



## A Review on Formulation and Evaluation of Floating Matrix Tablet

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### ABSTRACT

Recent advancements in science and technology have addressed physiological hurdles like short gastric residence periods (GRT) and inconsistent stomach emptying times (GET), paving the way for the study and advancement of rate-controlled oral drug delivery systems. Numerous efforts have been undertaken to increase patient compliance, therapeutic efficacy, and oral medication bioavailability. To address these needs, numerous controlled-release oral administration devices have been created. When it comes to localized gastric treatment and medications with a limited intestinal solubility and absorption window, The formulation technique of floating dosage forms is of paramount importance. The purpose of the floating- drugs delivery method is to increase bioavailability by extending the duration the stomach remains in one place after oral administration. The necessity to target medications to a particular area of the gastrointestinal tract (GIT), such the stomach, gave rise to the concept of gastric retention. Low density systems known as floating systems have enough buoyancy to pass over gastric contents and stay afloat there for an extended amount of time without slowing down the speed at which the stomach empties. By combining the right components using excipients such as hydrocolloids and inert fatty materials, and buoyancy-enhancing compounds, It is possible to develop floating dosage forms like tablets and capsules. One simple unit dose form that has the advantage of a prolonged drug release duration in the stomach is the floating matrix tablet. For medications with a limited absorption window, reduced stability at high alkaline pH, and improved solubility at low pH, gastro-retentive drugs delivery systems (GRDDS) have become increasingly popular. The goal of this review paper is to provide comprehensive information on the pharmaceutical underpinnings of floating tablet design, classification, benefits and drawbacks, and factors influencing the stomach retentions time of FDDES.

**Keywords:** Floating Drug Delivery System , Gastroretentive Drug Delivery System

## INTRODUCTION

Drug delivery systems that are gastro-retentive stay in the stomach and can increase oral bio-availability of medications with a specific upper gastrointestinal tract absorption window. Many strategies are currently being employed to extend the duration of gastric retention, such

as high-density system, polymeric bio adhesive system, expanding and swelling system, floating drug delivery mechanism.<sup>[1]</sup>

Therefore, controlling the location of a drug delivery system (DDS) in a particular GI tract segment is advantageous for a range of critical drugs, including those with stability issues or a restricted absorption window in the GIT.<sup>[2]</sup> It is preferred for the drug delivery to extend the time of stomach residency in order to generate an oral, site-specific, controlled release dosage form.<sup>[3]</sup>

The protract presence across the upper gastrointestinal system of the dose forms ensures a more predictable and the drug's sustained release, enhancing its therapeutic efficacy and patient compliance. This approach addresses challenges such as variable gastric emptying times and the limited absorption window of certain drugs. By maintaining dosage form in the optimal absorption site for prolonged periods, it maximizes drug bioavailability and minimizes the frequency of dosing. Therefore, the innovation in oral controlled release formulations lies in their ability to remain in upper gastro-intestinal tract or stomach till the drug is fully released, thereby optimizing drug therapy and improving patient outcomes.<sup>[4]</sup>

Novel dosage formulations intended to stay in the stomach for extended, consistent period of time are obviously attracting more attention, as seen by recent scientific and patent literature. Both academic and commercial research groups are interested in this. Several attempts have been made to create delivery systems that are gastro-retentive. In the last three decades, there have been notable technological and diverse developments in the creation of devices intended for retention in the upper gastrointestinal (GI) tract. These include low-density systems, bio-adhesive system, expand and swell system, raft system, and floating systems. Drugs with gastro-retentive systems have a substantially longer gastric residence time because they might stay in the stomach area for several hours. By improving the availability of novel products, gastro-retentive technology gives patients significant benefits and new therapeutic options.<sup>[5]</sup>

The GFDDS is unique among these gastroretentive delivery systems since it can be used with medications that have low bioavailability because of the upper gastrointestinal tract's (GIT) short absorption window. The dose form is precisely retained at the absorption site by the GFDDS, which greatly increases bioavailability.<sup>[6,7]</sup> Since medications with low bioavailability have limited capacity for the upper gastrointestinal tract to absorb, notion of floating drug delivery is especially pertinent to these drugs.<sup>[8,9]</sup>

Achieving more consistent and improved bioavailability is the main objective in the creation of floating tablets and floating medication delivery systems. Many scientists working in pharmaceuticals are currently concentrating on creating the FDDS. The benefit of only needing one dose to cover the whole course of therapy should be provided by this perfect system, which would deliver the active medication straight to the targeted location. Scientists have succeeded in developing such a system, which has encouraged further advancements in controlled release tablets.<sup>[10]</sup>

Consistent drug concentrations in target tissues, predictable and repeatable drug release, and maximising therapeutic effects with fewer and less frequent doses are the goals of controlled release systems. Increased therapeutic efficacy, better absorption, and possibly smaller dose

sizes are among the advantages. Gastric emptying of dosage forms is very varied. Controlled release system design, however, comes with a number of difficulties in ensuring improved absorption and bioavailability. <sup>[11]</sup>

Delivers the drug gently and at the proper speed by floating on the contents of the stomach. After the medication takes action, the stomach releases the leftover system. <sup>[12]</sup> Because they are easy to take, effervescent pills are becoming more and more popular in a variety of industries, such as pharmaceuticals and vitamins. When these tablets come into touch with liquids, such juice or water, they are designed to dissolve and form a solution. <sup>[13]</sup>

This also works well for local medication delivery to the small intestine and stomach. Due to gastro-retention, innovative drugs with suitable therapeutic impacts and substantial patient advantages are more readily available<sup>[14]</sup> A floating drug delivery device only works with medications that are less stable and poorly soluble in intestinal fluids because it keeps the medication in the stomach. It is founded upon the dense, which floats on, stomach contents. <sup>[15]</sup>

## ADVANTAGES

- 1.They are the m This system provides prolonged medication delivery, such as the dosage variation of the hydrodynamically balanced system (HBS) and modified gastric residence time, by remaining in the stomach for a few hours . <sup>[16]</sup>
- 2.Compared to all other oral routes, these are microbiologically and chemically stable. <sup>[17]</sup>
- 3.Because of its higher dose precision and reduced content volatility, the oral dosage form is primarily appropriate.<sup>[18]</sup>
- 4.FDDS benefit drug intended for local stomach action, such as antacids.
- 5.FDDS dose forms are advantageous when there is a lot of intestinal movement or diarrhoea because they let the drug stay in the stomach longer and produce a more positive.
- 6.Ferrous salts, for example, are among medications that benefit from the FDDS.
- 7.A medication's slow release into the body reduces counteractivity, which results in a higher drug.
- 8.FDDS enhances pharmacological effects and improves clinical outcomes by reducing drug concentration fluctuations over a key concentration.<sup>[19]</sup>

## DISADVANTAGES

- Floating devices are impractical for medications whose solubility or stability in stomach juices is problematic.
- It is not appropriate to take medications such as nifedipine for FDDS due to its high absorption throughout the GI tract and considerable first-pass metabolism; this is because of the risk of diminished systemic bioavailability from their delayed stomach emptying. The use of FDDS with drugs that irritate the stomach mucosa is also restricted.
- Having enough stomach fluids is necessary for the medication dosages to float and work correctly, which is one disadvantage of floating. [20-21]

## Classification Of FDDS

- Single-Unit-Floating Dosage system.
  - a. Non-effervescent system.
  - b. Effervescent system (Gasgenerating system).
- Multiple-Unit-Floating Dosage system.
  - a. Non-effervescent system.
  - b. Effervescent system. (Gasgenerating system)
  - c. Raft forming system.
  - d. Hollow microspheres.

### ➤ **Single -Unit-Floating Dosage system :-**

The round shells of the low-density method appear to have a density lower than stomach fluid, making them suitable for carrying drugs for controlled release. Using a device that floats in the stomach and is filled with fluid is another way to acquire a buoyant dosage form. Undercoating these shells with sugar polymeric materials such as cellulose acetate phthalate and methacrylic polymer has been done. [22]

#### a. Non-Effervescent system:-

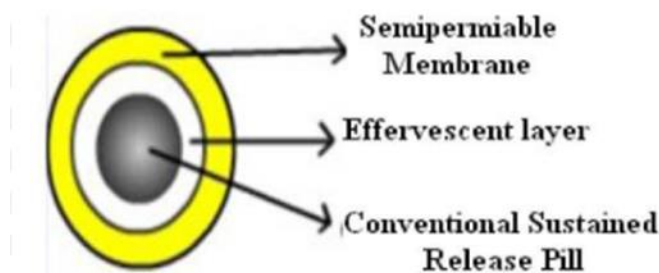
This sort of arrangement swells uncontrollably after ingestion by consuming so much gastric juice that it stops the food from leaving the stomach. Alginate beads, hollow microspheres, micro porous compartment systems, and colloidal gel barrier are a few examples of this kind of FDDS. Which is comprised of a microporous drug-housing component coupled with a gas-filled flotation chamber. The medicine that hasn't dissolved is kept within by sealing the other two walls that are in touch with the liquid. The gadget can expand to a large size and floats in the stomach for a long time. Once it is fully released, the shell breaks down and goes to the colon and gets eliminated. The stomach's in vivo residence period can be extended because of its floating design. Because of this, the gastrointestinal system's environment saw a longer overall transit time. [23-24]

#### b. Effervescent system (Gasgenerating system)

These systems are matrix types consisting of different effervescent chemicals including citric acid, tartaric acid, and sodium bicarbonate combined with swellable polymers like chitosan and methylcellulose. Because of the way they are constructed, CO<sub>2</sub> is held in inflated hydrocolloids and released providing the dose creates buoyancy when it comes into contact with the acidic contents of the stomach.<sup>[25]</sup>

### ➤ Multiple-Unit-Floating Dosage system

Despite much study and development, a major disadvantage of hydro dynamically balanced systems and other floating tablets is their all-or-nothing nature, which causes a significant fluctuation in the gastrointestinal transit time when taken orally. This issue was addressed by the development of poly unit floating systems, which lower the risk of dose-dumping and the inter-subject variability in absorption. Hollow microspheres, which can float on stomach fluid and have better gastric retention qualities, have been the subject of extensive investigation, and scientists are continuously investigating this area.<sup>[26]</sup>



**Figure:1 Multiple Unit Floating Dosage System**

#### a. Non-effervescent system:-

Compared to effervescent systems, there were comparatively few research in the literature on non-effervescent multiple unit systems. However, experts have not given much thought to the idea of creating a system using indomethacin and chitosan as the polymeric excipient. Given as a model drug, indomethacin is included in a multiple unit HBS produced using the extrusion process. An acetic acid, chitosan, and medication combination is needle-extruded, and the extrudate is then dried and chopped. In acidic environments, chitosan hydrates and floats, and by increasing the drug-polymer ratio, it could be able to trigger the required drug release.<sup>[27]</sup>

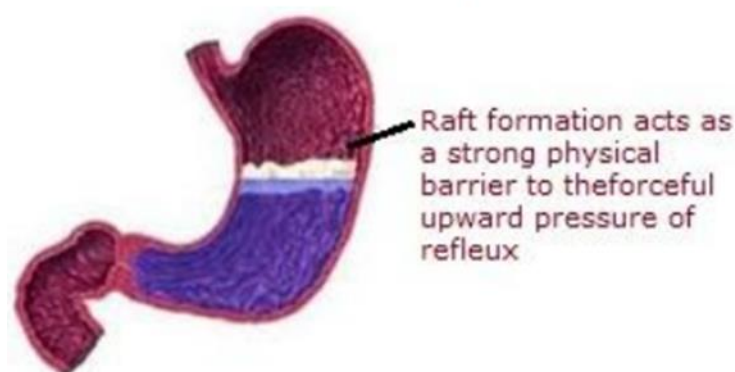
#### b. Effervescent system (Gas-generating system):-

Tetracycline-containing floating granules with a sustained release Hcl have been documented. The granules are divided into two phases of medicine granulates, A and B. HPMC, polyacrylic acid, and medication make up the components of A, which has 60 parts, and Bicarbonate, Sodium and thirty part, in B. Granules in Stage A made up of sixty parts by weight and stage B granules made up of thirty parts by weight are put into capsules after being combined with a lubricant. The granules show an 80% continuous release of medication about 6.5 hours, and after the capsule shell has dissolved in the dissolved solution, they remain floating for over 8 hours. It has been documented that pepstatin is available in floating mini capsules with a 0.1–0.2 mm diameter. A covering and a central core make up these mini

capsules. The HPMC layer is topped with pepsin. The emergence of various unit systems has given alginates a lot of attention.<sup>[28]</sup>

c. Raft forming system :-

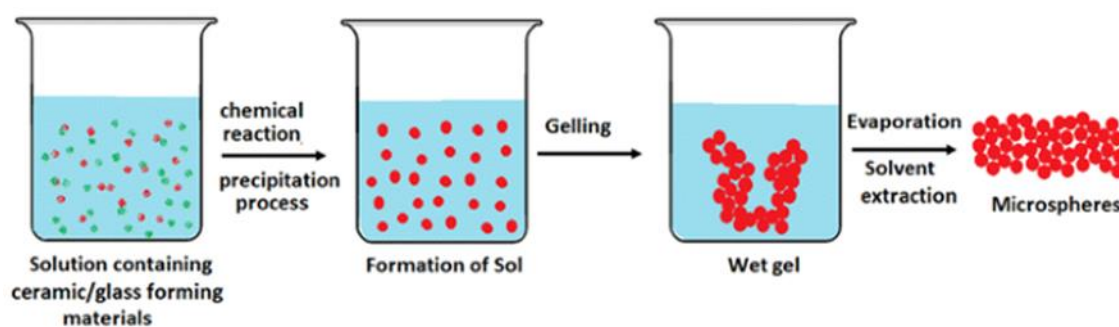
Raft Forming systems have garnered significant attention due to their ability to deliver drugs and antacids for gastrointestinal infections and illnesses. The mechanism underlying the development of rafts involves the formation of a cohesive gel that is viscous upon contact with stomach fluids. This part of the solution swells as a result of this process, creating a raft, which is a continuous layer.<sup>[29]</sup>



**Figure:2 Raft Forming System**

d. Hollow microspheres:-

Hollow microspheres, or micro-balloons, are created using an innovative method called emulsion solvent diffusion, and the drug was enclosed in their outer polymer shells. The micro-balloons stayed suspended on top of the surfactant-containing acidic dissolving media for nearly a whole 12-hour period in vitro.<sup>[30]</sup>



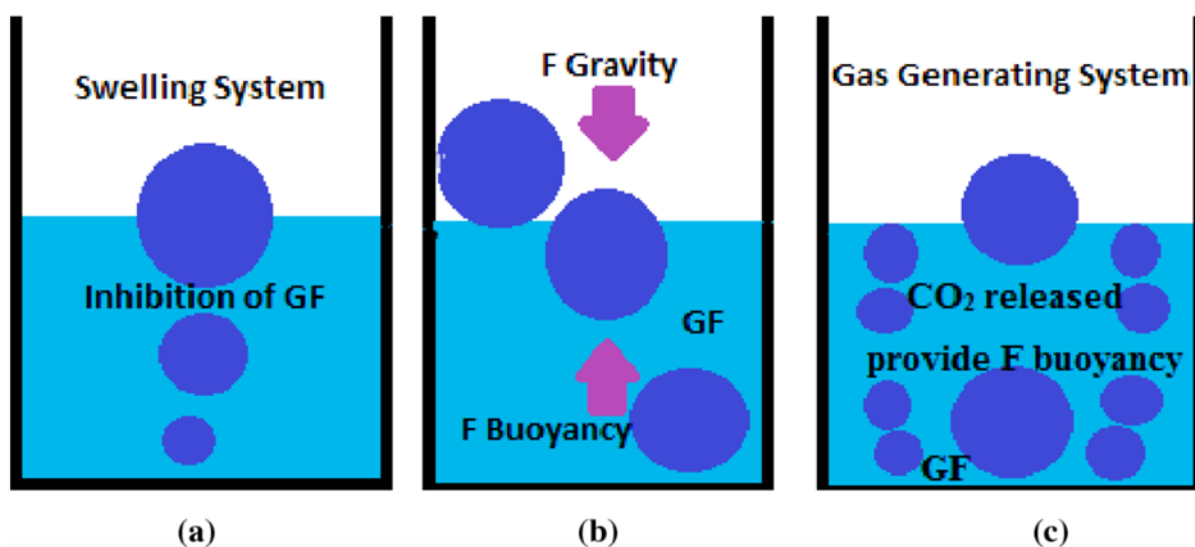
**Figure:3 Hollow Microspheres**

## Application of FDDS

1. FDDS is credited with improving medication efficacy since new research indicates that giving Diltiazem floating tablets twice day to hypertensive patients would be more beneficial than giving regular tablets.
2. For Parkinson patients, FDDS is useful in facilitating medication absorption over a 6-to 8-hour period and preserving a significant plasma concentration.
3. For treating *Helicobacter pylori*, the bacteria that causes peptic ulcers and chronic gastritis, FDDS was an excellent DDS.
4. FDDS are ideal HBS dose form for improving medication administration and lowering GI side effects. <sup>[31-32]</sup>

## Mechanism of FDDS

The medication is appropriately and gradually eliminated as it is floating on the stomach, from the body. The residual systems in the stomach flattens after medication discharge. To ensure that the buoyancy retention principle is successfully implemented and to maintain the dosage form buoyant on the meal's surface, a minimum degree of floating force (F) is also required. The measuring device for floating force kinetics calculates the force needed to move the principal submerged item, F, continuously during a certain period of time. More F on the positive side causes the object to float more readily. More F on the positive side causes the object to float more readily. By improving the floating forces' resilience and stability produced by the device, FDDS are made more stable and less likely to experience unanticipated changes in intragastric buoyancy capacity. <sup>[33]</sup>



**Figure:4 Mechanism of FDDS**

$$F = F_{\text{Buoyancy}} - F_{\text{Gravity}} = (D_f - D_s) \times g v$$

Where;

F=Total vertical force.

D<sub>f</sub> = Fluid density.

D<sub>s</sub> = Object density.

g = Acceleration due to gravity.

v = Volume.

**FACTORS IMPACTS ON FLOATING DRUG DELIVERY SYSTEM:-**

- 1) Density of the Dosage Forms.
- 2) Shape and Size of Dosage Forms.
- 3) Food intake & its nature.
- 4) Caloric content.
- 5) Effect of gender, age and posture.
- 6) Fed or unfed condition.
- 7) Concomitant drug administration.
- 8) Single or multiple unit formulation.
- 9) Biological factors.
- 10) Volume of liquids.

**1.Density of the Dosage Forms :-**

Floating is one density-dependent feature of dose form buoyancy. The dosage form's density (1.004 g/ml) should be less than the stomach's contents. The density needs to be less than 1.0gm/cm<sup>3</sup> in order for the floating attribute to be present. <sup>[34]</sup>

**2.Shape and size of dosage forms :-**

Dosage type units larger than 7.5 mm had higher gastric-retention times as compared to 9.9 mm diameter units.



Compared to conventional dosage forms, the tetrahedron and ring shape dosage forms showed enhanced GIT for a 24-hour retention rate of 90–100%. The flexural modulus of these dose forms were 22.5 and 48 kilo pounds per square inch (KSI).<sup>[35]</sup>

### **3. Food intake & its nature :-**

The consistency, volume, calorie content of meals are the primary determinants of the rate of stomach emptying. Meal nutritive density influences how quickly the stomach empties. As long as the meal contains the same number of calories, it doesn't matter if it is high in fat, protein, or carbohydrates. In contrast, an increase in acidity and caloric content causes the stomach to empty more slowly. This will reduce the rate at which food exits the stomach and prolong the period that the drug is delivered.<sup>[36]</sup>

### **4. Caloric Content:-**

The high-protein and high-fat meal may cause the stomach to retain food for an additional four to ten hours.<sup>[37]</sup> Since migrating myoelectric complexes (MMC) migrate infrequently, giving many meals as opposed to one can lead floating to climb by more than 400 minutes.

### **5. Effect of gender ,age and posture :-**

Women's stomachs empty more slowly than men's do. The mean gastric retention time (GRT) is not significantly different across the position effects. In older adults, especially those over 70, gastritis slows down the stomach's emptying because their gastric recovery time (GRT) is significantly longer. Diseases including diabetes, Crohn's disease, and others have an impact on how drugs are delivered.

### **6. Unfed or fed condition:-**

The gastrointestinal tract experiences burst of high motor activity known as MMCs every 1.5 to 2 hours. These MMCs are indicative of the motility while fasting. If the formulation is given concurrently with the MMCs extracting undigested material from the stomach, the general recovery time of the unit should be extremely short. Under the fed situation, MMC is delayed and GRT is notably longer.<sup>[38]</sup>

### **7. Concomitant and Drug Administration :-**

Prokinetic drugs for example metoclopramide, cisapride, opiates, codeine, and anticholinergics, such as propantheline and atropine.<sup>[39]</sup>

### **8. Single-or Multi-Unit Formulation:**

It is possible to co-administer units with different release profiles or containing incompatible compounds with multiple unit formulations, even though single unit dosage forms have a

reduced safety margin against dosage form failure. In spite of this, their unit failure is more foreseeable. [40]

### **9. Biological factors:-**

The FDDS is impacted by biological variables such as Crohn's disease and diabetes. [41]

### **10. Volume of liquids :-**

There are 25 to 50 millilitres in the stomach during rest. The duration of stomach emptying is influenced by the quantity of liquids administered. The process of emptying is hastened at high volumes. Fluids exit the stomach faster when taken at body temperature than when they are either warmer or colder. [42]

## **Drug candidate suitable for FDDS**

- a. Medications including furosemide, riboflavin, paminobenzoic acid, L-DOPA, and others possess a limited time window for gastric absorption.
- b. Medication that act locally in the stomach, such as misoprostol and antacids.
- c. A drug that is unstable in the environment of the intestines or colon (such as metronidazole, captopril, and ranitidine HCl).
- d. Drugs that change the normal microbiota of the colon (such as antibiotics like tetracycline, clarithromycin, and amoxicillin that are used in the treatment of *Helicobacter pylori*).
- e. Medications such as diazepam, Verapamil, and Chlordiazepoxide that are poorly. [43-45]

## **APPROACHES FOR PREPARING FLOATING DOSAGE FORM:**

Methods listed below able to applied to the preparation of floating dosage forms:

- (1) Making use of hydrocolloids that create gels, such as cellulose derivatives, gelatin, hydrophilic gums, and alginates.
- (2) Making use of of low density gastrointestinal substances, including phthalate-containing cellulose acetate and methacrylic polymer.
- (3) Putting it inside a capsule and lowering the particle size.
- (4) By generating gaseous carbon dioxide and then trapping it inside the gel network.
- (5) By using acrylic polymer to create hollow, drug-filled microballoons and enclosing them in capsules.

(6) An inflatable chamber that is filled with a liquid—like Stomach chamber inflation is achieved by using a solvent that gasifies at body temperature.

Following variables control efficacy of active medications in HBS:

- 1) The amount of active drug needed to achieve a desired therapeutic outcome.
- 2) Bulk Density
- 3) The qualities that are hydrophilic and hydrophobic
- 4) Stability in digestive juices <sup>[46]</sup>

## **FORMULATIONS OF FDDS :-**

FDDS can include following categories of factors. <sup>[47-48]</sup>

- ❖ Hydrocolloid.
- ❖ Inter fatty material.
- ❖ Release rate accelerant.
- ❖ Release rate retardant.
- ❖ Buoyancy increasing agent.
- ❖ Miscellaneous.

### **Hydrocolloid:-**

Hydrophilic gums and modified cellulose derivatives are examples of anionic or non-ionic hydrocolloids that are acceptable. Alginates, Veegum, Acacia, pectin, agar, Gelatin, sodium carboxy can all be utilised. The pH 1.2 stomach fluid serves as an acidic medium in which the hydrocolloids must hydrate. The formulation may begin with a bulk density greater than one, but it must be hydro-dynamically balanced in order to achieve a bulk density smaller than one to guarantee buoyancy when it enters the stomach fluid system.

### **Inert fatty materials :-**

Decrease the formulation's hydrophilic quality and hence raise its buoyancy are edible and pharmaceutically inert can be added. Examples include mineral oils, fatty acid, long chain alcohol, glyceride, refined grades of beeswax. These materials could make up between 5 and 75% of the total weight.

### **Release rate accelerants :-**

To change the pace at which a drug releases, an excipient, such as lactose or mannitol, can be added to a formulation. Between 5 and 60% of the weight may contain them.

### **Release rate retardant :-**

The solubility of drugs is decreased by insoluble materials including talc, magnesium stearate, and dicalcium phosphate, which also delays the release of the medication. These materials could make up between 5 and 60% of the total weight.

#### **Buoyancy increasing agents :-**

To increase the buoyancy of formulation, substances with a bulk density of less than 1, such as ethyl cellulose, can be utilised. Up to 80% of it can be adjusted based on weight.

#### **Miscellaneous :-**

Preservatives, stabilisers, and lubricants are examples of pharmaceutically approved adjuvants that can be added to dose forms based on specific needs. They have no negative effects on the systems' hydrodynamic equilibrium.

### **EVALUATION OF FLOATING DRUG DELIVERY SYSTEM:**

- Bulk Density.
- Tapped Density.
- Angle of repose.
- Compressibility Index.
- Hausner's Ratio.
- Buoyancy Studies.
- Swelling Index.
- Dissolution Study.
- Dimensional Analysis.
- Hardness.
- Friability.
- Size & Shape.
- Weight variation Tests(U.S.P)
- Disintegration Tests(U.S.P)

#### **Bulk Density :-**

A powder's bulk density was calculated by taking the mass and dividing it by the bulk volume, expressed in centimetres. After a typical sieve no. 20 pass, a graduated 100 ml cylinder was gently filled with a sample of powder weighing around 50 cm<sup>3</sup>. Three drops of the cylinder onto a hard wood surface occurred every two seconds, from a height of one inch. By dividing

the sample weight in grammes by the sample's ultimate volume in cubic centimetres inside the cylinder, the bulk density of each formulation was computed. The following formula was used to compute it. <sup>[49]</sup>

$$D_f = M/V_p$$

Where,

$D_f$  = Bulk density.

$M$  = Weight of sample in gram.

$V_p$  = Final volume of granule in cm<sup>3</sup>.

### **Tapped Density :-**

A powder's mass was divided by its tapped volume in centimetres to determine its tapped density. A 100 ml graduated cylinder is carefully filled with a quantity of powder, roughly 50 cm<sup>3</sup>, which has already passed through a typical number 20 sieve. The weight of the sample in grammes was then divided by the sample's ultimate tapped volume in cubic centimetres inside the cylinder to find each formulation's tapped density. The following equation was used to compute it. <sup>[50]</sup>

$$D_o = M/V_p$$

Where;

$D_o$  = Tapped density.

$M$  = Weight of sample in gram.

$V_p$  = Final volume of granule in cm.

### **Angle of repose:-**

The angle of repose is a useful tool for estimating the frictional forces in loose or powdered grains. This is the greatest angle that can exist between a granule or powder pile's surface and the horizontal plane. Granules may pass through a funnel that was set on a stand at a specific

height (h). After that, measurements were made on the granule heap's height and radius to ascertain its angle of repose. <sup>[51]</sup>

$$\tan\theta = (h/r)$$

$$\theta = \tan^{-1}(h/r)$$

Where;

$\theta$  = Angle of repose.

h = Height of pile.

r = Radius of pile.

| <b>Angle of Repose</b> | <b>Nature of Flow</b> |
|------------------------|-----------------------|
| <25                    | Excellent             |
| 25-30                  | Good                  |
| 30-40                  | Passable              |
| >40                    | Very poor             |

#### **Compressibility Index:-**

Following formula was used to compute the compressibility index following the measurement of the bulk and tapped densities.

$$\text{Compressibility index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

| <b>Carr's Index</b>      |                             |
|--------------------------|-----------------------------|
| <b>% Compressibility</b> | <b>Relative flowability</b> |
| 5 – 15                   | Excellent                   |
| 12 – 16                  | Good                        |
| 18 – 21                  | Fair                        |
| 23 – 28                  | Slightly poor               |
| 28 – 35                  | Poor                        |
| 35 – 38                  | Very poor                   |

**Hausner's Ratio :-**

The bulk and tapped density were estimated using the following formula, which was then utilised in the Hausner's ratio analysis.

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

**Buoyancy Studies:-**

The dissolving apparatus type II was used to visually record the FLT and TFT of floating tablets. It included 100 mL of 0.1 N HCl and a paddle running at 50 rpm (pH 1.2) at  $37 \pm 0.5$  °C. [52]

**Swelling Index:-**

At room temperature, the tablet swelling index was measured in 0.1 N HCl . At predetermined times, weight of the swelled tablet was calculated. This formula was used to get the swelling index.

$$\text{Swelling index} = (W_t - W_0) / W_0$$

**Dissolution Study:-**

The formulation's in vitro drug release was conducted in a sink environment at  $37 \pm 0.5$  °C and 50 rpm using the USP dissolving equipment type II paddle type. 900 millilitres of 0.1N HCl dissolving media were utilised. The samples were taken out for a duration of six hours at prearranged intervals, replaced with freshly diluted medium, and subjected to UV/visible spectrophotometer analysis.

**Dimensional Analysis:-**

A vernier calliper was used to measure the tablets' diameter and thickness. Each batch had twenty tablets, and average values were determined.

#### **Hardness:-**

To find the hardness of 20 randomly chosen tablets from each batch of formulations, a Monsanto-style hardness tester should be utilised.<sup>[53]</sup>

#### **Friability:-**

A tablet's ability to withstand abrasion is measured using a device called a Roche friabilator, which is used to test that property. The component of this is a plastic drum that is fixed to a machine that rotates 100 revolutions at 25 rpm. After being removed from the drum and wiped with a cloth, 20 tablets that were weighed before the test are weighed again. For a standard tablet, the weight fluctuation cannot be less than 0.5 to 1.0%.<sup>[54]</sup>

#### **Shape & Size :-**

The size and form of the particles have a major impact on the solubility rate and possible bioavailability of the medications. The particle size of the formulation is ascertained using a variety of techniques, including sieve analysis, air elutriation analysis, photo analysis, optical microscope, electro resistance counting techniques (Coulter counter), sedimentation techniques, laser diffraction methods, ultrasound attenuation spectroscopy, air pollution emissions measurements, etc.<sup>[55]</sup>

#### **Weight Variation Test (U.S.P) :-**

From each batch, ten tablet was chosen at random & weighed in addition to check for weight variance. According to US Pharmacopoeia, a little amount of weight fluctuation was allowed for tablets.

#### **Disintegration tests (U.S.P) :-**

Testing apparatus consists of six glass tubes measuring three inches each, including an open top and ten mesh screens beneath. At a rate of 28 to 32 cycles per minute, the basket is pushed up and down by 4-6 cm. Every tablet is prevented from floating by perforated plastic discs on top. Per the test, tablets ought to completely break down, with every particle going through the 10 mesh screen inside of them. Any remnants ought to have a gentle feel. The following are the disintegration times: Tablets without coating: 5–30 minutes; tablets with coating: 1–2 hours.<sup>[56]</sup>



### A List of Drugs Manufactured for FDDS with Single and Multiple Unit Forms

| Dosage Form | Drug Candidate  |
|-------------|---|
| Tablet      | Pentoxifyllin ,Chlorpheniramine maleate, Amoxicillin trihydrate, Verapamil HCl, Sotalol, Atenolol, Isosorbide mono nitrate, and Isosorbide-di-nitrate-acetaminophen,Ampicillin,Riboflavin-5-phosphate,Cinnamon,Diltiazem,Fluorouracil, Pirotetanide, Prednisolone |
| Capsule     | Misoprostal, diazepam, propranolol, urodeoxycholic acid, nicardipine, furosemide, Benserazide chlordiazepoxide HCl with L-DOPA  |
| Microsphere | Tranilast, Iboprufen, Aspirin, Griseofulvin, and Terfenadine  |
| Granule     | Prednisolone, Indomethacin  |
| Film        | Cinnarizine ,Drug delivery system   |
| Powder      | A few common drugs  |

### Some Marketed Formulation For Floating Drug Delivery System <sup>[57]</sup>

| Products | Content                                   | Manufacturer           | Formulation Type     |
|----------|---|------------------------|----------------------|
| Madopar  | Benserazide (25 mg)<br>,Levodopa (100 mg) | Roche Products,<br>USA | Floating, CR capsule |

|                   |  |                              |   |
|-------------------|--|------------------------------|---|
|                   |  |                              |   |
| Valrelease        | Diazepam (15 mg)                               | Hoffmann-LaRoche,<br>USA     | Floating capsule                                  |
| Liquid Gaviscon   | Mg carbonate (358 mg),<br>Al hydroxide (95 mg) | Glaxo Smith Kline,<br>India  | Effervescent floating liquid alginate preparation |
| Topalkan          | Al-Mg antacid                                  | Pierre Fabre Drug,<br>France | Floating liquid alginate preparation              |
| Almagate FlotCoat | Al-Mg antacid                                  | —————                        | Floating dosage form                              |
| Conviron          | Ferrous sulphate                               | Ranbaxy, India               | Colloidal gel forming FDOS                        |

### Conclusion:-

Gastro Retentive Drug Delivery System constitute distinct systems that have grown in significance during the past thirty years. In order to address the short comings of traditional methods of administration, a great deal of study have been done on gastric delivery system, especially lower-density compositions showing the greatest potential. gastric delivery system based controlled-release uses show promise for the ingestion about medications designed to handle circumstances affecting upper region of the gut, though they might come with shortcomings including the durability or dissolution relying upon pH values, a brief duration of action, or a limited period for intake. There have been a lot of gastro retentive controlled-release medications available, nearly all of which use a single-system method. Matrix activity was discovered significantly influenced by the nature of fluids, preservatives (for example, dewatering inhibitors), even extra monomers (for example, croscarmellose sodium) in the hydroxy propyl methyl cellulose tabs. A definite benefit of using croscarmellose sodium with cellulose microcrystalline would be that this enabled an accomplishment of both the GRDDS standards for performance. the accessibility of new items with new remedial potential outcomes and significant advantages for patients. Before long, the purported ' One day medicine ' definitions might be supplanted by novel gastro retentive items with delivery and ingestion periods of roughly one day.

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