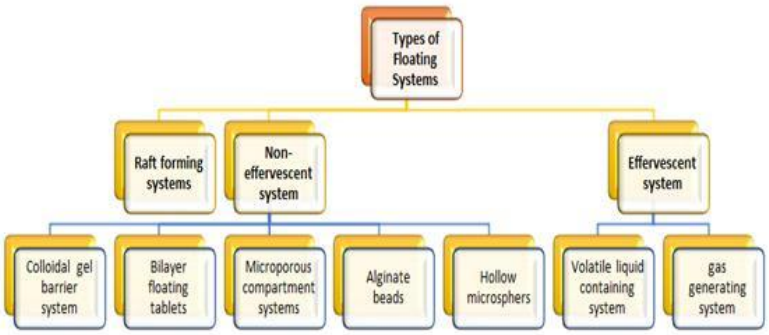

Figure 2: Classification of floating system

A. Non-Effervescent System

The non-effervescent FDDS primarily based on the system of swelling of the polymer or the adhesion to the mucosal layer of the gastrointestinal tract. Two of the most common excipient for non-effervescent FDDS are gel-forming or highly swellable cellulose type of hydrocolloid, polysaccharides.

a) Colloidal Gel Barrier System

The system corporation a high level of gel-forming around 20-75% w/w, highly swellable, cellulose type hydrocolloids, polysaccharides and also matrix-forming polymers. When coming into contact with gastric fluid, these hydrocolloids in the system will hydrate and forming a colloidal gel barrier around the surface. These gel barriers monitor the rate of penetration of the fluid to the device and the release of the drug.

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b) Bilayer Floating Tablet

Bilayer floating tablet contain of two-layer of immediate-release tablet that release the first dose of the system while the sustained release layer absorbs the gastric fluid and form a colloidal gel barrier on the superficial, it preserves the bulk density to less than one and will remain floating in the stomach.

c) Micro-Porous Compartment System

A Microporous section has pores placed on the top and bottom of the wall containing a packed medicine reservoir. The peripheral wall drug reservoir is completely sealed to seal the insoluble drug in the stomach surface. The entrapped in the room will be utilized to float the system on the stomach contents and into the fluid hole that will dissolve the drug to be absorbed in the intestine.

d) Alginate Beads

Multi-unit floating dosage forms are made from freeze-dried calcium alginate. Round beads with 2.5 mm diameter can be equipped with dripping sodium alginate soluble to a calcium chloride solution; this process will result in precipitation of calcium alginate which can form a porous system that can reinforce the capacity to float for more than 12 h and have some more time long.

e) Hollow Microspheres

Hollow microspheres are micro-balloons occupied with medication in the outer shell of the polymer and applied by the emulsion solvent diffusion method. Ethanol solution: aqueous dichloromethane and enteric solution of PVA of a turn temperature of 400 °C. The resulting gas phase is spread into polymer droplets by vaporization of dichloromethane.

B. Effervescent System

In an effervescent system, preparation is designed to produce carbon dioxide gas. Among them are carbonates, generating gas, and other organic acids. The design of the formulation is intended to decrease the density system that can be floating in the gastric fluid. The free CO_2 gas can mix rapidly in the tablet matrix in the case of single-layered tablets. The other way is through combining a matrix that contains a part of liquid, were later from the fusion, will produce gas that will evaporate at body temperature. This effervescent system can be categorized into two groups, gas-producing system and volatile liquid containing the system.

a) Volatile Liquid

The volatile liquid containing systems Inflatable chamber with a liquid can be included which provides sustained gastric retention of the drug delivery system. Liquids in this system include cyclopentane, either that gasifies at body temperature, which can result in inflammation of the chamber in the stomach. They contain a deformable hollow unit which osmotically controls floating systems. The system is differed into two compartments; the first section contains a drug and there is a volatile liquid in the second compartment.

b) Raft Forming Systems

Raft forming systems consume a fundamental mechanism by forming a thick interconnected gel in contact with gastric fluid, in which apiece part of the portion of the liquid forms a continuous layer called a raft. The formation of carbon dioxide gas can take this raft afloat. Also, carbon dioxide can avoid the discharge of gastric fluid into the oesophagus. This system usually contains a gelling agent, a carbonate or a bicarbonate base to make a less dense system and can make it float in the gastric solution.

III. APPROACHES TO DESIGN THE VARIOUS FLOATING DOSAGE FORM

Two types of floating Dosage systems - Single- and multiple-unit floating dosage systems have been designed by using the following approaches.

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Single-Unit Dosage Forms

A) Low-Density Approach

In this approach, the globular shells with density lower than that of gastric fluid can be used as carrier for drug for making single-unit floating dosage form. Popcorn, polystyrol and poprice have been used as drug carriers in coated shells26. For the undercoating of these shells sugar polymeric materials such as methacrylic polymer and cellulose acetate phthalate have been exploited. These shells are then further coated with a mixture of drug polymer.

B) Fluid- Filled Floating Chamber

In this type of dosage forms, a gas-filled floatation chamber is incorporated into a microporous component that covers the drug reservoir. Along the top and bottom walls there is provision for opening through which the GIT fluid enters into the device to dissolve the drug. The side walls in contact with the fluid are sealed to ensure undissolved drug remains in the device. The fluid present in the system for floatation could be air or any other suitable gas, liquid, or solid that has an appropriate specific gravity and should be inert.

C) Hydrodynamically Balanced Systems (HBS)

These systems enhance the absorption because they are designed such that they stay in GIT for prolong time. Drugs which have a better solubility in acidic environment and site-specific absorption in the upper part of GIT are suitable candidates for such systems. These dosage forms must have a bulk density of less than 1. It should maintain its structural integrity and should constantly release the drug.

D) Bilayer and Matrix Tablets

Floatable characteristics also shown by some types of bilayer and matrix tablets. The polymers which have been exploited are sodium carboxymethylcellulose (CMC), hydroxypropyl cellulose, Hydroxypropyl methylcellulose, ethyl cellulose and Crosspovidone.

E) 3-Layer Principle

By the development of an asymmetric configuration drug delivery system, 3-layer principle has been improved.3-layer principle helps in modulating the release extent and for achieving zero-order release kinetics. The design of the system is such that it floats on the stomach content and prolong gastric residence time which further results in longer total transit time which maximize the absorptive capacity.

Problems with single-unit formulations - Single-unit formulations can stick together or being obstructed in the GIT, which can cause irritation.

IV. MULTIPLE UNIT DOSAGE FORM

Multiple-unit dosage form is designed to develop a reliable formulation that provide all the benefits of a single-unit form and also overcome the disadvantages of single-unit formulations. Microspheres have been used because of their high loading capacity. The polymers such an albumin, starch, gelatin, polyacrylamine, polymethacrylate and polyalkylcyanoacrylate have been used for the preparation of microspheres. Microspheres show an excellent in vitro floatability because of its characteristic internal hollow structure. Several devices of carbon dioxide multiple-unit oral formulations have been described in the recent patent literature with features that unfold, extend or are inflated by carbon dioxide generated in the devices after administration.

List of Drugs formulated as single and multiple unit forms of Floating Drug Delivery System

Tablets	Ciprofloxacin, Chlorpheniraminemaleate, Theophylline, Furosemide, Captopril, Acetylsalicylic acid, Sotalol, Nimodipine.
Capsules	Chlordiazepoxide Hcl, Furosemide, Misoprostol, Diazepam.
Microspheres	Verapamil, Ketoprofen, Terfenadine, Tranilast, Ibuprofen.
Granules	Diclofenac sodium, Prednisolone, Indomethacin.

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Films	Drug Delivery Device, Cinnarizine.
Powders	Several basic drugs.

Factors affecting gastric retention time of the preparation:

1. **Density-**should be lower than that of the gastric fluidal contents (1.004 g/ml)
2. **Size-**the diameter of more than 7.5 mm.
3. **Incidence of feeding-**GRT can rise by more than 400 min when consecutive foods are dispense compared to a single meal due to low-frequency MMC.Caloric content can be increased by 4-10 with foods high in protein and fat.
4. **Gender-**average outpatient GRT in men (3.4 h) less than age and race matching with women (4.6 h) regardless of height, body weight and surface.

Advantages of Floating Drug Delivery:

1. **Enhanced Bioavailability:** The bioavailability of some drugs (e.g. riboflavin and levodopa) CR-GRDF is significantly Enhanced in comparison to administration of non-GRDF CR polymeric formulations.
2. **Enhanced First-Pass Biotransformation**: When the drug is presented to the metabolic Enzymes (cytochrome P-450, in particular CYP-3A4) in a sustained manner, the presystolic metabolism of the tested Compound may be considerably increased Rather than by a bolus input.
3. **Sustained drug delivery/reduced Frequency of Dosing:** The drugs having Short biological half-life, a sustained and Slow input from FDDS may result in a flip-flop pharmacokinetics and it reduces the Dose frequency. This feature is associated with improved patient compliance and thus Improves the therapy.
4. **Targeted therapy for local ailments in the Upper GIT:** The prolonged and sustained Administration of the drug from FDDS to The stomach may be useful for local therapy in the stomach.
5. **Reduced fluctuations of Drug Concentration:** The fluctuations in plasma Drug concentration are minimized, and Concentration-dependent adverse effects That are associated with peak concentrations Can be prevented. This feature is of special Importance for drugs with a narrow Therapeutic index that makes it possible to Obtain certain selectivity in the elicited Pharmacological effect of drugs that Activate different types of receptors at Different concentrations.
6. **Site specific Drug Delivery:** A floating Dosage form is a widely accepted approach Especially for drugs which have limited Absorption sites in upper small intestine.

Limitations/Disadvantages:

- These systems require a high level of fluid in the stomach for drug delivery to float and Work efficiently-coat.
- Not suitable for drugs that have solubility or Stability problem in GIT.
- Drugs such as Nifedipine which is well Absorbed along the entire GIT and which Undergoes first pass metabolism, may not be Desirable.
- Drugs which are irritant to gastric mucosa Are also not desirable or suitable.
- The drug substances that are unstable in the Acidic environment of the stomach are not Suitable candidates to be incorporated in the Systems.
- The dosage form should be administered with a full glass of water (200-250 ml).

Application of Floating Drug Delivery Systems

Floating drug delivery offers several applications for drugs having poor bioavailability because of the narrow absorption window in the upper part of the gastrointestinal tract. It retains the dosage form at the site of absorption and thus enhances the bioavailability. These are summarized as follows:

1. **Sustained Release Drug Delivery System:** HBS systems can remain in the stomach for long periods and, hence can release the drug over a prolonged period of time. The problem of short gastric residence time encountered with an oral CR formulation hence can be overcome with these systems. These systems have a bulk density of <1 as a result of which they can float on the gastric contents. These systems are relatively large

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in size and passing from the pyloric opening is prohibited e.g. Sustained release floating capsules of nicardipine hydrochloride were developed and were evaluated in vivo

2. **Site-Specific Drug Delivery:** These systems are particularly advantageous for drugs that are specifically absorbed from stomach or the proximal part of the small intestine, e.g. Riboflavin and furosemide e.g. Furosemide is primarily absorbed from the stomach followed by the duodenum. It has been reported that a monolithic floating dosage form with prolonged gastric residence time was developed and the bioavailability was increased. AUC obtained with the floating tablets was approximately 1.8 times those of conventional furosemide tablets.
3. **Absorption Enhancement:** Drugs that have poor bioavailability because of site specific absorption from the upper part of the gastrointestinal tract are potential candidates to Be formulated as floating drug delivery Systems, thereby maximizing their absorption. a significant increase in the bioavailability of floating dosage forms (42.9%) could be achieved as compared with commercially available LASIX tablets (33.4%) and enteric coated LASIX-long product (29.5%).

Drug Candidates Suitable for FDDS

- Drugs that have narrow absorption window in GIT (e.g. L-DOPA, paminobenzoic acid, furosemide, riboflavin).
- Drugs those are locally active in the stomach (e.g. misoprostol, antacids).
- Drugs those are unstable in the intestinal or colonic environment (e.g. captopril, ranitidine Hcl, metronidazole).
- Drugs that disturb normal colonic microbes (e.g. antibiotics used for the eradication of Helicobacter pylori, such as tetracycline, clarithromycin, amoxicillin).
- Drugs that exhibit low solubility at high pH values (e.g. diazepam, Chlordiazepoxide, verapamil).

Evaluation Parameters

1. **Size and Shape Evaluation:** The particle size and shape plays a major role in determining solubility rate of the drugs and thus potentially its bioavailability. The particle size of the formulation was determined using Sieve analysis (Jayant, Mumbai), Air elutriation (Bahco TM) analysis, Photo analysis, Optical microscope (Olympus, India, Pvt. Ltd), Electro résistance counting methods (Coulter counter), Sedimentation techniques, Laser diffraction methods, ultrasound attenuation spectroscopy, Air Pollution Emissions Measurements etc.
2. **Buoyancy/Floating test:** The time between introduction of the dosage form and its buoyancy on the simulated gastric fluid and the time during which the dosage form remain buoyant are measured. The time taken for the dosage form toemerge on the surface of a medium called floating lag time (FLT) or buoyancy lag time (BLT) and total duration of time by which dosage form remain buoyant is called total floating time (TFT).
3. **Surface Topography:** The surface topography and structures were determined using scanning electron microscope (SEM, JEOL JSM – 6701 F, Japan) operated with an acceleration voltage of 10k.v, Contact angle meter, Atomic Force Microscopy (AFM), Contact profilio-meter.
4. **Swelling Studies:** Swelling studies were performed to calculate molecular parameters of swollen polymers. Swelling studies was determined by using Dissolution apparatus, optical microscopy and other sophisticated techniques which include 1HNMR imaging, Confocal laser scanning micro- and fats scopy (CLSM), Cryogenic Scanning Electron Microscopy (Cryo-SEM), Light scattering imaging (LSI) etc. The swelling studies by using Dissolution apparatus (USP dissolution apparatus (usp-24) Lab-India Disso 2000) was calculated as per the following formula.

   Swelling ratio = Weight of wet formulation / Weight of formulations
5. **Determination of the Drug Content:** Percentage drug content provides how much amount of the drug that was present in the formulation. It should not exceed the limits acquired by the Standard monographs. Drug content was Determined by using HPLC, HPTLC methods, near infrared spectroscopy (NIRS), Microtitrimetric methods, Inductively Coupled Plasma Atomic Emission Spectrometer (ICPAES) and also by using spectroscopy Techniques.

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6. **Percentage Entrapment Efficiency:** Percentage entrapment efficiency was reliable for quantifying the phase distribution of drug in the pre-pared formulations. Entrapment Efficiency was deter-mined by using three Methods such as Micro dialysis method, Ultra Centrifugation, and pressure Ultra filtration.
7. **In-vitro Release Studies:** In vitro release Studies (USP dissolution apparatus LABINDIA Dissolution 2000) were performed to Provide the amount of the drug that is released at a definite time period. Release studies were Performed by using Franz diffusion cell system and synthetic membrane as well as different Types of dissolution apparatus.
8. **Fourier Transforms Infrared Analysis:** Fourier transform infrared spectroscopy (FTIR, Shimadzu, Model-RT-IR-8300) is a technique Mostly used to identify organic, polymeric, and Some inorganic materials as well as for Functional group determination. Fourier Transform Infrared Analysis (FTIR) Measurements of pure drug, polymer and drug loaded polymer formulations were obtained on FTIR. The pellets were prepared on KBr-press Under hydraulic pressure of 150 kg/cm2; the Spectra were scanned over the wave number Range of 3600 to 400 cm-1At the ambient Temperature.
9. **Differential Scanning Calorimetry (DSC):** Shimadzu, Model-DSC-60/DSC-50/ Metler Toledo are generally used to characterize water of hydration of pharmaceuticals. Thermograms of formulated preparations were Obtained using DSC instrument equipped with an intercooler. Indium/Zinc standards were Used to calibrate the DSC temperature and Enthalpy scale. The sample preparations were Hermitically sealed in an aluminium pan and Heated at a constant rate of 10°C/min; over a Temperature range of 25° C – 65°C.

Methods of Developing Floating Drug Delivery System -

1. **Direct Compression Technique:** It means compressing tablets directly from powder content without altering the substance's physical structure itself. Dicalcium trihydrate phosphate, tricalcium phosphate, etc. are the most widely used carriers.
2. **Effervescent Technique:** An effervescent reaction between organic acid (citric acid) and bicarbonate salts will fill the floating chamber of the drug delivery system with inert gas (CO2).
3. **Wet Granulation Technique:** Involves wet powder massaging, milling or drying. Wet granulation shapes the granules by binding the powders together with an adhesive rather than compacting them.
4. **Ionotropic Gelation Technique:** Gelation of anionic polysaccharide sodium alginate, the primary polymer of natural origin, was accomplished with opposite charged calcium ions (counter-ions) with the objective of forming instantaneous micro particles.
5. **Solvent Evaporation Technique:** Continuous phase ability is inadequate to remove the entire amount of liquid dispersal solvent. Solvent evaporates from the dispersal surface to receive hardened microspheres.
6. **Spray Drying Technique:** Involves dispersing the core layer into the liquefied coating content and spraying the core coating mixture into the environment so that the coating is solidified by rapidly evaporating in which the coating material is solubilized.
7. **Melt Solidification Technique:** This method involves emulsifying the molten mass in the aqueous phase followed by cooling it to solidify. Lipids, waxes, polyethylene glycol, etc. are the carriers used for this technique.
8. **Melt Granulation Technique:** This is the method that agglomerates the pharmaceutical powders using a meltable binder and does not use water or organic solvents for granulation.

Pharmacokinetic and Pharmacodynamic Aspects of FDDS

Pharmacokinetic Aspects of FDDS:

1. **Enhanced Bioavailability:** FDDS has studied with excellence increase in bioavailability of certain drugs with low therapeutic window solely due to poor GI absorption due to various factors contributing to lower bioavailability. The drugs those considered with narrow absorption window, FDDS shown the possibility of with enhanced bioavailability of the compound to the specific site needed. The bioavailability of control release (CR) floating systems of Riboflavin and Levodopa are significantly enhanced in comparison to the administration of the conventional formulation. On the other hand, CR polymeric formulations of certain

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bisphosphonates, including alendronate, are absorbed directly from the stomach. However, the magnitude of this pathway remains modest even in the case where the prolonged gastric retention of the bisphosphonate in rats is produced by experimental/surgical means. It may be concluded that several different processes, related to absorption and transit of the drug in the gastrointestinal tract, act concomitantly and influence the magnitude of drug absorption.

2. **Enhanced First-Pass Biotransformation:** In a similar fashion to increased efficacy of active transporters exhibiting limited capacity activity, the pre-systemic metabolism of the tested compound has considerably increased cause of FDDS, if the drug is presented to the metabolic enzymes (cytochrome P450, in particular, CYP3A4) in a sustained manner, rather than by a bolus input.
3. **Improved Bioavailability due to Reduced P-Glycoprotein (P-gp) Activity in the Duodenum:** In apparent contrast to the higher density of CYP3A4 at the upper part of the intestine, P-gp mRNA levels increase longitudinally along the intestine such that the highest levels are located in the colon. Therefore, for drugs that are P-gp substrate and do not undergo oxidative metabolism, such as Digoxin, floating systems may elevate absorption compared to the immediate and control release (CR) dosage forms.
4. **Targeted Therapy for Local Ailments in the Upper GIT:** The prolonged and sustained administration of the drug from the floating systems to the stomach may be advantageous for local therapy in the stomach and the small intestine.

Pharmacodynamic Aspects of FDDS

1. **Reduced Fluctuations of Drug Concentration:** Floating system of drug administration produces constant blood drug concentrations within a narrower range in comparison to the immediate release dosage forms on continuous input of the drug. Thus, fluctuations in drug effects are minimized andconcentration-dependent adverse effects that are associated with peak concentrations can be prevented. This feature is especially advantageous for drugs with a narrow therapeutic index.
2. **Improved Selectivity in Receptor Activation:** Minimization of fluctuations in drug concentration also makes it possible to obtain certain selectivity in the elicited pharmacological effect of drugs that activate different types of receptors at different concentrations.
3. **Reduced Counter-Activity of the Body:** In many cases, the pharmacological response, which intervenes with the natural physiologic processes, provokes a rebound activity of the body that minimizes drug activity. Slow input of the drug into the body as incase of FDDS is shown to minimize the counter activity leading to higher drug efficiency.

V. CONCLUSION

Development of an efficient gastro retentive dosage form for stomach specific drug transport is an Actual project. Floating Drug Delivery Systems offer the gain of better absorption of medication that are absorbed from the top part of stomach, which enhance the bioavailability and controlled delivery of many drugs with new and vital therapeutic options. This leads to less frequent dosing and more advantageous efficiency of the treatment. Good stability and better drug release as compared to other conventional dosage form make such system greater reliable. The most important criteria which has to be looked into for the productions of a floating drug delivery system is that the density of the dosage form should be less than that of gastric fluid. And hence, it can be concluded that these dosage forms serve the best in the treatment of diseases related to the GIT and for extracting a prolonged action from a drug with a short half-life. Although there are number of difficulties to be worked out to achieve prolonged gastric retention, a large number of companies are focusing toward commercializing this technique.

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