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Design and Evolution of Floating Drug Delivery System for Antimicrobial Drugs

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ABSTRACT
A controlled gastric retention system of ofloxacin has been developed to increase stomatal residence time and modulation of drug release behavior. Drugs and Polymer compatibility was investigated by giving a physical mixture of drugs and polymers differential scanning calorimetry and FTIR spectroscopy. Rice bran oil The trapped zinc pectinate particles contain ofloxacin, which can float in the stomach.conditions have been developed and evaluated. Gel particles are prepared by emulsification gelation method using low methoxy pectin (LMP) with a degree of esterification less than 50% (LMP) and a mixture of LMP and hydrophilic copolymers (naturalgums) such as gellan gum (GG), xanthan gum (XG) and karaya gum (KG) in three categories different rates. Effect of selected factors, such as oil ratio and amount The floating properties of copolymers were investigated. Studying the topography of pearls performed using a scanning electron microscope. Particles are rated as a percentage effective drug trapping, buoyancy and drug release in vitro. In vitro drug release Particle studies were performed in a simulated gastric environment using conventional USP dissolution method. All the zinc pectinate particles trapped in the oil will float if enough amount of oil used. Particles made with just LMP can't stand it release the drug for 8 hours, while the bead is made up of a mixture of LMP and copolymer demonstrated a prolonged release of ofloxacin over 8 hours. The results show that Particles of zinc pectinate trapped in rice bran oil hold the promise of being able to carry infections in the stomach.ofloxacin drug floating management. Here zinc chloride is used as crosslinking agent like,calcium chloride reacted with ofloxacin and tended to dissolve the drug onbinding supports itself

Keywords:- Ofloxacin, floating drug delivery systems, low methoxy pectin (LMP),gellan gum (GG), xanthan gum (XG), karaya gum (KG), zinc pectinate beads, rice branoil, gastric residence time.

I. INTRODUCTION:

FLOATING DRUG DELIVERY SYSTEMS

Floating drug delivery system designed to prolong stay in the stomach after oral administration administer, at a specific location, and control the release of a drug that is particularly useful for achieve controlled plasma levels and improve bioavailability. These systems are is retained in the stomach for a longer period and thus improves the bioavailability of medicine. The effective use of oral medications may depend on factors such as gastric emptying. process, gastrointestinal transit time of dosage form, drug release from dosage form and location drug absorption. Most oral medications have some physiological limitations such as altered gastrointestinal transit, due to altered gastric emptying resulting in uneven absorption properties, incomplete drug release and shorter dose retention formed in the stomach. This leads to incomplete absorption of the drug with an absorption window. especially in the upper part of the small intestine, because once the drug is absorbed, site, the remaining amount is not absorbed. All of the above requirements can be met and effective drug delivery to the absorption window, with local and therapeutic action Stomach disorders such as gastroesophageal reflux can be achieved by using flotation agents system (FDDS). The concept of this system has been described as a remedy Some people have trouble choking or choking when swallowing pills. He It has been suggested that this difficulty can be overcome by providing drugs with lower density.greater than 1.0 g/ml causes the tablet to float to the surface of the water. Since then, many kinds of stomach disorders stored drug delivery systems have been tested to overcome regional and dosing time limitations. absorbed in the gastrointestinal tract. Balanced hydrodynamic system (HBS) also called floating drug delivery

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system (FDDS) is an oral dosage form (capsule or tablet) designed to prolong the residence time of the dosage form within the GIT.1

ADVANTAGES OF FLOATING DRUG DELIVERY SYSTEM

¾ The FDDS formulation can be used for drugs that are absorbed through the stomach as well as intestines.

¾Efficacy of drugs administered on the principle of extended release FDDS was found to be independent of the absorption site of the product in question medicine.

¾ Use of extended-release tablets or capsules will result in Dissolve the drug in gastric juice. After emptying the contents of the stomach, Soluble drug is easily absorbed in the small intestine. We therefore expect that a The drug will be completely absorbed from the supernatant dosage form if it remains in solution even at alkaline pH of the small intestine. ¾ When peristalsis is strong and transit time is short, as may occur in some types of diarrhea, malabsorption is expected in such cases, which may

The advantage is to keep the drug in suspension in the stomach for a relatively better effect reply.

¾ Retention of the stomach will provide benefits such as medication management to absorption window in the small intestine.

¾ Some medications may benefit from the use of gastrointestinal restraint devices, such as those that act as localized in the stomach; the drug is absorbed mainly in the stomach; drugs are poorly soluble at alkaline pH; drugs with narrow absorption portals absorbed drugs quickly from the gastrointestinal tract and drugs, they are broken down in the colon.

DISADVANTAGES OF FLOATING DRUG DELIVERY SYSTEMS

There are certain situations where gastric retention is undesirable, such as:

¾ Aspirin and non-steroidal anti-inflammatory drugs are known to cause stomach damage, and Slow release of these drugs into the stomach is undesirable.

¾ Medicines that can irritate the stomach lining or are unstable in an acidic environment is not formed in the digestive system.

¾ In addition, other drugs such as isosorbide dinitrate are equally well absorbed. throughout the gastrointestinal tract will not benefit from incorporation into a gastric retention system.1

LIMITATIONS

¾ The main disadvantage of floating systems is the level requirement Fluid in the stomach allows the medicine to float.

¾ Floating systems are not feasible for drugs with solubility or internal stability problemsgastric fluid.

¾ Drugs that are absorbed through the gastrointestinal tract must undergo the first passmetabolism (nifedipine, propranolol, etc.) are not desirable candidates.

¾ The ability of the system to remain buoyant in the stomach depends on the subject positioned vertically.

FACTORS AFFECTING THE FLOATING DRUG DELIVERY SYSTEM

¾ Density of dosage form, size of dosage form and shape of dosage form.

¾ Single or multiple formulas.

¾ Amount of food, nature of food, frequency of eating and calorie content. ¾ Influence of gender, posture and age.1,2

DRUG CANDIDATES FOR FDDS

¾ Drugs with local activity in the stomach, e.g. misroprostol, antacids, etc.

¾ Drugs with a narrow gastrointestinal absorption window (GIT), e.g. L-DOPA, paraaminobenzoic acid, furosemide, riboflavin, etc.

¾ Drugs with low solubility at high pH values, e.g. diazepam, chlordiazepoxide, verapamil HCl.

¾ Drugs that act locally in the stomach as seen in the treatment of Helicobacter pylori with amoxicillin and ofloxacin and in the treatment of duodenal ulcers with H2 antagonists such as ranitidine and famotidine.

¾ Medicines that cause stomach irritation e. g. AIN. 3

DRUGS THOSE ARE UNSUITABLE FOR FDDS

¾ Drugs with very limited acid solubility, e.g. phenytoin, etc.

¾ Drugs that are unstable in the gastric environment, for example: erythromycin, etc.

¾ Drugs intended to be released selectively into the colon, e.g. 5-amino salicylic acid andcorticosteroids, etc.

APPLICATIONS AND TECHNOLOGIES

¾ A recent study shows that using floating diltiazem tablets twice daily canis more effective than regular pills in controlling blood pressure Hypertensive patients.

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¾ Madopar® HBS - contains L-dopa and benserazide - where the drug is released and absorbedover a period of 6 to 8 hours and maintains significant plasma concentrations in Parkinson's diseasepatients.
¾ Cytotech® -- contains misoprostol, a synthetic prostaglandin E1 analog, for prevention Stomach ulcers caused by nonsteroidal anti- inflammatory drugs (NSAIDs).
¾ Because it delivers high concentrations of drugs to the stomach lining, it is used for eradicationHelicobacter pylori (a bacteria that causes chronic gastritis and stomach ulcers).
¾ 5-fluorouracil has been successfully evaluated in patients with gastric tumors. ¾ Development of an HBS dosage form for tacrine that provides a better delivery system and reduces its GI indexside effects in Alzheimer's patients.
¾ Alza Corporation has developed a gastric retention platform for the OROS® system, which showed prolonged persistence in the dog model as the product remained in the stomach of the dog at12 hours after taking the drug and usually appears 24 hours.1

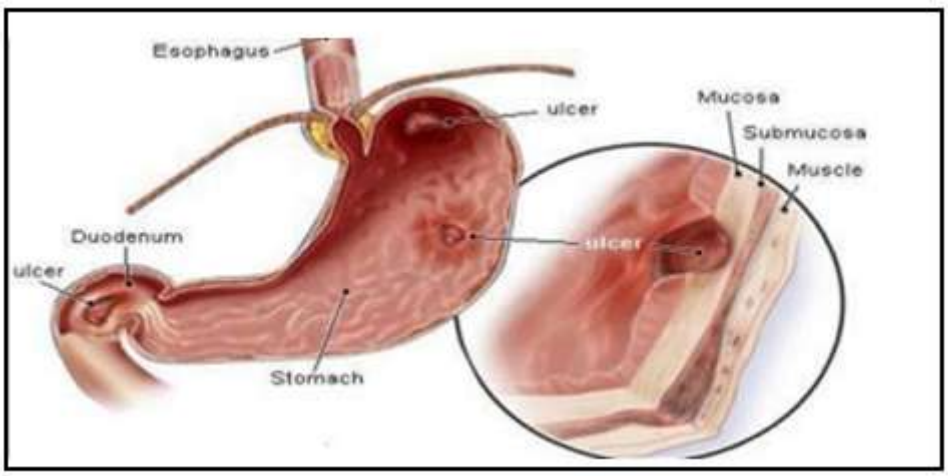
THE FACTORS WHICH GOVERN THE EFFECTIVENESS OF ACTIVE MEDICAMENTS IN FDDS ARE:
¾ Amount of active ingredients to produce therapeutic effects. ¾Clear density
¾ hydrophilic and ¾ hydrophobic properties Stability in gastric juice

Table . 1.1.1 Commonly used drugs in formulation of gastro retentive dosage forms.

METHODS FOR PREPARING FLOATING DOSAGE FORM
¾ Use hydrocolloids such as hydrophilic gum, gelatin, alginate, cellulose derivatives, etc.
¾ Use low density enteric soluble materials such as methacrylic polymer, cellulose acetate phthalate.
¾By reducing the particle size and pouring them into a capsule.
¾ By forming carbon dioxide gas then trapping it in the gel network.
¾ By preparing hollow microparticles from acrylic polymer and filling the capsules. ¾ By incorporating an inflatable chambercontaining a liquid, e.g. a gasification solventat body temperature, the stomach cavity swells.1

INTRODUCTION OF PEPTIC ULCERS
DEFINATION

Peptic ulcers are open ulcers located in the lining of the stomach, esophagus or duodenum (first part of the intestine). The stomach lining is normally protected from harmful effects stomach acid. When this protection fails, ulcers form. Ulcers are not caused by spicy foods either emphasize. Instead, it's usually caused by a bacteria called Helicobacter pylori. Long-lastingnonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen (Advil) can also cause ulcers.Causes of ulcers are conditions that can result in direct damage to the wall of the stomach or duodenum, such as heavy use of alcohol, radiation therapy, burns, and physical injury.



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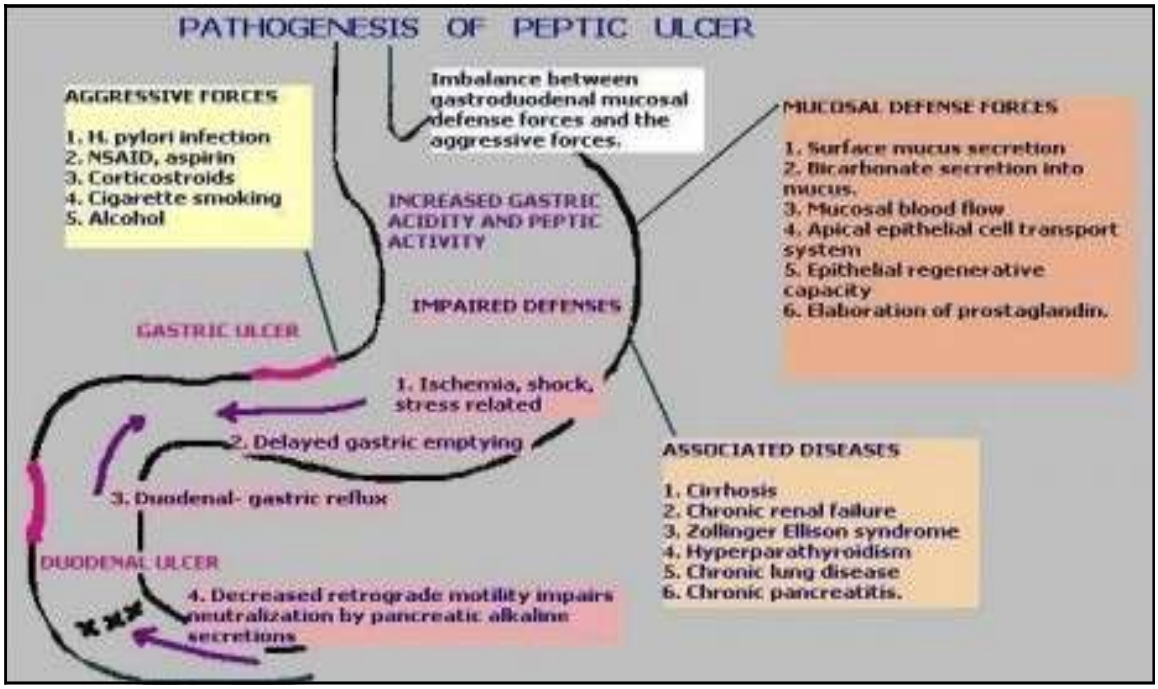
PATHOGENESIS OF PEPTIC ULCER:



Schematic representation pathogenesis of peptic ulcer:

Peptic ulcers are created due to an imbalance between the defenses of the duodenal mucosaThe mechanism and harmful effects of stomach acid and pepsin involve cumulative damagefrom environmental or immunological agents

Mechanism

Î H.pylori secretes urease (produces ammonia), protease (decomposes glycoproteins in the body).gastric mucus) or phospholipase. Î Bacterial lipopolysaccharide attracts inflammatory cells to the mucosa. Neutrophil releasemyeloperoxide.

Î A bacterial platelet-activating factor that promotes thrombotic occlusion of surface capillaries. Î Mucosal damage causes tissue nutrients to leak into the surface microenvironment,bacillus support.

Î Damage to the protective mucosal layer. Epithelial cells are susceptible to damageacid-peptic digestive effect. Î Inflammation of the stomach lining.
Î Chronic mucositis is more sensitive to acid-peptic damage and susceptible to gastric damage.ulcers. Î Ulcers occur at sites of chronic inflammation.
For example:
- Antrum- Junction of the antral mucosa and the base of the body (dividing between the inflamed mucosa antral mucosa and normal acid-secreting mucosa).

Î Pancreatitis - In the elderly, stomach ulcers are located more proximally because Proximal migration of the antrum-mucosal body junction.

TREATMENT:

Young patients with ulcer symptoms are often treated with antacids or H2 antagonists.Bismuth compounds can actually reduce or even eliminate the organisms, despite label warnings Some bismuth subsalicylate products indicate that no one should use this product with an ulcer. Patients taking nonsteroidal anti-inflammatory drugs (NSAIDs) may also experience it prescribe a prostaglandin analog (misoprostol) to help prevent peptic ulcers, May be a side effect of NSAIDs. In case of H.pylori infection, the most effective solution treatment is a combination of two antibiotics (e.g. clarithromycin, amoxicillin, ofloxacin,tetracycline, metronidazole) and proton pump inhibitors (PPIs), are sometimes implicated includes bismuth. In complicated and

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resistant cases, three antibiotics (eg amoxicillin + clarithromycin + metronidazole) can be used in combination with PPIs and sometimes with bismuth Compounds. An effective first-line treatment for uncomplicated cases would be ofloxacin +metronidazole + pantoprazole (PPI). When H.pylori is not present, use high doses of PPIs for long periods of time often used. Treatment for H.pylori usually clears the infection and reduces symptoms.and finally heal the ulcer. Recurrence of infection may occur and retreatment may be required.

Necessary, if necessary with other antibiotics. Since the widespread use of PPIs in the 1990s,Surgical procedures (such as "highly selective vagotomy") for uncomplicated duodenal ulcers have become more common.obsolete. Peptic ulcer disease is a surgical emergency and requires surgical repair perforation. Most bleeding ulcers require urgent endoscopy to stop the bleeding with electrocautery, injection or cutting.\

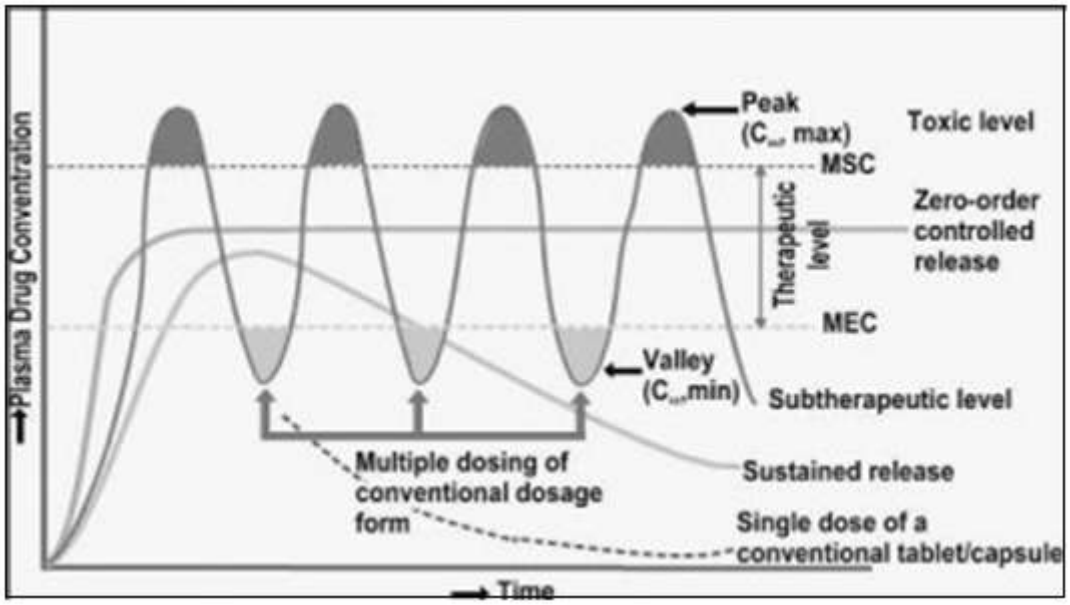
1.3.1 . ORAL DRUG DELIVERY

The oral route is the most commonly used route of administrationhas been explored for systemic drug delivery through various pharmaceuticals dosage form. The oral route is considered the most natural, simplest, most convenient and safest due to ease of administration, patient acceptance and cost-effective manufacturing process.

Orally administered pharmaceutical products are mainly immediate release products or Conventional drug delivery system, designed to release drug immediately for rapid treatment absorption. These immediate-release dosage forms have some limitations such as:

1. Drugs with short half-lives must be used frequently, increasing the risk of disease Missing medication doses leads to patient non-compliance with treatment.
2. Obtain a typical peak-valley plot of plasma concentration versus time, from theredifficulty maintaining balance (Figure 1.3.1).
3. Inevitable fluctuations in drug concentrations may result in underdosing or underdosing. Overdose when CSS values decrease or exceed the therapeutic range.
4. Fluctuating drug levels can cause many side effects. especially drugs with low therapeutic amplitude, in case of drug overdose.

To overcome the disadvantages of conventional drug delivery systems, several techniques are used advances have led to the development of controlled drug delivery systems is revolutionizing treatment methods and providing many therapeutic benefits. [6,7]



A hypothetical plasma concentration-time profiles from conventional multiple dosingand single doses of sustained and controlled delivery formulations.

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CONTROLLED DRUG DELIVERY SYSTEMS

Achieve and maintain drug concentrations within effective therapeutic limits different, often requiring multiple doses of medication, leading to fluctuating drug dosages. plasma concentration. Controlled drug delivery systems have been introduced to overcome this Disadvantage of drug level fluctuations associated with conventional dosage forms. The concept of sustained or extended release of biologically active substances has been appreciated and rationalized over decades. Controlled release refers to the use of a contained delivery device The goal is to deliver drugs into the patient's body at a predetermined rate or at specific timesor with specific version profile.[8]

Controlled drug delivery or modified drug delivery systems are conveniently divided into fourcategories.

1. Delayed release
2. Sustained release
3. Site-specific targeting
4. Receptor targeting

Advantages of controlled drug delivery system:

1. Avoid patient compliance issues.
2. Reduce the incidence and/or intensity of adverse effects and toxicity.
3. Improve treatment effectiveness
4. Use better medicine.
5. Release rate and location are controlled.
6. Blood concentration is more uniform.
7. Reduce medication frequency.
8. Treatment effects are more consistent and lasting.

Disadvantages

1. Increased variability between dosage units.
2. Poor in vitro - in vivo correlation.
3. Possibility of dose interruption due to dietary, physiological or formulation or chewing variations Patients grind oral formulations and thereby increase the risk of toxicity.
4. It is difficult to recall drugs in cases of poisoning, poisoning or hypersensitivity reactions
5. Stability issues.
6. Increased costs.
7. Develop faster tolerance and advice.

ORAL CONTROLLED DRUG DELIVERY SYSTEMS 6

Controlled-release oral drug delivery is a drug delivery system that provides continuous oral drug delivery.Administer the drug according to predictable and reproducible kinetics over a predetermined time period transport process through the gastrointestinal tract and also a system that targets the delivery of drugs to a specific areain the digestive tract with local or systemic effects. All pharmaceutical products is formulated for systemic oral use, regardless of route of administration.delivery (immediate, sustained, or controlled release) and dosage form design (solid,dispersion or liquid), must be developed within the framework of the intrinsic characteristics of gastrointestinal physiology.Therefore, a scientific framework is necessary for the successful development of oral drug delivery methodsThe system includes a basic understanding of (i) physicochemistry, pharmacokinetics and pharmacodynamic properties of the drug; (ii) anatomical and physiological characteristics of digestive tract and (iii) physicochemical characteristics and drug administration methods designed galena form. Conventional controlled oral dosage forms are mainly affected by two adversities. Gastric retention time (GRT) is short and gastric emptying time is unpredictable (TAKE). The relatively short gastrointestinal transit time of most medicinal products (8–12 hours) hinders formulation.

Unique daily dosage forms. These problems can be overcome by modifying the gastric systemblank formula. Therefore, it is desirable to formulate a controlled release dose.form provides extended stay in IG

BASIC GASTROINTESTINAL TRACT PHYSIOLOGY

The new design of controlled oral drug delivery system is mainly aimed atachieve higher and predictable drug bioavailability. However, development This process is hindered by a number of physiological difficulties, such as the inability to retain and locates the delivery system in the desired region of the gastrointestinal (GI) tract and is highly effectivealtered nature of gastric emptying. Predictably, it depends physiological state of the subject and pharmaceutical formulation design, emptyingThis process can last from a few minutes to 12 hours. This change can lead to unpredictable situations.bioavailability and time to maximum

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plasma concentration, as most drugs are preferred absorbed in the upper part of the small intestine.8 Additionally, GET times are relatively short in humans, usually lasts an average of 2 to 3 hours past the main absorption site (stomach or upper body). intestines), which can lead to incomplete clearance of the delivery system, leading to reduction dose effectiveness. Therefore, controlling the location of the distribution system at a specific location The gastrointestinal tract has many advantages, especially for drugs that can be absorbed window in the gastrointestinal tract or the drug has stability problems. These considerations have resulted development of controlled-release oral dosage forms with gastric retention.

GASTRIC EMPTYING

Anatomically, the stomach is divided into 3 regions: fundus, body and antrum (pylorus). The proximal part includes the fundus and body which acts as a reservoir for indigestible substances, while The antrum is where mixing movements are mainly carried out and acts as a pump to empty the stomach by motivating actions.

Gastric emptying occurs in the fasted state as well as in the fed state. However, the movement pattern is separated into two stages. During the fasting state, a series of electrical phenomena during digestion occur.which moves through both the stomach and intestines every 2 to 3 hours. This is called migration electromechanical cycle (MMC), is divided into 4 stages as follows (Figure 1.3.2).

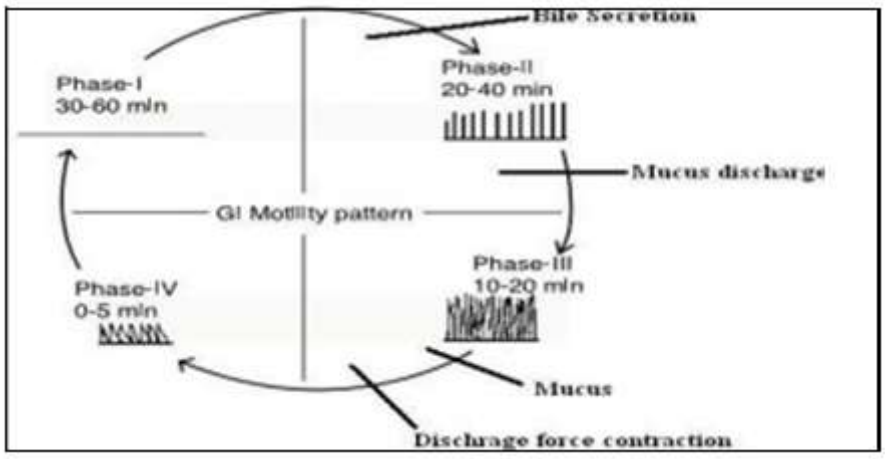
Phase I (basal phase): It lasts from 40 to 60 minutes with rare contractions

Phase II (preburst phase): It lasts 40 to 60 minutes with intermittent action potentials and The pains. As the stage progresses, the intensity and frequency also gradually increase.

hase III (burst phase): This lasts 4 to 6 minutes. It includes Short-term contractions. It is through this wave that all indigestible matter is swept away from the stomach to the small intestine. It is also known as the butler wave.

Phase IV: This phase lasts for 0 to 5 minutes and occurs between phases III and I of 2 consecutive cycles.

During the fed state onset of MMC is delayed resulting in slowdown of gastric emptying rate [.9, 10,11]



1.3.2 Schematic representation of interdigestive motility pattern.

APPRQACHES TO GASTRIC RETENTION

Over the past three decades, many different methods have been researched to increase retention Oral dosage forms include[9, 10, 11, 12]

¾ Floating system.
¾ Inflation and expansion system.
¾ Bio-adhesive system.
¾ Modified form system.
¾ High density system.
¾ And other slow gastric emptying devices.

FDDS or hydrodynamic equilibrium system has a lower apparent density than gastric fluid and hus remains floating in the stomach without affecting the rate of gastric emptying for a long timePeriod. As the system floats on the stomach contents, the drug is slowly released into it a desired speed of the system. This results in an increase in GRT and better control Fluctuations in plasma drug concentrations in some cases. The

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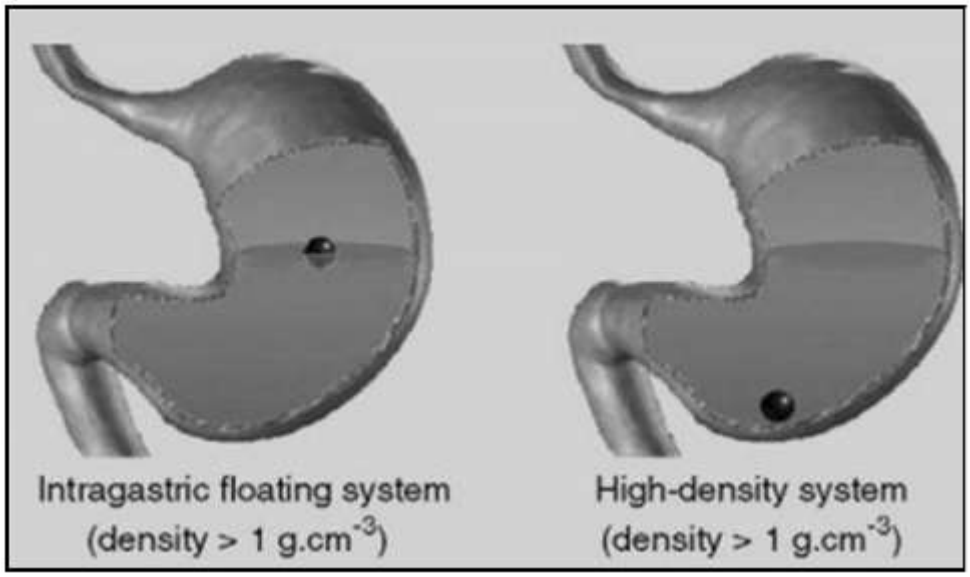
dosage form that causes swelling is that after ingestion, these products swell to the point prevent them from leaving the stomach through the pylorus. As a result, the dosage form is retained within long-term stomach. The bioadhesive system is used to position the delivery device in the lumen and body cavity.to enhance drug absorption in a sitspecific manner. The approach includes usage Bioadhesive polymers can adhere to the epithelial surface of the gastrointestinal tract.

Shape-shifting systems are non-degradable geometric forms molded from elastomers orextruded from a polyethylene blend, which expands the GRT based on size and shape.High-density formula includes coated particles, which have a density greater than that of stomach contents (~ 1,004 g/cm3) (Figure 1.3.3) Other interesting approaches to delay gastric emptying include simulating the feeding of indigestible products.polymers or salts of fatty acids that change the motility pattern of the stomach toward a nourished state,
reduces the rate of gastric emptying and allows a significant prolongation of drug release.



1.3.3 Schematic localization of an intragastric floating system and a high density system inthe stomach.

CLASSIFICATION OF FLOATING DRUG DELIVERY SYSTEMS (FDDS)

Based on the mechanism of buoyancy, FDDS are classified into following classes:

1. Effervescent systems.
2. Non-effervescent systems.
3. Raft forming systems.

1) Effervescent floating dosage forms:

Here, the flotation process is obtained by generating air bubbles(Figure 1.3.4). CO2 gas can be generated on site by incorporating carbonate or bicarbonateThe matrix is prepared with swellable polymers such as HPMC or polysaccharides. These Bicarbonate reacts with stomach acid to form bubbles of CO2, which become trapped in the swelling polymer base and provide buoyancy to the system. Foaming or gas-forming agents included sodium bicarbonate and citric or tartaric acid. Another way is to embed a matrix withTrapped fluid forms gas at body temperature

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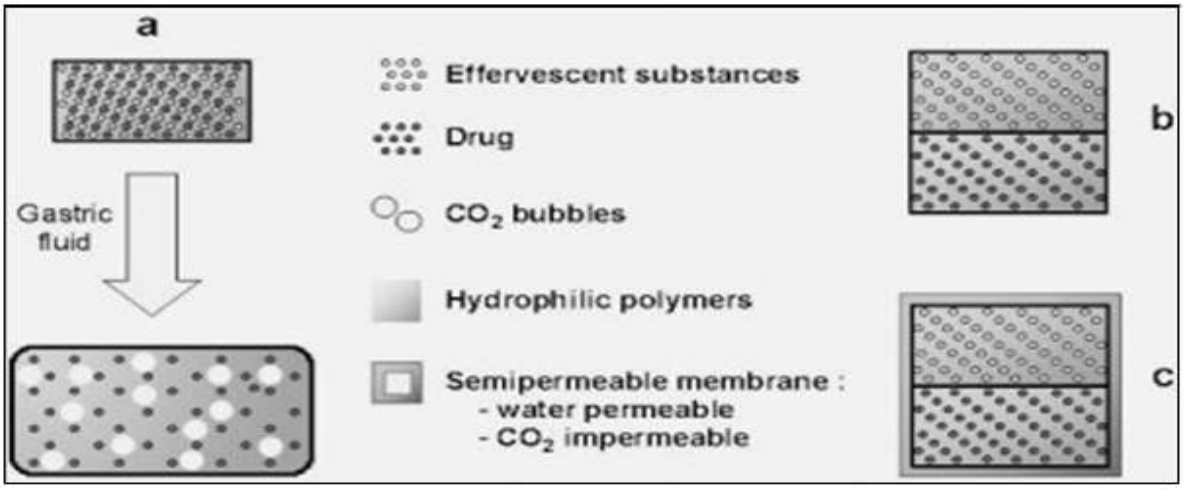
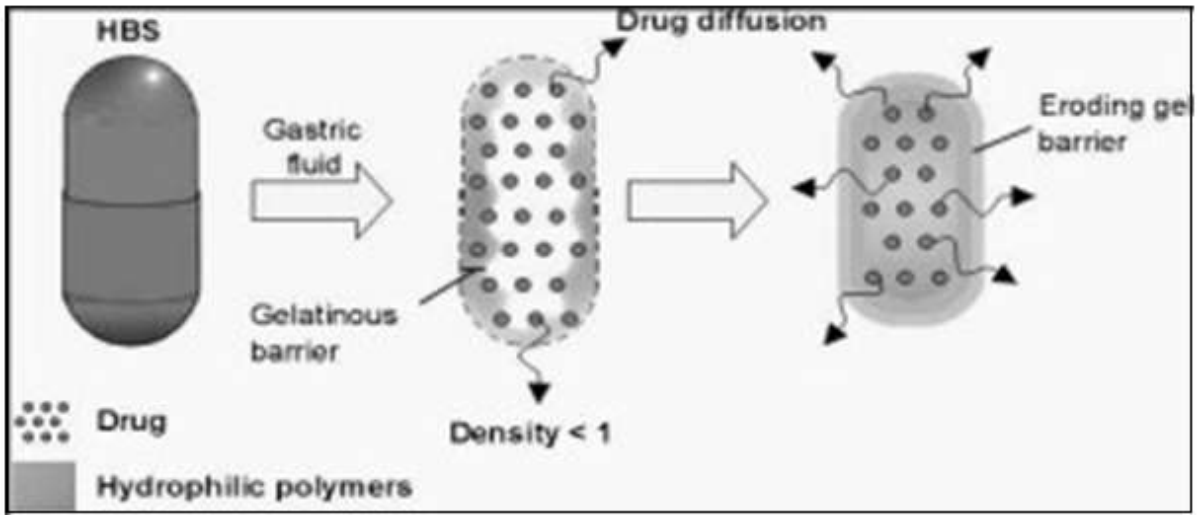


Gas generating systems: Schematic monolayer drug delivery system (a) Bilayer gasgenerating systems, with (c) or without (b) semipermeable membrane.

2) . Noneffervescent floating dosage forms:

Non-effervescent FDDS includes low density systemsand hydrodynamic balance system (HBS) (Figure 1.3.5). Most commonly used The excipients of non-effervescent FDDS are gel-forming or highly swelling cellulose hydrocolloids, polysaccharides and matrix-forming polymers such as polycarbonate, polyacrylate, gomethacrylate and polystyrene. These gel-forming hydrocolloids swell contact with gastric juices after oral administration and maintain relative integrity in shape and apparent density is less than one in the outer colloidal barrier. Gas is trapped due to swelling polymers provide buoyancy to these dosage forms. In addition, the gel structure also acts as a reservoir so that drug release is sustained as the drug is released slowly by controlled diffusion through glue fence.

Hydrodynamically balanced system (HBS). The gelatinous barrier formation resultsfromhydrophilic polymer swelling. Drug is released by diffusion and erosion of the gelbarrier.



3) . Raft forming Systems:

Here, the gelling solution (e.g. sodium alginate solution containscarbonate or bicarbonate) swells and forms a viscous gel containing trapped CO 2Bubbles come into contact with gastric juice. Formulations also often contain antacids such as aluminum hydroxide or calcium carbonate to reduce stomach acid. Because of raft formation

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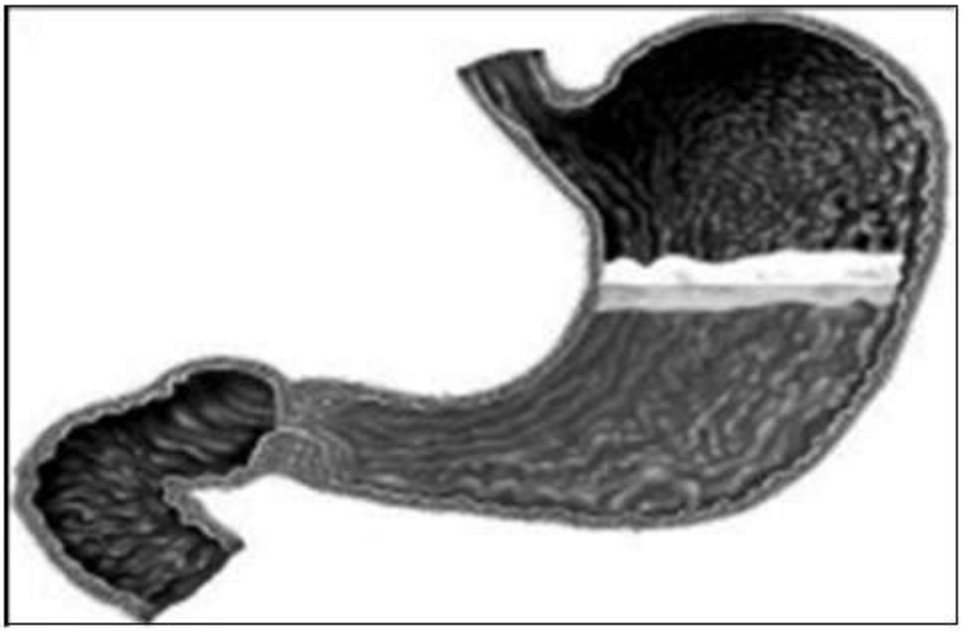
system that creates a layer over gastric juice, they are often used for gastroesophageal reflux treatment.



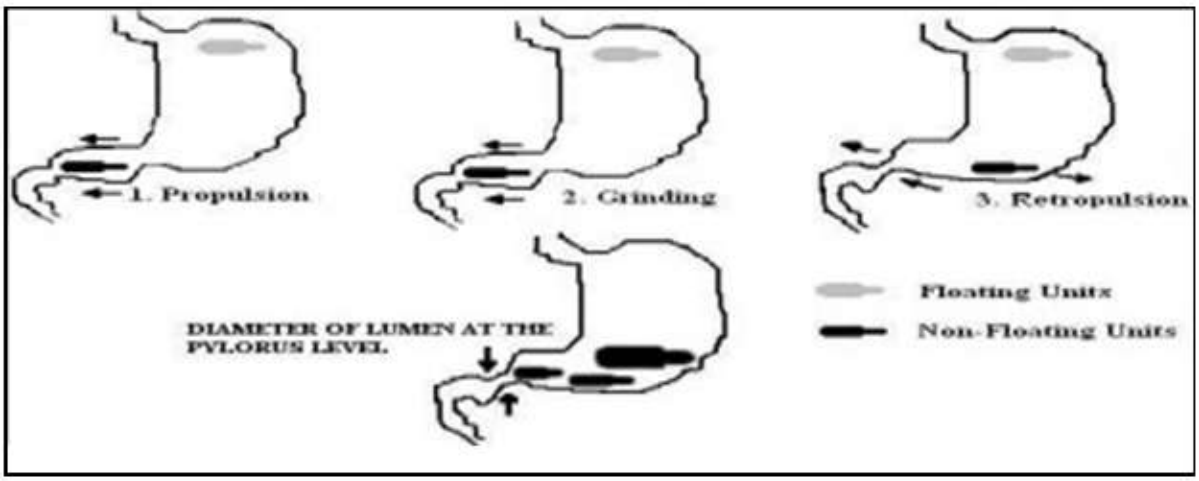
Schematic illustration of the barrier formed by a raft forming system.

1.3.8 APPROACHES TO DESIGN FLOATING DOSAGE FORM

The following approaches have been used for the design of floating dosage forms of single and multiple unit systems

1) Single unit dosage forms:

Floating unit dosage form is formulated into tablets or capsules using any technology such as the use of a low concentration dispersed drug matrix density polymers such as polyethylene oxide or the use of gas-forming agents within the polymer matrix.



Intragastric residence positions of floating and nonfloating units.

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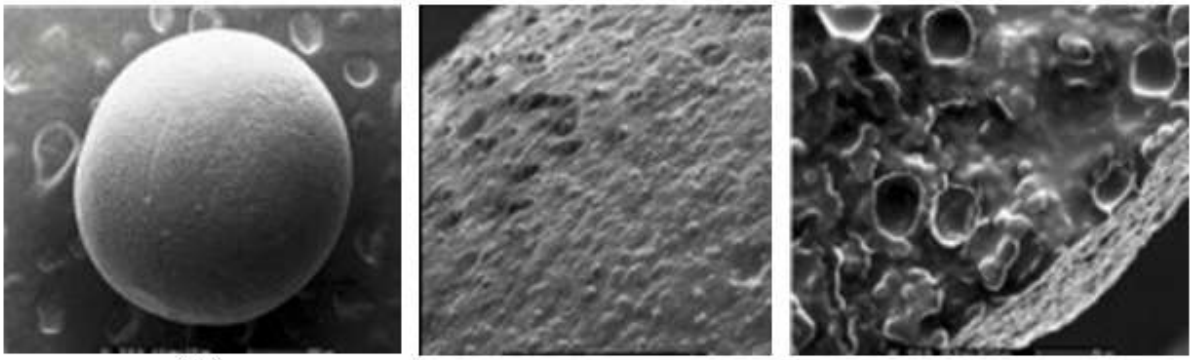
A floating dosage form can also be achieved using a system filled with a clear floating liquidstomach. Liquid-filled flotation chamber dosage forms include incorporating a gas-filled flotation chamber into the microporous component containing the drug reservoir. Gap or holes along the upper and lower walls through which fluid flows from the digestive tract goes in to dissolve the drug. The remaining two walls exposed to the liquid are sealed toThe insoluble medicine is still there. Different types of pellets (two-layer and base pellets) have been found to have buoyancy properties. Some of the polymers used are hydroxypropylcellulose, hydroxypropylmethylcellulose,Crosspovidone, sodium carboxymethylcellulose and ethylcellulose. Unitary formulations are associated with problems such as sticking or blockage in the digestive tract, which may pose a risk of irritation.

2) Multiple-unit dosage forms:

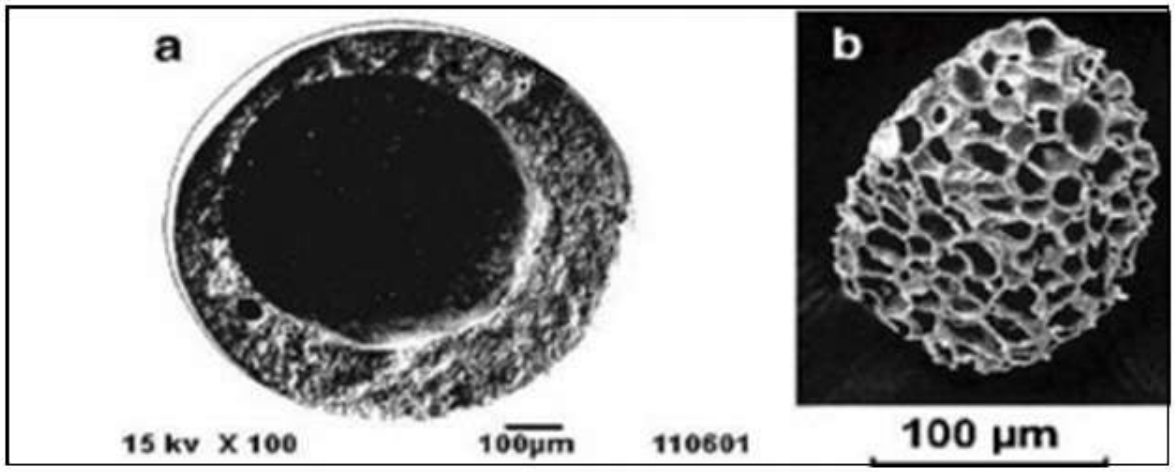
The purpose of designing a multi-unit dosage form is todevelop a reliable formulation that has all the advantages of a single form and also does not There are none of the above mentioned disadvantages of unitary formulas. In this pursuit Many multi-unit floating dosage forms have been designed such as;Free-floating microspheres are prepared from polymers such as albumin, gelatin, starch,gomethacrylate, polyacrylamine and polyalkylcyanoacrylate.

Microscope Have ONE characteristic hollow internal structure and exhibits excellent buoyancy in vitro.Low density oil and CO2 trapping particles (Figure 1.3.8) were also prepared using polymers such as pectin, sodium alginate and chitosan.



Scanning electron micrographs of (a and b) external and (c) internal structures of calcium pectinate containing olive oil

Spherical polymeric microsponges also referred to as “microballoons,” have been prepared(Fig.1.3.9).



Microballoons (a) and foam particles (b).

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Some devices have a feature that expands, opens or inflates using carbon dioxide generated internally.The following devices used have been described in recent patent documents. These dosages forms are excluded from the passage of the pyloric sphincter if their diameter is about 12 to 18 mm extended state is exceeded.

II. . OBJECTIVES OF THE WORK

The purpose of this study is to develop a FDDS formulation containing ofloxacin, will remain in the stomach for a long time to maximize drug bioavailability.

Research objectives include:

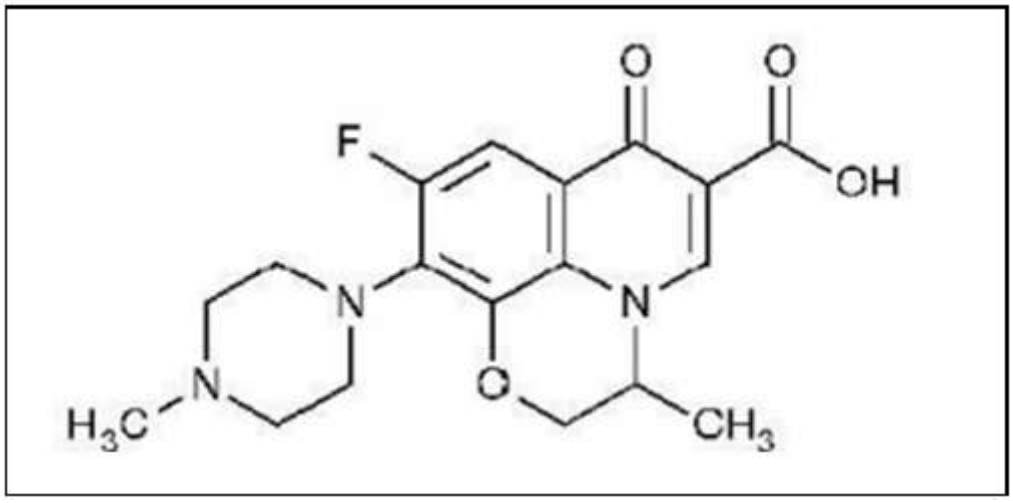
1. Develop analytical methods to estimate drug content in the formula.
2. Perform pre-formulation studies on possible drug and polymer interactions differential scanning calorimetry and infrared spectroscopy.
3. Growth and formation of floating particles trapped in the oil (stomach) of ofloxacin.
4. Evaluate the prepared dosage form based on various parameters such as size andSurface morphology by scanning electron microscope, drug content, drug substance trapping efficiency, swelling index and buoyancy properties.
5. Conduct ofloxacin release studies from in vitro formulations using conventional USP dissolution method.
6. Systematically study the contribution of some formula variables to growth drug release rate and buoyancy properties of FDDS.
7. Conduct short-term stability studies on the most satisfactory formulations according to ICH guidelines

III. REVIEW OF LITERATURE :

DRUG PROFILE [13, 14]
OFLOXACIN

Systematic (IUPAC) name:
RS)-7-fluoro-2-methyl-6-(4-methylpiperazin-1-yl)-10-oxo-4-oxa-1- azatricyclo[7.3.1.0]trideca-5(13),6,8,11-tetraene-11-carboxylic acid

Chemical structure



Synonyms: (+)-9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid

Molecular formula:- C18H20FN3O4

Molecular weight:- 361.38

Solubility: Soluble in glacial acetic acid; slightly soluble in water, methylene chloride andmethanol.

Description: Its pale yellow or bright yellow, crystalline powder.

Ofloxacin contains not less than 98.5percent and not more than 101.5percent of C18H20FN3O4, calculated on the dried basis.
Category: Antibacterial fluoroquinolone

Available forms:
Ofloxacin for systemic use is available in tablet form (various strengths), orally.solution for

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

injection (250 mg/ml) and solution for injection (multiple doses). It is also used as eye dropstrade name Exocin, known as Ocuflox in the United States) and ear drops (Floxin Otic and"Cetraxal Otic"). Ofloxacin is also used in animals. Its veterinary formulation is sold underMarfloxacin.

Pharmacokinetic data:
Bioavailability: 85% - 95%
Protein binding: 32%
Half-life: 8-9 hours
Routes: Oral, IV, topical (eye drops and ear drops)

Mode of action:

Ofloxacin is a broad-spectrum antibiotic active against gram-positive and gram-negative bacteria. It works by inhibiting DNA gyrase, type II topoisomerase and topoisomerase IV, which is an enzyme necessary for separation DNA, thereby inhibiting cell division. Fluoroquinolone interferes with DNA replication byInhibits an enzyme complex called DNA gyrase. It can also affect mammalian cells replication. In particular, some congeners of this drug family have high activity not only against bacterial topoisomerases but also against eukaryotic topoisomerases and is toxic to cultured mammalian cells and in vivo tumor models. Although quinolones are highly toxic to mammalian cells in culture, its cytotoxic mechanism of action is unknown. Recent studies have demonstrated a correlation between the cytotoxicity of quinolones on mammalian cells and induction of micronuclei. Therefore, some fluoroquinolones can damage your chromosomes eukaryotic cells.

Pharmacology

The bioavailability of ofloxacin in tablet form is approximately 98–44 days after oral administration, reaching peak serum concentrations within 1 to 2 hours.Between 65% and 80% of an orally administered dose of ofloxacin is excreted unchanged kidney within 48 hours after taking the medicine. Elimination is therefore mainly by renal excretion. However,4 to 8% of the ofloxacin dose is excreted in the feces. This will indicate a small portionThe degree of bile secretion is also present. Plasma half-life is approximately 4 to 5 hours.patients and approximately 6.4 to 7.4 hours in elderly patients.

Pharmacokinetics

After multiple doses of 200 mg and 300 mg, peakExpected serum concentrations were 2.2 µg/ml and 3.6 µg/ml, respectively, at steady state. In vitro,About 32% of the drug in plasma is bound to proteins. Ofloxacin is widely distributed inbody tissues. Ofloxacin has been detected in vesicular fluid, cervix, lung, ovarian and prostate tissue.fluid, prostate tissue, skin and phlegm. The pyridobenzoxazine ring appears to reduce levels metabolism of the parent compound. Less than 5% is excreted by the kidneys as desmethyl or Noxide metabolites; 4% to 8% in feces. There are several endogenous compounds has been reported to be affected by ofloxacin as an inhibitor, a surrogate, and a reducing agent.

Contraindications

Ofloxacin is currently considered contraindicated for treatment Some sexually transmitted diseases are caused by drug-resistant bacteria. Due to the growing popularity of Fluoroquinolone antibiotic resistance in Southeast Asia, ofloxacin use in patients People who have traveled to Southeast Asia are increasingly contraindicated. Use caution in patients with liver disease. The excretion of ofloxacin may be reduced in patients with severe liver function.disorders (eg, cirrhosis with or without ascites). Ofloxacin is also considered Contraindicated in children, during pregnancy, nursing mothers, patients withpsychiatric illness and in patients with epilepsy or other seizure disorders. Pregnancy:Research indicates that fluoroquinolones can rapidly cross the blood-placental barrier andblood milk barrier and widely distributed in fetal tissues. Maximum concentration in human milk are similar to levels achieved in plasma. Used by mothers who are breastfeedingofloxacin may cause serious side effects in a newborn baby. It is for this reason that the prescription of ofloxacin is contraindicated during pregnancy due to the risk of spontaneous abortion and stillbirthdefault.

Pediatric Use:

Oral and intravenous fluoroquinolones, including ofloxacin, are not approved by the FDA use in children due to the risk of permanent damage to the musculoskeletal system. in onestudy, it was stated that pediatric patients had a 3.8% risk of developing a serious problem.musculoskeletal adverse events. Therefore, there is a current ban on the use of ofloxacin and other drugs fluoroquinolones in children seems reasonable and is supported byVarious clinical studies. The risk of permanent injury may outweigh the potential benefits.

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Adverse effects:

Serious side effects occur more frequently with fluoroquinolones than with fluoroquinolonesany other antibiotics. Ofloxacin may cause peripheral neuropathy (irreversible).nerve damage), tendon damage, heart problems (prolonged QT interval/torsades de pointes),pseudomembranous colitis, rhabdomyolysis (muscle atrophy), Stevens-Johnson syndrome. THEadverse psychiatric events, as well as on the central nervous system and peripheral nervous systemThe association with ofloxacin has been well documented in the literature. C:\Documents and Settings\home07\Desktop\k\nisha\Theis\Articles\profiles\Ofloxacin.htm - cite_note-pmid10970974-76

Liver damage and blood sugar disorders have been associated with ofloxacin. More tension in 2005 ofloxacin-associated rhabdomyolysis. Reports of hepatotoxicity or severe hepatotoxicity,Hypersensitivity vasculitis occurring after treatment with ofloxacin has also been reported.Elderly patients may be at increased risk of tendinopathy (including tendon rupture), especially in casesconcomitant use of corticosteroids and these patients may also be more susceptible to prolonged treatment.QT interval. Prolonged patients, those with hypokalemia or on treatment withOther drugs that prolong the QT interval should be avoided with ofloxacin. Hematology Allergic reactions (including agranulocytosis, thrombocytopenia) and nephrotoxicity may follow several doses.

Interactions

Take ofloxacin, with magnesium or aluminum antacids, sucralfate orproducts containing calcium or iron may significantly reduce the absorption of ofloxacin,resulting in serum and urine concentrations that are significantly lower than desired. System management Ofloxacin has been shown to interfere with caffeine metabolism, increasing plasma concentrationstheophylline concentrations and enhances the effects of warfarin and its derivatives.Fluoroquinolone has an inhibitory effect on the cytochrome P-450 system, thereby reducing clearance of theophylline and increased blood theophylline concentration. The use of NSAIDs (noSteroid anti-inflammatory drugs are contraindicated during fluoroquinolone treatmentdue to the risk of serious central nervous system adverse reactions, including but not limited to seizure disorders.Fluoroquinolone has been shown to increase the anticoagulant effect of acenocoumarol.anisindione and dicoumarol. In addition, there is an increased risk of cardiotoxicity and toxicityarrhythmia when used concurrently with drugs such as dihydroquinidine barbiturate, quinidine,and quinidine barbiturate. Fluoroquinolones have also been reported to interact with GABA A receptor and cause neurological symptoms; this effect is augmented by certain nonsteroidal anti-inflammatory drugs.

Current or previous treatment with oral corticosteroids isassociated with an increased risk of Achilles tendon rupture, especially in elderly patients also use fluoroquinolones. Interactions may occur between oral hypoglycemic agents (e.g.,glyburide/glibenclamide) with insulin and fluoroquinolone antimicrobials have been reportedleading to enhanced hypoglycemic effects of these drugs.

Overdose

Current advice on the management of acute ofloxacin overdose is exhaustedstomach, with close observation and ensuring that the patient is treated properly.hydrated. Hemodialysis or peritoneal dialysis have only limited effectiveness. Overdose is possiblecause central nervous system toxicity, cardiovascular toxicity, tendon/joint toxicity andliver toxicity as well as kidney failure and seizures. However,seizures have been reported occur at therapeutic doses as well as serious psychiatric reactions. Patient serum concentrationshould be monitored during treatment to avoid drug overdose.

EXCIPIENT PROFILE

LOW METHOXY PECTIN (LMP) 15, 16

Non proprietary name:

Unites states pharmacopoeia:- Pectin

Synonyms Citrus pectin; E440; methopectin; methyl pectin; methyl pectinate; mexpectin;pectina; pectinic acid.

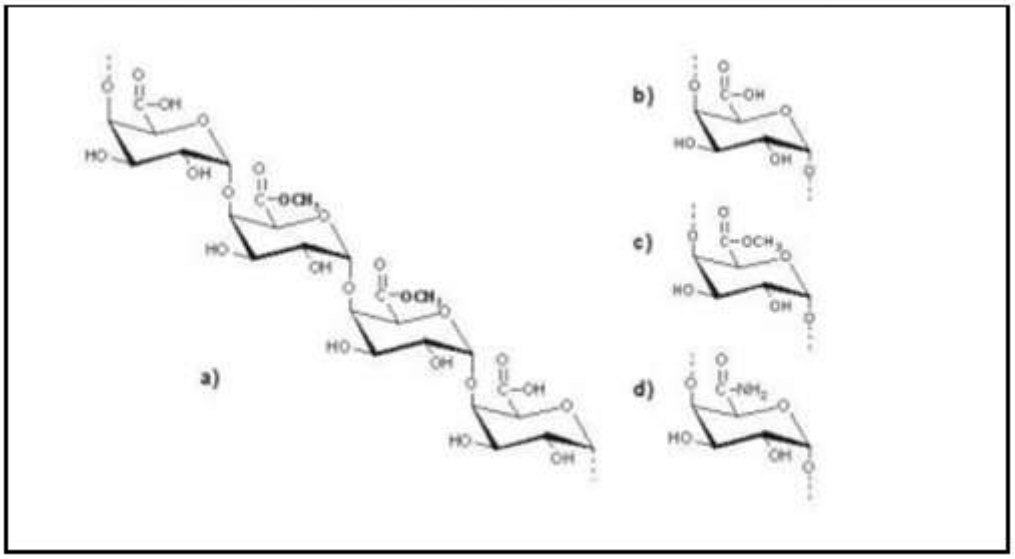
Chemical Name:-Pectin

Empirical formula and molecular weight:

Pectin is a high-molecular-weight, carbohydratelike plant constituent consisting primarily of chains of galacturonic acid units linked as 1,4-ceglucosides, with a molecular weight of 30000-100000.

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Structural formula



(a) A repeating segment of pectin molecule and functional groups
(b) Carboxyl; (c) Ester; (d) Amide in pectin chain.

Pectin is a complex polysaccharide consisting mainly of D-galacturonic acid residues esterified inα-(1-4) chain. The acid groups along the chain are largely esterified with internal methoxy groups natural products. Hydroxyl groups can also be acetylated. Esterification rate The galacturonic acid groups relative to the total galacturonic acid groups are called the degree of esterification.BELONG TO). DE- based pectins are high methoxy (HM) pectin and low methoxy pectin.(LM) pectin. The DE value of commercial HM pectin is typically between 60 and 75%, and thosefor LM pectin, they vary from 20 to 40%. Low methoxy pectin gels with calcium ions and does notdepending on the presence of acids or high solids content.

Functional category:- Adsorbent; emulsifying agent; gelling agent; thickening agent; stabilizingagent.
Description: Pectin occurs as a coarse or fine, yellowish-white, odorless powder that has amucilaginous taste.

pH 6.0–7.2
Solubility:- Soluble in water; insoluble in ethanol (95%) and other organic solvents.

Stability and storage conditions: Pectin is a nonreactive and stable material; it should be stored ina cool, dry place.
Stability and storage conditions:
Pectin is used in pharmaceutical and oral formulations and is commonly used considered a fundamentally non-toxic and non-irritating material. Low subcutaneous toxicity a route has been assigned.

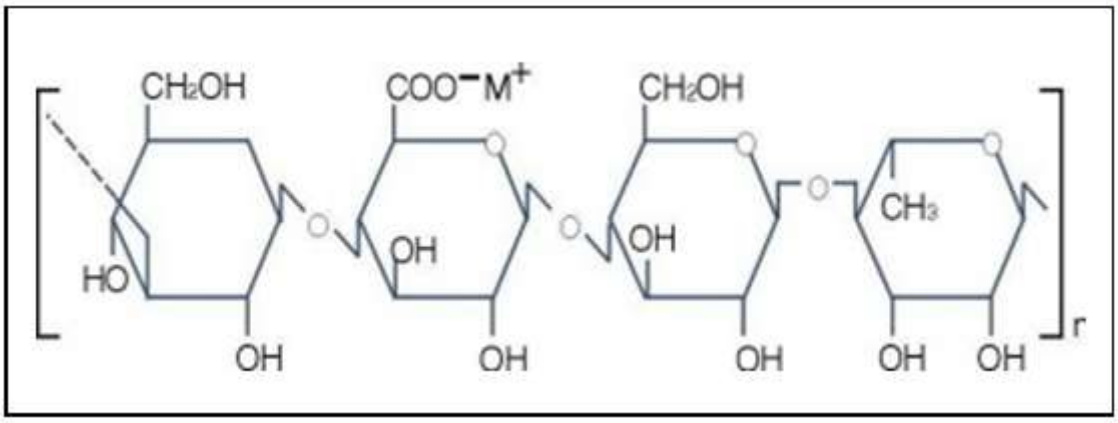
Mode of action:
Pectin has been used as an adsorbent and bulking agent, and is present inMulti-ingredient preparations for the treatment of diarrhea, constipation and obesity; he has also been used as an emulsion stabilizer. Pectin gel beads have been proven to be effective environment to control drug release in the gastrointestinal tract. Low methoxy contentPectin has been shown to have a release rate that is more sensitive to the calcium content in it recipe.

3.2.2 GELLAN GUM [17, 18, 19, 20]

Brand Names: Kelcogel®, Gelrite®, Phytagel, Gel-Gro

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Structure:-



Gellan gum is a high molecular weight polysaccharide (i.e. complex sugar) gum produced as Fermented products by pure culture of Sphingomonas eodea bacteria and includeTetrasaccharide repeating units of 1,3-D-glucose, 1,4-D-glucuronic acid, 1,4-D-glucose and 1,4-Lrhamnose. The producing organism is an aerobic, non-pathogenic, well-characterized Gram-negative bacterium. The general chemical structure of gellan gum is shown in the chemical diagram above.structure. Its structure consists of four linked monosaccharides (i.e. simple sugars), among whichone molecule of rhamnose (a sugar found in many plants), one molecule of glucuronic acid (aoxidized glucose molecule) and two glucose molecules (a component of sucrose, which isregular road). The exact molecular formula of gellan gum may vary slightly (e.g. depending onon the degree of neutralization of glucuronic acid with different salts. There are three basic principles form of gellan gum products, distinguished by their polysaccharide content, Percentage substitution of o-acetyl functional groups and/or protein content (including groupsresidues and other organic nitrogen sources).

Description: Off white powder
Formula weight: 70,000 Daltons with 95% 500,000 Daltons
Bulk density:- Approximately 836 kg/m3
Solubility: Soluble in water, forming a viscous solution; insoluble in ethanol
pH (1% solution): Neutral
Moisture content: 98.6%wb or 67.6% db
Loss on drying: Not more than 15% (105°, 2½h)
Gel strength: 550-850 (gm/cm)
Specific gravity: <1
Stability:- Stable at room temperature
Application Areas:-

Consumer Products: Air freshener gels
Microbiological: Plant tissue culture
Personal Care: Fluid-gel lotions and creams, suntan lotions, hair care products, eye makeup and foundation makeup, face masks and peels

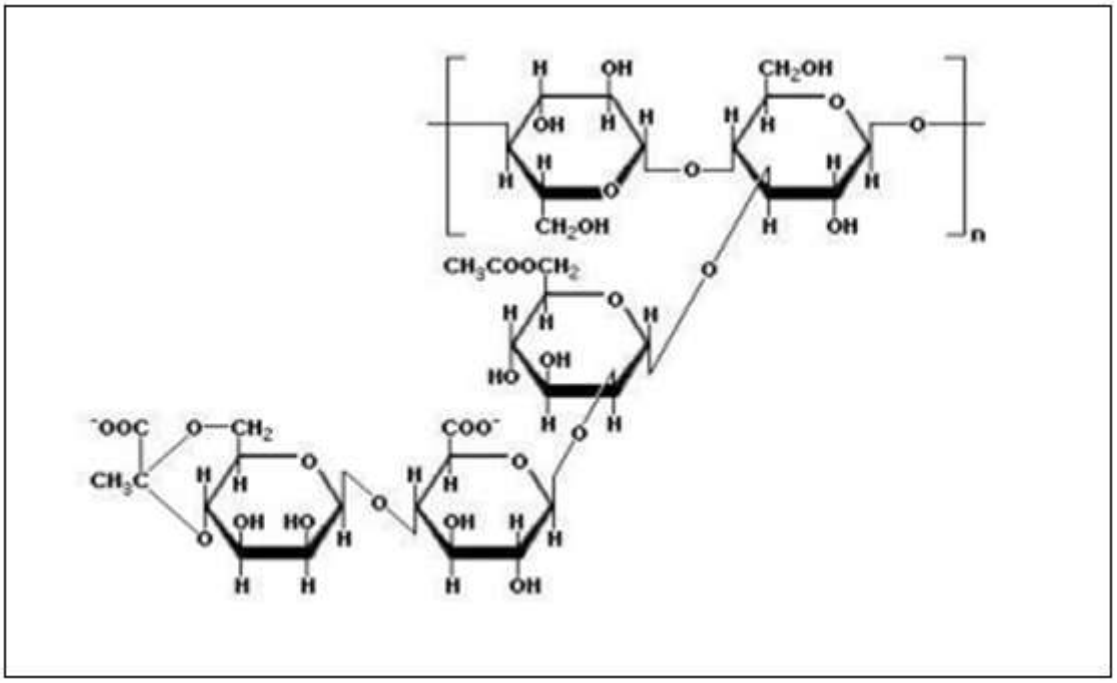
Oral Care: Toothpastes
Food industry: bakery fillings, confections, dairy products, dessert gels, frostings, icings and glazes, jams and jellies, low-fat spreads, microwavable foods, puddings, sauces, structured foods, and toppings.

Pharmaceutical: Encapsulation; novel drug delivery systems, including oral, mucosal and transdermal, tablet disintegration, and controlled-release applications

3.2.3 XANTHAN GUM [21, 22]
Non proprietary name:
Unites states pharmacopoeia: Xanthan gum
Synonyms:- Corn sugar gum; E415; Keltrol; polysaccharide B-1459; Rhodigel; Vanzan NF; Xantural
Chemical Name: Xanthan gum
Empirical formula and molecular weight:
C35H49O29)n. Xanthan gum is a high molecular weight compound polysaccharide gum by weight. It contains D-glucose and D- mannose as the predominant hexose units,with D-glucuronic acid and prepared as sodium, potassium or calcium salts

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Structure



Xanthan gum is a polysaccharide with a β-D-glucose backbone like cellulose, but every second glucose unit is attached to a trisaccharide consisting of mannose, glucuronic acid and mannose. The mannose closest to the backbone has an acetic acid ester on carbon 6, and the mannose at the end of the trisaccharide is linked via carbons 6 and 4 to the second carbon of pyruvic acid. Xanthan gum is produced by the bacteria Xanthomonas campestris, found on cruciferous vegetables such as cabbage and cauliflower. The negatively charged carboxyl groups on the side chains cause the molecules to form a very viscous liquid when mixed with water. Xanthan gum is used as a thickener for sauces, prevents ice crystals from forming in ice cream, and as a low-calorie substitute for fat. Xanthan gum is often mixed with guar gum because the viscosity of the combination is greater than when used individually.

unctional category: Stabilizing agent; suspending agent; viscosity-increasing agent
Description:- Xanthan gum occurs as a cream- or white-colored, odorless, free-flowing, fine powder.
pH: 6.0-8.0 for a 1% w/v aqueous solution
Solubility: Practically insoluble in ethanol and ether; soluble in cold or warm water.

Stability and Storage Conditions:

Xanthan gum is a stable material. Aqueous solution isstable over a wide pH range (pH 3-12), although they exhibit maximum stability at pH 4-10 and temperatures from 10 to 60°C. Xanthan gum solutions with concentrations less than 1% w/v can beAffected by temperatures above room temperature:for example, viscosity is reduced. THELoose materials must be stored in tightly closed containers in a cool, dry place.

Safety:

Xanthan gum is widely used in oral and topical pharmaceutical formulations, cosmetics,and foods and are generally considered non- toxic and non-irritating at the levels used as pharmaceutical excipients.

Applications:

Xanthan gum is widely used in oral and topical pharmaceutical formulations, cosmetics,and foods and are generally considered non- toxic and non-irritating at the levels used as pharmaceutical excipients.

3.2.4 KARAYA GUM [23, 24, 25, 26]
Scientific Name (s):

Sterculia urens Roxb. Family: Sterculiaceae. The gum also may be obtained from S. villosa, S. tragacantha, or other species of Sterculia.
Common Name(s):- Karaya, sterculia, Indian

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

tragacanth, Bassora tragacanth, kadaya, mucara,kadira, katila, kullo.

Synonym: Chemtrec **Physical Characteristics:**

The highest quality karaya gums are white, translucent and almost no shell left. Lower grades range in color from light yellow to brown and can contain up to3% insoluble impurities. Karaya gum powder is white to grayish white.

Solubility:-

Karaya gum, like tragacanth gum, is insoluble in water forming a clear solutionbut rather forms a colloidal sol. Powdered karaya gum swells in cold water to a level of 4% 3D44 sol which will produce a thick gel of uniform softness and texture. To be higherconcentration, it is necessary to cook the gum under steam pressure to dissolve. A 25% solution of 20D44 can be prepared in this way. It produces a thick, syrup-like liquid. Karaya eraser will form viscous soil in alcohol solutions containing up to 60% to 35% alcohol concentration.

Viscosity:-

The viscosity of karaya gum depends largely on its freshness, that is, itit has recently been harvested from the tree. Viscosity is affected by climatic and conditions evolution. Viscosity is also affected by storage. Powdered Karaya will lose its viscosity after being stored for more than 6 months. Karaya gum soil is very sensitive to alkalinity and peaksviscosity at pH 8.5. Above this pH level, the soil tends to become hard.

Chemical Characteristics:

Karaya gum is a complex high molecular weight polysaccharide.A molecular weight of up to 9,500,000 has been reported. By hydrolysis, it produces galactose,rhamnose and galacturonic acid. Karaya gum comes as a partially acetylated derivative. AcidThis number ranges from 13.4 to 22.7. The change in acid number is not affectedonly according to the origin of the sample but also according to the age of the sample. Gum has the special property of splittingfree acetic acid and this loss is loosely correlated with particle size. Trimethylamine does were also identified in the hydrolysis products. Karaya gum contains 12-14% moisture andless than 1 insoluble ash id.

pH:

The pH of a 1% gum karaya solution is 4.6. If small amounts of alkali are added to changethe pH to 7 or 8, the gum tends to have a buffering action effect and will gradually reduce the pH again to the acid size

Compatibility:-

Karaya gum is compatible with other plant hydrocolloids as well as proteins andcarbohydrates. There is an apparent incompatibility between karaya gum gel and pyrilamineMaleate, a hydrotrope and powerful antihistamine. Electrolytes also reduce viscosity as well excess acid. The alkali causes the gel to have a fibrous appearance.

Preservatives:

Karaya soil and jelly require preservatives because they are susceptiblebacterial attack. They are easily preserved with a mixture containing a maximum of 0.17% methyl and0.03% propyl o-hydroxybenzoate as well as with glycerin and propylene glycol. Like benzoic acid as well as sodium benzoate at a concentration of 0.1% will effectively protect karaya soil.

Uses:-

Industrial Application:In the oil and gas production industry, karaya gum is usedin drilling fluid formulations to remove lime deposits in wells. Added Karaya eraserlime-based drilling fluid to prevent dehydration after reducing viscosity by heating in90oc. for 10 hours.

Paper and pulp:Karaya gum is used in the paper industry to produce a number of gradesexceptional quality papers. It flattens the fibers and acts as a fiber binder. Use eraser karaya offers light exercises to improve strength and conditioning.

Leather and related products:In the leather industry, it is used as an ingredient in apparel.compositions and proportions that allow the tannic action of heavy preparations to be accelerated. GumKaraya is also used in the production of collagen fibers.

Other industrial products:Lower quality gum acts as a more effective binder in briquettes (masses of compressed coal dust). Textile:Karaya gum in powder form is used as an adhesive in many fabrics.

Career.

Medicinal uses:Karaya gum is also used to treat constipation, liver disease, and as a laxative. Also used forPenetration aids through gum powders, pastes, rings, discs, cardboard

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

sheetsBeneficial immediately after post-surgical treatment for sensitive skin/skin or to soothe skin,less likely to create a sweet taste and darker color, creating conditions for microorganisms to grow.

- Cosmetics: Gum karaya's film-forming properties make it useful in hair styling.styling lotions and finger lotions used in the beauty industry.
- Other uses:Also used in linoleum, enamel, jelly, varnish, ink, rubber preparations, oils.fabric, paper coating, polishing and engraving process.
- Pharmaceutical industry:The majority of karaya is used in two products. In the first product,Bulk laxative, karaya is typically processed in sizes ranging from 8 to 30 mesh. By absorbing water, coarseThe granules swell greatly, forming a very effective intermittent mucus. laxative.

The second important product is denture adhesive in which finely ground chewing gum is sprinkledplaque and swell when it touches the moist surface of the gums. This yields oneComfortable and tight fit of the sheet.

Solubility:-

Powdered chewing gum should be stored in an airtight container. Gum must be dried (sun/traydry) properly before putting it in the bag. Store in a cool, well-ventilated place. Ground everythingmaterial storage equipment. Flammable materials must be stored in high temperature areas and keep away from strong oxidizing agents.

RICE BRAN OIL [27, 28, 29]
Origin: Vegetable
Production Process: Pressed from rice bran, followed by an extraction, dewaxing, bleaching, deodorization and winterization process

Rice bran oil :-

s the oil extracted from the germ and inner husk of rice. It is notable for its veryhigh smoke point of 490 °F (254 °C) and its mild flavor, making it suitable for high-temperature cooking methods such as stir frying and deep frying

Physical characteristics:-
Appearance at 20 °C: Liquid Colour: Pale yellow
Odour: Typical Taste: Neutral
Density at 20 °C: 0.916 - 0.922
pH: 3.0 - 12.0

Properties: Medium greasy emollient, Long lasting skin feel, like Jojoba oil, Heat stable, Rich in tocotrienols and tocopherols.
Application: Creams and lotions, Foot care, Cosmetic for dry skin, Bath oils, Sun care

ZINC CHLORIDE [30, 31]
Synonyms: Zinc Chloride, Zinc Dichloride, Zinc Butter
Molecular Weight: 136.30
Chemical Formula: ZnCl2
Appearance: White crystalline granules, hygroscopic
Odor: Odorless
Solubility: 423 g/l00 g water at 25 0C (77 oF), soluble in ethanol, glycerol and acetone
Density: 2.91

Zinc chloride :-

Is the name of a chemical compound with the formula ZnCl2 and its hydrates. zincchloride, of which nine crystalline forms are known, is colorless or white and very soluble Water. ZnCl2 itself is hygroscopic and even watery. Therefore, the sample must be protectedfrom moisture sources, including water vapor in the surrounding air. Discover zinc chloride Widely applied in textile processing, metallurgical streams and chemical synthesis.

Applications:
As a metallurgical line, in organic synthesis, in textile processing, smoke bombs,Fingerprint detection, disinfection

Safety considerations:

Zinc chloride is a skin and respiratory irritant. Precautions that apply to anhydrous ZnCl2 are those applicable to other anhydrous metal halides, i.e. hydrolysis can be exothermic and contact should be avoided. Concentrated solutions are acidic and corrosive and specifically attack cellulose and silk as Lewis acids.

3.2 REVIEW OF WORK DONE ON OFLOXACIN: [32-35]
¾ **Arunachalam A et al,** developed ofloxacin-containing gelatin microspheres, which wereprepared by the coagulation phase separation method. The microspheres were analyzed for the presence of drugstrapping, bulk density, angle of repose, particle size and release pattern in vitro. DistinctiveA batch of microspheres is prepared by transforming the drug substance:polymer ratio and cross-linkingwith glutaraldehyde. They have a

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

spherical shape, as evidenced by microscopic images andscanning electron microscope and has a size range of 42 to 45 µm. Rate of drug-related traps is between 78 and 90% and they can sustain drug release for a period of 8 hours.

¾ **Abraham S et al,** have developed that, low bioavailability and therapeutic response are demonstratedwith common eye drops because the drug can be eliminated quickly before the cornea.remedied using a topical gel-forming system administered as eye drops and then undergoes a dead- end sol-gel transition. This work describes these Develop and evaluate a delivery system for antibacterial drugs into the eye ofloxacin, based on the concept of ion-activated in situ gelation. Sodium alginate is used asGelling agent combined with hydroxypropylcelluloseacts as a viscosity increasing agent. These formulations are therapeutically effective, sterile, stable andensure sustained drug release over a period of time.

¾ **Janardhan D et al,** developed the ofloxacin gastric retention drug delivery system to improvebioavailability by keeping it in the acidic environment of the stomach. Distinctive Formulations are formulated using varying concentrations of hydroxypropylmethylcellulose, sodium carboxymethylcellulose, sodium bicarbonate and citric acid. THEThese formulations have been evaluated for quality control testing and all physical parameters evaluated are within the acceptable limits of the Indian Pharmacopoeia. All recipesThe solubility was studied in vitro and compared with the commercially available formula.

¾ **Sangeetha S et al,** Control of ofloxacin sodium alginate nano formulationsgelation method and evaluation of its in vitro release properties. Particle sizeAnalysis was performed using a scanning electron microscope and the size range found was 656.6 ± 0.28nm. The carrying capacity of sodium alginate was evaluated pharmacologicallyThe polymer ratio and maximum drug amount are 33.2% for the 20 mcg/ml batch. AndWhere drug concentration increases, drug loading capacity decreases.The study showed that the drug was released from the nanocells by the Fickian diffusion process.with an acceptable version.

REVIEW OF WORK DONE ON POLYMERS: [36-42]

¾ **Badve S et al,** developed hollow calcium pectinate beads to release flotation substances pulsaticallydiclofenac sodium for timed drug therapy. The concept of being angry has beenapplied to increase gastric residence of a dosage form that has a lag phase followed by a phaseexplosive release. To overcome the limitations of different methods to transmit buoyancy force,Hollow/porous particles were prepared by a simple acid-base reaction procedure in an ionotropic reactioncross-linking. The resulting floating pellets are spongy (porosity 34%), hollow in volume density <1 and has 50% from 14 to 24 hours. In vivo studies using gamma scintigraphy determined aboveRabbits showed the ability to retain seeds in the stomach for up to 5 hours. Floating particles provide the expected biphasic release pattern with an initial lag time during flotation in acidic media, followed by rapid separation.pulse release in phosphate buffer.

¾ **Narkar M et al,** developed hollow calcium pectinate beads to release flotation substances pulsaticallydiclofenac sodium for timed drug therapy. The concept of being angry has been applied to increase gastric residence of a dosage form that has a lag phase followed by a phaseexplosive release. To overcome the limitations of different methods to transmit buoyancy force,Hollow/porous particles were prepared by a simple acid-base reaction procedure in an ionotropic reaction cross-linking. The resulting floating pellets are spongy (porosity 34%), hollow in volumedensity <1 and has 50% from 14 to 24 hours. In vivo studies using gamma scintigraphy determined aboveRabbits showed the ability to retain seeds in the stomach for up to 5 hours. Floating particles provide the expected biphasic releasepattern with an initial lag time during flotation in acidic media, followed by rapid separation.pulse release in phosphate buffer.

¾ **Elmowafy et al,** developed and evaluated gel-like polysaccharides in ionotropic emulsionspearl. They used different types of polysaccharides (sodium alginate and pectin), oil concentrations(10%, 20% and 30% w/w) and medicine:polymer (D:P) ratio (1:twelfth:1 and 3:1) researchaffects particle uniformity, drug trapping efficiency and drug release in vitro. Surnameconcluded that the delay in drug release of 4 h was due to the hydrophobic oil diffusion barrier, especially in the presence of a dense network of alginate particles

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

¾ **Prasanthi NL et al,** propanolol hydrochloride double-layer tablets are developed by xanthanchewing gum, locust bean gum, guar gum with drugs:The gum ratio is 1:0.25, 1:0.5 and 1:1 eachwet granulation method. The immediate release layer of the tablets is formulated using a super disintegrant such as sodium starch glycolate and the extended release layer is prepared usingUse gums with different medicine/candyratios. The prepared bilayer tablets are round in shapeshape and convex with a diameter of 8 mm. The medicinal content of the formulations was foundfrom 98.9 to 101.7%. The release of propanolol HCl lasts up to 12 hours and depending on the concentration of the gum. Better supported release with xanthangum at concentration 1:first.

¾ **Mishra et al,** developed a gastric retention system with controlled release of loratidine to increaseresidence time of the drug in the stomach. To achieve this purpose, they prepared floating ships stuck in oil.micro particles. Microbial particles are prepared by emulsion gelation method using low methoxy contentpectin. Light mineral oil and castor oil were used to give buoyancy to the microparticles.They discovered that 15% oil was needed to give the balls satisfactory buoyancy.

¾ **Hagesaether E et al,** studied the mucoadhesive properties of hydrogels before swellinggranules made from six types of pectin from three manufacturers. Different types of pectin mainly in the degree of methoxylation and amidation degree. Zinc ions are used as cross-linking agents.Mucoadhesive properties were tested on a fresh upside-down minipig.The intestines are attached to a rotating cylinder. High pectin pearl content methoxylation (70%) gives superior mucosal adhesion results compared to other typesformula, which may correlate with the lower amount of zinc in this formula,which then leads to less number of cross-links and higher mobility of the polymer chains of these particles. This study therefore also points to the importance of implementationMeasures mucoadhesion on related formulations.

¾ **Park et al,** developed and evaluated floating particles from a sodium alginate solution containing calcium carbonate or sodium bicarbonate as the gaseous agent with riboflavin as the model drug. In vitro release studies have revealed that calcium carbonate is superior to sodium bicarbonate as a gas agent in alginate granule preparations, with sustained release properties and improved buoyancy, making them excellent Great for floating drug delivery systems.

REVIEW OF WORK DONE ON FLOATING DRUG DELIVERY SYSTEM: [43-48]

¾ **Sriamornsak et al,** developed a new emulsion method for the preparation of calcium trapped in oil Pectinate gel beads have the ability to float in the stomach. Influence of selected factorssuch as oil type, oil ratio and pectin type in terms of morphology and buoyancyproperties have been studied. They discovered that the balls float if there is enough oilhas been used. They also concluded that the type of oil also plays an important role in transmissionfloating attribute

¾ **Pahwa R et al,** tested that the floating drug delivery system is gastric retentionPrecisely control the target drug release rate to a specific location, creating favorable conditions forgreatly affects health care. This can be achieved using different types of polymerssubstances consisting of natural polymers. Large number of derived groups, wide range ofmolecular weight, chemical composition changes and gelation properties of these polymers also offers exciting opportunities in the exciting and applied field of polymer science drug distribution technology. All these characteristics make them suitable candidates for designand production of new gastric retention drug delivery systems. The present article highlights recent efforts and advanced approaches exploiting several natural polymers in this field technology.

¾ **Karande et al,** evaluate and compare various formal and informal dissolution devicesProposal for floating drug delivery system. Floating drug delivery system has been evaluated by placing them in a USP type 2 dissolver(pallet), put them into the spiral wire ballast and let them dissolvein an improved dissolution apparatus. The overall results show the revised methodprovides a more reproducible solubility profile; Eliminates the risk of dosage form floating cling to the oars

¾ **Ishak R et al,** developed chitosan-treated alginate beads with metronidazole (MZ), oneCommon antibacterial drug used in the treatment of H.pylori, using the ionotropic gel method. ONE A factorial experiment (3×2×2) was used in which three polymers provided viscositynamely methylcellulose, carbopol 934P and κ-carrageenan, 2 concentrations (0.2 and

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

0.4D44 w/v) of chitosan as an encapsulated polymer and 2 concentrations (2.5 and 5% w/w) of low Magnesium stearate density as a flotation aid was tested. The effectiveness of drug trapping(%), percentage of floating particles and time required to release 80% of drug (T80%)are the responses that are evaluated. Granule formulation containing 0.5% κ-carrageenan, 0.4D44chitosan and 5% magnesium stearate shows immediate flotation, optimal medicine effective trapping and sustained drug release

¾ **Bera R et al,** developed floating particles for intragastric injection of furosemide Evaluate the effect of combined sunflower oil on the physicochemical properties of alginate pearls.. When preparing different batches of pearls, the ratio of sunflower oil/water(v/v), drug/polymer ratio (w/w), was kept as a two-level variable; tall or short. All seed batches float for 24 hours with a 5-10 minute delay. The liberation ofnext medication in 5 hours. Higher oil levels increase drug trapping efficiency (81-95%) but the drug release rate is slower compared to lower oil particle levels.

¾ **Stops et al,** designed floating alginate beads containing riboflavin to improve medicinebioavailability of drug delivery systems. They also studied the effects of pH dissolution medium on drug release and found that riboflavin release was slower in acidic mediummedia versus basic media.

IV. MATERIALS AND METHODS MATERIALS

Table 4.1.1 List of materials

Materials	Source
Ofloxacin	Apex formulations Pvt. Ltd, India
Low methoxy pectin (LMP)	Krishna Pectins Pvt. Ltd, India
Gellan gum (GG)	Sigma-Aldrich Chemicals, India
Xanthan gum (XG)	Sigma Aldrich, USA
Karaya gum (KG)	Morning Star Enterprises, India
Rice bran oil (RBO)	Sri Anjaneya Agrotech Pvt Ltd. India
Zinc chloride	High purity laboratory chemical, India

EQUIPEMENTS

Table 4.2.1 List of equipments

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Equipments	Model/ Company
UV-Visible Spectrophotometer	Spectrophotometer UV-1601, Shimadzu, Japan
Electronic balance	Sartorious BS/BT, Mumbai, India
Differential scanning calorimeter(DSC)	DSC-60, Shimadzu, Japan
Fourier transform infrared radiation(FTIR)	Shimadzu, model 840, Japan
USP dissolution apparatus	Tab Machines, Mumbai, India
Scanning electron microscope	JEOL JSM-840A
Environmental chamber	Remi electronics, Mumbai
Magnetic stirrer	Remi electronics, Mumbai
Dial thickness meter	Mitutoyo 2046F, Japan

METHODOLOGY

DRUG, POLYMER COMPATIBILITY STUDIES DIFFERENTIAL SCANNING CALORIMETRY (DSC)

Physical mixtures of ofloxacin and other polymers have been studied for compatibility by differential scanning calor-imetry (DSC) (DSC-60, Shimadzu, Japan). For DSC,Aluminum pan is used to place the sample. The heating ratewas kept at 10℃ incrementsper minute up to 350 oC for better information integration. Nitrogen gas is used toPurification at 30 ml/min

FOURIER TRANSFORM INFRARED RADIATION (FTIR)

Fourier transform infrared spectroscopy (FTIR) were imaged at room temperature using an infrared spectrometer (Simadzu, model 840, Japan). Spectra of the drug and polymer are taken and analyzed for any major interactions. They are performed qualitatively to evaluate the highest profile and for comparison purposes.target. The FTIR spectrum of the drug with the polymer was taken.49

DEVELOPMENT OF CALIBRATION CURVE

Ofloxacin equivalent to 100 mg was accurately weighed and added to a volume of 100 ml.ball. It was dissolved in 100 ml of 0.1 N hydrochloric acid buffer (pH 1.2) to obtain a stock solutionsolution A. From stock solution A, take 10 ml with a pipette and transfer to another solution 100 ml volumetric flask and make up with 0.1 N hydrochloric acid buffer.to obtain stock solution B. From stock solution B, 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 1.6,and 0.8 ml was pipetted and diluted to 10 ml with 0.1 N hydrochloric acid buffer to solutions at 1, 2, 3, 4, 5, 6, 7, and 8 µg/ml were obtained. The absorbance of each of these solutions is

PREPARATION OF FLOATING ZINC PECTINATE BEADS

Ofloxacin, LMP, GG, XG and KG were filtered separately through a No. 80 sieve.

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Ofloxacin(20% w/w dry weight of polymer) was dissolved in distilled water. LMP (3% w/v) aloneand polymer mixture (3% w/v) containing LMP and GG, LMP and XG, and LMP and KG in three different proportions is dissolved in the above dispersion system and in the formula withpolymer mixture (3% w/v) containing GG, XG, KG and LMP. Add the above mixtureRice bran oil (25% w/w) was added and stirred to form a homogeneous emulsion. The emulsion containing the drug is extruded through a 23 G needle into the zinc chloride solution (5% w/v) was gently stirred. The pearls can remain the samesolution for 30 minutes to improve their mechanical strength. The particles formed areSeparate, wash with water and dry at room temperature overnight. Painting4.3.1 lists the formulation variables for different formulations of ofloxacin float pearl. White granules without ofloxacin were also prepared using the same technique.50,51,52

Table 4.3.1 Formulation variables of various ofloxacin bead formulations

Formulation code	LMP : GG (3% w/v)	LMP : XG (3%w/v)	LMP : KG (3%w/v)	LMP:GG:XG:KG (3%w/v)	Oil (%w/w)
F Blank	10:0	10:0	10:0	-	-
F	10:0	10:0	10:0	15	15
	10:0	10:0	10:0	20	20
	10:0	10:0	10:0	25	25
F1	9:1	-	-	25	25
F2	8:2	-	-	-	25
F3	7:3	-	-	-	25
F4	-	9:1	-	-	25
F5	-	8:2	-	-	25
F 6	-	-	9:1	-	25
F7	-	-	8:2	-	25
F8	-	-	7:3	-	25
F9	-	-	-	8:0.66:0.66:0.66	25

EVALUATION OF PHYSICOCHEMICAL PARAMETERS OF FLOATINGBEAD OF ZINC PECTINATE

Determination of bead diameter

The diameter of the gel bead sample (25 beads) of each formulation was determined Use a dial thickness gauge. The measurement of each sample was repeated ten times. Mean diameter and standard deviation were recorded.

Drug Content

An accurately weighed sample of beads (100 mg) was crushed in a mortar and added to 100 ml of 0.1N hydrochloric acid buffer (pH 1.2). This mixture was kept overnight under stirring to elute complete drug from the polymer matrix. The mixture was filtered andanalyzed by spectrophotometry at a wavelength of 294.5 nm (UV spectrophotometer,1601, Shimadzu, Japan) against a mixture of pure marbles, treated in the same way. Medicine The content of each formulation was recorded as mg/100 mg gel granules.

Drug Entrapment Efficiency

The percentage drug entrapment efficiency (% EE) of each bead formulation was calculated using the following equation:[40, 54]

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

$$EE\ (\%) = \frac{\text{Actual Drug Content}}{\text{Theoretical Drug Content}} \times 100$$

DETERMINATION OF SWELLING INDEX

The swelling properties of zinc pectinate granules were studied in 0.1 N HCl (pH 1.2)18.cushion. Approximately 100 mg of granules were placed in the dissolution basket and weighed(W1); The baskets as well as the balls were immersed in 0.1 N HCl buffer. (W2) of the basket as well as the ball is determined in 8 hours:every 30 minutes for Initially every 2 hours, then every hour. The swelling index (SI) of each formulation is calculated using the following equation:

$$\%\ SI = \frac{W_2 - W_1}{W_1} \times 100$$

BUOYANCY STUDIES

Time period from introduction of FDDS into the environment until its emergence the upper part of the dissolution vessel (floating delay time) and the time spent in itThe formula continuously floats on the surface of the medium (flotation time) measured simultaneously in dissolution studies by visual observation.14,34

N VITRO DRUG RELEASE STUDIES

The in vitro release properties of ofloxacin floating gel beads (n=3) were evaluatedusing the USP XIV 2 dissolution tester (paddle method). Dissolution test was performed using 500 ml of 0.1 N HCl buffer as the dissolution medium maintained at 37 ± 0.5oC. The contents were stirred at 50 rpm. Take 5 ml of solution were removed at predetermined intervals of 8 h and 5 ml of fresh dissolution medium was obtainedbe replaced to maintain the condition of the sink. Sample aliquots were analyzed Spectrophotometric measurement at wavelength 294.5 nm (UV spectrophotometer, 1601, Shimadzu, Japan).55

STABILITY STUDIES

Stability studies were carried out according to ICH guidelines by storing the formulation F1 at 40±2°C and relative humidity 75±5 % for a period of two months in a programmable environmental test chamber (CHM-10S, Remi Instruments Ltd., Mumbai, India). The samples were withdrawn at 30 and 60 days and analyzed for the drug content, floating behavior and in vitro drug release.56, 57

SCANNING ELECTRON MICROSCOPY (SEM)

Check the surface morphology and external structure of dried woodFormulations F1, F4 and F7 (medicated granules and white granules) were produced using scanning electron microscope (SEM) (model JEOL, JSM-840A). The pattern is golden coated before scanning. 54

V. RESULTS

An attempt was made to produce floating particles containing ofloxacin zinc pectinate, embedded in oil,because it must act locally in the stomach and near the small intestine. THE The drug and polymer have been studied for compatibility to ensure that the drug polymer compatibility. Gel particles were prepared by emulsion gelation method. Preparation The particles were evaluated for various physicochemical parameters such as size and morphology, drug trapping efficiency, flotation characteristics, swelling studies and, inIn vitro release studies using conventional methods.

COMPATIBILITY STUDY DIFFERENTIAL SCANNING CALORIMETRY (DSC)

The DSC plot of the physical mixture of ofloxacin and polymer showed noneThe characteristic peaks of the polymer and ofloxacin peaks still exist but are slightly shifted from the original position (Figures 5.1.1.1 to 5.1.1.6).

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Table 5.1.1.1 Characteristic peaks for DSC samples

Sl No	Sample combinations	Characteristic peaks
1	Ofloxacin	274.5 ^{0}C
2	Ofloxacin and pectin	274.5 ^{0}C
3	Ofloxacin, pectin and gellan gum	270 ^{0}C
4	Ofloxacin, pectin and karaya gum	274.5 ^{0}C
5	Ofloxacin, pectin and xanthan gum	274.5 ^{0}C
6	Ofloxacin, pectin, gellan gum, karaya gum and xanthan gum	267.2 ^{0}C

The findings indicate that the drug and polymers are compatible with each other

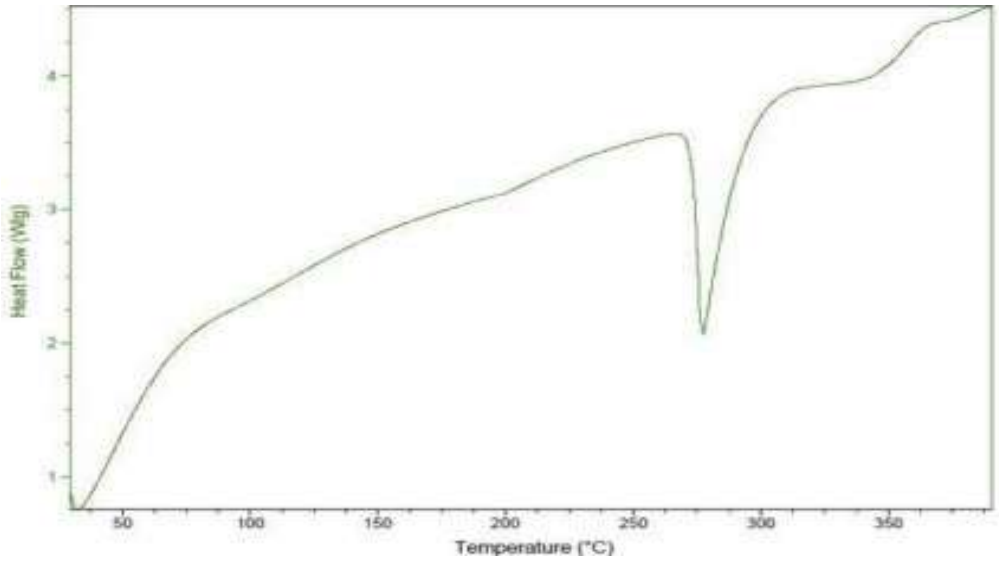


Figure 5.1.1.1 DSC thermogram of pure ofloxacin

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

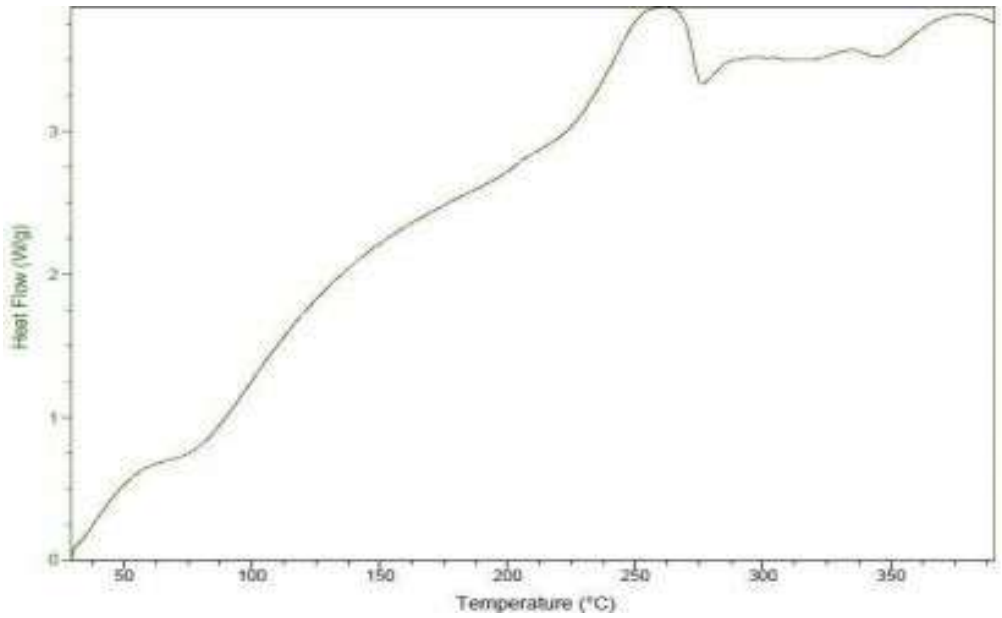


Figure 5.1.1.2 DSC thermogram of ofloxacin and LMP (physical mixture)

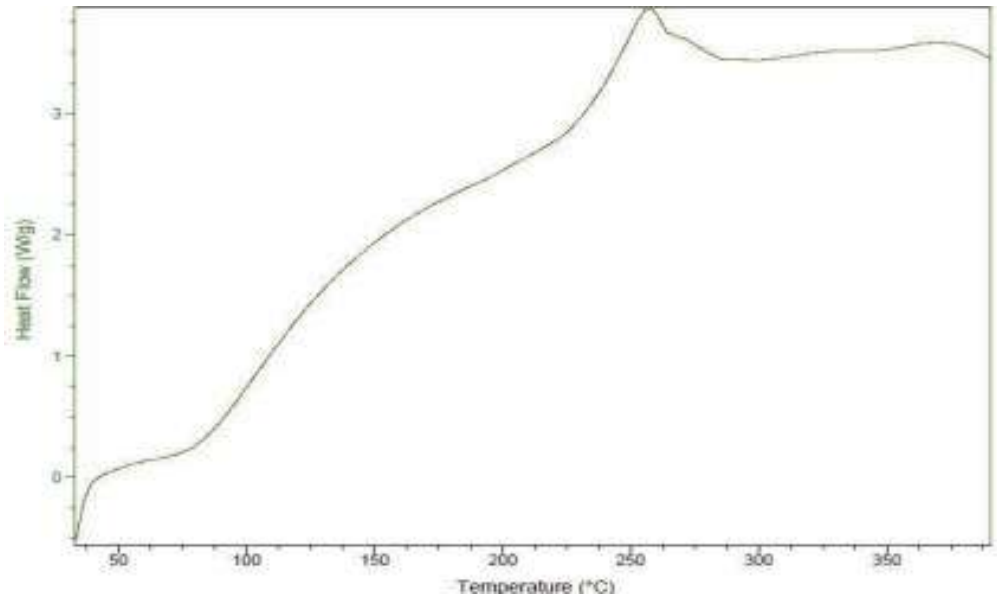


Figure 5.1.1.3 DSC thermogram of ofloxacin, LMP and GG (physical mixture)

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

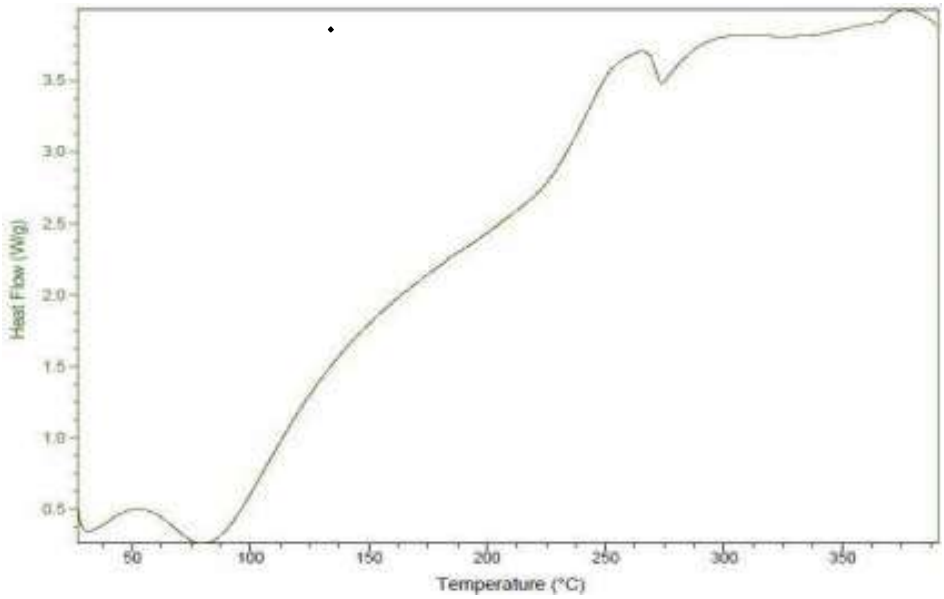


Figure 5.1.1.4 DSC thermogram ofofloxacin, LMP and KG (physical mixture)

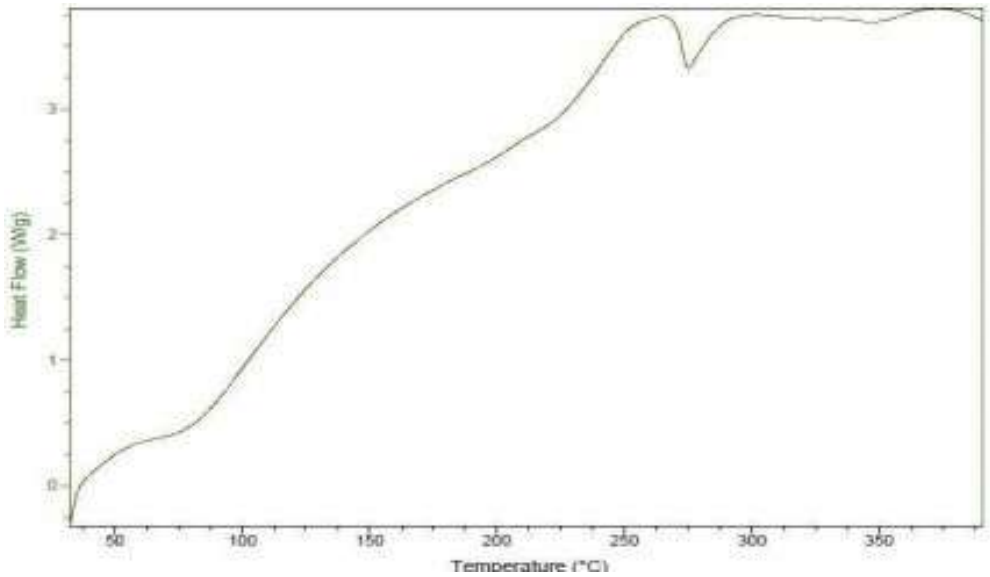


Figure 5.1.1.5 DSC thermogram of ofloxacin, LMP and XG (physical mixture)

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

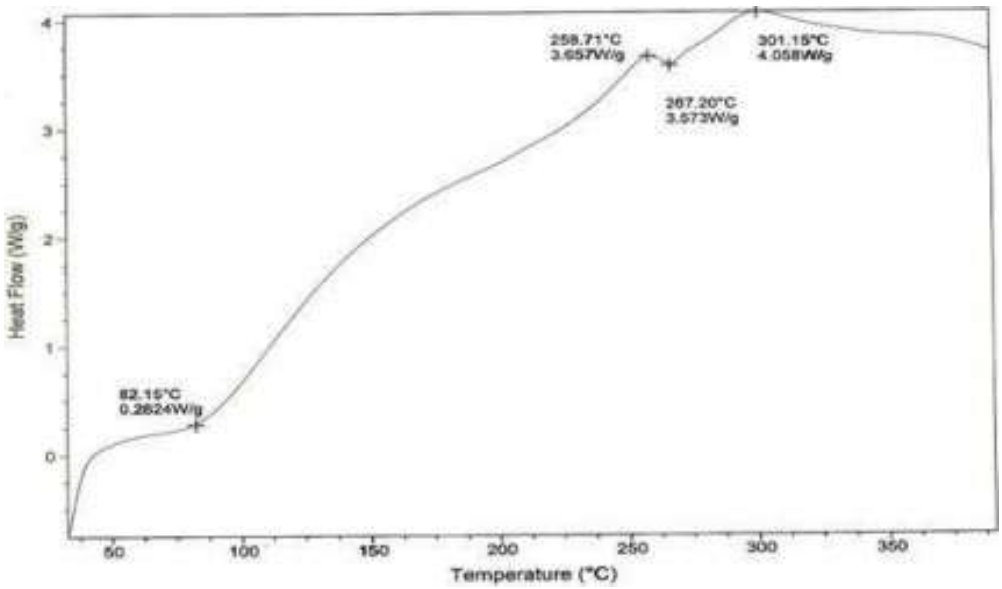
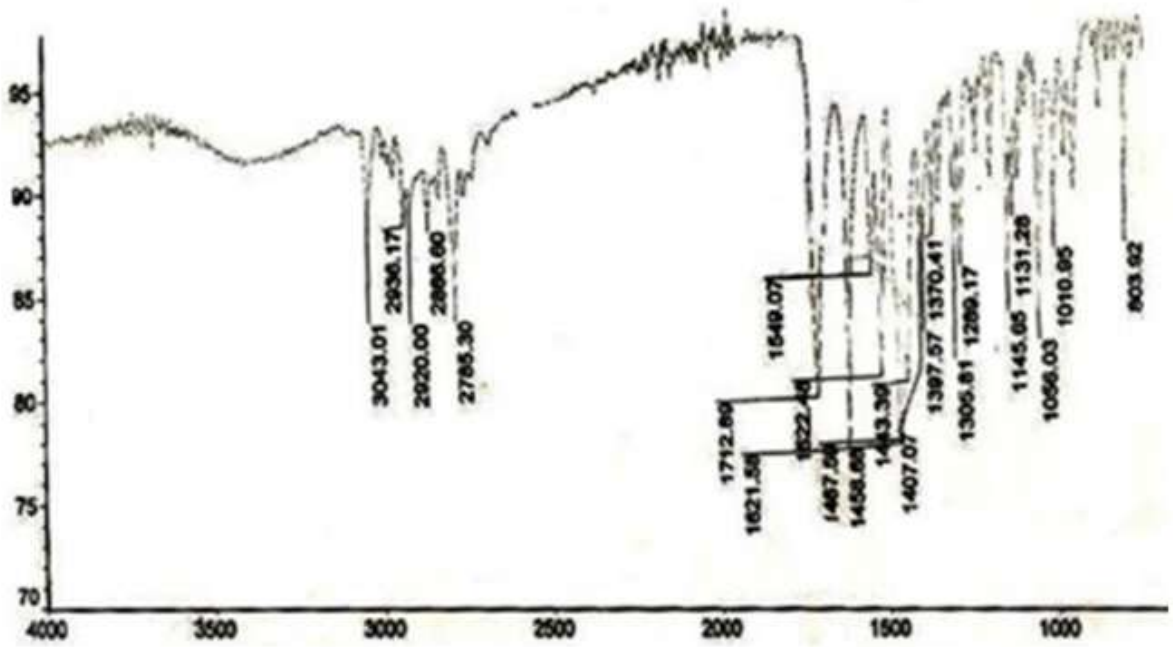


Figure 5.1.1.6 DSC thermogram of ofloxacin, LMP, GG, KG and XG (physical mixture)

DETERMINATION OF SWELLING INDEX

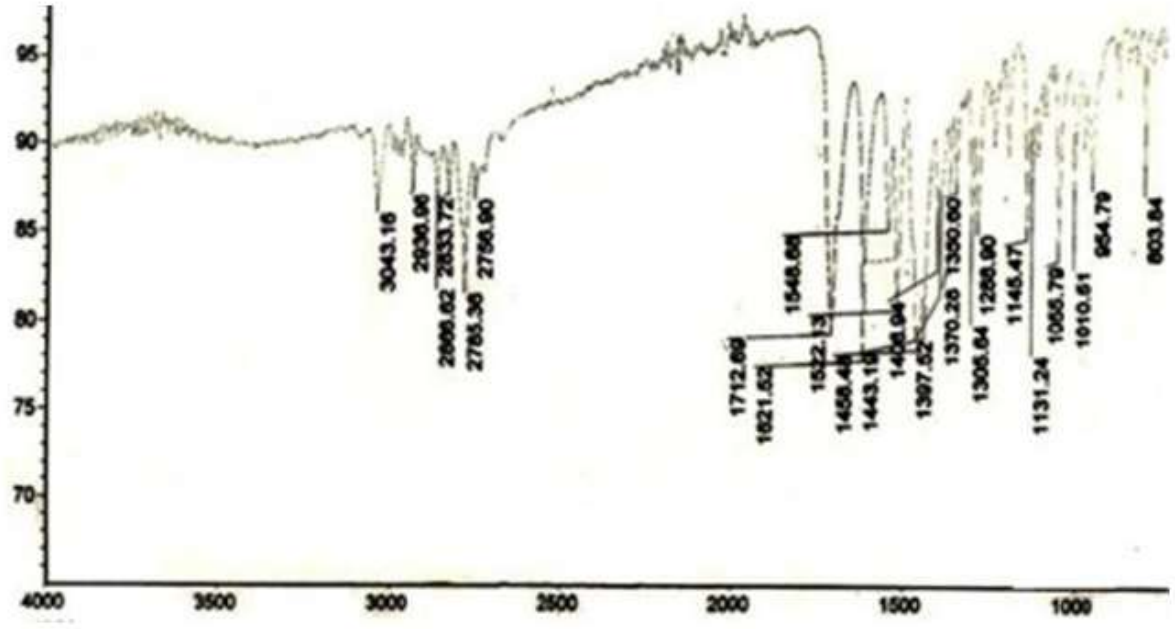
Following characteristic bands are seen for ofloxacin (Figure: 5.1.2.1) O-H stretching band at 3300 cm-1C-H stretching (aliphatic) 2936.17cm-1 C-H stretching (aromatic) 2785.3cm-1 C=O stretching 1712.89cm-1

All the above bands associated with the pure drug are present in the FTIR spectra of drug in combination with gellan gum, karaya gum and xanthan gum (Figure: 5.1.2.2 to 5.1.2.6). This shows that there is no chemical interaction taking place between drug and excipients.



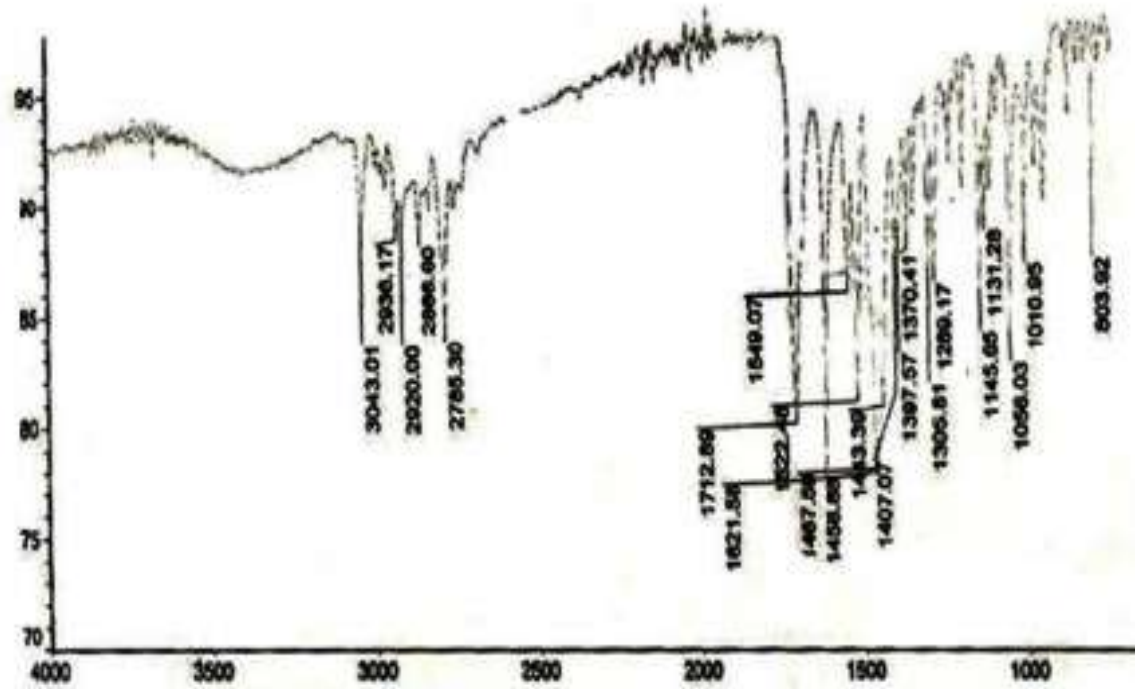
International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Figure 5.1.2.1 FTIR spectra of pure ofloxacin



Wavenumbers (cm-1)

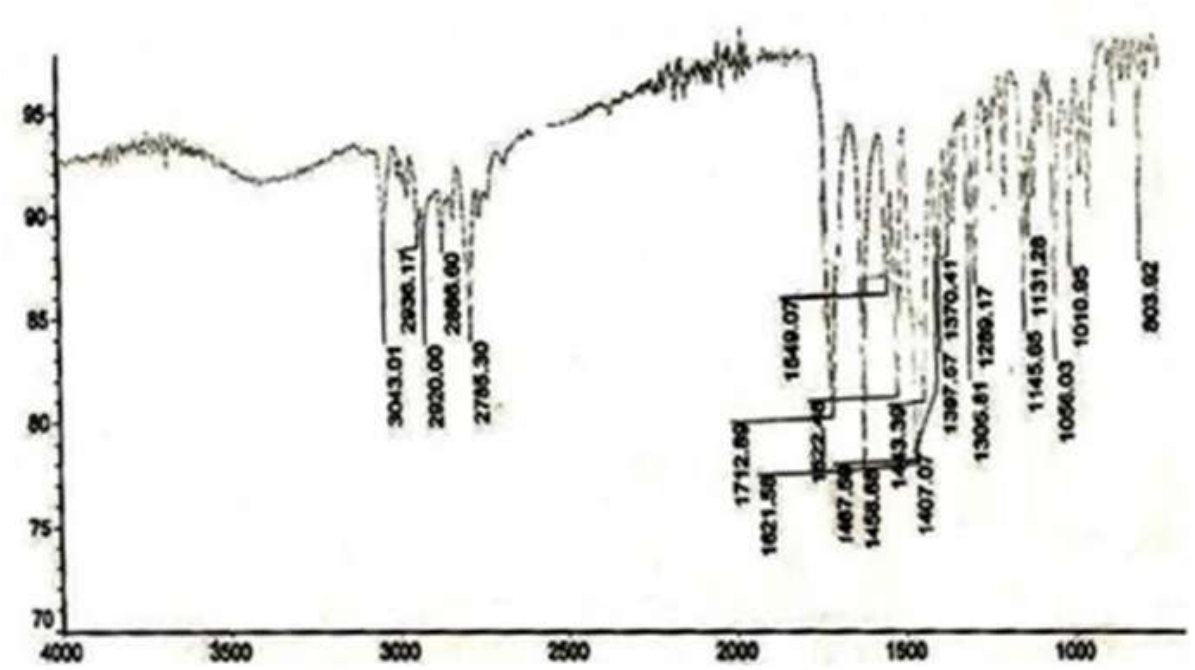
Figure 5.1.2.2 FTIR spectra of ofloxacin and LMP (physical mixture)



Wavenumbers (cm-1)

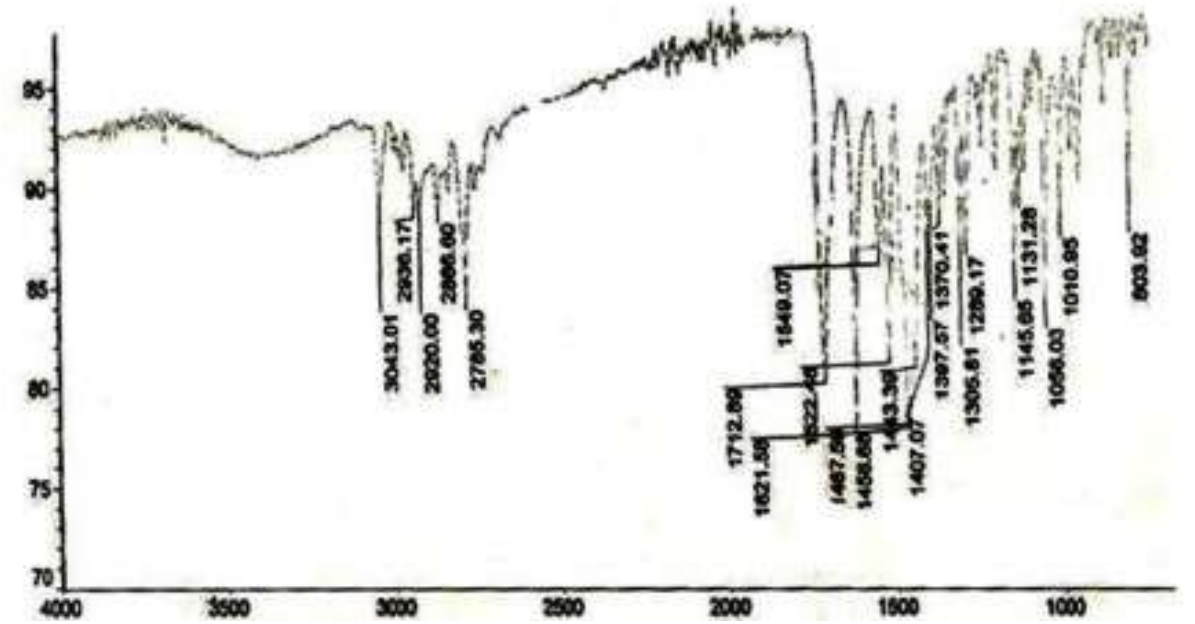
Figure 5.1.2.3 FTIR spectra of ofloxacin, LMP and GG (physical mixture)

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781



Wavenumbers (cm-1)

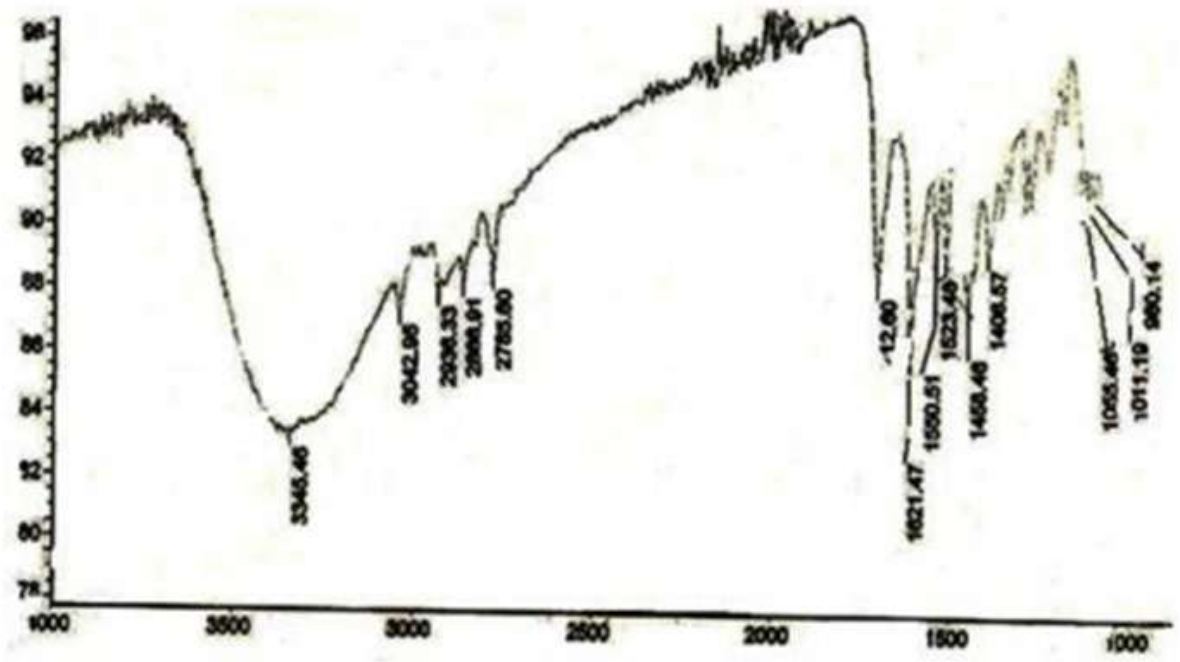
Figure 5.1.2.4 FTIR spectra of ofloxacin, LMP and KG (physical mixture)



Wavenumbers (cm-1)

Figure 5.1.2.5 FTIR spectra of ofloxacin, LMP and XG (physical mixture)

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781



Wavenumbers
(cm-1)Figure 5.1.2.6 FTIR spectra of ofloxacin, LMP, GG, KG and XG (physicalmixture)

DEVELOPMENT OF CALIBRATION CURVE

Table 5.2.1 Concentration and absorbance obtained for standard plot of ofloxacin in0.1 N hydrochloric acid buffer(pH 1.2)

Sl. No.	Concentration (µ/ml)	Absorbance ± SD
1	0	0
2	1	0.096±0.002
3	2	0.203±0.003
4	3	0.285±0.001
5	4	0.383±0.003
6	5	0.467±0.004
7	6	0.559±0.003
8	7	0.650±0.001
9	8	0.751±0.001

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

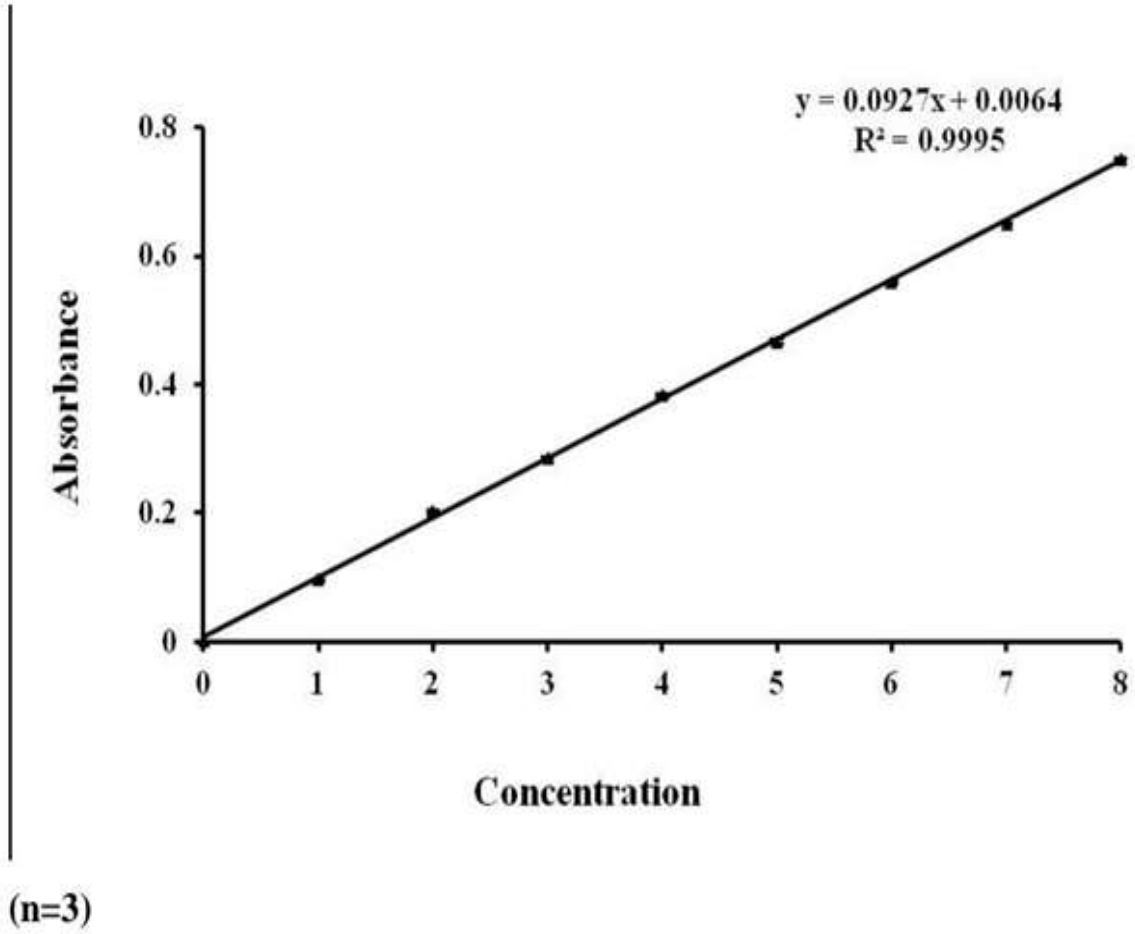


Figure 5.2.1 Calibration curve of ofloxacin

EVALUATION OF PHYSICOCHEMICAL PARAMETERS OF FLOATING ZINC PECTINATE BEADS

Particle size analysis

The prepared beads were almost spherical and translucent. The mean surface diameter of10 formulations was between 1.691±0.022 (mean±SD) and 2.099±0.041 (mean±SD) (Table5.3.1).

Drug entrapment efficiency

The percent drug entrapment efficiency for various ofloxacin floating bead formulations was found to vary between 57.49% and 78.81% (Table 5.3.1).

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Table 5.3.1 Characterization of floating zinc pectinate beads

Formulation code	Mean Diameter ± SD (mm)	Drug content (mg)	% EE	% Swelling Index
F blank	1.691±0.022	-	-	
F	1.693±0.015	2.437±0.037	57.49	0.74
F1	1.751±0.023	1.236±0.017	78.81	2.42
F2	1.841±0.022	1.620±0.054	69.16	1.79
F3	1.898±0.018	1.551±0.114	72.13	2.21
F4	2.193±0.017	1.681±0.023	76.20	1.01
F5	1.836±0.018	1.621±0.063	60.61	3.75
F6	2.057±0.069	1.362±0.035	74.28	1.22
F7	2.009±0.027	1.713±0.111	65.40	2.10
F8	2.099±0.041	1.417±0.027	62.98	1.74
F9	2.008±0.063	1.434±0.240	58.95	0.72

Floating properties:-

The buoyancy of the prepared particles was evaluated along with dissolution studies. THEOil-free seeds immediately flow into 0.1 N HCl (pH 1.2), while seeds containingSufficient amount of rice bran oil (25%) works instantly and wonderfully flotation capacity (table 5.3.2).

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Table 5.3.2 Buoyancy characteristics of floating zinc pectinate beads

Formulation code	Amount of oil (%w/w)	FLT (min)	Floating duration (h)
F blank	-	NF	NF
F	10	NF	NF
F	15	NF	NF
F	25	0	24
F1	25	0	24
F2	25	0	24
F3	25	0	24
F4	25	0	24
F5	25	0	24
F6	25	0	24
F7	25	0	24
F8	25	0	24
F9	25	0	24

(NF= No floating)

- IN VITRO RELEASE PROFILE

CONVENTIONAL METHOD

An in vitro drug release study on floating ofloxacin beads was performed in 0.1 N HCl (pH 1.2).during 8 hours. In 0.1 N HCl, the particles showed biphasic release characteristicsA rapid initial release of the drug (burst effect) is followed by a gradual, sustained release of the drug. The drug release phase begins after 1 hour and lasts up to 8 hours. Formula F contains onlyLMP was unable to sustain ofloxacin release for up to 8 hours. He released the complete medicine at 4 hours end. Meanwhile the formula contains GG; F1, F2 and F3 released 87.51%, 74.33and 74.76% of the drug respectively after 8 hours and the release profile is presented inFigure 5.4.1. Formula contains XG; F4 and F5 release 80.74% and 59.85% medicine after 8 hours respectively. The release profile of these particles is shown inFigure 5.4.2. The formula contains KG; F6, F7 and F8 released 76.41%, 68.52 D44 and 66.00% of the drug after 8 hours,respectively.Their publication recordsThe particles are shown in Figure 5.4.3. Formulations containing GG, XG and KG are commercially available corresponding to 62.40% of the drug after 8 hours. The release profile of these particles isshown in figure 5.4.3.

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Table 5.4.1 *In vitro* release characteristics of formulation F

Sl no	Time (h)	SQRT	Log time	Cum. % drug release	Log % drug remaining	Log % drug release
1	0	0	-	0	2	-
2	0.5	0.7071	-0.3010	65.92±1.71	1.5325	1.8190
3	1	1	0	74.47±2.20	1.4071	1.8721
4	1.5	1.2247	0.1760	82.01±0.77	1.2550	1.9139
5	2	1.4142	0.3010	86.26±1.04	1.1481	1.9358
6	3	1.7320	0.4771	93.56±0.99	0.8089	1.9711
7	4	2	0.6020	99.14±0.86	-0.0655	1.9962

Table 5.4.2 In vitro release characteristics of formulation F1

Sl no	Time (h)	SQRT	Log time	Cum. % drug release	Log % drug remaining	Log % drug release
1	0	0	-	0	2	-
2	0.5	0.7071	-0.3010	47.46±1.59	1.7205	1.6763
3	1	1	0	51.68±1.52	1.6841	1.7133
4	1.5	1.2247	0.1760	58.01±1.56	1.6231	1.7635
5	2	1.4142	0.3010	60.36±2.25	1.5981	1.7807
6	3	1.7320	0.4771	68.36±1.88	1.5002	1.8348
7	4	2	0.6020	71.6±1.84	1.4533	1.8549
8	5	2.2360	0.6989	77.65±0.27	1.3493	1.8901
9	6	2.4494	0.7781	78.48±0.84	1.3328	1.8948
10	7	2.6457	0.8450	83.05±3.47	1.2292	1.9193
11	8	2.8284	0.9030	87.51±1.14	1.0966	1.9421

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Table 5.4.3 *In vitro* release characteristics of formulation F2

Sl. No	Time (h)	SQRT	Log time	Cum. % drug release	Log % drug remaining	Log % drug release
1	0	0	-	0	2	-
2	0.5	0.7071	-0.3010	36.98±2.00	1.7995	1.5681
3	1	1	0	45.55±2.73	1.7361	1.6585
4	1.5	1.2247	0.1760	52.62±1.23	1.6756	1.7212
5	2	1.4142	0.3010	57.15±3.35	1.6321	1.7570
6	3	1.7320	0.4771	61.1±3.42	1.5911	1.7860
7	4	2	0.6020	65.65±3.51	1.5360	1.8172
8	5	2.2360	0.6989	69.07±1.47	1.4904	1.8393
9	6	2.4494	0.7781	70.28±0.91	14730	1.8468
10	7	2.6457	0.8450	73.09±1.082	1.4310	1.8639
11	8	2.8284	0.9030	74.33±0.40	1.4092	1.8712

Table 5.4.4 In vitro release characteristics of formulation F3

Sl. No	Time (h)	SQRT	Log time	Cum. % drug release	Log % drug remaining	Log % drug release
1	0	0	-	0	2	-
2	0.5	0.7071	-0.3010	44.59±3.05	1.7436	1.6492
3	1	1	0	52.33±2.29	1.6782	1.7188
4	1.5	1.2247	0.1760	57.47±0.57	1.6287	1.7594
5	2	1.4142	0.3010	59.89±1.46	1.6033	1.7774
6	3	1.7320	0.4771	61.59±1.04	1.5844	1.7810
7	4	2	0.6020	63.81±2.95	1.5586	1.8049
8	5	2.2360	0.6989	66.83±2.58	1.5207	1.8251
9	6	2.4494	0.7781	69.71±0.32	1.4813	1.8433
10	7	2.6457	0.8450	72.52±1.08	1.4390	1.8605
11	8	2.8284	0.9030	74.76±1.90	1.4021	1.8737

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Table 5.4.5 *In vitro* release characteristics of formulation F4

Sl. No	Time (h)	SQRT	Log time	Cum. % drug release	Log % drug remaining	Log % drug release
1	0	0	-	0	2	-
2	0.5	0.7071	-0.3010	45.89±0.94	1.7333	1.6617
3	1	1	0	57.21±2.17	1.6313	1.7575
4	1.5	1.2247	0.1760	59.51±3.02	1.6073	1.7746
5	2	1.4142	0.3010	63.16±1.98	1.5663	1.8004
6	3	1.7320	0.4771	66.49±2.06	1.5252	1.8228
7	4	2	0.6020	68.27±3.01	1.5015	1.8342
8	5	2.2360	0.6989	71.97±1.81	1.4476	1.8572
9	6	2.4494	0.7781	75.58±1.14	1.3877	1.8784
10	7	2.6457	0.8450	78.78±0.37	1.3267	1.8964
11	8	2.8284	0.9030	80.74±4.11	1.2847	1.9071

Table 5.4.6 In vitro release characteristics of formulation F5

Sl. No	Time (h)	SQRT	Log time	Cum. % drug release	Log % drug remaining	Log % drug release
1	0	0	-	0	2	-
2	0.5	0.7071	-0.3010	30.74±1.19	1.8405	1.4877
3	1	1	0	43.50±2.96	1.7520	1.6385
4	1.5	1.2247	0.1760	46.37±2.60	1.7294	1.6662
5	2	1.4142	0.3010	48.34±1.05	1.7132	1.6843
6	3	1.7320	0.4771	51.01±3.13	1.6895	1.7083
7	4	2	0.6020	53.14±2.69	1.6708	1.7254
8	5	2.2360	0.6989	54.86±0.60	1.6546	1.7393
9	6	2.4494	0.7781	56.66±2.42	1.6369	1.7533
10	7	2.6457	0.8450	58.96±1.19	1.6132	1.7706
11	8	2.8284	0.9030	59.85±2.15	1.6037	1.7771

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Table 5.4.7 In vitro release characteristics of formulation F6

Sl. No	Time (h)	SQRT	Log time	Cum. % drug release	Log % drug remaining	Log % drug release
1	0	0	-	0	2	-
2	0.5	0.7071	-0.3010	47.71±1.28	1.7184	1.6786
3	1	1	0	58.12±1.04	1.6220	1.7643
4	1.5	1.2247	0.1760	61.28±1.52	1.5879	1.7873
5	2	1.4142	0.3010	63.94±3.49	1.5570	1.8058
6	3	1.7320	0.4771	66.39±0.98	1.5265	1.8221
7	4	2	0.6020	68.37±1.84	1.5000	1.8349
8	5	2.2360	0.6989	71.71±1.29	1.4516	1.8556
9	6	2.4494	0.7781	73.50±0.98	1.4232	1.8663
10	7	2.6457	0.8450	75±0.24	1.3979	1.8751
11	8	2.8284	0.9030	76.41±2.89	1.3727	1.8832

Table 5.4.8 In vitro release characteristics of formulation F7

Sl. No	Time (h)	SQRT	Log time	Cum. % drug release	Log % drug remaining	Log % drug release
1	0	0	-	0	2	-
2	0.5	0.7071	-0.3010	40.16±0.96	1.7771	1.6038
3	1	1	0	44.84±0.91	1.7416	1.6517
4	1.5	1.2247	0.1760	49.91±2.28	1.6998	1.6982
5	2	1.4142	0.3010	52.77±2.56	1.6742	1.7224
6	3	1.7320	0.4771	55.92±0.62	1.6442	1.7476
7	4	2	0.6020	58.67±0.68	1.6163	1.7684
8	5	2.2360	0.6989	60.89±1.07	1.5923	1.7845
9	6	2.4494	0.7781	63.78±0.96	1.5589	1.8047
10	7	2.6457	0.8450	66.59±0.27	1.5239	1.8234
11	8	2.8284	0.9030	68.52±0.96	1.4980	1.8358

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Table 5.4.9 *In vitro* release characteristics of formulation F8

Sl. No	Time (h)	SQRT	Log time	Cum. % drug release	Log % drug remaining	Log % drug release
1	0	0	-	0	2	-
2	0.5	0.7071	-0.3010	32.6±1.91	1.8287	1.5132
3	1	1	0	38.78±0.99	1.7869	1.5886
4	1.5	1.2247	0.1760	44.76±0.76	1.7423	1.6509
5	2	1.4142	0.3010	47.47±0.37	1.7204	1.6764
6	3	1.7320	0.4771	51.15±1.03	1.6889	1.7088
7	4	2	0.6020	55.13±0.59	1.6521	1.7414
8	5	2.2360	0.6989	57.92±0.62	1.6241	1.7628
9	6	2.4494	0.7781	60.44±1.51	1.5973	1.7813
10	7	2.6457	0.8450	63.47±3.21	1.5627	1.8026
11	8	2.8284	0.9030	66.00±1.16	1.5315	1.8214

Table 5.4.10 In vitro release characteristics of formulation F9

Sl. No	Time (h)	SQRT	Log time	Cum. % drug release	Log % drug remaining	Log % drug release
1	0	0	-	0	2	-
2	0.5	0.7071	-0.3010	32.6±1.91	1.8287	1.5132
3	1	1	0	40.09±0.15	1.7775	1.6030
4	1.5	1.2247	0.1760	45.13±0.79	1.7393	1.6545
5	2	1.4142	0.3010	47.47±0.37	1.7204	1.6764
6	3	1.7320	0.4771	51.15±1.03	1.6889	1.7088
7	4	2	0.6020	55.13±0.59	1.6521	1.7414
8	5	2.2360	0.6989	57.92±0.62	1.6241	1.7628
9	6	2.4494	0.7781	58.87±0.51	1.6142	1.7699
10	7	2.6457	0.8450	60.66±0.57	1.5948	1.7829
11	8	2.8284	0.9030	62.40±1.87	1.5752	1.7952

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

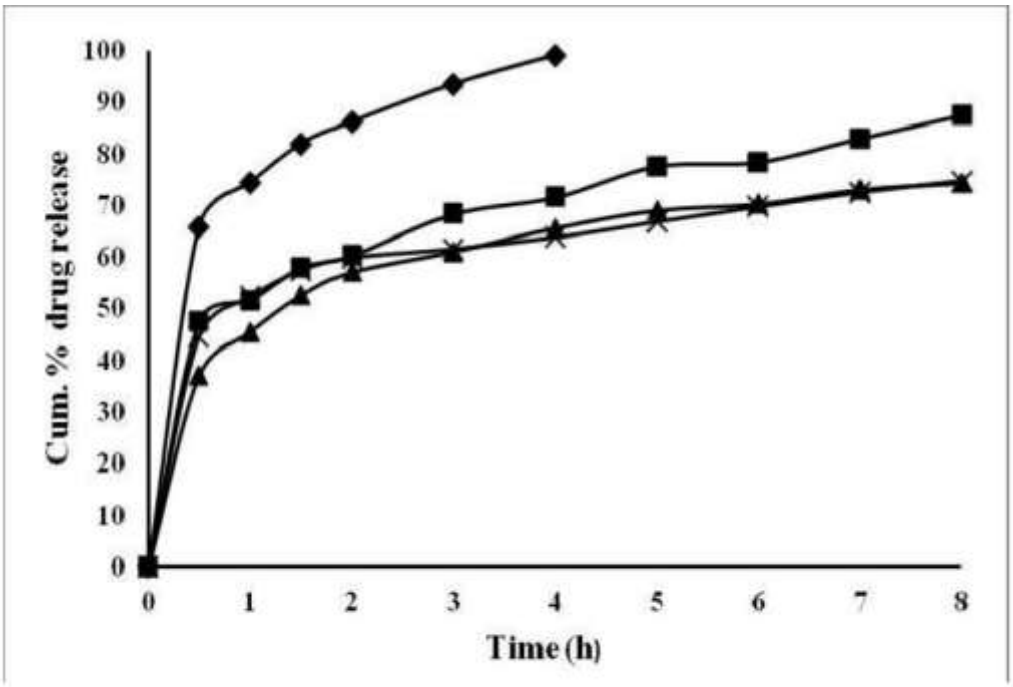


Figure 5.4.1 Comparison of *in vitro* dissolution characteristics of F (♦), F1 (■), F2 (▲), F3 (×) (n = 3)

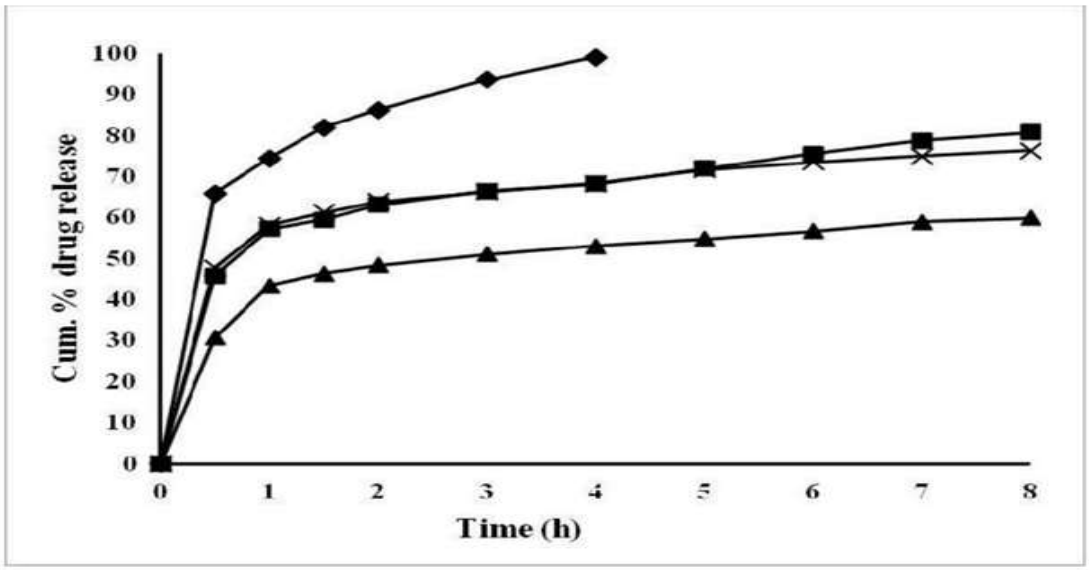


Figure 5.4.2 Comparison of *in vitro* dissolution characteristics of F (♦), F4 (■), F5 (▲), F6 (×) (n = 3)

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

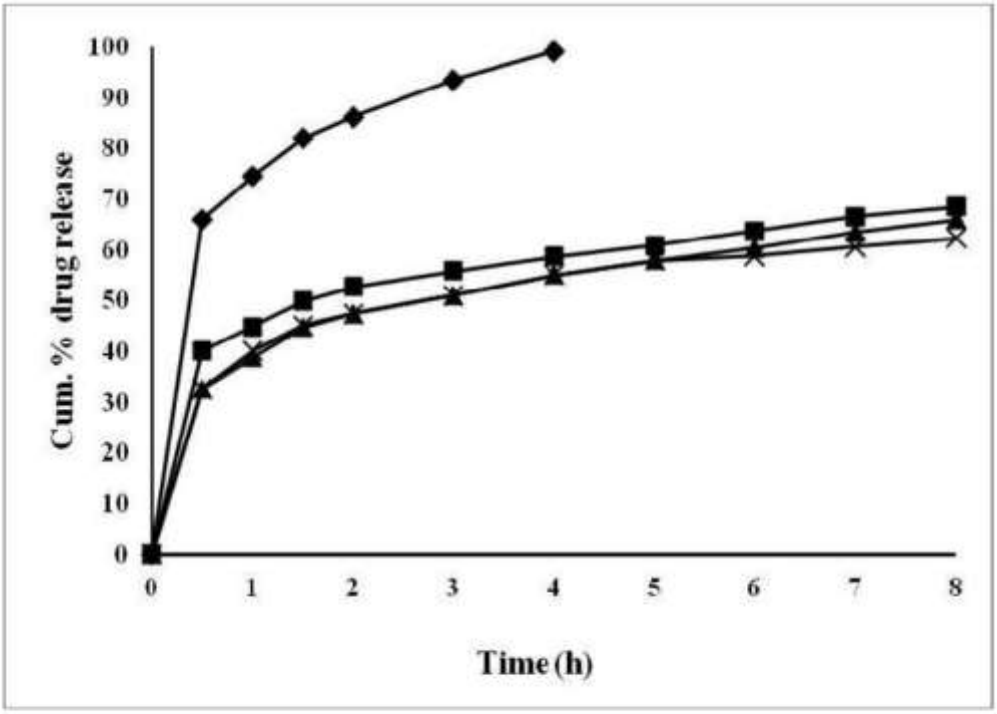


Figure 5.4.3 Comparison of *in vitro* dissolution characteristics of F (♦), F7 (■), F8 (▲), F9 (×) (n = 3)

ANALYSIS OF RELEASE PATTERN [58, 61]

To analyze the drug release from the beads, the in vitro dissolution data was fitted to:

a) Zero order (Cumulative percentage drug released Vs Time)
b) First order (Log cumulative percentage drug remaining Vs Time)
c) Higuchi release model (Cumulative percentage drug released Vs Square root of time)
d) Korsemeyer and peppas model (Log percentage drug released Vs Log time).

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

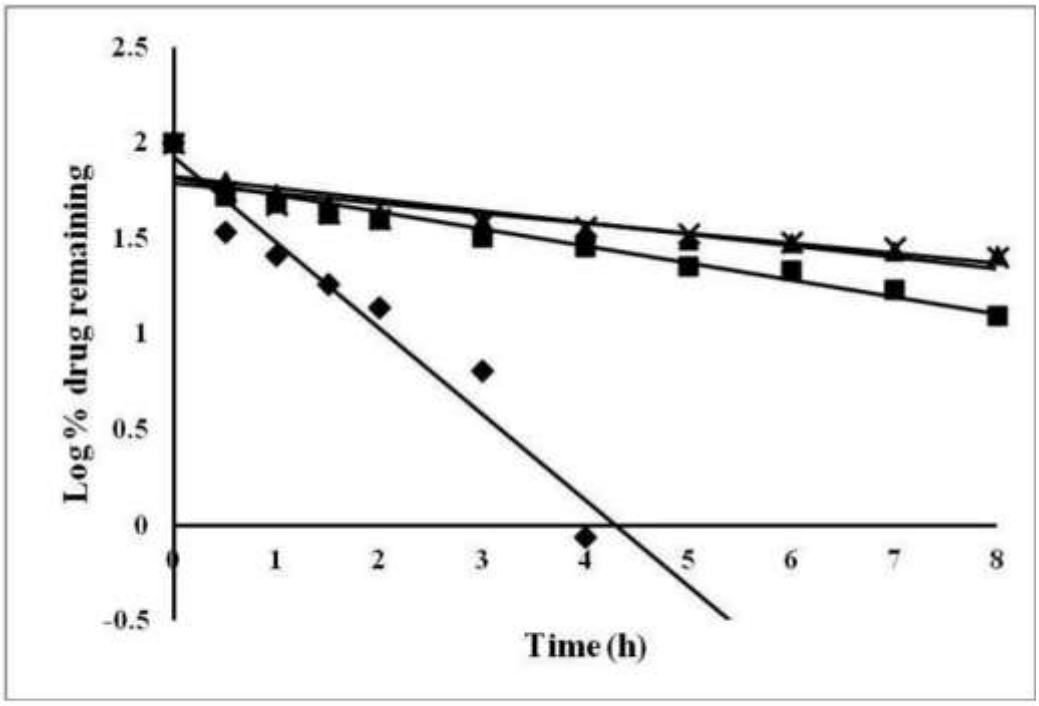


Figure 5.5.1 First order plot of F (♦), F1 (■), F2 (▲), F3 (□)

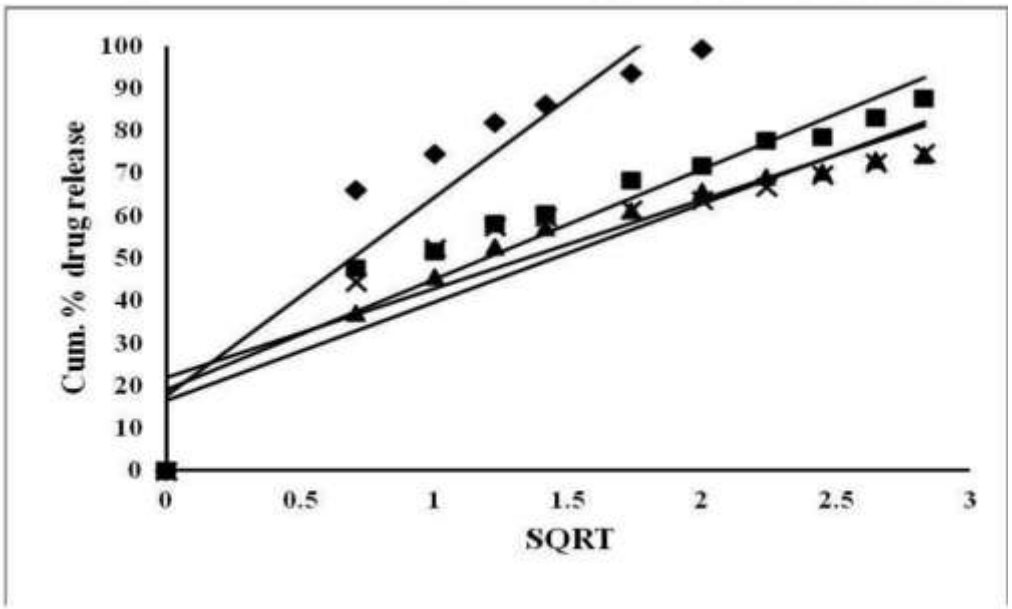


Figure 5.5.2 Higuchi plot of F (♦), F1 (■), F2 (▲), F3 (×)

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

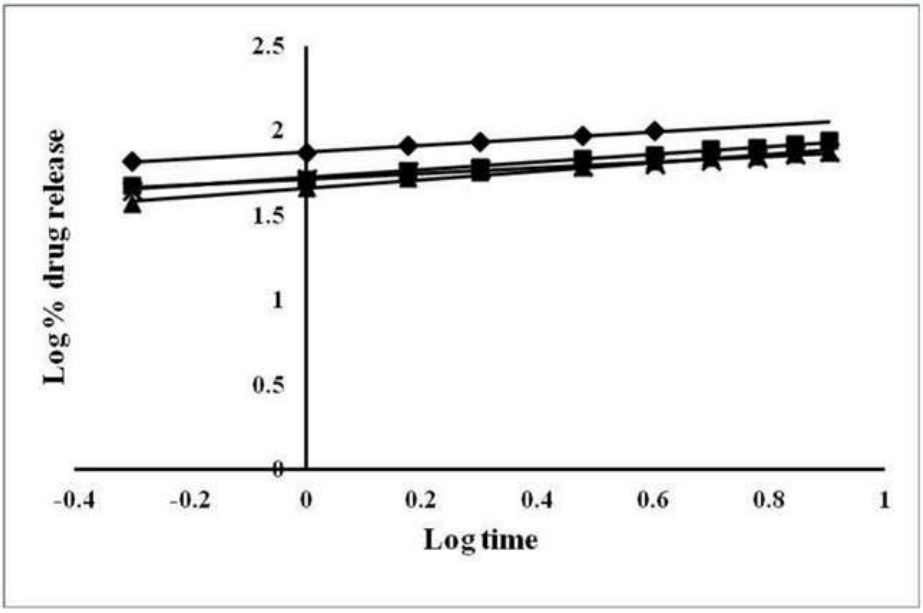


Figure 5.5.3 Korsemeyer and peppas plot for F (♦), F1 (■), F2 (▲), F3 (×)

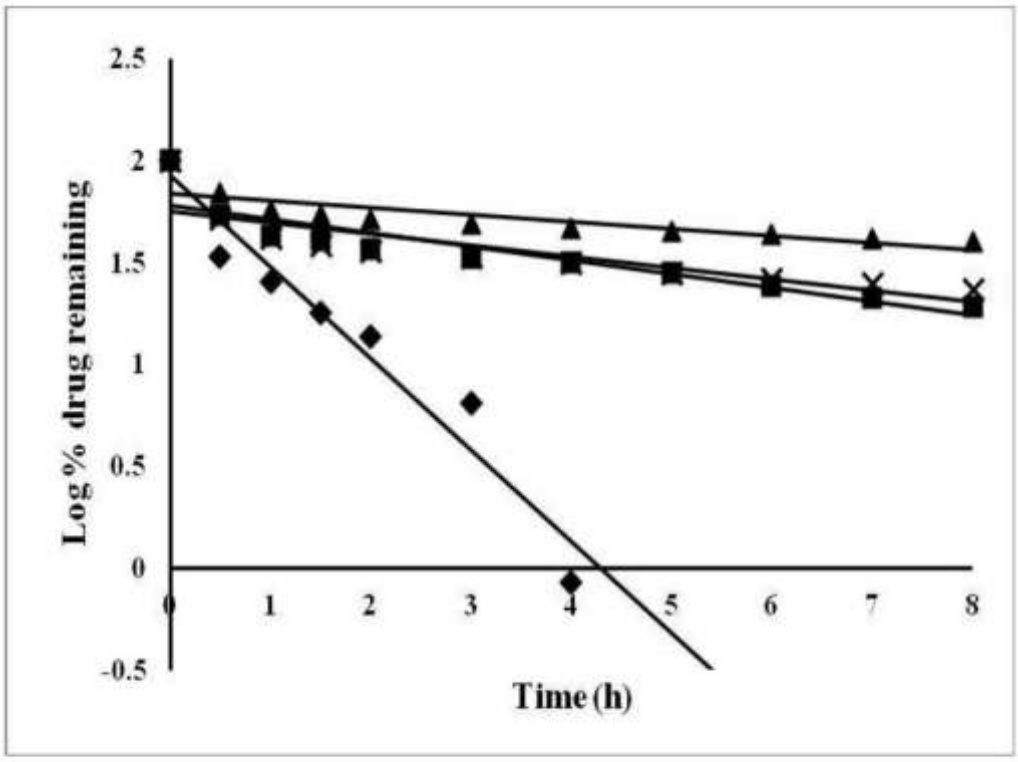


Figure 5.5.4 First order plot of F (♦), F4 (■), F5 (▲), F6 (×)

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

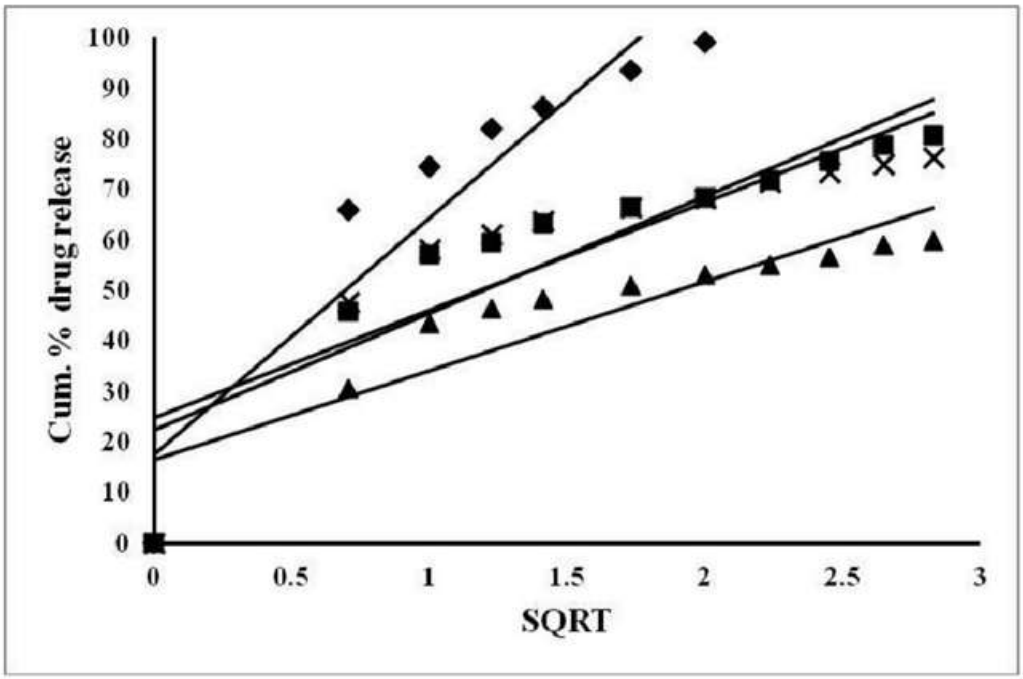


Figure 5.5.5 Higuchi plot of F (♦), F4 (■), F5 (▲), F6 (×)

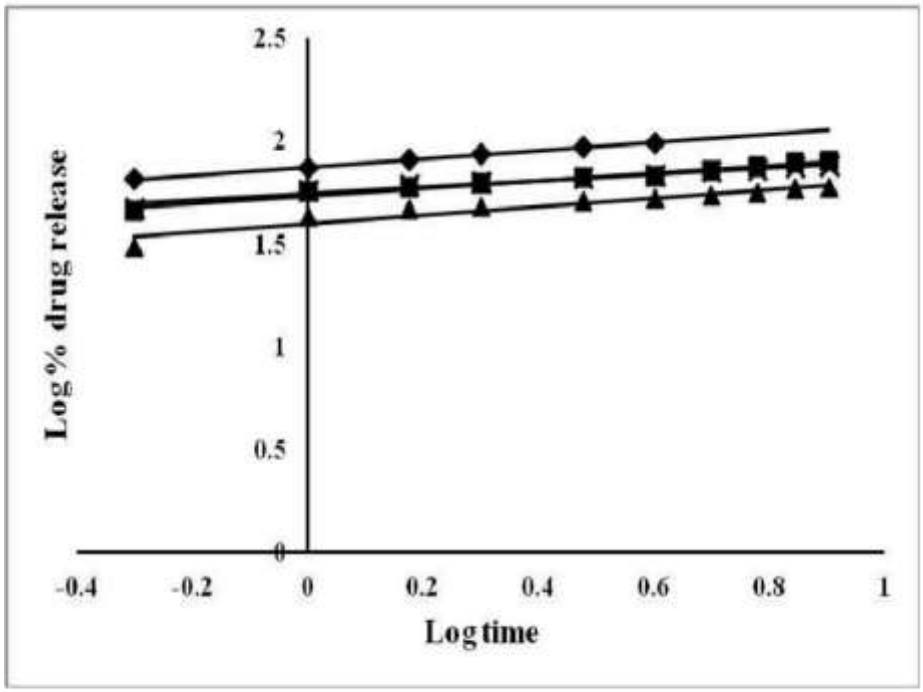


Figure 5.5.6 Korsemeyer and peppas plot for F (♦), F4 (■), F5 (▲), F6 (×)

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

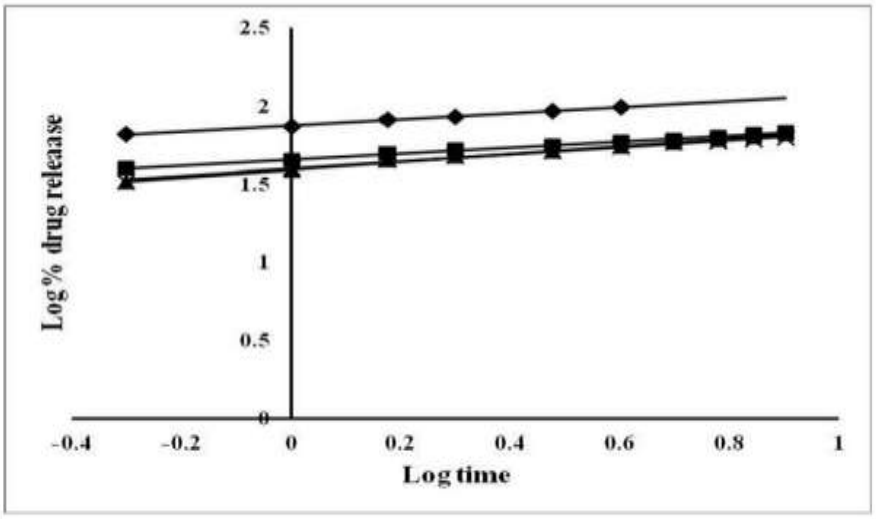


Figure 5.5.9 Korsemeyer and peppas plot for F (♦), F7 (■), F8 (▲), F9 (×)

Table 5.5.1 Kinetics of release pattern

Sl no	Formulation code	r^2 for zero order equation	r^2 for first order equation	r^2 for higuchi equation	n value for peppas equation	r^2 value for peppas equation
1	F	0.606	0.944	0.870	0.198	0.998
2	F1	0.683	0.922	0.887	0.225	0.986
3	F2	0.657	0.980	0.880	0.246	0.983
4	F3	0.567	0.762	0.793	0.170	0.979
5	F4	0.583	0.823	0.815	0.185	0.976
6	F5	0.567	0.695	0.810	0.206	0.915
7	F6	0.503	0.715	0.753	0.154	0.967
8	F7	0.604	0.779	0.832	0.189	0.995
9	F8	0.692	0.840	0.899	0.247	0.995
10	F9	0.634	0.774	0.863	0.226	0.988

STABILITY STUDIES

Due to the potential usefulness of the formulation, stability studies have been performedFormula F1 for 2 months according to ICH guidelines. At the end of each month,The formulation has been tested for drug, buoyancy and release in vitro learn. The results are presented in Table 5.8.1.

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Table 5.8.1 Stability study of formulation F1

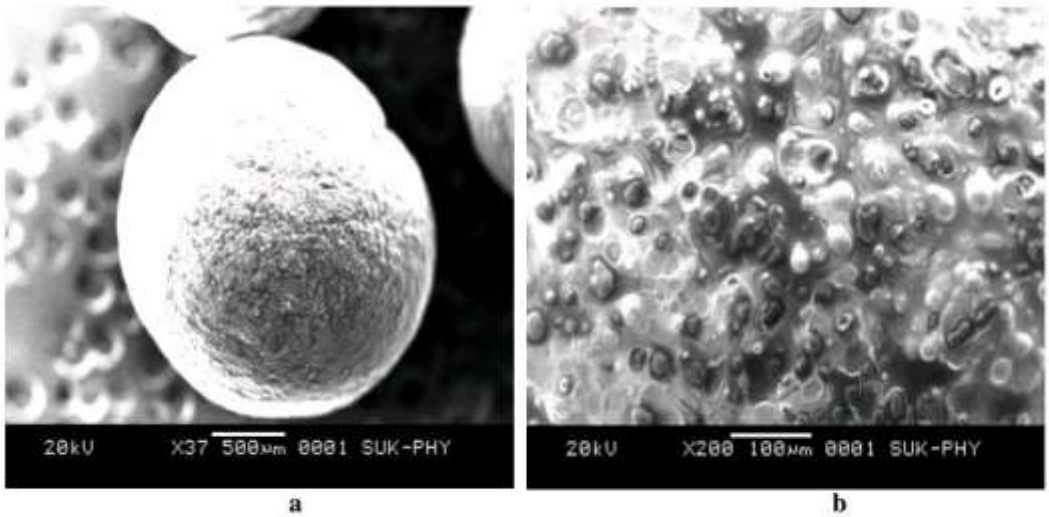
Time	Drug content ± SD (mg)	Floating behavior		Drug release at the end of 8h
		FLT (min)	Floating duration (h)	
Zero month	1.236±0.017	0	24	87.51±1.14
First Month	1.222±0.021	0	24	80.21±1.21
Second Month	1.182±0.056	0	24	75.32±1.32

SCANNING ELECTRON MICROSCOPY

Scanning electron microscopy of empty and drug-containing particles (both external andinternal structure) are illustrated in Figures 5.9.1 and 5.9.2.

Table 5.9.1 Formulation code for SEM

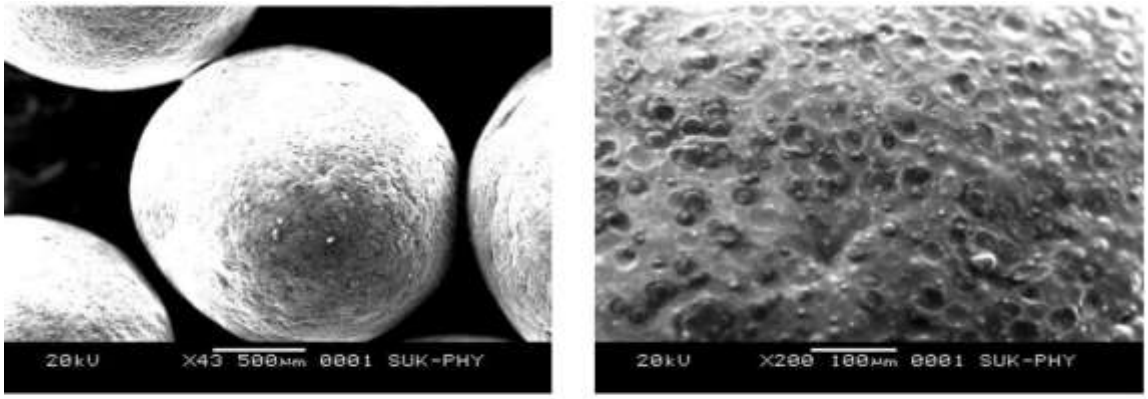
Sl. No.	Formulation code
1.	F 0 drug unloaded (LMP:GG, 9:1)
2.	F 1 drug loaded (LMP:GG,9:1)
3.	F 4 drug loaded (LMP:XG,9:1)
4.	F 7 drug loaded (LMP:KG,9:1)



a b

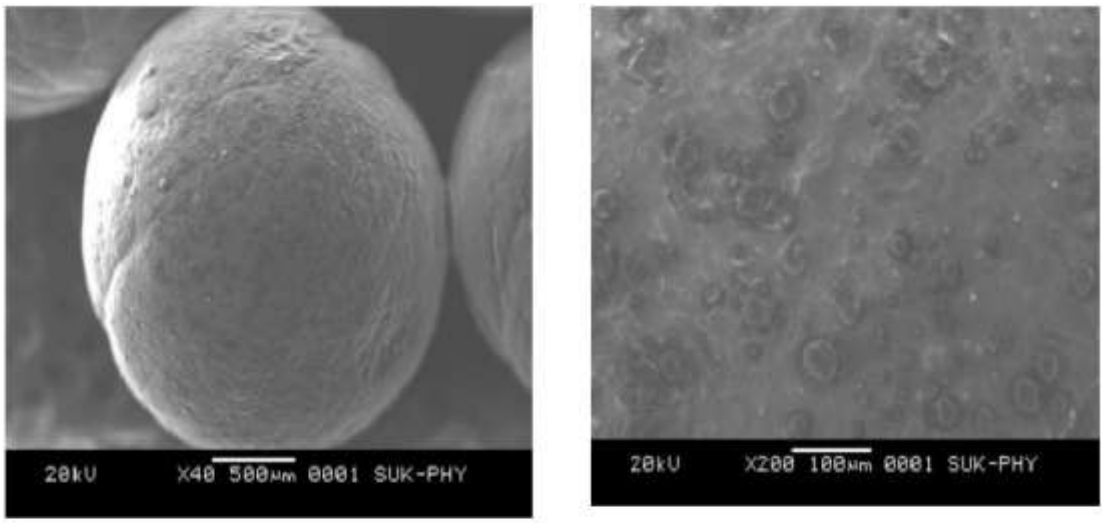
Figure 5.9.1 Scanning electron microscopy of (a) external and (b) surface morphology of drug loaded floating beads (F0)

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781



a b

Figure 5.9.2 Scanning electron microscopy of (a) external and (b) surface morphology of drug loaded floating beads (F1)



a b

Figure 5.9.3 Scanning electron microscopy of (a) external and (b) surface morphology of drug loaded floating beads (F4)

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

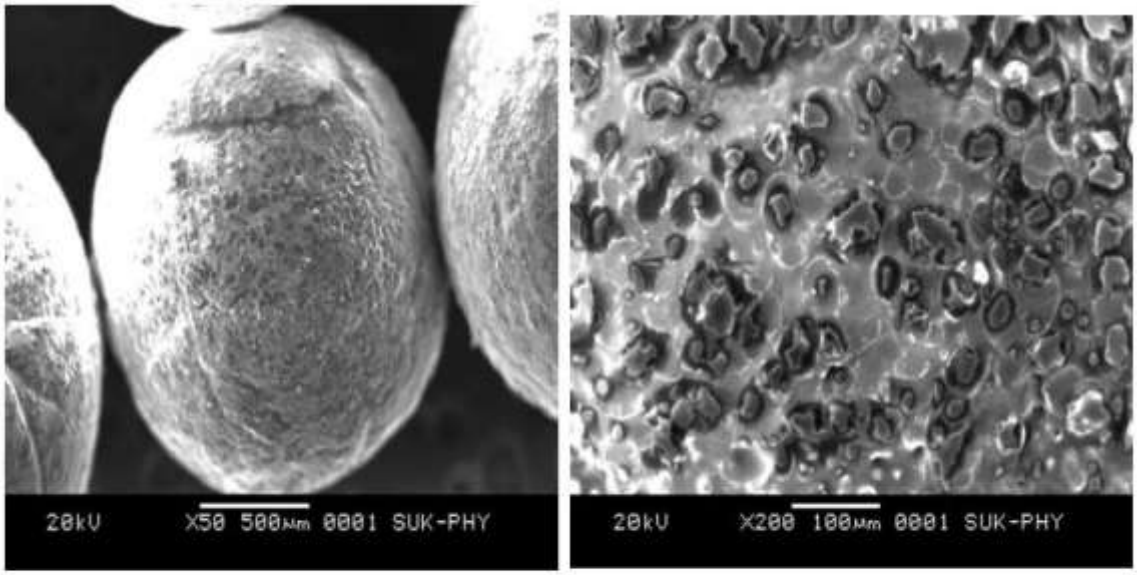


Figure 5.9.4 Scanning electron microscopy of (a) external and (b) surface morphology of drug loaded floating beads (F7)

VI. DISCUSSION:-

Oral drug delivery systems represent one of the pioneering areas of controlled drug delivery.system. Floating drug delivery system belongs to oral controlled drug delivery systemgroup has the ability to float in the stomach for a long time.In the present work, an attempt was made to prepare floating zinc trapped in oil.Pectinate granules contain ofloxacin to deliver the drug to the gastric mucosa over a long period of time Period. The prepared particles were evaluated for their physicochemical properties such as size and morphology, drug trapping efficiency, swelling and floating behaviorCharacteristics and release properties of drugs in vitro.

PREFQRMULATION STUDIES

DRUG. POLYMER COMPATIBILITY STUDIES

Differential Scanning Calorimetry (DSC)

Thermograms were obtained using pure ofloxacin and a physical mixture ofOfloxacin and the polymer showed no potential incompatibility between the polymer and the drug. DSCTemperature measurement of pure ofloxacin showed an endothermic peak at 274.5 0C (Fig5.1.1.1). DSC thermogram of the physical mixture of ofloxacin and polymer did not show any polymer-specific peaks and ofloxacin peaks were still presentbut slightly deviated from their original position (Figures 5.1.1.2 to 5.1.1.6), possiblyprobably due to ionic interactions and characteristics of drug synthesis reactionsAssume there are no incompatibility issues. Certain changes at the peak of the drug, e.gchanges in maximum surface area, shape or temperature have been noted, but these are simply the result ofmix the ingredients.

FOURIER TRANSFORM INFRARED RADIATION (FTIR)

All bands related to the pure drug are present in the FTIR spectrum of the drug inCombined with gellan gum, karaya gum and xanthan gum. This shows that there is not Chemical interactions take place between the drug and the polymer

PREPARATION OF FLOATING ZINC PECTINATE BEADS

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Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

Pectin with a low degree of esterification (DE) can form gels by ionotropic gelation withZn2+ ions. When the rice bran oil emulsion contains pectin, zinc is addedchloride solution, spherical gel particles are then immediately formed in itIntermolecular cross-links are formed between zinc and negative metal ions The charged carboxyl group of the pectin molecule (Figure:6.2.1). The gel beads were Easy training without any complicated equipment. It was found that the uniformity of emulsion isnecessarybecause there is no homogeneity; The oil separates from the pectin solutioneven though it is mixed with a stirrer.43 Pectin helps emulsify the mixture of water and oilstage in the homogenization process. However, the emulsifying properties are limitedwhen the oil concentration increases to more than 30%w/w. At this concentrationupwards, oil begins to flow out of the pearl. The balls stuck in the oil are spherical,transparent and slightly yellow. It was found that rice bran oil was at least 25% w/wis necessary to give the balls adequate buoyancy (table 5.3.2).

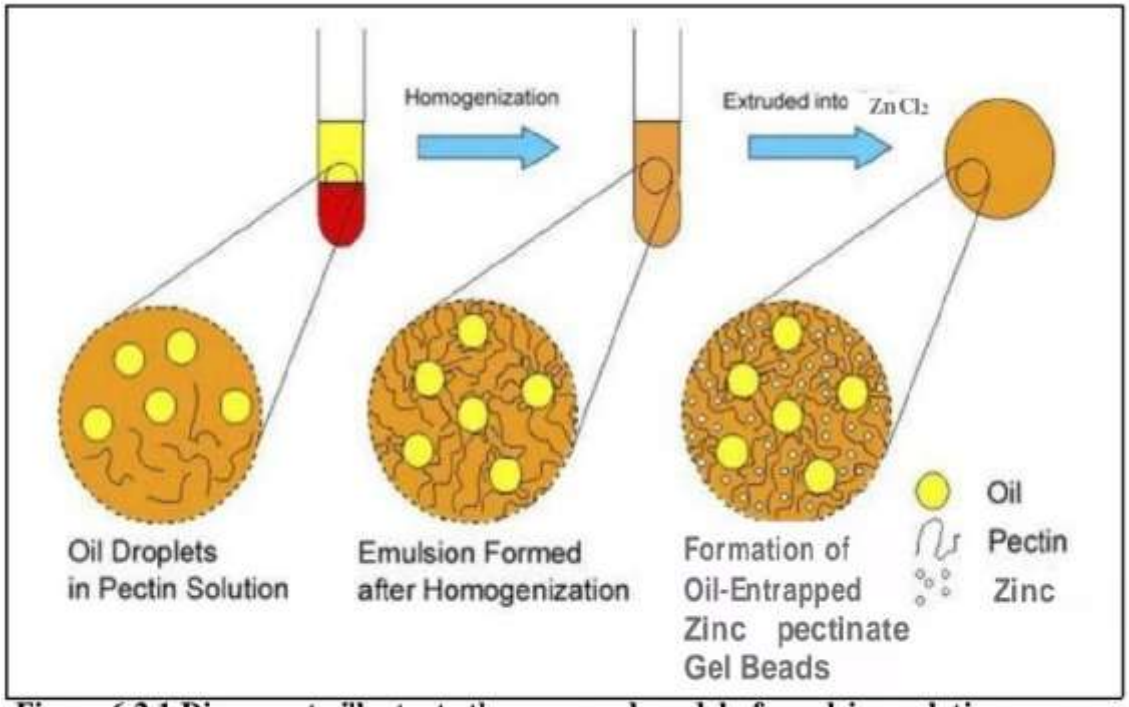

Figure 6.2.1 Diagram to illustrate the proposed model of emulsion-gelation process by which the oil entrapped zinc pectinate gel beads are formed.[43]

PHYSICOCHEMICAL PARAMETERS OF FLOATING ZINC PECTINATEBEADS

Bead diameter

The particles formed are spherical. Average particle diameter of retained pure oil Drug-free zinc pectinate granules were 1.691 ± 0.022 (mean ± standard deviation), but Loading the drug into the particles increases the size of the particles, e.g. g. people see that The mean diameter of formulation F increased to 1.693 ± 0.015 (mean ± standard deviation) after drug administration.loading. It was found that the combination of copolymers such as GG, KG and Particle formulation leads to a further increase in particle diameter, as in the case formulas from F1 to F9 (Table 5.3.1). When the process parameters are constant, The added materials are responsible for the change in size of zinc pectinate particles.14

Scanning electron microscopy

Scanning electron micrographs of the outer and inner surfaces of the blank and partsParticles containing drugs with formulas F1, F4 and F7 are shown in Figures 5.9.2, 5.9.3 and5.9.4. The particles (empty and drug-containing) have a spherical shape and an external surface smooth with slightly rougher surface/shrinkage probably due to drying.

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internalThe surface of the empty particles has a sponge-like nature with small droplets trapped.Oil creates buoyancy for pearls. In the particles containing the drug, the inner surface slightly porous, which is due to the drug and polymer controlling the homogenization rate dispersed in polymer matrix.38,40,43,50

Drug entrapment efficiency

The percent drug trapping efficiency (%EE) of ofloxacin-containing particles isshown in table 5.3.1.

The achieved particle trapping efficiency rates ranged from 57.49 D44 to 78.81%. Formula F1 showed the highest drug trapping abilityand formula Fshowed the lowest drug trap rate. Drug F trapping efficiency is low This formulation may be due to the highly porous nature of the zinc pectinate base,Therefore, the drug can diffuse back into the cross-linking solution from the beadsmatrix during the cross-linking phase.53 Drug binding also increases with addition copolymer in pearl formulation. Here zinc chloride is used as a crosslinkerAgents, such as calcium chloride, react with ofloxacin and tend to dissolve the drug in main cross-linking medium.62

SWELLING INDEX

Studies on the swelling properties of the seeds were carried out in 0.1 N HCl. Not availablea change in the swelling rate of particles in 0.1 N HCl was observed.18 Particlesnor did it swell or erode significantly during the dissolution study in 0.1 N HCl. Therefore,From these results it can be assumed that drug release is not under control swelling that is instead controlled by the dissolution of ofloxacin in the medium for dissolution and diffusion of ofloxacin through the polymer matrix.33

BUOYANCY STUDIES

The buoyancy of the prepared particles was evaluated along with dissolution studies. THEOil-free seeds were immediately soaked in 0.1 N HCl (pH 1.2), while seeds containingJust the right amount of rice bran oil (F to F9) is instant and wonderfulfloating capacity. It was found that a minimum of 25% w/w rice bran oil is requiredcreate buoyancy for gel beads (Table 5.3.2). Therefore, buoyancy is determined asis directly related to the amount of oil trapped in the polymer matrix. The remaining gemsfloated throughout the study period (8 h) and the particles continued to float for up to 24 h (Table5.3.2). It was found that varying the concentration of polymers and copolymers in the particlesThe formulas do not affect the float delay or float time of the clear balls dissolution media.

IN VITRO DRUG RELEASE STUDIES

In vitro drug release profiles of all particle formulations (F to F9) followed the conventional pathwayThis method is presented in Tables 5.4.1 to 5.4.10. Gel beads in 0.1 N HCl (pH 1.2),exhibits biphasic release characteristics, with an initial rapid drug release followed by a phaseThe drug release phase is slower and prolonged, gradually increasing after 1 hour. Formula F released 74.47% of the drug in 1 hour but did not maintain the drug released over the next 7 hours and released 99.14% of the drug after 3 hours.Formulations F1, F2 and F3, containing GG as well as LMP, released 87.51%,The amount of drug is 74.33% and 74.76% after 8 hours, respectively (Figure 5.4.1).Formulas F4, F5 and F6, containing KG as well as LMP, release 80.74%,The drug effectiveness after 8 hours is 59.85% and 76.41%, respectively (Figure 5.4.2).Formulations F7 and F8, containing XG as well as LMP, released 68.52% and 66.00 D44 of the drug, respectively, after 8 hours (Figure 5.4.3). Formula F9 contains LMP as well as GG, KG, XG releasing 62.40% of the amount medicine after 8 hours (Figure 5.4.3). The results showed that the incorporation of rate-controlling polymers such as GG, KG and XGThe granular formulation can sustain drug release from zinc pecinate trapped in the oil pearl. Incorporation of these copolymers into a zinc pectinate matrix increases viscosity of the polymer matrix and thus reduces drug release. Resultalso showed that as the copolymer concentration increased in the formulation, drug release is further reduced and more sustained drug release is observed becauseAs the copolymer concentration increases, the viscosity of the polymer matrix increases further reinforced.

KINETICS OF DRUG RELEASE

In vitro release data for all batches were adjusted to level 0, level 1, Higuchiand the Korsemeyer and Peppas equations. It is observed that for formulas F, F1 and F2, r2 is higher when fitting a first-order equation (r2 = 0.944), showing that areleases the first order of formula F, while all other formulas, from F3 to F9, follow the Higuchi model. The n value of the Korsemeyer-Peppas model for all formula was found to be less than 0.5 (n<0.5), indicating that the drug released from the pearls by Fician diffusion (case I).

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 5 Sep-Oct 2023, pp: 686-740 www.ijprajournal.com ISSN: 2249-7781

STBILITY STUDIES

At various time intervals, samples were evaluated for the stability studies. There were nomore difference in the drug content and the floating properties at the various samplingintervals. The in vitro drug release profiles were super imposable which confirms thestability of the product.

. VII. CONCLUSION

Ofloxacin is an antibacterial fluoroquinolone. It is widely prescribed in gastric ulcers,duodenal ulcer, Zollinger-Ellison syndrome and gastroesophageal reflux.Ofloxacin exhibits pH-dependent solubility. It is more soluble in acidic pH andSlightly soluble in neutral or alkaline pH conditions. However, the drug crazeoccurs in the intestine, negatively affecting absorption in the lower part of the intestine. intestine. Therefore, it is necessary to have systems that stay in the stomach for a relatively long time.time and release the active compound in a sustained manner.34

The plasma half-life of ofloxacin is 5 to 8 hours with an oral bioavailability of 95% and The most appropriate dose is 200 to 400 mg once daily in the morning.63

The purpose of this study is to develop a delivery system in which maintenanceofloxacin can be obtained to increase the local effect in the stomach area againstHelicobacter pylori bacteria. So this investigation focuses ondevelopment of zinc pectinate particles trapped in rice bran oil containing ofloxacin, after oral administration has been designed to prolong residence time in the stomach,increase drug bioavailability.

A suitable method for drug analysis by UV spectroscopy has been developed.

Ofloxacin shows maximum absorption at 294.5 nm in hydrochloric medium at pH 1.2.acid buffer. The value of the regression coefficient (r2) turns out to be 0.999, showslinear relationship between concentration and absorbance. Research on drug preparationand DSC and FTIR polymer compatibility confirmed the purity of drug and showed no interaction between drug and polymerVarious formulations of ofloxacin flotation beads have been developed using polymers such asLMP alone and mixtures of LMP with flow control polymers such as GG, KG and XG.The particles were prepared by emulsion gelation method. Rice bran oil is used to impart the buoyancy of the ball due to its low density. The particles are spherical in nature and Evaluation of drug content and trapping efficiency showed that particles were formedUsing LMP alone will result in low and trapped drug content.Granules made up of a mixture of LMP and GG have the highest drug content andtrap compared to other formulations. The particles do not swell or corrode much in the dissolution medium, indicating the drugrelease depends on the dissolution and diffusion of the drug through the polymermatrix.

Grain buoyancy studies have demonstrated that rice bran oil contains a minimum of 25% w/w is necessary to provide satisfactory buoyancy to the pearl. The particles showInstant, excellent buoyancy and buoyancy on dissolved mediathroughout the research period. In vitro drug release studies showed that LMP alone could not sustain drug release.over a sufficient period of time while the incorporation of polymers controls the rate asGG, KG and XG are copolymers that can effectively maintain drug release from beads recipe. The results showed that the particles were made up of a mixture of LMP and GG(F1) showed the highest drug release compared to other formulations. So the expression F1 is chosen as the optimal formula. The formulation chosen had no changes in drug content, buoyancy or in vitroDrug release characteristics after storage at 75 ± 5% relative humidity at 40 ± 2°C in a two-month stability study. Therefore, the objective of the present work is to develop a dosage form of ofloxacin usingUse low density oils and different ratios and release rates in combination Polymer control was performed successfully.

SCOPE FOR FURTHER STUDY

™ The developed formulation has potential for other drugs to haveabsorption window in the upper part of the GIT.

™ This work can be extended to in vivo studies of in vitro-in vivo correlationsand gamma scintigraphy using various experimental .
.....animal models.

™ Work can be done to study the influence of other parameters such asbiological adhesion.

™ The goal of further research is to develop a unique floating ring dosage formcombined form of soluble and insoluble gastric fractions,
.....and to evaluate it suitability for delivering specific drugs into the stomach.

™ Concept combines buoyancy and oscillation principles for responserequirements of the “ideal” delivery system for therapeutic
.....purposes over time for arthritis is being

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studied. ™ Study different geometric shapes, in a way that surpasses the previous .....onesresearch, enlarged size with high hardness, on stomach retention ability.

SUMMARY

The aim of the study was to develop and characterize the physical properties of trapped floating oil Ofloxacin zinc peptinate granules. Ofloxacin is an antibacterial fluoroquinolone. That isintended to act on the gastric mucosa. Ofloxacin is more soluble at acidic pH and Slightly soluble in neutral or alkaline pH conditions. However, the drug crazeoccurs in the intestine, negatively affecting absorption in the lower part of the intestine.intestine. Therefore, the development of a sustained-release formulation of ofloxacin is necessary.beneficial if the system can survive in the stomach for a long time.Different types of matrix forming polymers such as LMP, GG, KG and XG have been used to current research. Rice bran oil is used to give pearls buoyancy.These drugs and polymers were studied for compatibility using DSC and FTIR.this suggests that there is no interaction between the drug and the polymer.

All granule formulations exhibited satisfactory flotation characteristics. All These formulations were subjected to in vitro release studies using hydrochloric acid pH 1.2.buffer in a conventional dissolution apparatus. The results indicate that LMP alone cannotmaintained drug release but mixing LMP with other copolymers maintained the drugreleased for more than 8 hours. To analyze the drug release mechanism from seeds,In vitro release data were incorporated into different release models. It has been observed that drug release according to the Higuchi model and find the drug release mechanism by hypothetical diffusion.

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