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Review Article

A REVIEW ON FLOATING TABLET

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ABSTRACT

Pharmaceutical industries have received much interest in pharmaceutical research in the area of oral drug delivery more over on Gastro retentive drug delivery system that is Floating Drug Delivery System (FDDS).The objective of this study to review on FDDS focusing on its current advancement and its future. Floating systems are low density systems that have sufficiently buoyancy to flow over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. Floating dosage forms can be prepared as tablets, capsule by adding suitable ingredients with excipients like hydrocolloids, inert fatty materials and buoyancy increasing agents. Various categories of drugs like antacids, antidiabetic, antifungal and anticancer drugs are formulated into FDDS. FDDS have bulk density less than gastric fluids that have sufficient buoyancy to float over the gastric contents and remain in the stomach for longer duration of time. This review article is in pursuit of giving detailed information on the pharmaceutical basis of their design, classification, advantages and disadvantages, factors affecting gastric residence time of FDDS, applications, and formulation of floating tablet.

Introduction

Floating systems or dynamically controlled systems are low density systems that have sufficiently buoyancy to flow over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. This result is an increased gastric retention time and a better control of the fluctuations in plasma drug concentration. Oral controlled release dosage forms have been developed over the past three decades due to their considerable therapeutic advantages such as:

1. Easily administrations.
2. Low cost of therapy.
3. Patient compliance and flexibility in formulation.

The ultimate goal of any drug delivery is Effective disease / disorder management, minimum side effects and greater patient compliance in the cost effective manner. More than 50% of the drug delivery systems available in the market are oral drug delivery systems. Controlled release drug delivery systems (CRDDS) provide drug release at a predetermined, predictable, and controlled rate. Controlled release drug delivery system is capable of achieving the benefits like maintenance of optimum therapeutic drug concentration in blood with predictable and reproducible release rates for extended time period, enhancement of activity of duration for short half life drugs, elimination of side effects, reducing frequency of dosing and wastage of drugs, optimized therapy and better patient compliances. The controlled gastric retention of solid dosage forms may be achieved by mucoadhesive systems that causes bioadhesion to stomach mucosa, floating systems, swelling and expanding systems, modified-shape systems, high density systems and other delayed gastric emptying devices. Gastro retentive dosage form can remain in the gastric region for several hours and hence significantly prolong the gastric residence time of drugs. Prolonged gastric retention improves bioavailability, reduces drug waste, and improves solubility of drugs that are less soluble in a high pH environment. Gastro retention helps to provide better availability of new products with suitable therapeutic activity and substantial benefits for patients.

The successful development of oral controlled drug delivery systems requires an understanding of the three aspects of the system, namely.

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1. The physiochemical characteristics of the drug.
2. Anatomy and physiology of GIT and Characteristics of Dosage forms[1].

Basic anatomy and physiology of stomach

The main function of the stomach is to process and transport foo d.

Substantial enzymatic digestion is
initiated in stomach, particularly of proteins. Anatomically the stomach is divided into 3 regions: fundus, body, and antrum (pylorus). The proximal part made of fundus and body acts as a reservoir for undigested material, whereas the antrum is the main site for mixing motions and act as a pump for gastric emptying by propelling action. Gastric emptying occurs during fasting as well as fed states. The pattern of motility is however distinct in the 2 states. During the fasting state an inter digestive series of electrical events take place, which cycle both through stomach and intestine every 2 to 3 hours. This is called the interdigestive myloelectric cycle (IMC) or migrating myloelectric cycle (MMC), which is further divided into following 4 phases as described by Wilson and Washington.[2]

1. **Phase I** (basal phase) lasts from 40 to 60 minutes with rare contractions.
2. **Phase II** (pre-burst phase) lasts for 40 to 60 minutes with intermittent action potential and contractions. As the phase progresses the intensity and frequency also increases gradually.
3. **Phase III** (burst phase) lasts f or 4 to 6 minutes. It includes intense and regular contractions for short period. It is due to this wave that all the undigested material is swept out of the stomach down to the small intestine. It is also known as the housekeeper wave.
4. **Phase IV** lasts for 0 to 5 minutes and occurs between phases III and I of 2 consecutive cycles.

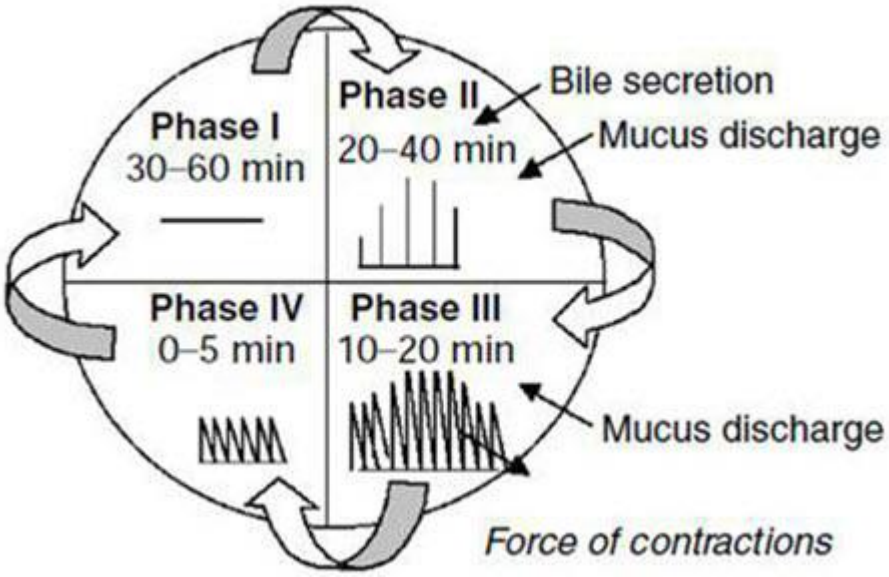

Fig 1: Motility Pattern in GIT

Advantages of Floating Drug Delivery System

1. The floating drug delivery systems are advantageous for drugs absorbed through the stomach or proximal part of the small intestine. E.g. Ferrous salts, furosemide.
2. The efficacy of the medicaments administered utilizing the sustained release principle of floating formulation has been found to be independent of the site of particular medicaments.
3. The floating drug delivery systems are advantageous for drugs meant for local action in the stomach. E.g. antacids
4. Acidic substances like aspirin cause irritation on the stomach wall when come in contact with it. Hence HBS formulation may be useful for the administration of aspirin and other similar drugs.
5. Complete absorption of the drug from the floating dosage form is expected even at the alkaline pH of the intestine. The dissolution of the drug in gastric fluid occurs and then the dissolved drug is available for absorption in the small intestine after emptying of the stomach contents.
6. Enhanced bioavailability.
7. Sustained drug delivery/reduced frequency of dosing.
8. Reduced counter-activity of the body.

Disadvantages of Floating Drug Delivery System

1. Floating system is not feasible for those drugs that have solubility or stability problem in GI tract.

2. These systems require a high level of fluid in the stomach for drug delivery to float and work efficiently.
3. Drugs such as nifedipine, which under goes first pass metabolism may not be desirable for the preparation of these types of systems.
4. Drugs which are irritant to Gastric mucosa are also not desirable.
5. The drug substances that are unstable in the acidic environment of the stomach are not suitable candidates to be incorporated in the systems.

Floating system

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. After release of drug, the residual system is emptied from the stomach[3].

Classification of floating system

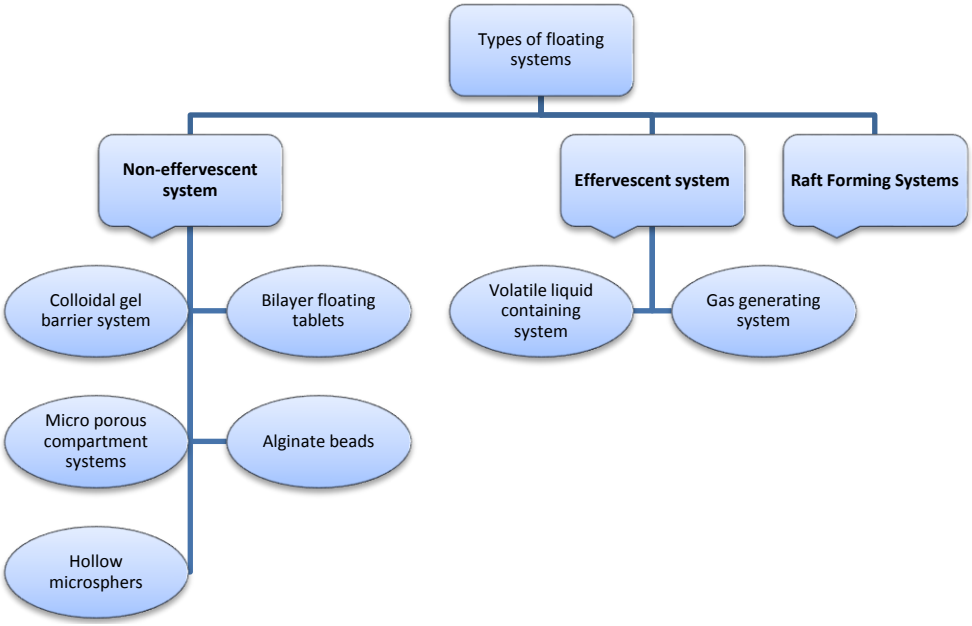

Fig 2: Classification of Floating System

Non-effervescent system

The non effervescent FDDS based on mechanism of swelling of polymer or bioadhesion to mucosal layer in GI tract. The most commonly used excipients in non effervescent FDDS are gel forming or highly swellable cellulose type hydrocolloids, polysaccharides and matrix forming material such as polycarbonate, polyacrylate, polymethacrylate, polystyrene as well as bio-adhesive polymer such as chitosan and carbopol. The various type of this systems are as follows: [4].

Colloidal Gel Barrier System

Hydrodynamically balanced system first designed by Sheth and Tossounian. They remain buoyant in the stomach due to gel-forming hydrocolloids and this enhances GRT and increases the amount of drug at the absorption site. Various gel forming agents used in this system are highly soluble cellulose type hydrocolloids which are hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, polysaccharides and matrix forming polymers such as polycarbophil, polystyrene[5].

Bilayer floating tablet

A bilayer tablet contain two layer immediate release layer which release initial dose from system while the another sustained release layer absorbs gastric fluid, forming an impermeable colloidal gel barrier on its surface, and maintain a bulk density of less than unity and thereby it remains buoyant in the stomach[6].

Micro porous Compartment System

In this inside the micro porous compartment which has pores in the top and bottom walls contains encapsulated drug reservoir. In drug reservoir peripheral walls are completely sealed due to this sealing direct contact of undissolved drug with gastric surface is prevented. Entrapped air in the floating chamber stimulates the system to float over gastric content. Through an aperture the gastric fluid enters which dissolves the drug for absorption across intestine [7].

Alginate beads

Multi unit floating dosage forms are developed from freeze dried calcium alginate. Spherical beads of approximately 2.5 mm diameter can be prepared by dropping a sodium alginate solution into aqueous solution of calcium chloride, causing precipitation

of calcium alginate leading to formation of porous system, which can maintain a floating force for over 12 hours. When compared with solid beads, which gave a short residence, time of 1 hour, and these floating beads gave a prolonged residence time of more than 5.5 hours[1].

Hollow microspheres

Hollow microspheres (microballons), loaded with drug in their outer polymer shells were prepared by a novel emulsion solvent diffusion method. The ethanol: dichloromethane solution of drug and enteric acrylic polymer was poured into an agitated aqueous solution of PVA that was thermally controlled at 400 C. The gas phase generated in dispersed polymer droplet by evaporation of dichloromethane formed an internal cavity in microsphere of polymer with drug. The microballons floated continuously over the surface of acidic dissolution media containing surfactant for more than 12 hours *in vitro*[8].

Effervescent system

Effervescent systems include use of gas generating agents, carbonates (e.g. Sodium bicarbonate) and other organic acid (e.g. citric acid and tartaric acid) present in the formulation to produce carbon dioxide (CO_2) gas, thus reducing the density of system and making it float on the gastric fluid. An alternative is the incorporation of matrix containing portion of liquid, which produce gas that evaporate at body temperature[9].

These effervescent systems further classified into two types.

Volatile liquid containing systems

Inflatable chamber with a liquid can be incorporated which provide sustained gastric retention of drug delivery system. Liquids in this system include cyclopentane, ether that gasifies at body temperature which causes inflatation of the chamber in the stomach. They contain hollow deformable unit which are osmotically controlled floating systems. System is divided into two compartments first compartment contains drug and there is volatile liquid in the second compartment [10].

Gas generating systems

It basically contains polymers that gasify at body temperature effervescent compounds such as sodium bicarbonate, citric acid, tartaric acid, swellable polymers like methocel, and polysaccharides like chitosan. Resin beads loaded with bicarbonate and coated with ethylcellulose is the most common approach for preparation of these systems. The ethycellulose coating is insoluble but permeable to water which release carbon dioxide due to which it float[11].

Raft forming systems

Raft forming systems have received much attention for the delivery of antacids and drug delivery for gastrointestinal infections and disorders. The basic mechanism involved in the raft formation includes the formation of viscous cohesive gel in contact with gastric fluids, wherein each portion of the liquid swells forming a continuous layer called a raft. The raft floats because of the buoyancy created by the formation of CO_2 and act as a barrier to prevent the reflux of gastric Contents like HCl and enzymes into the esophagus. Usually, the system contains a gel forming agent and alkaline bicarbonates or carbonates responsible for the formation of to make the system less dense and float on the gastric fluids [12].

Factors Affecting Gastric Residence Time of FDDS

There are several factors that can affect gastric emptying of an oral dosage form which include density, size and shape of dosage form, feeding state, biological factors such as age, gender, posture, body mass index, disease state etc[13].

Effect of Dosage Form Size & Shape

Small size tablets are emptied from the stomach during the digestive phase while large size units are expelled during the house keeping waves found that floating unit with a diameter equal or less than 7.5 mm had larger gastric residence time (GRT) compared to non-floating units but the GRT was similar for floating and non-floating units having a large diameter of 9.9 mm. They found that GRT of non-floating units were much more variable and highly dependent on their size which are in the order of small < medium < large units. Moreover, in supine subjects, size influences GRT of floating and non- floating form. Tetrahedron and ring shaped devices have a better GRT as compared with other shapes[14].

Gender Posture & Age

Mean ambulatory GRT in males (3.4±0.6 hour) is less compared with their age and race-matched female counterparts (4.6±1.2 hour) regardless of their weight, height and body surface. Women emptied their stomach at a lower rate than men even when hormonal changes due to menstrual cycle were minimized. The mean GRT in the supine state (3.4±0.8 hour) was not stastically significant from that in the upright, ambulatory state (3.5±0.7 hour). In case of elderly, the GRT was prolonged especially in subject more than 70 years old (mean GRT – 5.8 hour)[15].

Effect of Food & Specific Gravity

To float FDDS in the stomach, the density of dosage form should be less than gastric content i.e.1.0 g/cm^3. Since, the bulk density of a dosage form is not a sole measure to describe its buoyant capabilities because the magnitude of floating strength may vary as a function of time and gradually decrease after immersing dosage form into fluid as a result of development of its hydrodynamic equilibrium. Various studies have shown the intake of food as main determinant of gastric emptying rather than food. Presence of food is the most important factor effecting GRT than buoyancy. GRT is significantly increased under fed condition since onset of MMC is delayed. Studies show that GRT for both floating and non-floating single unit are shorter in fasted subjects (less than 2 hour), but significantly prolonged after a meal (around 4 hour)[16].

Natural of Meal & Frequency of Food

Feeding of indigestible polymers or fatty acid salts can change the motility pattern of the stomach to fed state, to increase gastric emptying rate and prolonging the drug release. Diet rich in protein and fat can increase GRT by 4-10 hours[17].

Application of floating drug delievery system

Enhanced Bioavailability

The bioavailability of riboflavin CR-GRDF is significantly enhanced in comparison to the administration of non-GRDF CR polymeric formulations. There are several different processes, related to absorption and transit of the drug in the gastrointestinal tract, that act concomitantly to influence the magnitude of drug absorption[18].

Sustained Drug Delivery

Oral CR formulations are encountered with problems such as gastric residence time in the GIT. These problems can be overcome with the HBS systems which can remain in the stomach for long periods and have a bulk density <1 as a result of which they can float on the gastric contents. These systems are relatively larger in size and passing from the pyloric opening is prohibited[19].

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[20].

Absorption or Bioavailability 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%)[21].

Reduced fluctuations of drug concentration

Continuous input of the drug following CRGRDF administration produces blood drug concentrations within a narrower range compared to the immediate release dosage forms. Thus, fluctuations in drug effects 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

Formulation of floating tablets

- **Polymers**
- **Sustained release polymer**
- **Effervescent generating system**
- **Hydrocolloids**
- **Inert fatty materials**
- **Release rate accelerants**
- **Release rate retardant**
- **Buoyancy increasing agents**
- **Low density material**
- **Miscellaneous**

1. **Polymers:** The following polymers used in preparations of floating drugs - HPMC K4, HPMC K4 M, HPMC K15, Calcium alginate, Eudragit S100, Eudragit RL, Methocel K4M, Polyethylene oxide, a Cyclodextrin, HPMC 4000, HPMC 100, CMC, Polyethylene glycol, polycarbonate, PVA, Polycarbo-nate, Sodium alginate, HPC-L, CP 934P, HPC, Eudragit S, HPMC, Metolose S.M. 100, Propylene foam, Eudragit RS, ethyl cellulose, poly methyl methacrylate, PVP, HPC-H, HPC-M, Polyox, Acrylic polymer, E4 M and Carbopol.
2. **Sustained release polymer:** These are the polymers which are used for sustained release action. E.g. HPMC K100M, HPMC K15M, HPMC ELV, Polycarbonate, Polyethylene glycol, Sodium alginate, Carbopol, Eudragit
3. **Effervescent generating system:** E.g. Citric acid, Tartaric Acid, Sodium Bicarbonate, Citroglycine etc
4. **Hydrocolloids:** Suitable hydrocolloids are synthethics, anionic or non ionic like hydrophilic gumes, modified cellulose derivatives. E.g. Accasia, pectin, agar, alginates, gelatin, casein, bentonite, veegum, MC, HPC, HEC, and Na CMC can be used. The hydrocolloids must hydrate in acidic medium i.e. gastric fluid is having pH 1.2.Although the bulk density of the formulation may initially be more than one, but when gastric fluid is enter in the system, it should be hydrodynamically balanced to have a bulk density of less than one to assure buoyancy
5. **Inert fatty materials:** Edible, pharmaceutical inert fatty material, having a specific gravity less than one can be added to the formulation to decrease the hydrophilic property of formulation and hence increases the buoyancy. Example: Purified grades of beeswax, fatty acids, long chain alcohols, glycerides, and mineral oils can be used
6. **Release rate accelerants:** The release rate of the medicament from the formulation can be modified by including excipient like lactose and/or mannitol. These may be present from about 5-60% by weight

7. **Release rate retardant:** Insoluble substances such as dicalcium phosphate, talc, magnesium stearate decreased the solubility and hence retard the release of medicaments
8. **Buoyancy increasing agents:** Materials like ethyl cellulose, which has bulk density less than one, can be used for enhancing the buoyancy of the formulation. It may be adapted up to 80 % by weight
9. **Low density material:** Polypropylene foam powder
10. **Miscellaneous:** Pharmaceutically acceptable adjuvant like preservatives, stabilizers, and lubricants can be incorporates in the dosage forms as per the requirements. They do not adversely affect the hydrodynamic balance of the systems.

Table 1: Polymers used in floating drug delivery

Hydrochlorides	**HPMC 1000,HPMC 4000, , β Cyclodextrin, Sodium alginate, HPC-L, CP 934P, HPC, Eudragit S, HPMC, Metolose S.M. 100, PVP, HPC-H, HPC-M, HPMC K15, Polyox, HPMC K4, Acrylic polymer, E4 M and Carbopol.**
Inert fatty materials	Beeswax, fatty acids, long chain fatty alcohols, Gelucires 39/01 and 43/01.
Effervescent agents	Sodium bicarbonate, citric acid, tartaric acid, Di-SGC (Di-Sodium Glycine Carbonate, CG (Citroglycine).
Release rate accelerants(5%-60%)	lactose, mannitol.
Release rate retardants (5%-60%)	Dicalcium phosphate, talc, magnesium stearate.
Buoyancy increasing agents (upto80%)	Ethyl cellulose.

Methods of preparation

1. **Methodology for single layer floating tablets:** Basically single layer floating tablets are prepared by compression methods. For this normally three basic compression methods are used. They are as follows:-
   - Direct compression,
   - Dry granulation,
   - Wet granulation.

- **Direct compression method:** Direct compression is the process of compressing tablets directly from powdered materials without modifying physical nature of materials into the tablets. This method is used for crystalline chemicals having good compressible characteristic and flow properties such as: Potassium salt (chloride, chlorate, bromide), Ammonium chloride, Sodium chloride, Methenamine etc. Compressed tablets are prepared by single compression using tablet machines. After a quantity of powdered or granulated tabletting material flow into a die, the upper and lower punches of the tablet machine compress the material under a high pressure (~tons/in^2).
- **Dry granulation method:** It is defined as the formation of granules by slugging, if the tablet ingredients are sensitive to moisture and/or unable to withstand elevated temperature during drying
- **Wet granulation method:** In wet granulation the active ingredient, diluents and disintegrants are mixed or blended well in a rapid mixer granulator (RMG). The RMG is a multi-purpose chopper which consists of an impeller and a chopper and is used for high speed dispersion of dry powders and aqueous or solvent granulations.Moist materials from wet milling steps are placed on large trays and placed in drying chambers with a circulating air current and thermo stable heat controller. Commonly used dryers are tray dryer, fluidized bed dryer. After drying, the granules are reduced in particle size by passing through smaller mesh screen. After this, the lubricant or glidant is added as fine powder to promote flow of granules. These granules are then compressed to get a tablet. Dry granulation when compared with wet granulation has a shorter, more cost-effective manufacturing process. Because it does not entail heat or moisture, dry granulation is especially suitable for active ingredients that are sensitive to solvents, or labile to moisture and elevated temperatures

2. **Methodology for bilayer floating tablets**
   a) Oros ® Push Pull Technology
   b) L-Oros Tm Technology
   c) DUROS Technology
   d) Elan Drug Technologies' Dual Release Drug Delivery System
   e) EN SO TROL Technology
   f) Rotab Bilayer
   g) Geminex Technology

- **Oros ® Push Pull Technology:** It is two or three layer system, a drug layer and push layer. Drug layer contain drug with other agents and due to this drug is less soluble. Sometimes suspending agent and osmotic agent are also added. The tablet core is surrounded by semi permeable membrane
- **L-Oros Tm Technology:** Alza developed L-OROS system due to solubility problem. The system contain a drug in dissolved state in a lipid soft gel product which is produced first and then barrier membrane, after which osmotic membrane and semi permeable membrane coat is applied and is then drilled out through external orifice

- **DUROS Technology:** This technology is also known as miniature drug dispensing system which works like a miniature syringe and release small quantity of drug consistently over a period of time .There is an outer cylindrical titanium alloy reservoir which has high impact strength due to which drug molecules inside it are protected from enzymes
- **Elan Drug Technologies' Dual Release Drug Delivery System:** The DUREDASTM Technology provides combination release of drugs together and different release pattern of single drug i.e. it provides sustained release as well as immediate release. This technology provides various advantages i.e. two drug components provide tailored release and its another benefit is that it consist of bilayered tablet technology in which it contain modified as well as immediate release pattern in one tablet. In these different controlled release formulations are combined together.
- **EN SO TROL Technology:** An integrated approach is used by Shire laboratory for drug delivery system which focuses on identification and incorporation of enhancer which is identified to form optimized dosage form in controlled release system. By this enhancement in solubility is achieved
- **RoTab Bilayer:** RoTab bilayer when using is switched to production mode. Dose and compression force is automatically regulated by adjusting filling speed and die table. Hardness is also regulated when required
- **Geminex Technology:** In this drug delivery system at different times more than one drug can be delivered. This technology basically increases the therapeutic efficacy of the drug by decreasing its side effects. It is useful both to industry as well as patient as in single tablet it provides delivery of drug at different rates[21].

Conclusion

Drug absorption in the gastrointestinal tract is a highly variable procedure and prolonging gastric retention of the dosage form extends the time for drug absorption. Gastro-retentive floating drug delivery systems have emerged as an efficient means of enhancing the bioavailability and controlled delivery of many drugs. The increasing sophistication of delivery technology will ensure the development of increase number of gastroretentive drug delivery to optimize the delivery of molecules that exhibit absorption window, low bioavailability and extensive first pass metabolism. FDDS promises to be a potential approach for gastric retention. 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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