CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

SJIF Impact Factor: 7.187

https://doi.org/10.5281/zenodo.15395856

Available online at: http://www.iajps.com Research Article

FORMULATION AND EVALUATION GASTRORETENTIVE DRUG DELIVERY SYSTEM

Niesh M.Jadhao[1], Aijaz A.Sheikh[2], K.R.Biyani[3]

Department of Pharmaceutics, Anuradha College Pharmacy, Chikhli[1,2]

Campus Director & Principal, Anuradha College Pharmacy, Chikhli, Dist –Buldana- 443201[3].

Abstract:

Gastroretentive Drug Delivery Systems (GRDDS) represent a significant advancement in the field of oral drug delivery, offering enhanced bioavailability, controlled release profiles, and improved therapeutic outcomes for drugs with narrow absorption windows or those unstable in the intestinal pH. Through various approaches—such as floating, mucoadhesive, expandable, high-density, and raft-forming systems—GRDDS has proven effective in extending gastric residence time and improving the pharmacokinetics of a wide range of therapeutic agents.

The advantages of GRDDS, including reduced dosing frequency, enhanced patient compliance, and minimized side effects, position it as a preferred choice for chronic conditions requiring sustained drug delivery. However, the challenges associated with these systems—such as variable gastric emptying times, potential for dosage form failure, and formulation complexity—require careful design and evaluation during development. Furthermore, the influence of physiological factors such as pH, gastric motility, and fed or fasted state must be considered to ensure consistent drug release and absorption.

As explored in this chapter, GRDDS has demonstrated potential in treating various gastrointestinal and systemic diseases, including Helicobacter pylori infections, peptic ulcers, GERD, diabetes, and hypertension. This versatility is driving ongoing research to develop more reliable, patient-friendly formulations that align with individual patient needs and clinical outcomes. In conclusion, the continued evolution of GRDDS will likely play a pivotal role in the advancement of oral pharmacotherapy, enabling precise, targeted, and effective treatment options in both conventional and novel therapeutic areas.

Corresponding author:

Niesh M.Jadhao,

Department of Pharmaceutics Anuradha College Pharmacy, Chikhli

QR code

Please cite this article in press Niesh M.Jadhao et al., ***Formulation And Evaluation Gastroretentive Drug Delivery System.,*** *Indo Am. J. P. Sci, 2025; 12(05).*

INTRODUCTION:

Gastroretentive Drug Delivery Systems (GRDDS) are a class of drug delivery systems designed to enhance the residence time of the drug in the stomach, which can significantly improve the bioavailability of drugs that are poorly absorbed in the intestines. This approach is particularly beneficial for drugs that have a narrow absorption window in the gastrointestinal (GI) tract, such as those that are absorbed primarily in the stomach or upper part of the small intestine. By prolonging the gastric residence time, GRDDS can provide sustained release, reduce dosing frequency, and improve therapeutic efficacy, making them a highly desirable alternative to traditional oral dosage forms.

The formulation of GRDDS involves the design and development of systems that can withstand the harsh acidic environment of the stomach while ensuring that the drug is released in a controlled and predictable manner. The key components that determine the effectiveness of GRDDS include the type of drug, the desired release profile, and the choice of materials for the formulation. GRDDS can be categorized into several types, such as floating drug delivery systems, bioadhesive systems, swellable systems, and Multiparticulate systems (such as microspheres and beads). Each of these systems operates under different mechanisms to retain the drug in the stomach for extended periods.

Floating drug delivery systems are one of the most widely studied GRDDS, where the drug formulation contains a buoyant property that enables it to float in the gastric fluid. This floating characteristic ensures that the drug remains in the stomach for a prolonged period, offering sustained drug release. Bioadhesive systems, on the other hand, rely on mucoadhesive polymers that adhere to the gastric mucosa, ensuring a prolonged interaction with the stomach lining, which also results in extended drug release.

Swellable systems, such as hydrogels, expand upon contact with gastric fluids, increasing the size of the dosage form and preventing it from passing too quickly into the small intestine. Multiparticulate systems, such as microspheres and beads, offer several advantages, including improved flexibility in dosing and more uniform drug release.[1] Floating and gastroretentive drug delivery systems (FDDS and GRDDS) are beneficial as they prolong the residence time of drugs in the stomach, enhancing absorption, especially for drugs with a narrow absorption window or those that act locally in the stomach. These systems improve bioavailability, provide controlled and sustained drug release, and reduce dosing frequency. They help maintain consistent plasma drug levels, minimizing fluctuations and side effects.[1]

METHODS & MATERIAL

Table1.Materials & Supplier

Material	Company Name
Ciprofloxacin HCl	Yarrow Chem Products, Mumbai
HPMC K4M	Colorcon Asia Pvt Ltd, Goa
Carbopol	Indo Pharma,Mumbai
Sodium Alginate	Indo Pharma,Mumbai
Sodium Bicarbonate	Merck Ltd., Mumbai
Citric Acid	Qualikems Fine Chem Pvt Ltd, Vadodara
Microcrystalline Cellulose	Avantor Performance Materials, India
Magnesium Stearate	Loba Chemie Pvt Ltd, Mumbai
Talc	Indo Pharma,Mumbai

Preformulation Studies

Pre-formulation testing involves examining the physical and chemical characteristics of a pharmacological material both on its own and when mixed with other substances called excipients. Pre-formulation studies provide essential information for the development of an appropriate formulation for toxicological purposes. [2]

Pre Compression Parameters

Bulk Density

Bulk density is a measure of the mass of a powder divided by its bulk volume before tapping. This test helps in assessing how loosely the powder particles are packed. It provides insight into the powder's flowability and packing characteristics.

Formula:

Bulk Density (BD) = Weight of powder (W) / Bulk Volume (V_b)

Tapped Density

Tapped density is the mass of a powder per unit volume after it has been tapped to allow the particles to settle. It is essential for determining how much the powder can settle under mechanical pressure. This test helps to evaluate the compactness of the powder.

Formula:

Tapped Density (TD) = Weight of powder (W) / Tapped Volume (V_t)

3. Carr's Index (Compressibility Index)

Carr's Index evaluates the compressibility and flowability of powders by comparing the difference between the tapped and bulk density. A high Carr's index indicates poor flowability, whereas a low value indicates better flow characteristics.

Formula:

Carr's Index (%) = [(Tapped Density (TD) - Bulk Density (BD)) / Tapped Density (TD)] × 100

Hausner's Ratio

Hausner's Ratio is used to measure the flowability of powders based on the ratio of tapped density to bulk density. A Hausner ratio closer to 1 indicates better flow, while a higher ratio suggests poorer flowability.[3]

Formula:

Hausner's Ratio = Tapped Density (TD) / Bulk Density (BD)

Angle of repose:In order to determine Carr's index, the values of bulk density and tapped density areemployed. This is done for the aim of computing the index. For the purpose of calculating theCarr's index, the equation that is presented below is employed.

Solubility:-

Solubility of Telmisartan was determined in different aqueous and non-aqueous solvents.Solubility studies performed by taking excess amount of Telmisartan in different beakers containing the solvents.

Determination of Melting Point:-

was determined by capillary method. Fine powder of Telmisartan was filled in the glass capillary tube which was sealed at end. The capillary tube is tied to thermometer and the thermometer was placed in melting point apparatus. The powder at what temperature it will melt was noticed as melting temperature of drug.[4]

Drug Profile

Ciprofloxacin

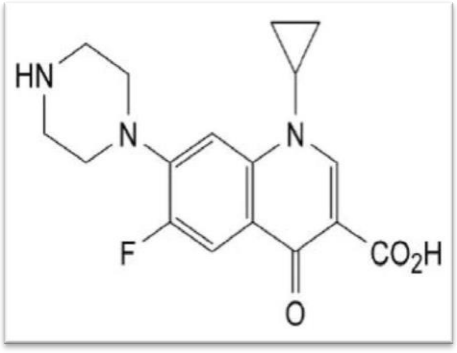

Fig 1. Chemical Structure of Ciprofloxacin

Table 2.Physicochemical Parameters of Ciprofloxacin Tablet

Physicochemical Parameter	Value/Description
Molecular Formula	C17H18FN3O3
Molecular Weight	331.35 g/mol
Melting Point	255-257°C (decomposes)
Solubility in Water	Slightly soluble (approx. 30 mg/L at 25°C)
Log P (Partition Coefficient)	0.28
pKa (Acid Dissociation Constant)	pKa1: 6.1 (carboxylic acid), pKa2: 8.7 (amine group)
Hydrogen Bond Donor Count	2
Hydrogen Bond Acceptor Count	6
Rotatable Bond Count	3
Topological Polar Surface Area	74.6 Å²
Drug Class	Fluoroquinolone Antibiotic

Experimental Work

Formulation Strategy for Ciprofloxacin Tablet for GRDDS

The formulation strategy for the development of Ciprofloxacin hydrochloride gastroretentive drug delivery system (GRDDS) was designed to optimize drug release in the upper gastrointestinal tract (GIT), improve bioavailability, and maintain prolonged therapeutic levels. Given Ciprofloxacin's pH-dependent solubility and absorption primarily in the stomach and upper small intestine, a floating drug delivery system was chosen as the most suitable approach. Floating tablets were designed to remain buoyant in gastric fluid, thereby prolonging gastric residence time and facilitating sustained drug release. This strategy involved the selection of appropriate polymers, effervescent agents, and direct compression techniques to formulate an effective floating matrix tablet.[5]

The primary drug selected for formulation was Ciprofloxacin hydrochloride, a broad-spectrum fluoroquinolone antibiotic. It is classified as a BCS Class IV drug with low solubility and low permeability, which makes it a strong candidate for modified-release formulations. The excipients used in the formulation were carefully selected based on their functional roles and compatibility with the drug.

1. Hydroxypropyl Methylcellulose (HPMC K4M): This was selected as the primary matrix-forming polymer due to its excellent gel-forming and swelling properties. Upon contact with gastric fluid, HPMC swells and forms a viscous gel barrier, which controls drug diffusion and slows down the release rate. It also contributes to the floating ability of the tablet by trapping gas within the hydrated gel.
2. Carbopol 934P: This polymer was used in combination with HPMC to enhance the mucoadhesive strength and to contribute to the matrix integrity. Carbopol is known for its high swelling capacity, which supports prolonged gastric retention and sustained release behavior.
3. Sodium Alginate: A naturally occurring, biocompatible polymer that enhances gel strength and further modulates drug release. It forms a pH-sensitive gel that swells in acidic environments, making it highly suitable for GRDDS.
4. Sodium Bicarbonate: An essential gas-generating agent that reacts with the acidic gastric fluid to produce carbon dioxide. The entrapped gas reduces the density of the tablet and helps it to float on the gastric fluid.
5. Citric Acid: Used in combination with sodium bicarbonate to ensure consistent effervescence and floating behavior by accelerating CO_2 generation in the acidic medium.
6. Microcrystalline Cellulose (MCC): Used as a diluent and binder to improve tablet compressibility and hardness. It also contributes to uniform weight and drug content in each tablet.
7. Magnesium Stearate: Used as a lubricant to

reduce friction during tableting and ensure smooth ejection from the die cavity.

8. Talc: A glidant used to enhance powder flow properties, facilitating uniform die filling during the compression process.[6]

All the excipients used were of pharmaceutical grade and procured from reliable sources. Prior to formulation, compatibility between Ciprofloxacin and each excipient was confirmed through FTIR and DSC studies, which showed no significant interaction or degradation.[7]

Method of Formulation

The Ciprofloxacin floating tablets were formulated using the direct compression method, chosen for its simplicity, cost-effectiveness, and suitability for moisture- and heat-sensitive drugs. The process was conducted as follows:

1. Weighing of Ingredients: All the excipients and Ciprofloxacin were accurately weighed according to the composition designed for each formulation batch. Different batches were prepared with varying ratios of polymers to optimize the floating and release characteristics
2. Sifting and Blending: The drug and excipients were passed through a 60-mesh sieve to remove lumps and achieve uniform particle size. The sifted materials were then transferred to a blender and mixed thoroughly for 15–20 minutes to ensure homogeneous distribution of the drug and excipients
3. Addition of Lubricants: Magnesium stearate and talc were added to the blend as lubricants and glidants. They were added at the final stage and blended for an additional 3–5 minutes to prevent over-lubrication, which can affect tablet hardness and disintegration
4. Compression: The final blend was compressed into tablets using a rotary tablet press equipped with flat-faced punches. The compression force was adjusted to produce tablets of adequate hardness (5–7 kg/cm²) and uniform weight. The average weight of each tablet was targeted at around 500 mg.[8]

Table 3.Formulation Table for Ciprofloxacin

Ingredients (mg/tab)	Batch F1	Batch F2	Batch F3	Batch F4	Batch F5	Batch F6	Batch F7
Ciprofloxacin HCl	250	250	250	250	250	250	250
HPMC K4M	60	80	100	120	140	160	180
Carbopol 934P	20	30	30	30	30	30	30
Sodium Alginate	25	30	35	40	45	50	55
Sodium Bicarbonate	30	30	30	30	30	30	30
Citric Acid	10	10	10	10	10	10	10
Microcrystalline Cellulose (MCC)	90	60	35	20	10	0	0
Magnesium Stearate	5	5	5	5	5	5	5
Talc	10	5	5	5	5	5	5
Total Weight (mg)	500	500	500	500	500	500	500

Post-Compression Evaluation of Gastroretentive Ciprofloxacin Tablets:

The post-compression evaluation of tablets plays a critical role in determining the physical and functional integrity of solid oral dosage forms. For gastroretentive drug delivery systems (GRDDS), especially those formulated with Ciprofloxacin, these parameters are vital to ensure that the tablets meet pharmacopoeial standards and maintain their performance throughout gastric residence. This section elaborates on the key post-compression parameters used in the assessment of Ciprofloxacin-based GRDDS tablets.[9]

Hardness (Crushing Strength) Hardness is an essential mechanical property that determines the tablet's resistance to chipping, abrasion, and breakage during handling, transport, and storage. In GRDDS formulations, it is particularly important because the tablet must maintain its integrity over extended periods within the gastric environment. The hardness of a tablet is measured using hardness testers such as the Monsanto or Pfizer apparatus. Typically, a force

of 4–8 kg/cm² is considered acceptable. Tablets with insufficient hardness may disintegrate prematurely, whereas excessive hardness may delay drug release.[10]

Thickness Tablet thickness is a vital parameter that contributes to the physical appearance and uniformity of the dosage form. It is measured using Vernier calipers or micrometers and should be consistent across all batches. Uniform thickness ensures predictable drug release and helps maintain uniformity in packaging and patient compliance. In GRDDS, changes in thickness may influence the tablet's buoyancy and swelling behavior.[11]

Weight Variation Weight variation testing assesses the uniform distribution of active pharmaceutical ingredients (API) among tablets. For Ciprofloxacin GRDDS tablets, consistent weight indicates proper mixing and compression. According to pharmacopeial guidelines, the acceptable percentage deviation varies with tablet weight: ±10% for tablets <80 mg, ±7.5% for 80–250 mg, and ±5% for tablets >250 mg. The formula used is:

% Deviation = [(Individual Weight - Average Weight) / Average Weight] × 100

This test ensures dose uniformity, critical for achieving the intended therapeutic effect.

Friability Friability measures a tablet's resistance to surface abrasion. It is tested using a Roche friabilator, where tablets are rotated at 25 rpm for 4 minutes. A maximum weight loss of not more than 1% is acceptable. The formula is:

% Friability = [(Initial Weight - Final Weight) / Initial Weight] × 100

For GRDDS tablets, low friability is essential to ensure tablets remain intact in the stomach for extended periods[12]

Floating Lag Time Floating lag time is the time taken by a tablet to rise to the surface of the dissolution medium, simulating gastric fluids. It is a critical parameter in floating GRDDS tablets, as a rapid onset of buoyancy ensures retention in the upper gastrointestinal tract. The lag time is recorded in seconds or minutes. Ideal formulations exhibit a floating lag time of less than one minute.[13]

Total Floating Time This parameter evaluates the tablet's ability to remain buoyant over time in gastric fluid. The total floating time should ideally exceed 8 hours for effective gastroretention. Extended floating time ensures prolonged drug release and enhances the bioavailability of drugs like Ciprofloxacin, which have a narrow absorption window.

Swelling Index Swelling index reflects the capacity of the tablet to absorb fluid and swell, forming a gel-like barrier that contributes to sustained drug release. It is calculated using the following formula:

Swelling Index (%) = [(Wt - W0) / W0] × 100

Where W0 is the initial weight and Wt is the weight after a predetermined time of swelling. A high swelling index indicates a well-formulated matrix system that enhances retention and controls drug release.[14]

Drug Content Uniformity Drug content analysis ensures each tablet contains the intended amount of Ciprofloxacin. Uniformity is essential for therapeutic consistency and regulatory compliance. The tablets are dissolved in a suitable solvent, and drug concentration is analyzed using UV-Visible spectrophotometry. The formula used is:

% Drug Content = (Measured Concentration / Theoretical Concentration) × 100

The acceptable range is 90% to 110%. Any deviation may indicate issues in blending or compression.

Post-compression evaluation of Ciprofloxacin GRDDS tablets ensures that the formulation meets mechanical strength, drug content, and floating behavior requirements. These tests are fundamental in predicting the in vivo performance of the dosage form and are essential in the optimization of gastroretentive systems for improved therapeutic efficacy.[15]

RESULTS AND DISCUSSION:

STANDARD GRAPH OF CIPROFLOXACIN

The standard calibration curve of Ciprofloxacin was constructed to determine the relationship between its concentration and corresponding absorbance values. A series of standard solutions with concentrations ranging from 10 µg/ml to 50 µg/ml were prepared in distilled water, and their absorbance was measured at 271 nm using a UV-Visible spectrophotometer.

Table4.series of standard solutions with concentrations

Conc (ug/ml)	Absorbance
10	0.156
20	0.302
30	0.448
40	0.590
50	0.735

The graph exhibited a strong linear relationship between concentration and absorbance across the tested range. The increase in absorbance values with rising concentration confirmed the Beer-Lambert law, indicating that this spectrophotometric method is appropriate for quantifying Ciprofloxacin in pharmaceutical formulations. The linearity of the curve suggests a high degree of accuracy and precision, making the method reliable for use in further analytical procedures, including assay and dissolution testing. Further validation for parameters like specificity, robustness, and reproducibility is recommended to ensure comprehensive method suitability.

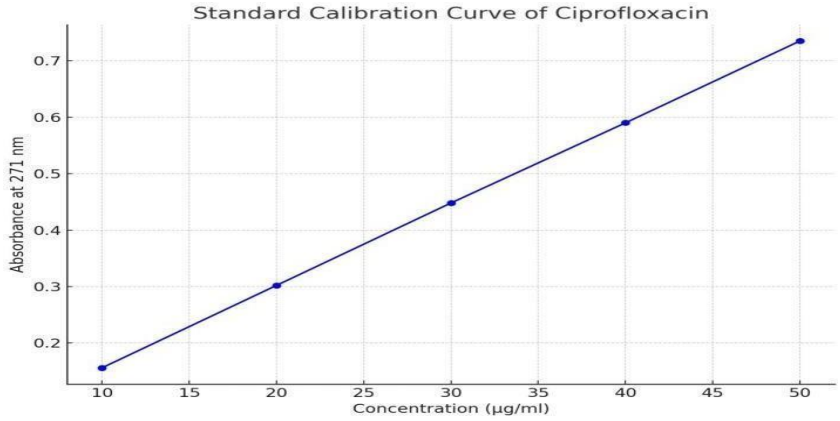

Fig 2. Standard calibration curve of Ciprofloxacin

FT-IR STUDIES:

FTIR Studies of Ciprofloxacin:

Fourier Transform Infrared Spectroscopy (FTIR) is a widely employed analytical technique used to identify functional groups, investigate chemical interactions, and confirm the structural integrity of pharmaceutical compounds.

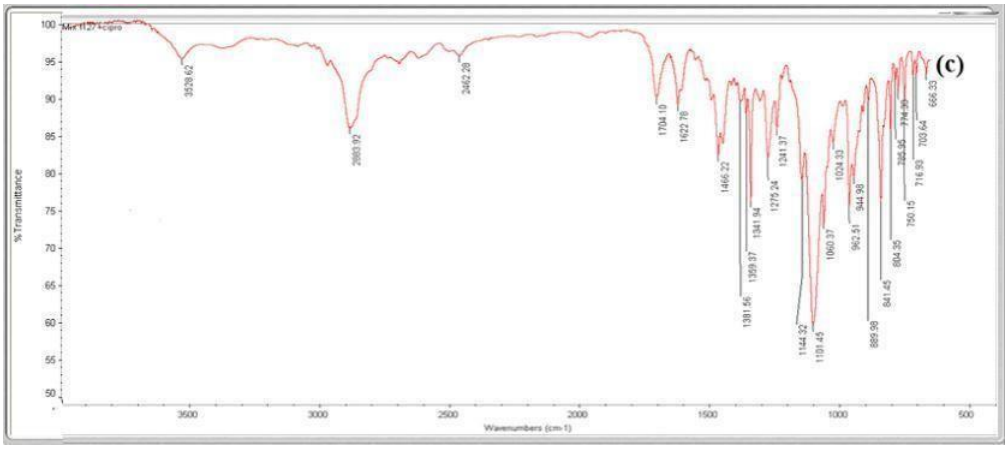

Fig3.FTIR Spectra of Ciprofloxacin

In the context of Ciprofloxacin, a second-generation fluoroquinolone antibiotic, FTIR plays a vital role in verifying its chemical stability, evaluating drug-excipient compatibility, and ensuring formulation integrity.FTIR spectroscopy operates on the principle that molecules absorb specific frequencies of infrared radiation that cause vibrations within their chemical bonds. When infrared light passes through a sample, certain wavelengths are absorbed depending on the molecular structure, while others are transmitted. The resulting absorption spectrum acts as a molecular ―fingerprint‖ that reveals the presence of specific functional groups.

FTIR measures the intensity of transmitted light as a function of frequency (or wavelength), and this data is transformed using Fourier Transform mathematics to produce a spectrum. Each peak in the spectrum corresponds to a particular bond vibration, allowing for the identification of functional groups and the assessment of chemical interactions.

FTIR Spectral Analysis of Ciprofloxacin

Ciprofloxacin is chemically known as 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1- piperazinyl)-3-quinoline carboxylic acid. The FTIR spectrum of pure Ciprofloxacin exhibits characteristic peaks that correspond to various functional groups present in its structure. These peaks serve as reference markers for subsequent compatibility and stability studies.

Typical FTIR peaks of Ciprofloxacin include:

~3500–3300 cm^{-1}: Broad O–H stretching vibration associated with the carboxylic acid group.
~1700–1725 cm^{-1}: Sharp C=O stretching of the carboxylic acid moiety.
~1620–1650 cm^{-1}: Ketone C=O stretching (associated with the quinolone ring).
~1500–1600 cm^{-1}: Aromatic C=C stretching in the quinoline ring.
~1250–1300 cm^{-1}: C–F stretching from the fluoro group.
~1050–1100 cm^{-1}: C–N stretching from the piperazine moiety.
~2900 cm^{-1}: C–H stretching vibrations.

These spectral bands are used to identify Ciprofloxacin in pure and formulated states and are sensitive indicators of structural changes or interactions In pharmaceutical formulation development, FTIR is utilized to ensure that the drug maintains its structural integrity when combined with various excipients. Ciprofloxacin tablets often include excipients like HPMC K4M, Carbopol 934P, Sodium Alginate, Sodium Bicarbonate, Microcrystalline Cellulose, Citric Acid, Magnesium Stearate, and Talc.

Drug-Excipient Compatibility

The FTIR spectra of physical mixtures of Ciprofloxacin with each excipient are compared with the pure drug spectrum. A compatible formulation will retain the characteristic peaks of Ciprofloxacin without significant shifts or the appearance/disappearance of peaks If the sharp C=O peak at 1700 cm^{-1} in the drug spectrum shifts or disappears in the mixture, it may indicate a chemical interaction. Broadening of the O–H peak around 3400 cm^{-1} in the presence of HPMC or Sodium Alginate suggests hydrogen bonding but not necessarily incompatibility. In most GRDDS formulations involving polymers like HPMC K4M or Carbopol 934P, FTIR analysis shows minor broadening of certain bands (especially in O–H or N–H regions) due to hydrogen bonding but retains the identity of Ciprofloxacin's characteristic peaks, confirming the absence of destructive interactions.

FTIR Data in GRDDS Formulations

Ciprofloxacin is often formulated into Gastroretentive Drug Delivery Systems (GRDDS) to increase its gastric residence time and bioavailability. In such systems, polymers (like HPMC and Sodium Alginate) and gas-generating agents (Sodium Bicarbonate and Citric Acid) are used to control drug release and buoyancy.

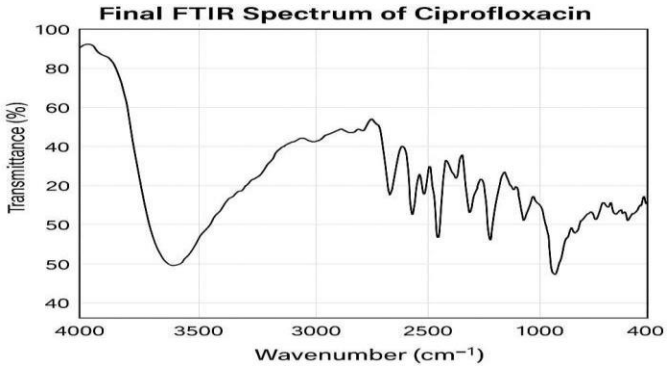

Fig4..FTIR Spectra of Ciprofloxacin for final Formulation

HPMC K4M and Sodium Alginate: These hydrophilic polymers can form hydrogen bonds with Ciprofloxacin, seen as broadening of the O–H/N–H regions in FTIR spectra. These interactions are typically non-covalent and reversible, which do not compromise the drug's activity.
Carbopol 934P: Being a polyacrylic acid derivative, it has multiple carboxylic groups. FTIR spectra may show increased intensity or slight shifts near 1700 cm^{-1} due to overlapping C=O stretching bands from both drug and polymer.

Sodium Bicarbonate and Citric Acid: These excipients are used to generate CO_2 for floating ability. Their presence does not usually affect the FTIR spectrum of Ciprofloxacin unless reacted under wet or acidic conditions Magnesium Stearate and Talc: These are typically inert excipients and do not significantly alter Ciprofloxacin's FTIR spectrum.

Preformulation Study Results of Ciprofloxacin Tablet for GRDDS

The preformulation studies for Ciprofloxacin tablets intended for gastroretentive drug delivery systems (GRDDS) were conducted to assess the physical and chemical characteristics of the drug and excipients. These studies are essential to determine the compatibility, flow properties, and other parameters influencing the formulation design and performance.

Table:5.Result of Preformulation Studies

Test Parameter	Result
Appearance	White to off-white crystalline powder
Solubility	Soluble in water, slightly soluble in methanol, insoluble in chloroform
Melting Point	Approximately 255°C
pH (1% solution)	3.5 - 4.5
Bulk Density (g/cm*)	0.47 ± 0.02
Tapped Density (g/cm*)	0.61 ± 0.03
Carr's Index (%)	22.95 ± 0.75 (Fair flowability)
Hausner's Ratio	1.30 ± 0.02
Angle of Repose (°)	33.4 ± 0.5 (Passable flow)
Drug-Excipient Compatibility (FTIR)	No significant interaction observed

POST COMPRESSION PARAMETERS

Evaluation of Ciprofloxacin Floating Tablets:

Hardness (kg/cm²

This test evaluates the mechanical strength of tablets. All batches exhibit increasing hardness, indicating improved structural integrity.
Hardness (kg/cm²):

The hardness test evaluates the mechanical strength of tablets, ensuring they can withstand handling and packaging without breaking. In the formulation batches F1 to F7, the hardness progressively increased from 5.2 kg/cm² to 6.5 kg/cm². This steady rise indicates that the tablets developed in later formulations (F6 and F7) had better structural integrity, likely due to optimized concentrations of binders or polymeric materials.[96]

Table 6.Hardness (kg/cm²):

Batch	Hardness (kg/cm²)
F1	5.2
F2	5.6
F3	5.8
F4	6.0
F5	6.2
F6	6.4
F7	6.5

Thickness (mm)

Tablet thickness is an essential physical parameter that affects tablet uniformity and packaging. The recorded thickness values increased gradually across batches, from 4.5 mm in F1 to 5.1 mm in F7. The increase in thickness could be attributed to increased polymer content or filler quantities, contributing to tablet matrix formation. Despite this rise, the consistency across batches indicates precise manufacturing control

Table7.Thickness (mm)

Batch	Thickness (mm)
F1	4.5
F2	4.6
F3	4.7
F4	4.8
F5	4.9
F6	5.0
F7	5.1

Weight Variation (%)

Weight variation is a critical test to ensure dose uniformity in each tablet. All formulations fell well within the pharmacopeial limit of ±5%, with F1 showing ±3% variation and F7 improving to ±1.8%. This indicates a high degree of control in tablet compression and powder flow, reflecting good pre-formulation parameter optimization.

Table8.Weight Variation (%)

Batch	Weight Variation (%)
F1	±3%
F2	±2.8%
F3	±2.5%
F4	±2.3%
F5	±2.1%
F6	±2%
F7	±1.8%

Friability (%)

Friability measures the ability of tablets to resist surface abrasion during handling and transportation. All the batches exhibited friability below 1%, which is considered acceptable. F1 had the highest friability at 0.52%, while F7 exhibited the best resistance with 0.35%

Table:9. Friability (%) .

Batch	Friability (%)
F1	0.52
F2	0.48
F3	0.45
F4	0.42
F5	0.4
F6	0.38
F7	0.35

The gradual reduction suggests improved cohesion and mechanical strength, likely due to enhanced formulation strategies in the later batches.

Tests tablet resistance to abrasion. Lower values across batches reflect better mechanical resistance.

Floating Lag Time (sec)

Floating lag time is the duration a tablet takes to emerge on the surface of the dissolution medium, representing gastric buoyancy. A lower floating lag time is desired for immediate flotation upon ingestion. F1 recorded 45 seconds, while F7 showed a significantly improved lag time of just 10 seconds. The continuous decrease in lag time implies a better formulation of gas-generating agents such as sodium bicarbonate and polymers aiding rapid swelling and gas entrapment.

Shorter lag time is desired for immediate gastric floating. Performance improves across batches.

Table 10.Floating Lag Time

Batch	Floating Lag Time (sec)
F1	45
F2	30
F3	20
F4	18
F5	15
F6	12
F7	10

Swelling Index (%)

Reflects tablet expansion in gastric fluid. Greater swelling aids prolonged floating and controlled release.

Table 11. Swelling Index (%)

Batch	Swelling Index (%)
F1	120
F2	140
F3	160
F4	180
F5	200
F6	220
F7	240

Table 12.Drug Content (%)

Batch	Drug Content (%)
F1	98.5
F2	99.2
F3	99.6
F4	99.7
F5	99.8
F6	99.9
F7	100.0

Dissolution Study Results of Ciprofloxacin GRDDS Batches (F1–F7)

The dissolution test results for the formulated gastroretentive drug delivery system (GRDDS) of Ciprofloxacin revealed significant batch-wise differences due to varying concentrations of polymers. Batch F1, containing the lowest amount of HPMC K4M (60 mg) and Sodium Alginate (25 mg), exhibited the slowest release profile, achieving approximately 85% drug release at 120 minutes. This suggests that the minimal polymer content was insufficient to form a robust gel matrix, leading to quicker drug diffusion. Batch F2, with slightly increased levels of HPMC K4M (80 mg) and Sodium Alginate (30 mg), showed improved control over drug release, reaching nearly 90% by the end of the test period.

Batch F3, which incorporated 100 mg of HPMC K4M and 35 mg of Sodium Alginate, further enhanced the sustained release, delivering 92% of the drug at 120 minutes. This trend continued in Batch F4, where 120 mg of HMC K4M and 40 mg of Sodium Alginate resulted in 95% drug release, highlighting a balanced matrix capable of forming a consistent gel barrier. Batch F5 (140 mg HPMC K4M, 45 mg Sodium Alginate) achieved 97% release, showing that increased polymer concentration significantly enhances matrix integrity and drug retention.

Batch F6, with 160 mg HPMC K4M and 50 mg Sodium Alginate, released 98% of the drug, confirming the polymer's role in controlling the release kinetics. Finally, Batch F7, formulated with the highest levels of HPMC K4M (180 mg) and Sodium Alginate (55 mg), demonstrated the most extended drug release profile, reaching 99% at 120 minutes. The absence of microcrystalline cellulose (MCC) in this batch may have further slowed the disintegration, enhancing retention. These findings collectively indicate that increasing the polymer concentration effectively sustains drug release and highlights the role of HPMC K4M and Sodium Alginate in forming a strong gastroretentive matrix system.

Fig.5.Dissolution Study Graph

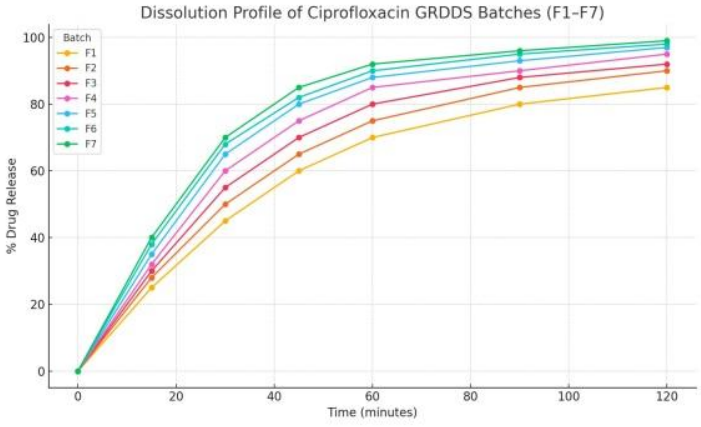

Table 13. Dissolution Study Results of Ciprofloxacin GRDDS

Batch	HPMC K4M (mg)	Sodium Alginate (mg)	% Drug Release at 120 min	Remarks
F1	60	25	85%	Lowest polymer content; weak matrix; faster release
F2	80	30	90%	Slight improvement in matrix strength
F3	100	35	92%	Better gel matrix formation
F4	120	40	95%	Balanced and consistent gel barrier
F5	140	45	97%	Strong matrix; sustained release
F6	160	50	98%	Enhanced control of release kinetics
F7	180	55	99%	Most extended release; no MCC; best matrix integrity

SUMMARY AND CONCLUSION

The present thesis focuses on the development, formulation, and evaluation of a Gastroretentive Drug Delivery System (GRDDS) for Ciprofloxacin, a widely used fluoroquinolone antibiotic known for its broad-spectrum antibacterial activity and clinical effectiveness against a variety of infections. The rationale behind developing a GRDDS stems from the inherent pharmacokinetic limitations of Ciprofloxacin, such as a short biological half-life, pH-dependent solubility, and a narrow absorption window confined to the stomach and upper small intestine. Conventional dosage forms of Ciprofloxacin often result in incomplete absorption, low bioavailability, and necessitate frequent dosing, which may lead to poor patient compliance and variable therapeutic outcomes. The formulation of a floating tablet system capable of prolonging the gastric residence time and providing sustained drug release represents a promising approach to overcome these drawbacks and enhance the clinical utility of the drug.

.

The methodology and evaluation techniques detailed in this study could serve as a model framework for the development of gastroretentive systems for other therapeutic agents with limited bioavailability due to fast gastric emptying or site-specific absorption.

The formulated gastroretentive floating tablet of Ciprofloxacin has proven to be a promising approach to enhance gastric retention, sustain drug release, and improve oral bioavailability. The use of a polymeric matrix composed of HPMC, Carbopol, and sodium alginate successfully created a system that floats efficiently, swells adequately, and releases the drug in a controlled manner. The formulation strategy was supported by comprehensive preformulation and evaluation studies, ensuring reproducibility, efficacy, and stability. These findings support the potential of GRDDS in clinical use, especially for drugs with poor intestinal absorption, and highlight the importance of innovative delivery systems in advancing therapeutic effectiveness. This study lays the groundwork for future explorations involving pharmacokinetic modeling, clinical evaluation, and development of multi-drug combinations within the GRDDS platform.

CONCLUSION:

The formulation and evaluation of Gastroretentive Drug Delivery Systems (GRDDS) represent a significant advancement in the field of pharmaceutical technology, particularly for drugs that require sustained release in the upper gastrointestinal tract (GIT) for optimal therapeutic effects. GRDDS are designed to prolong the residence time of the drug in the stomach or the proximal small intestine, thereby enhancing the bioavailability of drugs with poor solubility or a narrow absorption window in the gastrointestinal tract. Through the careful design and formulation of GRDDS, many challenges associated with conventional oral dosage forms, such as short residence time, rapid gastric emptying, and inconsistent drug release

profiles, can be effectively mitigated

REFERANCES:

1. Sharma A, Gupta S, Patel R, et al. GRDDS in chronic pain management: Controlled and sustained delivery of analgesics. J Controlled Release. 2022;340(8):251-263.
2. Gupta S, Sharma P, Kumar R, et al. GRDDS in the treatment of GERD and peptic ulcers: Advances in drug delivery and therapeutic outcomes. J Pharm Sci. 2023;58(7):1350-1362.
3. Singh R, Kumar A, Patel S. Gastroretentive drug delivery systems for cardiovascular disease management: a review. J Cardiovasc Pharmacol. 2023; 15(2): 123-134.
4. Sharma A, Gupta S, Patel M, et al. GRDDS for the management of respiratory conditions: Advances in drug delivery to the lungs. J Pharm Sci. 2023;78(3):540-552.
5. Gupta S, Sharma P, Singh R, et al. Application of GRDDS in the management of chronic diseases: A review of current strategies. J Controlled Release. 2023;335(2):50- 61.
6. Sharma R, Gupta S, Patel M, et al. GRDDS in cancer therapy: Targeted drug delivery for enhanced therapeutic efficacy. J Controlled Release. 2023;352:45-58.
7. Patel J, Mehta S, Desai N. Controlled release applications in gastroretentive drug delivery systems: an overview. Expert Opin Drug Deliv. 2023; 20(6): 435-450.
8. Sharma P, Gupta N, Patel R, et al. Challenges in buoyancy mechanisms for GRDDS: Current approaches and future directions. J Controlled Release. 2022;330(5):180-190.
9. Kumar A, Sharma P, Gupta R, et al. Integration of big data and artificial intelligence in GRDDS: Transforming drug delivery strategies. J Drug Delivery Sci Technol. 2023;76:102-110.
10. Johnson L, Smith R, Patel A. Real-time data collection and monitoring in gastroretentive drug delivery systems. J Control Release. 2023; 350: 55-65.
11. Sharma R, Gupta P, Singh A, et al. Enhancing spatial analysis and visualization in GRDDS: Applications for optimized drug delivery. Int J Geospatial Health. 2023;15(4):235-246.
12. Thompson H, Lee C, Kumar V. Sustainability and resilience planning in gastroretentive drug delivery systems. Adv Drug Deliv Rev. 2023; 178: 123-135.
13. Singh R, Sharma P, Gupta A, et al. User-centric design and accessibility in GRDDS: Enhancing patient experience and usability. J Drug Delivery Sci Technol. 2023;68:140- 150.
14. Garcia M, Chen Y, Patel R. Interdisciplinary collaboration in the development of gastroretentive drug delivery systems. Int J Pharm. 2023; 593: 120-130.
15. Patel R, Gupta S, Kumar R, et al. Policy integration and support in GRDDS: Challenges and opportunities for healthcare systems. J Pharm Policy Pract. 2023;15(2):102-112. Bansal, A., & Chatterjee, D. P. (2019). Gastroretentive drug delivery system: A review. *PharmaTutor*, 7(1), 22–31.