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# Beyond the Surface Unveiling the Intricacies of Floating Drug Delivery Systems

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**Abstract:** *Writing an overview on the FDDS served the goal of comprehending the fundamentals of drifting as a means of achieving stomach retention. Both the effervescent and inertvarieties of floating tablets are created using various methods based on buoyancy principles in the production of FDDS. API which are unstable at the lower intestine environment, have a restricted absorptionwindow at the upper GIT, are less soluble in higher pH values, and are active locally can be delivered using FDDS. The technique of design in a floating single unit and several units system, the physical & formulation, and variable impacting stomach retain are all included in the development of FDDS. Reviewing numerous in-vitro and in-vivo procedures with an eye on performance and use in FDDS, the review concentrates on and summarizes these methods. When an appropriate component and gas-generating agent are included, it is possible to administer floating dosage forms in formsthat are not intended for oral administration, such as tablets and capsules. The method is helpful in solving a number of issues that came up when developing drug dosages. Along with current and unique advancements, the review paper sheds light on several strategies employed at development of floating Forms of dosage.*

**Keywords:** FDDS, GIT, Gastric retention, Bioavailability, prolong release, in vitro buoyancy

## I. INTRODUCTION

Any drug delivery system's goal is to provide a therapeutic dose of the medication at theappropriatelocation within the body so that it can be quickly attained and then kept at the targeted concentration. Not every medication or therapeutic agent ingested orally is absorbed evenly throughout the GIT. Certain medications are only absorbed in a certain area of the Gastroretentive tract. One of the cutting-edge methods for oral sustained release medication delivery is known as FDDS. Drugs those have narrow absorption window and have more solubility in gastric region are suitable candidates for FDDS.FDDS extends the duration of dosage forms' retention in the stomach or upper gastrointestinal system, enhancing the drug's solubility, bioavailability, and therapeutic efficacy. FDDS are designed to keep medication in the stomach and are useful for medications that are poorly soluble or unstable in intestinal fluid. The fundamental working principle of FDDS is to make the dosage less thick than the stomach contents so that it floats atop them. FDDS are hydro dynamically controlled low density systems that have enough buoyancy to float above the stomach's contents and stay buoyant there for an extended amount of time without slowing down the stomach's emptying rate. A straightforward and useful method for achieving prolonged drug release and an extended dosage form's stomach residence duration is the buoyant preparation principle. By simultaneously administering pharmacological agents that delay stomach emptying, solid dosage forms can be managed in their gastrointestinal retention. Other mechanisms that can be used to do this include mucoadheshion, flotation, sedimentation, expansion, and changed shape systems. Low density systems having enough buoyancy to float over the stomach's contents and remain buoyant in the stomach for an extended amount of time are known as floating or dynamically controlled systems. The process of absorbing drugs from the gastrointestinal tract is intricate and diverse. It is commonly known that contact time with the small intestinal mucosa affects how much a medicine is absorbed through the digestive tract. Small intestine transit time is therefore a crucial factor for drugs that are not fully absorbed.

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## II. THE STOMACH'S INTRAINTESTINAL PHYSIOLOGY

The intricate structure and functions, fluctuations in pH, bile salt, enzyme concentration, and the mucosal absorptive surface of the gastrointestinal tract, spanning from the oral cavity to the duodenum, greatly impact the release, disintegration, and assimilation of a medicine when taken orally. In both fed and fasted states, there are two different GI motility and secretory patterns in humans and animals. As the state of food may affect the absorption of medications taken orally.

**The stomach is divided into three parts anatomically:**

Fundus, Body, and Pylorus Antrum. The autrum is the primary location for mixing motion and functions as a pump of stomach emptying by thrusting action, while the proximal portion, composed of funds and body, serves as a reservoir for undigested materials. Gastric emptying happens throughout both the fasting and fed states.

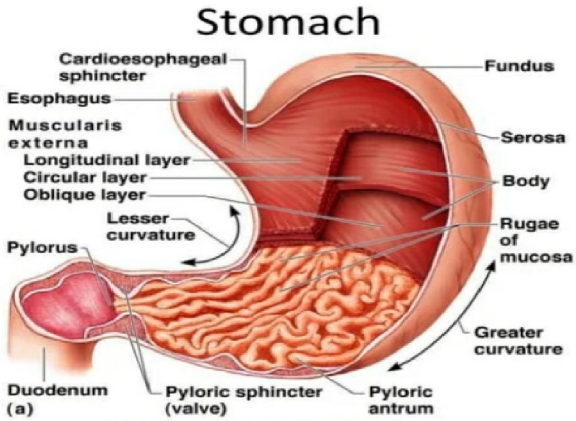


**Figure 1:Physiology of stomach**

Throughout the fasting stage, an electrical event known as the inter digestive my low electric cycle, also known as the migrating myoelectric cycle (MMC), cycles across the stomach and intestine every two to three hours. Stages, also known as the digestive motility pattern, are further separated into four phases following the consumption of a mixed meal. These phases correspond to the contraction charge pattern that changes from the fasted to the fed condition.

**PHASE I:** (Basic phase) ended in 30-60 min.

It is characterized by sporadic contraction, absence of electrical and secretory activity, and contractile motion.

**PHASE II:** (Pre burst phase) ended in 20-40 min.

With sporadic contractions and action potentials. Both the intensity and frequency steadily rise as the phase goes on. While the gastric mucosa discharges later in phase II and continues into phase III, bile reaches the duodenum during this phase.

**PHASE III:** (Burst phase) ended in 10-20 min.

It involves the gut and brief, consistent contractions. All of the undigested material is pushed out of the stomach and into the small intestine as a result of this wave. Another name for it is the "housekeeper wave."

**PHASE IV:** Ends for 0–5 minutes and takes place in the interval between cycles 1 and 2 in a row. This initiates a series of electrical impulses related to digestion that start in the stomach, travel to the terminal ileum while fasting, and continue cyclically for two to three hours. Feeding causes the prostaglandin motility, a continuous pattern of contraction and spike potential, to emerge.

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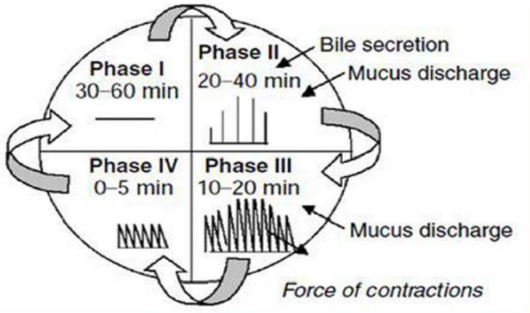


**Figure 2. Phase of gastric motility**

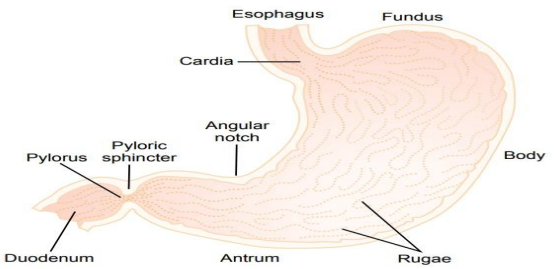


**Figure 3: Physiology and anatomy of stomach**

The pattern of contractions changes from the fasted to the fed state after a mixed meal is consumed. This pattern, also known as the digestive motility pattern, includes continuous contractions similar to those in phase II of the fasted state. As a result, feeding habits that are directed in suspension toward the pylorus are getting smaller. The delayed start of MMC during the fed state causes the stomach empty rate to slow down. Orally administered controlled release dosage forms are primarily susceptible to two complications: short gastrointestinal residence time and unexpected gastric emptying rate, according to Scientigraphic studies evaluating gastric empty rates.

## III. CLASSIFICATION

Effervescent floating drug delivery system:
Gas generating system:
(Conventional single layer or multiple layer)
Volatile liquid containing system:
Non – effervescent floating drug delivery system:
Hydro dynamically balancesystem.
Micro porous compartment system.
Hollow microsphere / Floating microsphere
Alginate floating beads.
Raft forming floating drug delivery system:
(In-situ gel formation system)
Effervescent and non-effervescent floating drug delivery systems are the two formulation variables used to categorize floating drug delivery systems.

## IV. EFFERVESENT FLOATING DRUG DELIVERY SYSYTEM:

These systems are matrix-type ones that are made with the aid of effervescent substances like sodium bicarbonate, tartaric acid, and citric acid as well as well-able polymers like methylcellulose and chitosan. They are designed such that CO2 is released and trapped in the swelling hydrocolloids when it comes into touch with the acidic stomach liquid, giving the dose forms buoyancy.

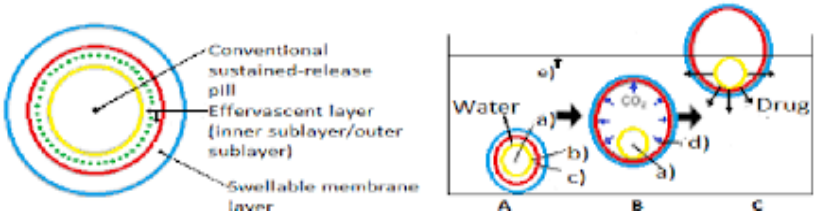


**Figure 4. Effervescent floating drug delivery system**

This gives the dose form buoyancy. In the event of a single layer tablet, the liberated carbon dioxide may get thoroughly combined with the tablet matrix. To prevent direct interaction between the two agents, a newly developed multiple-type floating dosage system that contained sodium bicarbonate and tartaric acid was split into two sub-layers

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between the effervescent layer and the swell able membrane layer. A swell able polymer membrane made of pure shell and polymer acetate encircled the sub layer. This system calmed down and was allowed to become an effervescent agent when it was submerged in the buffer at 37 °C. The effervescent agent, which results in pills that swell and have a density of less than 1.0g/ml. It was discovered that the system possessed good buoyancy.

**Gas generating system:** This low density floating drug delivery method relies on the release of carbon dioxide (CO2) when oral medication comes into touch with stomach fluids. The substance is designed so that, once entering the stomach, it reacts with the acidic gastric fluid to liberate CO2, which becomes trapped in a gel-based hydrocolloid. It keeps the dose form buoyant and causes it to move upward. In the end, it results in a drop in the dose form's specific gravity, which makes the chime float.

The method is made up of double-layered sustained release (SR) pills that resemble seeds. The effervescent inner layer is made up of tartaric acid and sodium bicarbonate.

**Volatile liquid containing system**:(osmotically controlled drug delivery system) this system, which is osmotically floating, is made up of a convertible, collapsed hollow deformable unit. A mobile, deformable, pressure-sensitive unit would have housing attached to it. The first chamber usually contains an active medicine, while the second is a volatile liquid such as. The drug reservoir can float because cyclopentane or ether vaporizes to generate a gas at physiological temperature. With the aid of a bio reliable plug that lets the vapour out, it is ejected from the stomach.

**Intra gastric floating drug delivery system:**Systems may not be able to float in the stomach due to the flotation chamber, which may be sealed within a micro porous compartment and filled with air, vacuum, or inert gas.

**Inflatable gastrointestinal delivery system:**This method has an inflatable capsule that expands in the stomach due to the liquid within that is gratified at body temperature. The medication reservoir and inflammation chamber are enclosed in a capsule.With this procedure, a body-temperature-gratified liquid inside an inflatable capsule causes it to expand in the stomach. A capsule encloses the inflammatory chamber and medicine reservoir.

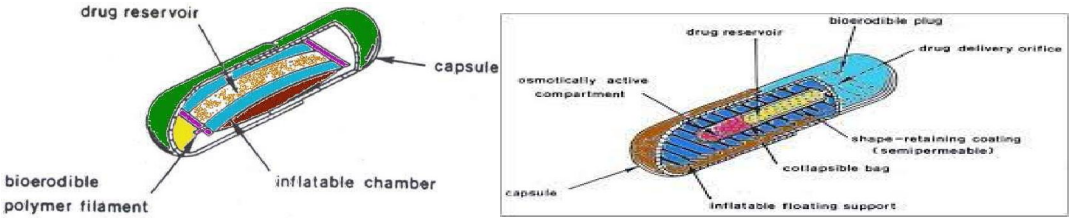


**Figure 5. Volatile liquid containg system.**

**Intra gastric osmotically drug delivery system :**

Squeezed within a capsule along with an inflatable floating support and an osmotic pressure compressed drug delivery device. The capsule breaks down in the stomach, releasing CDDS osmotically.

The interior inflatable support creates a polymeric bag for the passageway, which is inflated with liquids that are satisfied at body temperature. The two parts of the osmotic pressure CDDD are the salt that imbibes water from the GIT and releases drug, and the drug reservoir compartment, which is impermeable to vapour and liquid drug delivery system aperture.

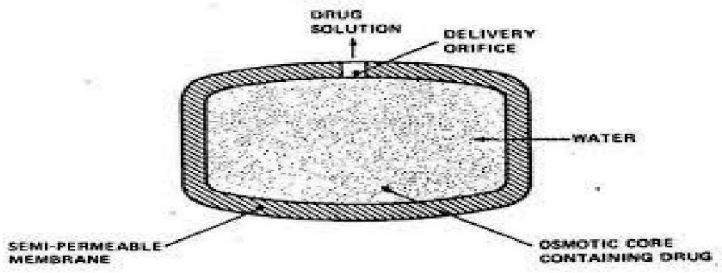


**Figure 6. Osmotically Control drug delivery system.**

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## IV. NON – EFFERVESENT FLOATING DRUG DELIVERY SYSTEM:

Non-effervescent floating medicine tablets are made of polysaccharides, matrix-forming polymers such as polycarbonate, polyacrylates, polymethacylate, and polystyrene, and a gel that forms a swelling cellulose kind of hydrocolloid. The approved technique of formulation involves blending the medicine thoroughly and producing a gel upon oral administration. When in contact with stomach juices, this dosage form expands and achieves a bulk density of less than 1. The dose form is buoyant due to the trapped air within the inflated matrix.

Through the gelatinous mass, the dosage-formed swelling gel-like structure acts as a reservoir and permits a sustained release of the drug.

**Hydro dynamically balanced systems:**

The colloidal gate barrier system is another name for the floating drug delivery system. The hydro dynamically balanced system was initially developed in 1957 by Seth & Tossoonian and comprises medications containing gel-forming hydrocolloids. This approach increases the amount of medicine that reaches the absorption site in solution form and lengthens the stomach retention period. It contains medications that create gels in the stomach due to the hydrocolloids they contain. In such a system, the hydrocolloid in the system hydrates to generate a colloids get barrier to its surrounding when it comes into contact with gastro-intestinal (GI) fluids. Examples of these hydrocolloids include hydroxypropyl methylcellulose (HPMC), polysaccharide, and matrix-forming polymers like polystyrene.

**Micro porous compartment system:**

This technology combines pores at the top and bottom walls with the encapsulation approach of a drug reservoir inside a micro-porous compartment. The drug reservoir compartment's periphery is tightly sealed to shield the stomach surface from coming into direct touch with the undissolved drug. The delivery system floats over the gastric content in the stomach due to the flotation chamber made of trapped air. In order to limit drug absorption, gastric fluid escapes through the aperture to the extent that it dissolves the medication and transports it throughout the intestine in a container.

**Floating microsphere / hollow microsphere:**

A controlled release form of a chemical can be delivered to the target site via a variety of techniques. Using polymeric microblings as drug carriers is one such method. The hollow microsphere, floating microsphere, and micro balloon are other names for this structure. These microspheres are thought to be the most promising buoyant systems due of their centrally located sacred space, which gives them additional advantages. Using a unique emulsion solvent diffusion approach, hollow microscopes, also known as micro balloons, are created and loaded with a medicine within their outer polymer shell. A heated, thermally regulated PVA aqueous solution at 40 o C is filled with the drug's ethanol dichloromethane solution and an enteric acrylic polymer. The stomach produced in scattered polymer droplets.

They can be prepared by two methods:

- Solvent evaporation technique :
- Emulsion solvent diffusion method.

The radiographic investigations demonstrated that when individuals were given micro balloons orally, they were distributed throughout the upper stomach and remained there for three hours during peristaltic periods.

**Alginate floating beads:**

Calcium alginate has been frozen to create multi-unit floating dosage forms. Calcium alginate can be made by dropping sodium alginate solution into an aqueous solution of calcium chloride, resulting in the creation of a spherical lead with a diameter of around 2.5 mm. Following the separation, shaping, and freezing in liquid nitrogen, the beads are freeze dried for 24 hours at 4000 C, resulting in the production of a porous system that can sustain a floating force for more than 12 hours. With these floating heads, the residence period was extended to over 5.5 hours.

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## V. RAFT – FORMING SYSTEM

A lot of research is being done on raft-forming devices for the delivery of medications for gastro infections and antacids. Because facilities distribute the medication gradually into the stomach, when a gel forming solution comes into contact with gastric fluid, it expands and forms a viscous cohesive gel entrapped with CO2 bubbles, creating a raft layer on top of the gastric fluid.

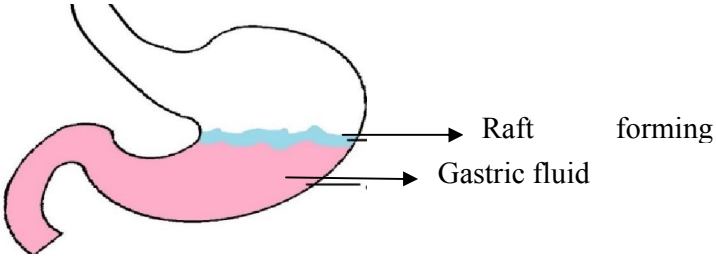


**Figure 7. Raft Forming System**

## VI. ADVANTAGES OF FLOATING DRUG DELIVERY SYSTEM

- Simple & conventional techniques for formulation site specific drug delivery system.
- Improvement of bioavailability & therapeutic efficiency of the drugs & possible reduction of dose.
- Maintenance of constant therapeutic level over prolonged period and thus reduction influence in therapeutic level minimizing the risk of resistance especially in case of antibiotics.
- Maintenance of a constant therapeutic level over a prolonged period and thus reduction influences therapeutic level, minimizing the risk of resistance especially in case of antibiotics.
- For drugs with a relatively short half-life, sustained release may result in a flip – flop pharmacokinetics & also enable reduced frequency of dosing with improved patient compliance.
- They also have an advantage over their conventional system as it can be used to overcome the adversities of gastric retention time (GRT) as well as the gastric emptying time (GET). As these systems are expected to remain buoyant on the gastric fluid without affecting the intrinsic rate of employment become there that of the gastric fluid.
- Gastro retentive drug delivery can produce prolonged and sustained release of drugs from dosage forms which avail local therapy in the stomach and small intestine. Hence, they are useful in the treatment of disorders related to the stomach & small intestine.
- Dosage formulations with gastro-retentive properties reduce the flotation of medication concentration and effect. As a result, negative consequences related to peak concentration that are concentration dependent can be shown. This characteristic is especially crucial for medications with a limited therapeutic index. Gastro retentive drug delivery can minimize the counter activity of the body, leading to higher drug efficiency.

## VII. DISADVANTAGES OF FLOATING DRUG DELIVERY SYSTEM:

- The major disadvantages of a floating drug delivery system is due to the necessity of a sufficient level of gastric fluid for floating without a sink. However, this limitation can be overcome by an adhesive polymer that easily adheres to gastric mucosa.
- The Gastric empty of a floating system may occur at random and is highly dependent on its dimensions. Therefore, patients should have a dosage prior to going to bed.
- Drug that cause irritation & lesion to gastric mucosa are not suitable to be formulated floating drug delivery system.
- The floating drug delivery system is not feasible for those drugs that have solubility or stability problems in gastric fluids.
- Drugs such as nifedipine , which is well absorbed along the entire GI tract & which undergo significant first pass metabolism for FDDS reduced the slow gastric emptying may lead to reduced systemic bioavailability .

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## VIII. LIMITATIONS

- FDDS must be taken after a meal, however the digestive state influences the drug's absorption and determines how long it stays in the body and how quickly it empty's.
- The dosage form's capacity to float is contingent upon its level of hydration. To keep these tablets floating in vivo, water administration must be administered on an intermittent basis. The mucus on the wall of stomach is in a state of constant renewal, resulting in unpredictableaberrance.
- One of the main disadvantages of a floating system is that it requires a sufficient amount of gastric juices to float without the need for a sink. To get around this restriction, the dosage form can be coated with a bio-effective polymer that binds to the gastrointestinal mucosa very quickly. Gastric emptying in a floating system can irritate the mucosal and can be trapped at random and is greatly influenced by its dimension, so dimensions should not take their medication before bed.

## IX. EVALUATION PARAMETERS FOR FLOATING DRUG DELIVERY SYSTEM

1. **Shape and size of tablet:** The drug's solubility rate and, thus, its potential are significantly influenced by the size and shape of the particles. They are compared to tablets made for FDDS and scrutinized under a microscope to ascertain their form, consistency, and bioavailability. Via the use of sieve analysis, air elutriation, photo analysis, optical microscope, electro resistance counting, sedimentation technique, laser diffraction method, ultrasound attenuation, spectroscopy, air pollution, and emissions measurement, the particle size of the formulation was ascertained.
2. **Tablet dimensions:** According to official compendia, a calibrated venire capillary is used to enhance the thickness and diameter of the tablet in FDDS form, same like with the conventional tablet. Each formulation's three tablets are chosen at random, and each tablet's thickness is measured separately.
3. **Determination of hardness of tablet:** Using a Monsanto-style hardness tester, sample sizes of twenty tablets should be raised at random within each formulation batch to determine the tablet's hardness.
4. **Weight variations:**Twenty tablets are chosen at random, their weights are precisely measured, and the average weight of the pills is computed. Next, the weight difference between a person and the average is computed.
5. **Measurement of the density / Specific gravity of the formulation:** The tablets' apparent densities are computed in triplicate using their masses and volumes. Using the following mathematical formula for cylinders, the volume V of the cylindrical tablet is computed from its height H and radius R (both measured with a micrometer gauge):
   $V = A \times r^2 \times h$
   Benzene can be used as the displacement medium in a displacement method to estimate the specific gravity/density method.
6. **Floating capacity of the tablet:** Through the use of a continuous floating monitoring system and a statically designed experiment, the impact of a formation variable on the floating properties of a gastric floating medication delivery system was identified.
7. **Floating time:**Typically, buoyancy tests are conducted in stimulated stomach fluid (SGF), which is kept around 3700 degrees Celsius. Floating time is defined as the amount of time that the dose form remains continually afloat on the dissolving media.
8. **Determination of drug contact tables:**The amount of the drug that was contained in the formulation can be found out by looking at the percentage drug content. It shouldn't go over the restrictions set by the typical monograph. A random selection of ten tablets is taken from each batch and placed into a 100 ml volumetric flask that has been filled with 0.1N HCl. Mix and set aside for 30 minutes, then remove 1 milliliter from the test tube. After that, the samples are appropriately diluted and spectroscopic ally examined at an appropriate wavelength. The near infrared spectroscopy (NIRS), micro-trimetric techniques, inductively cooled plasma atomic emission spectrometer (ICPAES), high-performance thin-layer chromatography (HPLC), and spectroscopy methods were all used to determine the drug content.

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## X. IN – VIVO EVLUATION OF FLOTING DRUG DELIVERY SYSTEM

The table was positioned within the vessel for disintegration. Five milliliters of the sample are taken out every one, two, three, four, five, six, eight, ten, and twelve hours. Whenever else a necessary time interval arises. The amount of dissolve media that remains after every sample. The mean values that were plotted over time were the opposite in the release studies, which used tablets with "n" tablets. Using a UV visible spectrometer, each sample is examined at its maximum wavelength in comparison to a blank reagent, and the associated concentration is calculated using the appropriate calibration curve.

**A] Buoyancy / floating test:**It is calculated to get the amount of time the dosage form takes to float on top of the dissolving medium once it is submerged in it. The dissolving test may include measurements of these factors. The term "total floating time" (TFT) refers to the total amount of time that the dosage form remains buoyant. It is defined as the time between the introduction of the dosage form and the remaining buoyancy of the stimulated gastric fluid, as well as the amount of time it takes for the dosage form to emerge on the surface of a medium.

**B] Swelling test:**In order to determine the molecular characteristics of a swollen polymer, swelling studies were conducted. Dissolution apparatus, optical microscopy, and advanced techniques, such as IHNMR, image confocal laser scanning micro and fats copy (CLSM), cryogenic scanning electron microscopy (cryo-SEM), and light scattering imaging (LSI), were used to determine swelling investigations. Examining a dose form's weight growth or waste uptake allows one to gauge how swollen it is. The increase in tablet thickness and/or diameter over time can be used to quantify the dimensional changes. The equation provides a way to express water uptake in terms of % weight gain.

Wu = (Wt. – WO) x 100

Where, Wu = water uptake,Wt. = weight of dosage form at time, WO = initial weight of dosage form.

**C] Fourier Transforms Infrared Analysis:**Fourier transform infrared spectroscopy, also known as FTIR (Shimadzo, model RT, IR-8300), is a technique that is primarily used to identify organic polymers and some inorganic materials. It is also useful for measuring pure drug polymers and drug-leaded polymer formulations. The spectra were scanned over the wave number range of 3600 to 4000 cm-1 at the temperature. The pellets were manufactured on a CB Press with hydraulic pressure of 150 kg/cm2.

**D] Different scanning calorimetric (DSC):**Pharmaceutical hydration uses DSC (Shimadzu, model DSC-60/DSC-50/metler toldeo) to describe water. A DSC device with an intercooler was used to get three grams of the prepared material. The enthalpy and temperature scales of the DSC were calibrated using indium/zinc standards. The sample preparation was cooked to a steady temperature between 25 and 65 degrees Celsius while being hermetically enclosed in an aluminum pan. Nitrogen gas was purged from the atmosphere at a rate of 50 milliliters per minute to preserve its inertness.

## XI. FUTURE POTENTIAL

Floating drug delivery systems have gained attention in recent years due to their potential for improving drug delivery and efficiency. FDDS are made to float on top of the stomach juice and release medication continuously over an extended length of time. This can minimize side effects, increase bioavailability, and decrease frequency.

The future potential of FDDS is vast and holds promise in several areas including:

**Improved patient compliance :**

FDDS can help patients comply with medication regimens by reducing the need for frequency dosing.

**Targeted drug delivery :**

Medication distribution can be targeted to particular regions of the gastrointestinal system using FDDS, which improves medication delivery efficiency and lowers side effects. Novel drug delivery system:

The development of FDDS has opened up new possibility for drug delivery such as using micro-or Nano scale floating particles.

**Combination therapy :**

FDDS can be used to deliver multiple drug simultaneously, improving patient outcome and reducing the need for multiple medications.

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Over all the feature potential of FDDS is promising and ongoing research is expected to lead to further advancement and application in drug delivery system. However we are close as we have ever been to see a greater transition of gastric retention devices from development level of the manufacturing & commercial level.

## XII. CONCLUSION

One method that has shown promise for the targeted and continuous release of medication in the gastrointestinal tract is the floating drug delivery system. Prolonged drug absorption is made possible by these systems' ability to float in the stomach environment, which also reduces systemic side effects. Numerous floating medication delivery systems, such as floating tablets, capsules, and microspheres, have been created; each has its own special benefits and drawbacks. The performance of these systems is influenced by a number of factors, such as formulation methods, drug characteristics, and polymer selection. To successfully construct a floating drug delivery system with desired drug release profiles and pharmacokinetics features, it is imperative to optimize these parameters. Despite the fact that there are certain obstacles to overcome before actively.

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