IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

FORMULATION AND EVALUATION OF OFLOXACIN FLOATING TABLET

by

PRABHAT KUMAR

Under the Supervision/Guidance of

Dr Tarun Parashar

Associate Professor

UTTARANCHAL INSTITUTE OF PHARMACEUTICAL SCIENCES,

UTTARANCHAL UNIVERSITY, DEHRADUN

INTRODUCTION

The oral delivery of drugs is the most favored route of administration because of ease of administration. Drug bioavailability of oral dosage forms is subjective by various factors. One of the significant factors is a gastric residence time (GRT) of these dosage forms.[1] Truly, gastric retention has received important interest in the past few years as many of the conventional oral delivery systems have some limits related to fast gastric emptying time. Gastro-retentive dosage form is a type of novel drug delivery system which can persist in the stomach for prolonged period of time and thus increases the GRT of drugs. Gastro-retention helps to improve bioavailability of drugs.

Gastro-retentive drug delivery is an approach to prolong gastric residence time, there by targeting site-specific drug release in the upper gastrointestinal tract (GIT) for local or systemic effects.[1] Gastro-retentive dosage forms can remain in the gastric region for longperiodsandhencesignificantlyprolongthegastricretentiontime(GRT)ofdrugs.Overthe last few decades, several gastro-retentive drug delivery approaches being designed and developed, including: high density (sinking) systems that is retained in the bottom of thestomach,lowdensity(floating)systemsthatcausesbuoyancyingastricfluid,mucoadhesive systems that causes bio-adhesion to stomach mucosa, un-foldable, extendible, or swellable systems which limits emptying of the dosage forms through the pyloric sphincter of stomach, super-porous hydrogel systems, magnetic systems etc.[1]

- Intra gastric floating gastro-intestinal drug system.
- Inflatable gastrointestinal delivery system.

- Intragastric -osmotically controlled drug delivery system.
- Floating capsules.
- Floating tablets.
- Non-effervescent system.[3]

Basic Physiology and Problems:

The process of gastric emptying occurs both during fasting and fed states; however, the patteren of motility differs markedly in two states. During the fasting state an inter-digestive series of electrical event stake place, which cycle through both stomach and intestine every 2 to 3 hours. This is called the inter digestive mylo-electric cycle or migrating mylo-electric cycle (MMC) which is further divided into following 4 phases. In the fed state, the gastric emptying rate is slowed since the onset of MMC is delayed. Over all, there latively brief gastric transit time of most drugs. These problems can be exacerbated by alterations in gastric emptying that occur due to the factors such as age, race, sex and disease states, as they may have a seriously affect the release of a drug from the delivery system. So, it is desirable to have a controlled release product that exhibits an extended gastric residence and a drug release profile independent of patient related variables.[2]

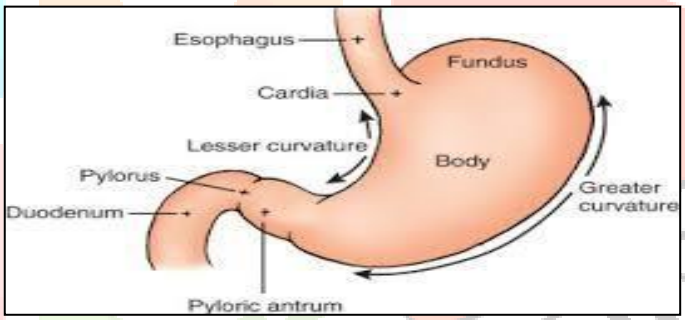


Fig no. 1: Physiology of Stomach

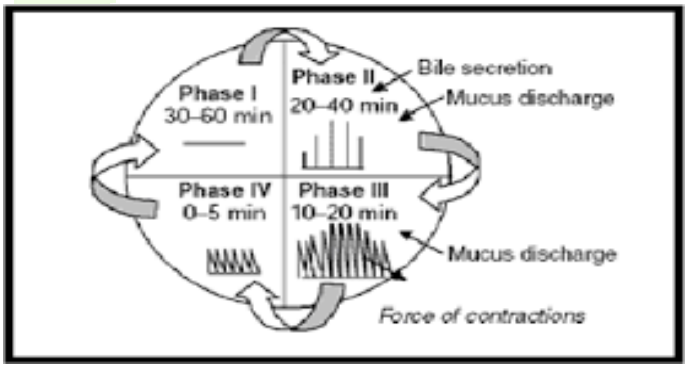


Fig no. 2: Schematic presentation of MMC

Floating Drug Delivery System (FDDS):

Floating Drug Delivery Systems (FDDS) have a bulk density lower than gastric fluids and thus remain buoyant in the stomach for a prolonged period of time, without affecting the gastric emptying rate. While the system is floating on the gastric contents, the drug is released slowly at a desired rate from the system. After the release of the drug, the residual system is emptied from the stomach.[11] This results in

an increase in the GRT and a better control of fluctuations in the plasma drug concentrations.

The system is floating on the stomach, the drug is released gradually at the desired rate from system. After releasing drug, the residual system is flattened from the stomach besides a minimal gastric content needed to permit suitable attainment of the buoyancy retention principle, a minimal level of floating force(F) is also essential to retain dosage form constantly buoyant on surface of the meal. The apparatus used to measure the floating force kinetics operates by measuring continuously the force equivalent to F (as a function of time) that is mandatory to main submerged object. If F is on the higher positive side, object floats better. The apparatus helps in optimizing floating drug delivery system with respect to stability and durability of floating forces formed in order to stop the problems of unexpected intra-gastric buoyancy capability variation. [12]

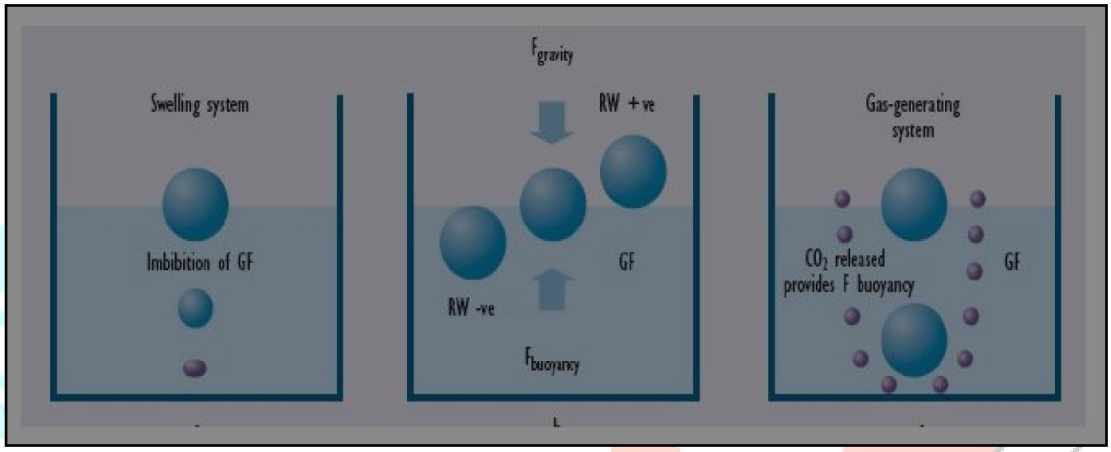


Fig no. 3: Mechanism of Floating system

Classification of floating drug delivery system[13]

A. **Effervescent system floating drug delivery system:** These are specific drug delivery systems that include a matrix type and as well able polymer like methylcellulose or chitosan, as well as effervescent chemicals like sodium bicarbonate, tartaric acid, and citric acid. These are designed in such a way that when they come intocontact with stomach juice, $CO_2$is released and entrapped in a swelling hydrocolloid, which provides buoyancy for the dosage form.

Gas Generating system: Low-density FDDS is based on the emission of CO2 following oral delivery when it comes into contact with stomach contents. The materials are designed so that after entering the stomach, CO_2 is liberated as a result of an interaction with acidic gastric content, and then contained in the gel-based hydrocolloid. It causes the dose form to rise in the air and retains its buoyancy. As a result, the specific gravity of the dose form decreases, resulting in a float on the chime. The CO_2generating components are blended in a single layer or multi-layered form within the tablet matrix to establish a gas generating mechanism in the hydrocolloid layer, while the medication in the other layer results in a prolonged release effect.

I. **Volatile liquid containing systems:** This is an osmotically regulated floating system that consists of a device that is made up of a hollow deformable unit in collapsed state. Internally, the

housing would be connected to its deformable unit and divided into a first and second chamber separated by an impermeable, pressure-sensitive movable unit. The first chamber normally contains an active drug, while the second chamber contains a volatile liquid, such as cyclopentane or ether, which is vaporized at a physiological temperature to create a gas, allowing the drug reservoir to float. With the help of a bio-erodible plug, the unit is evacuated from the stomach, allowing the vapour to escape.

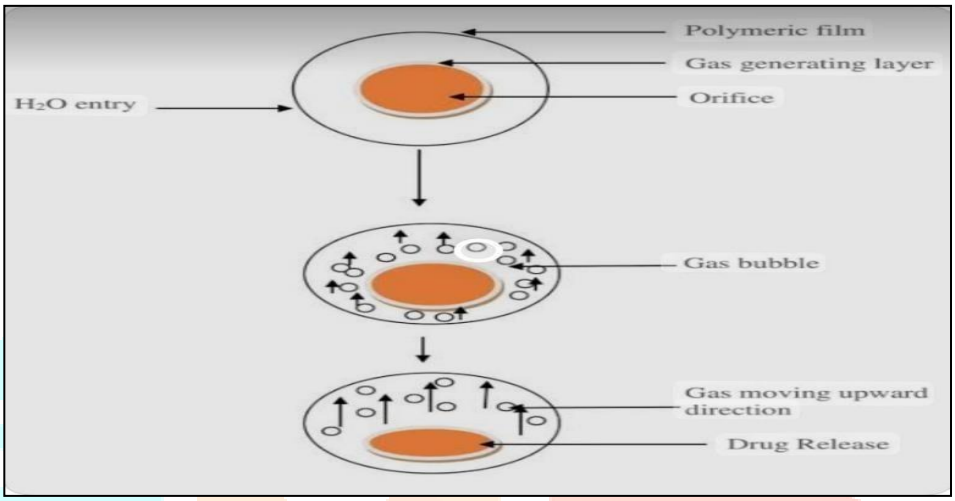


Fig no. 4: Mechanism of Floating via CO2

B. **Non-Effervescence FDDS:** Non-Effervescent Floating Drug Delivery Systems are made up of polysaccharide-based gel-forming (or) swellable cellulose hydrocolloids, as well as matrix-forming polymers such as polycarbonate, polymethacrylate, and polystyrene. The standard formulation approach is combining the medicine with gel-forming hydrocolloids, which swell in contact with gastric fluid during oral administration and preserve shape and a bulk density barrier. The air trapped by the swelled polymer gives the dosage forms buoyancy.

C. **Colloidal gel barrier system:** This technique increases the amount of medication that reaches its absorption site in solution form by extending stomach retention time. It basically consists of a medication mixed with gel-forming hydrocolloids to keep it buoyant in the stomach. One or more gel-forming cellulose type hydrocolloids, such as hydroxypropyl methylcellulose (HPMC), poly-saccharides, and matrix-forming polymers, such as polycarbophil, polystyrene, and polyacrylate, are included in such a system. The hydrocolloid in the system hydrates when it comes into touch with GI fluid, forming a colloid gel barrier to its surroundings.

D. **Microporous compartments systems:** This approach uses a drug reservoir that is encapsulated inside a microporous compartment having pores on the top and bottom walls. The drug reservoir compartment's peripheral wall is entirely sealed to prevent undissolved drug from coming into contact with the stomach surface. The delivery system floats over the gastric content in the stomach due to the flotation chamber, which is made up of entrapped air. Gastric fluid penetrates via the aperture to the extent that it prevents them from being separated from the drug and transports the dissolved drug across the intestine for absorption.

E. **Floating Microsphere/Micro-balloons:** Micro-balloons, commonly known as hollow microspheres, area very effective buoyant mechanism. Inside the microsphere, it is made up of a core hollow region. A unique solvent Diffusion method for emulsion is used to create hollow microspheres that are loaded with amedicine in their outer polymer shelf.

F. **Alginate Beads/Floating Beads:** Calcium alginate spherical beads of about 2.5 mm in diameter have been developed and can be fabricated by adding sodium alginate solution to an aqueous solution of calcium chloride, resulting in calcium alginate precipitation. The beads are then separated, snap- frozen in liquid nitrogen, and packaged. After being freeze-dried at 400°C for 24 hours, a porous system is formed. This constructed system would maintain a floating force for more than 12 hours, and these floating beads have a residence time of more than 5.5 hours.

G. **Raft-forming systems:** For the administration of antacids and drugs for gastro-infection and disorders, raft- forming systems are receiving a lot of interest. When a gel-forming solution comes into contact with gastric fluid, it expands and creates a viscous cohesive gel encased in co2 bubbles, establishing a raft layer on top of the gastric fluid, allowing the medicine to be released slowly in the stomach.

Advantages of FDDS [14]

- Floating dosage forms such as tablets or capsules will remains in the solution for prolonged time even at the alkaline pH of the intestines.
- FDDS are advantageous for drugs meant for local action in the stomach eg: Antacids[14]
- Acidic substance like aspirin causes irritation on the stomach wall when come in contact with it hence; HBS/FDDS formulations may be useful for the administration of aspirin and other similar drugs.
- Controlled delivery of drugs. Minimizing the mucosal irritation due to drugs, by drug releasing slowly at controlled rate.

Disadvantages of FDDS [15]

- Floating systems are not feasible for those drugs that have solubility or stability problems in gastric-fluids.
- Drugs that cause irritation and lesion to gastric mucosa are not suitable to be formulated as floating drug delivery systems.

Drugs that could be used in floating medication delivery systems:

In general, molecules that have low colonic absorption but have superior absorption capabilities at the upper gastro-intestinal tract are good candidates for Controlled-GRDF, a component of the GIT:

- ❖ Calcium supplement, chlordiazepoxide, and cinnarizine, for example, are absorbed mostly from the stomach and upper GI-tract.
- ❖ H2 receptor antagonists, antacids, and misoprostol are examples of drugs that operate locally in

the stomach.

- ❖ Ranitidine HCL and metronidazole are examples of drugs that degrade in the gut.
- ❖ Amoxicillin trihydrate, for example, is a drug that disrupts typical colonic microorganisms.

Factors Affecting Floating Drug Delivery System[16]

- **Density of Dosage form:** The dosage form's density should be less than the contents of the stomach (1.004gm/ml). Floating feature necessitates a density of less than 1.0gm/cm^{3}as a result; dose forms with a lower density than the gastric contents might float to the top of the stomach, whereas high density systems sink to the bottom.
- **Shape and size of dosage form**: Other factors that influence stomach retention include the shape and size of the dose form. When comparing dosage form units with a diameter of more than 7.5 mm to those with a diameter of 9.9 mm, it has been found that those with a diameter of more than 7.5 mm boost GRT. When compared to other shapes, the dosage form with tetra-hedron and ring shape devises with a flexural modulus of 48 and 22.5 kilo pounds per square inch (KSI)is claimed to have improved GIT retention for 90to 100 percent retention at 24 hours.
- **Food intake and its nature**: Food intake, viscosity and volume of food, caloric value, and feeding frequency all have a significant impact on dosage form gastric retention. The gastric retention time (GRT) of the dose form is affected by the presence or absence of food in the gastrointestinal tract (GIT). Feeding indigestible polymers, or fatty acid salts might cause changes in the digestive system. The shift in the stomach's motility pattern to fed state results in as lower gastric emptying rate and longer medication release.
- **Caloric content**: With a high-protein, high-fat meal, the gastric retention time (GRT)can be enhanced by 4 to 10 hours. When floating for several days in a row, the time spent floating can climb by almost 400 minutes. Due to the low frequency of migrating myoelectric complexes, multiple meals are supplied rather than a single meal (MMC).
- **Effect of gender, posture and age**: Females' stomach emptying rates are slower than males. In terms of the mean stomach retention time, the effect of posture does not make a significant difference (GRT). Because elderly people, particularly those over the age of 70, have a much longer GRT, stomach emptying is retarded. Drug delivery is also affected by diseases such as diabetes and Crohn's disease.
- **Concomitant drug administration:** Floating time can be affected by anticholinergics like atropine and propantheline, opiates like codeine, and prokinetic drugs like metoclopramide and cis a pride.
- **Single or multiple unit formulation**: When compared to single unit dosage forms, multiple unit formulations are more predictable dueto unit failure, allowco-administration of units with distinct release profiles or containing in compatible chemicals, and provide a higher margin of safety against dosage form failure.

Application of Floating Drug delivery system (17-18)

- **Enhanced Bioavailability:** In comparison to the administration of non-GRDF CR-polymeric formulations, riboflavin CR-GRDF has a much higher bioavailability. There are various processes that function in concert to determine the magnitude of drug absorption, including drug absorption and transit in the gastrointestinal system.
- **Enhanced first-pass Biotransformation**: The pre-systemic metabolism of the tested compound may be significantly increased when the drug is presented to the metabolic enzymes (cyto-chrome P450, in particular CYP3A4) in a sustained manner rather than by a bolus input, similar to the increased efficacy of active transporters with capacity limited activity.
- **Sustained drug delivery/reduced frequency dosing**: of for medications with a short biological half-life, persistent and slow input from CR-GRDF may cause a pharmacokinetic flip-flop, allowing for lower dose frequency. This characteristic has been linked to increased patient compliance, which enhances therapy.
- **Targeted therapy for local ailments in the upper GIT:** Longer and more consistent drug administration from GRDF to the stomach may be beneficial for local therapy in the stomach and small intestine. Therapeutic medication concentrations can be achieved locally with this method of administration, but systemic amounts are negligible after drug absorption and dispersion.
- **Reduced Fluctuation of drug concentration:** In comparison to immediate release dosage forms, continuous input of the drug after CRGRDF treatment creates blood drug concentrations with in a tighter range. As a result, pharmacological impact variations are reduced, and concentration-dependent adverse effects associated with peak concentrations can be avoided. This is especially important for medications with a limited therapeutic index.
- **Minimization of fluctuation in drug concentration:** It allows for a degree of selectivity in the pharmacological response evoked by medicines that activate various types of receptors at varying doses.
- **Reduced counter-activity of the body:** In many circumstances, when a pharmaceutical response interferes with natural physiologic processes, the body responds with are bound activity that reduces drug activity. Slowing the drug's entry into the body has been proven to reduce counter-activity, resulting in greater pharmacological efficacy.
- **Extented time over critical (effective) concentration:** The clinical response is not connected with peak concentration for certain medications having non-concentration dependent pharmacodynamics, such as beta lactam antibiotics, but rather with the duration of time over a key therapeutic concentration. The sustained route of administration allows for a longer period of time over a critical concentration, which increases pharmacological effect sand clinical results.
- **Minimized adverse activity at the colon:** The amount of medicine that enters the colon is reduced when the drug is retained in the GRDF at the stomach. As a result, the drug's unwanted effects in the colon may be avoided. This pharmacodynamic aspect justifies GRDF formulation

for beta-lactam antibiotics that are only absorbed from the small intestine and whose presence in the colon causes microorganism resistance to develop.

- **Site specific drug delivery:** A floating dose form is a viable option, particularly for medicines with few absorption sites in the upper small intestine. The controlled, gradual distribution of the medicine to the stomach ensures enough local therapeutic levels while limiting the drug's systemic exposure. The drug's adverse effects in the blood circulation are reduced as a result. Furthermore, a site guided delivery system's longer stomach availability may lower dose frequency.

Floating film system[19]

Floating film drug delivery system has emerged as advanced alternative to traditional dosage forms like tablets, capsules and liquids. A drug loaded thin film strip fill into capsule is typically designed for oral drug delivery. Floating films offers advantages as preparation of film is very simple, time saving, economically beneficial and chances of cross contamination is very less, also handling of films is very-east as compared with microspheres. Floating film is drug loaded polymeric films consisting of an active- pharmaceutical ingredients, polymers, film forming agents, plasticizer and suitable solvent. Films can be prepared by solvent evaporation method in which drug and polymer are mixed with sufficient quality of solvents. Other ingredients are added accordingly, poured in petri plate and allowed to dry to give thin layered smooth film. Dug release profile can be modified by using different polymers can be applied. Layer -by-layer technique in which one layer is of controlled release polymer and another layer is of sustained release polymer.

AIM AND OBJECTIVE

Aim: The aim of the present study is Formulation and Evaluation of floating tablet of Ofloxacin for sustained release floating tablet that can remain in the stomach for an extended period and release the drug gradually to improve its therapeutic efficacy. The drug is mainly used in the treatment of bacterial infection, including: Urinary tract infection, Respiratory tract infection, GIT-infection, Skin and soft Tissue infection, and Sexually transmitted infections.

Objectives:

1. To formulate a stable and effective ofloxacin floating tablet using appropriate excipients.
2. To optimize the formulation variables such as polymer type, concentration, and drug polymer ratio for sustained drug release.
3. To characterize the floating tablet for its physicochemical properties such as Hardness, Thickness, weight variation etc.
4. To evaluate the in-vitro drug release pattern of the floating tablet using dissolution studies.
5. To access the stability of the optimized ofloxacin floating tablet under various storage conditions.

These objectives are essential in developing ofloxacin floating tablet that can improve drug bioavailability, reduce dosing frequency, and enhance patient compliance.

Experimental Protocol:

Pre-formulation study:

- Organoleptic properties,
- Melting point,
- Particle size,
- Determination of absorbance maxima(λmax) by UV.

Evaluation of Formulations:

Precompression Parameter:

- Bulk density
- Tapped density
- Angle of Repose
- Hasuner`s Ratio

Post compression Parameter:

- Weight Variation
- Thickness of tablets
- Hardness
- Friability
- Disintegration
- Swelling index
- In-Vitro drug release

LITERATURE REVIEW:

- **Suvarna Chittam, *et al*; (2020)** In this research, their main aim is to develop integrated floating film of furosemide to enhance its solubility by increasing gastric residence, by changing pH so that insoluble furosemide get dissolved and convert from crystalline form to amorphous form so ultimately enhance its bioavailability. Furosemide is BSC class IV drug which shows pH dependent solubility and permeability. It is very poorly soluble in stomach medium (0.006mg/ml) and having high permeability through stomach, but its solubility increases with pH but it is impermeable limitation. They used solvent casting method using different polymers, gelatin and carboxy methyl cellulose sodium, sodium alginate and glycerine, as plasticizer, sodium hydroxide as solubility enhancer. So, finally they concluded that floating film enhance the bioavailability of furosemide by prolonging its duration in the stomach via the floating dosage forms and also

enhanced its solubility by using hydrophilic polymers and sodium hydroxide as solubility enhancer.[21]

- **Anggun Hari Kusumawati, *et al*.; (2020)** formulated and evaluated non-effervescent floating tablet of Captopril using combination of polymer HPMC and NA-CMC. They proposed that captopril has a rapid elimination half-life for about 2-3 hours and degrades in the intestine, increase in pH causes captopril to become unstable and degrades HPMC can control drug release and inhibit excessive erosion of tablets, while CMC-Na can be used to increase the viscocity of preparation so that it will take more time the drug to floats in the gastric. The aims of this research is to determine the influence of the combination of HPMC and CMC-Na polymers against the physical properties and dissolutions profiles of floating captopril tablets. They showed that the differences in the concentration of HPMC and CMC-Na affected the results of tablet hardness, the more concentration of HPMC were used it would increase tablet hardness, and the more concentration of CMC-Na used would reduce tablet hardness .[22]

- **Sanjay kumar mishra, *et, al*;(2019)** anticancer Nizatidine floating microsphere to develop gastro-retentive drug delivery formulation for enhancing GRT, including the physiological and formulated variables affects gastric retention. In this research they prepared floating microsphere by solvent evaporation (oil-in-water emulsion) method, Poly (methyl methacrylate) was dissolved in a mixture of diethyl formamide and dichloromethane at room temperature and drug (Nizatidine Hydrochloride was dispersed in the above mixture. They observed that increase in concentration of the drug, the entrapment efficiency increased. further, increase in drug concentration, the entrapment efficiency decreased. As the floating microspheres showed a good buoyancy and drug release property it was concluded that it has a great potential for its use both in powder form for dry suspension and granular form for tablet.[23]

- **Mirmeera Girish Niharika,*et al*; (2018)** they used different strategies in the development of FDDS by constructing the effervescent and non-effervescent type of floating tablets basis of which is buoyancy mechanism. They proposed that the drugs are active locally with an arrow absorption window in the upper gastrointestinal tract, unstable in the lower intestinal environment and posseses low solubility with higher pH value. In this review, floating dosage forms can be delivered in conventional forms like tablets, capsules with the addition of suitable ingredients along with gas generating agent. According to low density FDDS is based on the release of co2 upon contact with gastric-fluids after oral administration. The materials are formulated in such a way that after entering in the stomach, co2 is liberated due to reaction with acidic gastric content and which get entrapped in the gel-based hydrocolloid. It produces an upward motion of the dosage form and maintains its buoyancy. There for ethe study suggested that drug absorption in the gastrointestinal tract is a highly variable procedure and prolonge gastric retention of the dosage form that leads to extend the time for drug absorption.[24]

- **Anh Q.Vo, *et al*; (2016)** a novel floating controlled release drug delivery system prepared by Hot-Melt extrusion .They proposed that novel floating pellets were prepared using the hot-melt extrusion technology, uniformly foamed strands were created by liquid injection pumping and screw configuration modification, the pallets internal structure was investigated using scanning electron microscopy(SEM) . In this research, floating pellets were prepared by HME in conjunction with liquid-vapour phase transitions and polymer expansion at elevated temperatures, the pallets physiological properties such as their dissolution profiles, buoyancy strength, specific surface area, polymorphism of API and drug distribution within the matrix. Finally they concluded that the novel dosage form can be used as a platform for manufacturing controlled-release DDS. The modified screw configuration was crucial to maintain the process stability, as well as top reserve the API's crystalline form, which is presumed to enhance the physical stability of the dosage form.[25]
- **Namdeo Shinde *et al*; (2015)** floating film drug delivery system: an effective approach of Gastro-retentive, they proposed floating film is drug loaded polymeric film mainly comprised of active pharmaceutical ingredient, polymer, film for mingagent and plasticizer with suitable solvent and they prepared by solvent evaporation tenchnique. This article gives emphasis on eneral consideration of GRDDS with their evaluation and application, layer-by-layer film technique will become a promising alternative for multi drug therapy in which controlled or sustained delivery of drug is possible by using different polymers. Thickness of film is directly related to accuracy of dose in the film. Multi-layer approach will gain more importance in associated diseases like hypertension and diabetes etc. The main aim of this research is to develop such system which will control there lease of drug according to need.[27]
- **Nitasha Sharma *et al*; (2015)** development and characterization of novel gastro-retentive raft forming floating film of atenolol, atenolol is a hydrophilic selective β, antagonist used primarily in cardiovascular disease. Chemically it is describe as 4-[2 hydroxyl 3-isopropyl amino propoxy]-phenyl-acetamide. Absorption of an oral dose is raid and consistent but incomplete, bioavailability of atenolol is only 50%. In this research they proposed to develop a gastro-retentive floating raft forming film of atenolol using solvent casting technique. The films were characterized in terms of drug-excipient compatibility by FTIR, drug content, swelling, folding endurance, thermal behaviour by DSC, effect of processing parameters on drug state by X-ray diffraction. The prepared floating raft forming films were thin, flexible smooth and uniform. and were subjected to various physiochemical characterization such as weight uniformity, drug content, thickness, folding endurance and surface pH. The folding endurance of floating film was found to be in the range of 200±5 to 400±5, the folding endurance value was increased with an increase in polymer concentration. Finally, they formed a floating raft system for atenolol had been successfully developed with long buoyancy and controlled release profile from the hydrophilic matrices. This study is expected to provide clinicians with a new choice of safe product with better bioavailability for the treatment of hypertension.[28]

- **Saigeethika S.*1 , Gautam Singhviet, al 2012:**formulated and evaluated of floating tablet of ofloxacin which is expected to deliver the drug in controlled manner with reduced frequency of drug administration, improve patient compliance and bioavailability of Ofloxacin. Floating tablet of Ofloxacin were prepared by wet granulation method. Floating tablets were assessed for, physical appearance, melting point, FT – IR spectra, drug- excipients interaction, FTIR study for drug excipient interaction, determination of absorption maxima (λmax), entrapment efficiency, surface morphology by SEM, interpretation of drug release mechanism by kinetic models, with a view to obtain oral controlled released of Ofloxacin. It was formulated as an approach to increase the gastric residence time and there by improve its bioavailability. Two polymer, Carbopol and PVP-K30 were used for better sustained release characteristics with excellent in-vitro drug release.[29]

- **Pramod Patil et. al., 29 (2011)** developed floating tablets of ofloxacin by wet granulation method incorporating natural polymers i.e. guar gum, locust bean gum, either alone or in combination (with HPMC K100M) as swelling polymer along with sodium bicarbonate (as gas generating agent). Tablet were designed to prolong the gastric residence time following oral administration and evaluated for parameters i.e. Weight variation, Hardness, Friability, Drug content, Swelling index and in-vitro buoyancy study & in-vitro drug release studies. Based on the evaluation results, two batches were selected as the optimized formulations. These results indicated that the selected formulations were stable. The drug release from optimized formulations followed Higuchi kinetic model and the mechanism was found to be non-Fickian/anomalous according to Korsmeyer–Peppas equation.
- **Banik K*et al* ;(2020)** successfully formulated alginate microspheres of Repaglinide using calcium chloride as a cross linking agent and prepared by inotropic gelation method. Microspheres were prepared by using 2%, 2.2% sodium alginate concentrations. Polymers (HPMC, Ethyl-cellulose, Carbopol934Pwere used in combination concentration to prepare Microspheres. Repaglinide is an antidiabetic drug in the class of medications known as meglitinides and was invented in 1983. Repaglinide is an oral medication used in addition to diet and exercise for blood sugar control in type 2 diabetes mellitus. The mechanism of action of repaglinide involves promoting insulin release from β-islet cells of the pancreas like other antidiabetic drugs. Microspheres were evaluated for micromeritic properties like angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio and for drug content. The in vitro drug release study was done for micro spheres all formulations. The mean particle size ,*invitro* Buoyancy, Encapsulation efficiency%, Percentage yield(%) were within limits. Floating Microspheres of Repaglinide found to improved patient compliance by decreasing dosing frequency. Gastric retention time was increased because of buoyancy. Enhanced absorption of drugs which solubilise only in stomach. Drug was released in controlled manner for prolonged period at site-specific.[30]

- **Meghana K J *et al;* (2019)** studied and evaluate floating microspheres containing anti-diabetic drug of Saxagliptin. Method: Microspheres were prepared by Ionotropic gelation method. The release microspheres were formulated using different polymers Eudragit RL, HPMC K4M, and Gum Acacia with different concentrations. The formulations were evaluated for Particle size, in vitro release studies, FTIR spectra, DSC studies, and micrometric properties. Prepared microspheres were characterized for their particle size, drug entrapment efficiencies (79.50%-96.86%), percentage Buoyancy (93.87%-98.86%). The FTIR spectra and DSC studies have shown stable properties of Sitagliptin and revealed the absence of interactions between the drug and selected polymers. The invitro release studies were performed in 0.1 N HCL, which showed a release of 92.64% at the end of 24 hours in case of the best formulation. Fitting to the in vitro release data to Korsmeyer Peppas equation indicated that Quasi–Ficki an diffusion of drug release. Conclusion: It can be concluded that Saxagliptin floating micro-spheres produces prolonged and site-specific drug delivery for the treatment of Diabetes mellitus.[31]
- **PrakashS*etal*;(2016)** Successfully formulated and evaluated bilayer tablets of Metformin Hydrochloride and Sitagliptin Phosphate as fixed dose combination tablets for effective treatment of type II diabetes mellitus. The main focus was to reduce the dose, dosage frequency, dose related gastrointestinal side effects of metformin and to improve its bioavailability which in turn improve the patient compliance. Pre-formulation studies including drug excipient compatibility were conducted for both drugs. Different formulations of sustained release, floating Metformin HCl tablets were prepared by using hydrophilic polymers like HPMC K100 and Sodium CMC. Sitagliptin immediate release formulations were prepared using crospovidone, croscarmellose sodium and sodium starch glycol-lateas super disintegrants. From the bilayer tablet Sitagliptin layer disintegrated in 52 sec, Metformin layer started floating after 5.2 min and gave total floating time 18-24 hrs with good swelling index, good post compression parameters. In vitro dissolution study of bilayer tablet was done in USP typeII along with UV spectrophotometer gave cumulative % drug release of Sitagliptin as 99.15% at 30 min and 97.65 % of Metformin at 12 hrs. Combination of HPMC K100 and Sodium CMC gave good sustained release for 12 hrs indicating the best formulation among others. Among the three super disintegrants used sodium starch glycolate showed good disintegration of sitagliptin layer. It was found that the viscosity of the polymer had major influence on swelling process, matrix integrity, as well as floating capability, concluded that linear relationship exists between swelling process and viscosity of polymer.[32]
- **Krishna K*etal*;(2014)** Prepared sitagliptin phosphate floating tablet by direct compression. Lactose was used as diluent. Nine formulations of sitagliptin phosphate were prepared using HPMCK100 and HPMCK4 Mas released elaying agents at different concentrations of 10, 15 and 20% w/w. The prepared tablets were evaluated for organoleptic characteristics, friability, hardness, disintegration test, weight variation and in vitro drug dissolution study. All formulations are found to be rapidly dispersed and rapidly dissolving into the medium in in-vitro dissolution test. The tablets were of less weight variations. Among all formulations, containing 15% HPMCK

100 was found to be best. The complete dissolution of drugs was found to be within 24 hours indicating a good dissolution time. The used of release retarding polymers in floating tablets of Sitagliptin found to be a good formulation.[33]

- **Lodhe S. *et al*; (2008)** Verapamil hydrochloride bi-layer floating tablets have two layers one immediate release layer and second floating sustained release layer. Verapamil hydrochloride bi-layer floating tablet releases drug in two phases i.e immediate and sustained drug release. Direct compression method was used to formulate bi-layer floating tablets. All bi-layer formulation float more than 12 h and sustained drug release above 12 h. Kinetic release study suggests that release mechanism is quasi Fickian. The optimized formulation was selected based on in vitro characteristics and used in vivo-radio graphic studies in rabbits by in corporating BaSO4. This showed that, tablet significantly float in rabbit stomach formorethan7h. [34]
- **Singh Badana *et al*;(2000)** Designed an experiment for present preparation of famotidine floating microspheres, evaluation of Floating Drug Delivery System (FDDS)in vitro, prediction of the release, and optimization of stirring speed and polymers ratio stomatch target release profile was investigated. Floating microspheres were prepared by solvent evaporation (Oil-in-water emulsion) technique using hydroxyl propyl methyl cellulose (HPMC) and Ethyl cellulose (EC) as the rate controlling polymers. Particle size analysis, drug entrapment efficiency, surface topography, buoyancy percentage and release studies were performed. Results showed that the polymer ratio and stirring speed affected the size, in corporation efficiency and drug release of microspheres (> 12 h), floating time (> 12 hr) and the best result were obtained at the ratio of HPMC:EC(1:6). The mean particle size of prepared floating microspheres increased but the drug release rate from the microspheres decreased as the polymer concentration increased. The developed floating microspheres of famotidine may be used in clinic for prolonged drug release in stomach for at least 12 hrs, thereby improving the bioavailability and patient compliance.[35]

  Gattani et. al. *et al;* (2008) Formulated and evaluated floating multi-particulate oral DDS of diltiazem hydrochloride, which can provide SR. The work also aims to study various parameters affecting the behavior of floating multi particulate in oral dosage form. FM were prepared by non-aqueous emulsification solvent evaporation technique using ethyl-cellulose (EC) and Eudragit RS-100 as the rate controlling polymer. The invitro performance was evaluated by the usual pharmacopeial and other tests such as drug-polymer compatibility, (%)yield, particle size analysis, drug entrapment efficiency, surface topography, in vitro floatability and release studies. The data obtained in this study thus suggest that a micro particulate floating dosage form of Diltiazem hydrochloride can be successfully designed to give controlled delivery and improved oral bioavailability.[36]
- **Ali *et al*; (2007)** Developed an HBS of Metformin as a single-unit floating capsule. Various grades of low-density polymers were used for the formulation of this system. Capsules prepared with HPMCK4M and EC gave the best in vitro percentage release and were taken as the optimized

formulation. In vivo studies were carried out in rabbits to assess the buoyancy as well as the pharmacokinetic parameters of the formulation using gamma scinti-graphy. The formulation remainedbuoyantduring5hours of study in rabbits. The comparative pharmacokinetic study was performed by administration of the optimized HBS capsules and immediate release capsules, both with radio labeled metformin, using gamma counter. There was an increase in AUC in optimized HBS capsules of metformin when compared with immediate release formulation.[37]

- **El-Kamel *et al*; (2001)** Designed an SR system for Ketoprofen to increase its residence time in the stomach without contact with mucosa through the preparation of FM by the emulsion solvent diffusion technique. The floating multi-unit system for Ketoprofen was prepared using Eudragit RS 100 (ES) alone or in a mixture with the permeable Eudragit RL (ERL). The floating microparticles of Ketoprofen prepared with a suitable ratio of ES100 to ERL provided a convenient dosage form for achieving best performance regarding flow, release and floating properties.[38]
- **Dave *et al*; (2004)** developed a Gastro-retentive DDS of ranitidine hydrochloride using guar gum, xanthan gum, and HPMC. Sodium bicarbonate was incorporated as a gas-generating agent. The effect of citric acid and stearic acid on drug release profile and floating properties was investigated. A 3 2 full factorial design was Chapter-2 Literature Review Padmavathi College of Pharmacy and Research Institute 33 applied to systemically optimize the drug release profile and the results showed that allow amount of citric acid and a high amount of stearic acid favored SR of ranitidine hydrochloride from a gastro retentive formulation.[39]
- **EL-Gibaly *et al*; (2002)** prepared floating microcapsules containing melatonin by the ionic interaction of Cs and a negatively charged surfactant, sodium Dioctyl sulfo-succinate (DOS). The effect of various factors (cross-linking time, DOS and Cs concentration, as well as drug/polymer ratio) on microcapsule properties was evaluated. Cs concentration and drug/polymer ratio had a remarkable effect on drug entrapment in DOS/Cs microcapsules.[41]
- **Srivastava *et al*,(2005)** prepared FM of Cimetidine by the solvent evaporation method using the polymers HPMC and EC. In vitro data obtained for FM showed excellent float ability, good buoyancy and prolonged drug release. Microspheres of different sizes and drug content could be obtained by varying the formulation variables.[42]
- **Kroge*letal*.,(1999)** developed and evaluated floating and pulsatile DDS of Chlorpheniramine Maleate based on a reservoir system consisting of a drug containing effervescent core and a polymeric coating. Ideally, the expansion of the core could result in1.A floating dosage form with a prolonged residence time and extended drug release or 2. A pulsatile dosage form, in which the drug is released rapidly in a time, controlled fashion after rupturing of the coating.[43]

MATERIAL AND METHODS:

Table: 1 List of Materials used in experiment:

S.No.	Materials	Supplier/Manufacturer
1.	Ofloxacin	Gift Sample from IKON PHARMACHEM, Sara, Selaqui, Dehradun, Uttrakhand
2.	Carbopol 940	Central Drug House Pvt. Ltd
3.	Poly vinyl pyrollidine	Central Drug House Pvt. Ltd
4.	Sodium Bicarbonate	Central Drug House Pvt. Ltd
5.	Magnesium stearate	Central Drug House Pvt. Ltd
6.	Talc	Central Drug House Pvt. Ltd

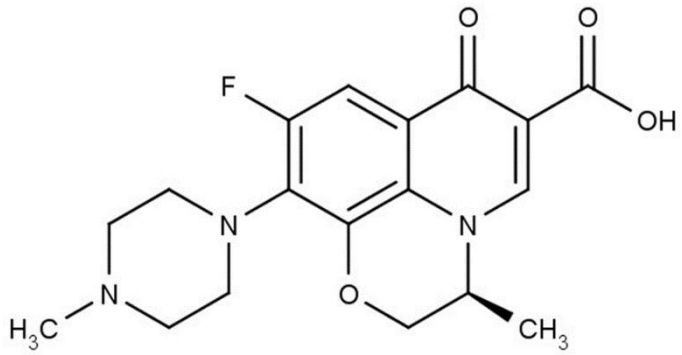
Table: 2 List of equipment used in experiment:

S.No.	Name	Supplier/manufacturer
1.	Double beam UV spectrophotometer	Shimadzu Instrument Pvt. Ltd.
2.	Digital weighing balance	
3.	Digital pH meter	Hanna instrument
4.	Magnetic Stirrer	Spincotech Pvt. Ltd.
5.	Dissolution test apparatus	Veggo apparatus
6.	Bath Sonicator	Associated Scientific Technology
7.	Vernier caliper	Popular India

Drug Profile [44]:

Ofloxacin: Ofloxacin is a fluoro-quinolone, broad spectrum antibiotic, rapidly well absorbed from the gastrointestinal tract. Half- life of Ofloxacin is 9 hours and is used in the treatment of urinary, respiratory, gastrointestinal, skin and soft tissue infections

Chemicalstructureof Ofloxacin



Chemical Name: 9-Fluro-2,3- Dihydro-3-Methyl-10-[4-Methyl-1-Piperazinyl]-7-oxo-7H Pyrido[1,2,3-De] 1,4Benzoxazine-6-Carboxylic acid hemihydrates

MolecularFormula:$C_{18}H_{20}FN_3O_4$

Molecularweight: 397.8

Category : Fluoroquinolone antibiotics

Appearance : It occurs as an off-white to pale yellow crystalline powder

Solubility : Ofloxacin is soluble in a variety of solvents. The solubility of ofloxacin is generally higher in organic solvents such as methanol, ethanol, chloroform and acetone, compared to water.

Melting Point : The melting point found to be 155°C.

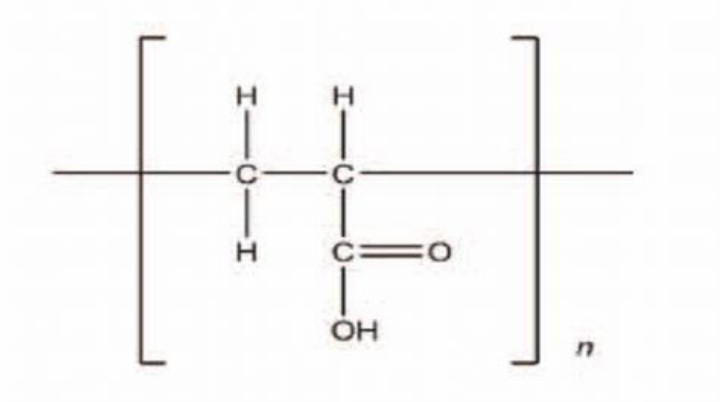
Storage : It is light sensitive and to be stored in a dark place. [44]

Polymer profile

Carbopol 940: Carbopol 940 polymer is a white powder, crosslinked polyacrylic acid polymer. It is an extremely efficient rheology modifier capable of providing high viscosity.

Chemical name : Carbomer 940, Polyacrylic acid

Structural Formula :



Chemical structure of Carbopol

Physical and Chemical Properties:

- Molecular weight : 72.06g/mol
- Colour : Pearl White
- Nature : a white powder, crosslinked polyacrylic acid polymer
- Density : 1.2g/ml
- Specific Gravity : 0.9567
- Solubility : soluble in water after neutralization they are soluble in 95%ethanol and glycerin
- Viscosity :40000-60000cP
- Melting Point : 12.5°C
- Stability and storage: store cool and dry in a good ventilated area. Keep container tightly closed. Avoid contact with alkali substance. Additional informatios to storage conditions: Product is strongly hygroscopic and is swelling in water.

MAGNESIUM STEARATE: Magnesium stearate is widely used in cosmetics, foods, and pharmaceutical formulations. It is primarily used as a lubricant in capsule and tablet manufacture at concentrations between 0.25% and 5.0% w/w. It is also used in barrier creams.

Molecular Formula: C36H70MgO4

Synonym: Dibasic magnesium stearate; Magnesium di-stearate; Magnesium octa-decanoate; Octadecanoic acid magnesium salt; Stearic acid magnesium salt.

Physical and Chemical Properties:

- Molecularweight :591.24
- Colour : Light wight
- Nature : Amourphous
- Odour : faint odour
- Taste : Unpleasant
- Solubility : Practically insoluble in ethanol (95%), ether and water; slightly soluble in warm benzene and warm ethanol (95%).
- Melting point : 88.5°C

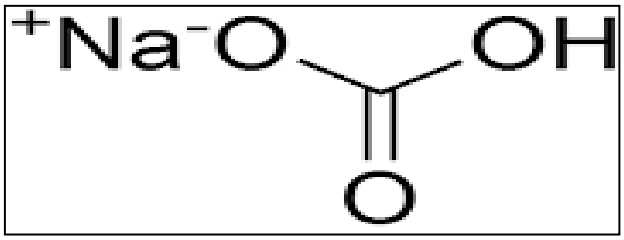
Stability and Storage Conditions: Magnesium stearate is stable and should be stored in a well-closed container in a cool, dry place.

Incompatibilities: Incompatible with strong acids, alkalis, and iron salts. Avoid mixing with strong oxidizing materials. Magnesium stearate cannot be used in products containing aspirin, some vitamins, and most alkaloidal salts.

Sodium Bicarbonate

Chemical Name: NaHCO3

Synonym: Carbonic acid mono sodium salt



Structural Formula

Chemical structure of Sodium Bicarbonate

Physical and chemical properties:

- Molecular weight: 84.01
- Colour : White
- Nature : Crystalline powder
- Odour : Odour-less
- Taste : Saline/Slight alkaline
- Density : 0.869-2.173g/cm^3
- Moisture content: lessthan1%w/w
- Solubility : Soluble in water, practically soluble in ethanol and ether.
- Melting point: 270°C (with decomposition)
- Functional category: Alkaline agent, Therapeutic agent
- Stability and storage: Sodium bicarbonate is stable in dry air but slowly decomposed in moist air and should there for be store in well-closed container in a cool dry place.

TALC:

Non-proprietory Names: BP: Purified Talc, USP: Talc

Synonyms: Hydrous magnesium calcium silicate, Hydrous magnesium silicate, Magnesium hydrogen metasilicate, Powdered talc, Talcum.

Chemical Name: Talc

Empirical Formula: Mg6(Si2O5)4(OH)4

Functional Category: Anticaking agent, Glidant, tablet and capsule diluent, tablet and capsule lubricant

Applications in Pharmaceutical Formulation: Talc was once widely used in oral solid dosage formulations as a lubricant and diluent, although today it is less commonly used. However, it is widely used as a dissolution retardant in the development of controlled-release products. Talc is also used as a lubricant in tablet formulations; in a novel powder coating for extended-release pellets; and as an adsorbant. Talc is a natural material; it may therefore frequently contain microorganisms and should be sterilized when used as a dusting powder.

Talc is additionally used to clarify liquids and is also used in cosmetics and food products, mainly for its lubricant properties.

Description: Talc is a very fine, white to grayish-white, odorless, impalpable, unctuous, crystalline powder. It adheres readily to the skin and is soft to the touch and free from grittiness.

Acidity/alkalinity: pH = 7–10 for a 20% w/v aqueous dispersion.

Solubility: Practically insoluble in dilute acids and alkalis, organic solvents, and water.

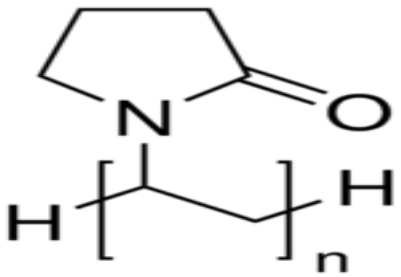
Stability and Storage Conditions: Talc is a stable material and may be sterilized by heating at 1608C for not less than 1 hour. Stored in a well-closed container in a cool, dry place. Incompatible with quaternary ammonium compounds.

PVP-K30: PVP also commonly called Polyvidone or Povidone, is a water-soluble polymer made from the monomer N-vinylpyrrolidone. It is used as a binder in many pharmaceutical tablets.

Chemical Formula: [C6H9NO]n

Chemical name: Polyvinylpyrrolidone

Chemical structure:



Physical and Chemical Properties:

- Molecular weight: 2500-2,500,000 g/mol
- Appearance: white to light yellow hygroscopic, amorphous powder
- Density :1.2 g/cm^3

- Solubility : soluble in water, methanol, ethanol, alcohol, chloroform and glycerol
- Melting point: 150 to 180 °C

Pre-formulationStudies[45]: Pre-formulation studies are the first step in the rational development of dosage form of a drug substance. The objectives of Pre-formulation studies are to develop a portfolio of the information about the drug substance, so this information is useful to develop formulation. Pre-formulation investigations are designed to identify those physiochemical properties and excipients that may influence the formulation design, method of manufacture, and pharmacokinetic biopharmaceutical properties of resulting product. Following are the test performed for Pre-formulation study which included compatibility studies, Organoleptic properties, determination of melting point, determination of solubility studies and determination of partition coefficient.

1. **Organoleptic Properties:** The colour, odour and taste of the drug were characterized and recorded.
2. **Solubility studies:** The solubility of drug was determined in different solvent system. Sufficient amount of the drug was added to 5ml of each solvent in a volumetric flask and shaken. The sample was kept at room temperature for24 hrs. Then the samples were filtered, diluted and examined for the absence or presence of drug particles.
3. **Determination of λ max of drug sample:** Appropriate dilution of Ofloxacin drug sample was prepared from the standard stock solution. Using UV Spectrophotometer, the diluted sample was scanned over the range of 200-400 nm and the λ max was determined.

Preparation of Ofloxacin Floating Tablet:

Ofloxacin tablet were prepared using wet granulation technique.

The composition of different formulations of ofloxacin floating tablet is shown in down the table. All the intragranular ingredients except PVP were passed through sieve no 40#. After sieving, all the ingredients were weighed accurately and mixed thoroughly following geometric method.

Granulation was done with a solution of PVP k-30 in sufficient iso-propyl alcohol. The granules passed through 8# were dried in conventional hot air oven at 45 degree C.

Drying of granules was stopped when samples reached a loss on drying value less than 2%, the granules were sized through sieve 20# and lubricated with magnesium stearate and talc. The above blend was the compressed using automatic punching machine.

S.no	Composition	F1	F2	F3
1.	Ofloxacin	500mg	500mg	500mg
2.	Carbopol	25mg	30mg	28mg
3.	PVP-K30	4.5mg	3.5mg	6.5mg
4.	Sodium bicarbonate	25.5mg	21.5mg	25.5mg
5.	Magnesium stearate	3mg	3mg	3mg
6.	Talc	2mg	2mg	2mg
	Total	**560mg**	**560mg**	**560mg**

Table: 3 Different Formulation

Evaluation of Ofloxacin floating tablet

a) **Weight uniformity:** Randomly select 10 tablets and calculate their average weight. The individual weight of tablet does not deviate significant from the average weight. The average weight of tablet is in between 559mg ±5mg.

b) **Thickness:** The thickness of the tablets can be measured by vernier caliper at different points of tablets. Thickness is found to be 3.4cm ± 0.5cm.

c) **Folding Endurance:** Folding endurance is performed to determined the folding capacity of the film at extreme conditions. To determine folding endurance the tablets is folded at the same place until it break. The number of the times tablets folded without breaking is folding endurance value.

d) **Dispersion Test:** A film was placed in 200 ml of 6.8 pH phosphate buffer and was stirred for 3 min. Then, the resulting solution was passed through sieve number 22. The film passed the dispersion test only when no residue is left on the screen.

e) **Drug Content**: Tablets was cut and dissolved in100 ml of pH 6.8 phosphate buffer using magnetic stirrer. Then, the solution was filtered through a filter medium. 1 ml of filtered solution was diluted with 10 ml of buffer, and the drug content was analyzed with the ultraviolet (UV) spectroscopic method.

f) **Hardness:** Hardness of tablets was determined by Monsanto hardness tester. The hardness of tablets is an indication of its strength. The force is measured in Kg and the hardness of uncoated tablets satisfactory about 3-6 kg/cm². Ten tablets of each formulation were selected Randomly and hardness of tablets was determine.

g) **Friability:** 10 Tablets were randomly selected from each formulation. Than accurately weight and place in the Roches Friabilator and operate 25 RPM for 5 minutes. The tablets were dedusted and reweighed. Percent friability is calculated by given below formula and tablet that loss than 1% weight were considered to be compliant.

%Friability = (W1-W2)/W1*100

Where, W1= initial weight, W2= final weight

W1=5.40g, W2=5.36g

%Friability= (5.40-5.36)/5.40*100

Hence, the %Friability of 10 tablets is **0.74%**

RESULT AND CONCLUSION

Pre-formulation Studies:

1. **Organoleptic Properties:** The colour, odour, and taste of the drug were characterized and recorded. The result is shown in table:

Table4: Organoleptic properties of drug

S.No.	Parameters	Observation
1.	Description	Powder
2.	Colour	Off-white pale yellow
3.	Odour	Odour-less
4.	Taste	Unpleasant

2. **Melting point:** The melting point of Ofloxacin was determined by using melting point apparatus and it was found to be 254^0C.

3. **Solubility:** The solubility of the drug were characterized and recorded

Table5: Solubility studies of drug in different solvents

S.No.	Solvent	Solubility
1.	De-ionised water	Slightly Soluble
2.	0.1NHCL	Soluble
3.	6.8phosphatebuffer	Soluble
4.	Ethanol	Freely Soluble
5.	7.4PhosphateBuffer	Soluble

4. **Determination of λ max of drug sample:** Calibration curve of the drug was prepared into phosphate buffer pH 6.8. The calibration curve of Ofloxacin 500mg was determine by to prepare standard solution with known concentration of Ofloxacin measure their specific values at a specific wavelength using Spectrophotometer and then plot the absorbance values against the corresponding concentrations of ofloxacin, using a scatter plot. Draw a based-fit line through the data points on the scatter plot. This line represents the calibration curve.

Table 6: Absorbance of Ofloxacin drug sample in 6.8 phosphate buffer

S.no.	Concentration(µg/ml)	Absorbance
1	1	0.122
2	2	0.250
3	3	0.375
4	4	0.500
5	5	0.616
6	6	0.730

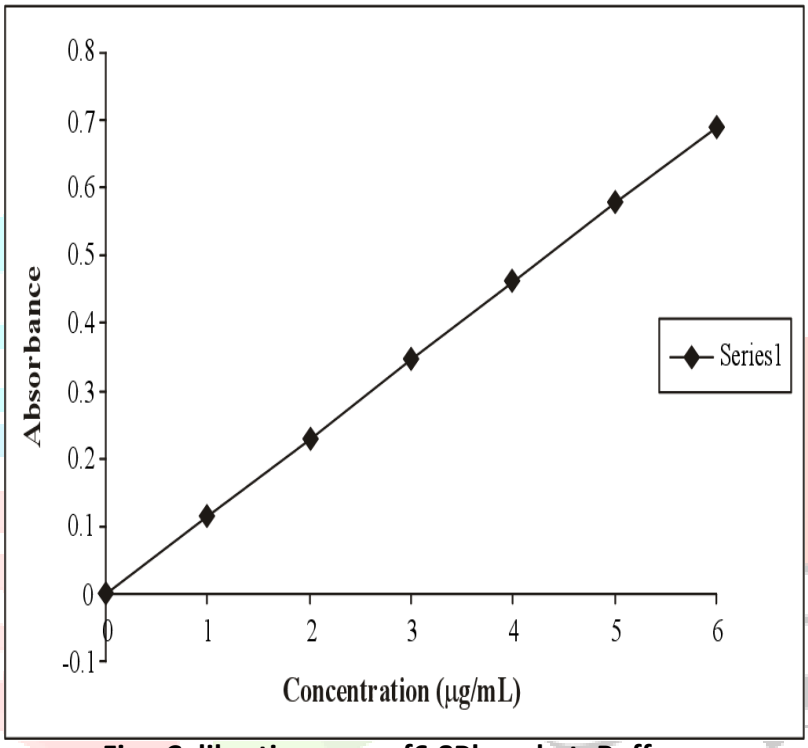


Fig.: Calibrationcurveof6.8PhosphateBuffer

Precompression Parameter:

1. **Bulk Density:** It is the ratio of total mass of powder (m) to the bulk volume (Vo) of powder.

   Db=m/Vo

2. **Tapped Density:** It is the ratio of total mass of powder (m) to the tapped volume (Vi) of powder.

   Dt=m/Vi

3. **Compressibility Index**: The flowability of powder can be evaluated via evaluating the bulk density (ρo) and tapped density (ρt) of powder and the rate at which it packed down. Compressibility index calculated by means of= (pt-po)/pt*100

   Where, ρo = Bulk density g/ml, ρt = Tapped density g/ml.

4. **Hausner's Ratio:** It is evaluated by means of taking Tapped density and it divided by Bulk density by the usage of following formula.

   Hausner's Ratio= Tapped density / Bulk density

5. Angle of Repose:

The frictional forces in a loose powder or granules can be measured via angle of repose. This is the maximum angle possible between the surface of a pile of powder or granules and the horizontal plane. The granules are allowed to flow through the funnel fixed to a stand at fixed height (h). The angle of repose, then calculated by measuring the height and radius of the heap of granules formed.

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

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

Where, θ = angle of repose, h = height of the heap, r = radius of the heap

Table 7: Precompression Parameter

Batches	Bulk Density (g/sq.cm)	Tapped density (g/sq.cm)	Compressibility index	Hasuner`s ratio	Angle of repose θ
F1	0.458	0.589	16.33	1.23	27
F2	0.469	0.698	17.12	1.49	28
F3	0.502	0.756	18.96	1.23	27

Post-compression Parameter:

a) **Weight uniformity:** Calculated average weight is 554mg.

b) **Thickness:** The thickness of the tablet measured by vernier caliper is 0.34cm

c) **Hardness:** of the tablets was tested using a Monsanto hardness tester and hardness of the tablet is found to be 5-8 kg

d) **In Vitro Buoyancy Studies:** The in vitro buoyancy was determined by floating lag time. The tablets were placed in a 100 ml beaker containing pH 1.2 buffers. The time required for the tablet to rise to the surface and float was determined as floating lag time. This test was performed on 3 tablets from each batch.

Fig.: Photograph showing the floating of Ofloxacin floating tablet

Table 8: Physical Characterization of Different Formulation

Code	Uniformity of weight (mg)	Hardness (kg/sq.cm)	Friability %	Drug content (mg)	Floating lag time (sec)	Total floating time(hr)
F1	557.20	5.7	0.74	498.73	15	6
F2	562.13	6.5	0.69	476.25	45	24
F3	559.70	6.8	0.64	482.86	37	24

In-Vitro Dissolution Studies: The release rate of ofloxacin from floating tablets was determined using dissolution testing Apparatus USP II (paddle method). The dissolution test was performed using 900 mL of pH 1.2 buffer, at 37 ± 0.5°C and 50 rpm. A sample of 10ml was withdrawn from the dissolution apparatus at regular time intervals up to 24 hrs. These were filtered and diluted to a suitable concentration with pH 1.2 buffer. The samples were replaced with the same volume of fresh dissolution medium in basket. Absorbance of these solutions was measured at 294 nm using a UV/VIS spectrophotometer (JASCO). Cumulative percentage drug release was calculated using an equation obtained from a standard curve. $y = 0.094x + 0.017$.

CONCLUSION: Floating tablet of Fluoroquinolone antibiotics i.e., Ofloxacin can be, formulated as an approach to increase gastric residence time as well as bioavailability and thereby showing increased therapeutic efficacy. The study's goal was to create and assess floating pills for ofloxacin. Wet granulation was used to create the tablets while employing various excipient concentrations. The assessed parameters for the prepared tablets-including weight variation, hardness, thickness, friability, and medication content-were all found to be within acceptable ranges. The most crucial characteristics are the floating lag time and floating duration of the tablets. As a result, formulation

was chosen as the optimal formulation for the production of Ofloxacin gastro retentive tablets that can ensure 100% bioavailability. Diffusion-controlled Ofloxacin gastro retentive tablets were created and tested.

Ofloxacin floating medication delivery tablets were created to lengthen gastrointestinal residence time and, as a result, eliminate Helicobacter pylori infection. The improved formula, which also had outstanding floating qualities, demonstrated greater sustained drug relese.

REFERENCES:

1. Amit Kumar Nayak, Ruma Maji, Biswarup Das. Gastro-retentive drug delivery system: areview,2010, ISSN0974-2441
2. Bhavjit Kaur, Shivani Sharma, Geetika Sharma, Rupinder Saini, Sukhdev Singh, Meenu Nagpal, Upendra K Jain, Mandeep Sharma. A Review of Floating Drug Delivery System. Asian Journal of Biomedical and Pharmaceutical Sciences 03 (24); 2013; ISSN: 2249 –622X
3. Juhi Dubey, Navneet Verma, Floating drug delivery system: A review, Department of pharmaceutics, IFTM University, Moradabad, UP, 2013, ISSN:0975-8232
4. Kharia AA, Hiremath SN, Singhai AK and Jain SK: Design and optimization of floating drug delivery system of acyclovir. Indian Journal of Pharmaceutical Sciences 2010;72(5):599-06.
5. Dolas RT, Hosmani A, Bhandari A, Kumar Band Somvanshi S: Novel Sustained Release Gastro-retentive Drug Delivery System: A Review. International Journal of PharmaResearchandDevelopment2011;2(1):26-41.
6. Chordiya MA, Gangurde HH, Senthil Kumaran Kand Kothari LP: Formulation development and *invitro* evaluation of gastro-retentive hollow microspheres of famotidine. International Journal of Pharmaceutical Investigation 2011; 1: 105–111.
7. Eriedman E and Kirmayer D: Novel Gastro-retentive Delivery System. US Patent2011/0268666.
8. Swetha S, Allena RT and Gowda DV: A comprehensive review on gastro-retentive drug delivery systems. International Journal of Pharmaceutical and Biomedical Research 2012; 3:1285-1293.
9. Prajapati S and Dharamsi A: Floating drug delivery for prolonging gastric retention of dosage form. Indian Journal of Novel Drug Delivery2013; 5:15-27.
10. Ukawala R, Singhvi G, Jain S, Shukla V, Yadav N, and Sharma S: Design and characterization of controlled release gastro-retentive floating tablet of an atypical psychotropic agent. Journal of Pharmacy and Bio-allied Sciences2012; 4: S88–S89.
11. Tomar Preeti, Shukla Vaibhav, Kharia Ankit Anand, Chatterjee D.P. Oriental college of pharmacy, Bhopal,2013, ISSN:2320-7418.
12. Bhalla N, Goswami M, Floating Drug Delivery System. International Journal of Pharmaceutical Research and Allied Science. (2012)4,20-28.

13. Beena Kumari, Recent Development in floating drug delivery system: A review, Department of pharmaceutical education and research, Sinepat, Haryana, 2018; 4(2):131-139.
14. Meenakshi J, Ujjwal N, Jyotsana K, Devendra S. A review: Gastro-retentive drug delivery system. Indian Journal of Pharmaceutical and Biological Research; 2015 3(1):82-92.
15. Pande SD, Kumari P, Vaidya V, Gulhane N. Floating drug delivery system (FDDS): A new way for oral drug delivery system. International Journal of Pharma Clinic and Science ;2013,3(1):1-13
16. Vishal B, Nirmala SL, Hari Kumar. Floating Drug Delivery System: A Review. Pharmacophore 2013; 4(1): 26-38.
17. Prashant Patil, Priyanka Baviskar, Ravindra B. Saudagar. Pharmaceutics, R.G. Sapkal college of pharmacy, Nashik;2019, ISSN: 2250-1177
18. Chikhalikar SS and Wakade RB: Floating Drug Delivery System – An Approach to Oral Controlled Drug Delivery. International Journal of Pharm Tech Research 2012.
19. Sharath M, Goud C, Pandey VP, REVIEW ARTICLE ON GASTRORETENTIVE DRUG DELIVERY SYSTEM, IJPBS, 2016; 6(3): 158-165.
20. Chudiwal V, Shahi S, Chudiwal S and Ahale D. Innovative Technologies for Gastro-Retentive Drug Delivery Systems. Asian Journal of Pharmaceutical Education and Research.2017; 6(4): 22-28
21. Suvarna Chittam, Ashok Bhosle, Govind Raghunath Sable, College of pharmacy, Saswad, Pune, Maharashtra, India. Development and Evaluation of Floating and expanding Gastro-retentive Film of Furosemide.
22. Anggun Hari Kusuma-wati, Lin Lidia Putama Mursal, Formulation and Evaluation Non – Effervescent Floating Tablet of Caotopril Using Combinations of Polymers HPMC and CMC-Na, University of Buana Perjuangan Karawang, Indonesia, 2020: ISSN–2581-8945, Vol3No04.
23. Sanjay Kumar Mishra, M.K.Gupta. Characterization and Evaluation of Nizatidine Floating Microspheres based for Anti-ulcer activity10.13040/IJPSR.09758232.10(10).4557-67.
24. Mirmeera Girish Niharika, Kannan Krishnamoorthy, Madhukar Akkala. Over view on floating Drug Delivery System Int. JApp Pharma,Vol10,Issue 6,2018,65-71.
25. Anh Q. Vo, Xin Feng,Joseph T.Morott , Manjeet B. Pimparade, Roshan V. Tiwari Feng Zhang and Michael A.Repka. Department of Pharmaceutics and Drug Delivery, School of Pharmacy, The University of Mississippi. 2016)\, 98:108-12.
26. J. S. Patil, V. B. Biradar, P. R. Biradar, S. S. Shiralashetti, S. C. Marapur, P. B. Gaurav. Design and evaluation of Gastro-retentive Drug Delivery System of Anti-Ulcer Drugs J.FoodPharm.Sci.220151-5.
27. Namdeo Shinde, Bhaskar Bangar, Floating fil drug delivery system: Ane ffective approach of gastro-retentive, 2015; DOI: 10.13140/RG2.1.3964.4326.
28. Nitasha Sharma, Rajendra Awasthi. Development and characterization raft forming floating film of atenolol. Indian Drugs, 201552(3): 15-23.
29. Saigeethika S, Gautam Singhvi and Ramanjaneyulu, formulation and evaluation of Ofloxacin Floating Tablet,29 October, 2012.

30. Pramod P; Someshwara Rao B, Suresh V K; Basavaraj; Chetan S; Anand A; "Formulation and In Vitro Evaluation of Floating Matrix Tablets of Ofloxacin" Asian J. Res. Pharm. Sci2011; Vol.1(1); pp-17- 22.
31. Banik K & Kumar PB. (2020) Formulation and Evaluation of Floating Microspheres of Repaglinide by Ionic Gelation Method. J Pharm Drug Res, 3(2): 382-395.
32. Meghana K J, Ashok Kumar P, Suresh V Kulkarni, Manjunath K. Formulation and In-Vitro Evaluation of Floating Microspheres of Anti Diabetic Drug. Int J Pharma Res Health Sci. 2019; 7(3): 3007-3012.
33. Prakash S. Pujari, Pravin S. Uttekar, Pravin D. Chaudhari and Pradnya S. Bamane. Formulation Development and Evaluation of Bilayer Floating Tablet of Antidiabetic Drugs. Der Pharmacia Lettre, 2016, 8(21): 34-54.
34. Krishna Keerthi Brahm and a metal, Carib. j. Sci Tech,2014;2:270-281.
35. Lodhe S. Verapimil hydrochloride bi-layer floating tablets. Int. j. Pharm. Sci. 2008 49-52
36. Singh BN, Kim KH, Floating drug delivery systems: an approach to oral controlled drug delivery via gastric-retention. J control release. 2000feb3; 63(3): 235-59
37. Gattani YS, Durg acharan AB. Formulation and evaluation of intragastric floating drug delivery system of diltiazem hydrochloride. Asian j pharm2008; 4:228-31.
38. Ali J, Arora S, Ahuja A, Babbar AK, Sharma RK, Khar RK, et al. Formulation and development of hydrodynamically balanced system for metformin: In vitro and in vivo-evaluation. Eur J Pharma Biopharm 2007; 67;196-201
39. EL-kamel, M Sokar, VF Naggar. Preparation and evaluation of ketoprofen floating oral delivery system. International journal of pharmaceutics 220(1-2), 13-21-2001
40. Dave BS, Amin AF, Patel MM. Gastro-retentive drug delivery system of ranitidine hydrochloride formulation and in-vitro evaluation. AAPS Pharmasci Tech. 2004apr8; 5(2): e34. PMCID: PMC2750469.
41. EL-Gibaly. Development and in-vitro evaluation of novel floating chitison micro capsule for oral use: comparison with non-floating chitosan microspheres. International journal of pharmaceutics. December 2002: S0378-5173(02)00396-4
42. Srivastava AK, Ridhurkar DN, Wadhwa S. Floating microspheres of cimetidine: formulation, characterization and in-vitro evaluation. Acta Pharm. 2005 sep;55(3):277-85. PMID:16375838.
43. Raymond CR, She-sky PJ, Quinn ME. Handbook of pharmaceutical excipients. 6th ed, Royal Pharmaceutical excipients. 6th ed, Royal Pharmaceutical society of Great Britain publisher.2009; pg.578-582,586-590,214-217,400-402
44. Gajanand Yadav1 *, and Tara Chand, Formulation and Optimization Evaluation of Floating Tablet of Ofloxacin Regional college of Pharmacy, Jaipur, (Rajasthan)-302022
45. Namdeo Shinde, Bhaskar Bangar, Floating film drug delivery system: An effective approach of gastro-retentive, 2015; DOI: 10. 13140/RG2. 1. 3964. 4326.