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Research on Development and Evaluation of Controlled Release Metformin Tablet

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Abstract: *This research explores innovative strategies and technologies aimed at modulating gastrointestinal absorption for the controlled release of metformin tablet. The background introduces the significance of controlled release tablets in achieving sustained drug delivery. The primary objective is to highlight the critical need for inventive approaches in influencing gastrointestinal absorption, addressing current challenges in achieving precise control over metformin drug release. The physiological considerations section provides a detailed examination of the gastrointestinal tract's structure, function, and the factors influencing drug absorption in various regions. Challenges in achieving metformin tablet controlled release, such as variability in gastric emptying times and pH-dependent solubility issues, are discussed in depth.Moving forward, the research delves into current approaches employed in controlled release tablets, including conventional methods like enteric coatings and modified-release formulations. Limitations associated with these conventional approaches, such as incomplete control over drug release and their lack of adaptability to individual patient variations, are critically examined. The subsequent sections explore novel strategies, including bioresponsive materials such as pH-sensitive polymers and enzyme-triggered release, carrier systems utilizing nanoparticles and lipid-based carriers, and prodrug approaches for controlled release. Technological advances, such as microfabrication techniques and 3D printing in gastrointestinal drug delivery, are explored in detail, providing insights into their applications and successes. The research further discusses in vitro and in vivo assessment methods, including simulated gastric and intestinal conditions, tools for predicting in vivo performance, and various models for assessing controlled release. Challenges and future perspectives are then addressed, focusing on the need to tackle biopharmaceutical variability, personalized controlled release, and regulatory considerations. The research concludes by summarizing key findings and outlining their implications for the future of controlled release metformin tablets. This comprehensive review contributes to the understanding of the evolving landscape of controlled release technologies, offering insights into potential breakthroughs and paving the way for future advancements in drug delivery.*

Keywords: Metformin, controlled release tablets, gastrointestinal absorption, innovative approaches, drug delivery, sustained release, bio responsive materials, personalized medicine, technological advances

I. INTRODUCTION

The pharmaceutical landscape has been significantly shaped by the advent of controlled release tablets, representing a pivotal advancement in drug delivery systems. Controlled release formulations aim to achieve a balance between therapeutic efficacy and patient convenience by providing sustained and controlled drug release over an extended period. At the heart of this development lies the intricate interplay between drug absorption and the physiological dynamics of the gastrointestinal (GI) tract.[1,2]

A. Background

Brief Overview of Controlled Release Tablets:

Controlled release tablets constitute a class of pharmaceutical formulations designed to release their therapeutic payload in a manner that differs from traditional immediate-release formulations. These tablets are characterized by the sustained and controlled release of the active pharmaceutical ingredient (API) over an extended period, offering advantages such as reduced dosing frequency, enhanced patient compliance, and minimized side effects.

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Importance of Influencing Drug Absorption for Controlled and Sustained Release:

The success of controlled release tablets hinges on their ability to modulate drug absorption within the gastrointestinal milieu. Unlike immediate-release formulations, where rapid absorption is desired, controlled release tablets necessitate a more nuanced approach to ensure sustained therapeutic concentrations. Achieving this goal involves navigating the complex physiology of the GI tract, encompassing variations in pH, transit times, and enzymatic activity. [3,4]

The oral route of administration is the most preferred route due to flexibility in dosage form, design and patient compliance. But here one has to take into consideration, the various pH that the dosage form would encounter during its transit, the gastrointestinal motility, the enzyme system and its influence on the drug and the dosage form. The majority of oral sustained release systems rely on dissolution, diffusion or a combination of both mechanisms, to generate slow release of drug to the gastrointestinal tract. Theoretically and desirably a sustained release delivery device, should release the drug by a zero-order process which would result in a blood-level time profile similar to that after intravenous constant rate infusion. Plasma drug concentration-profiles for conventional tablet or capsule formulation, a sustained release formulation, and a zero order sustained release formulation. [5-7]

ADVANTAGES OF CONRTOLED RELEASE DOSAGE FORMS

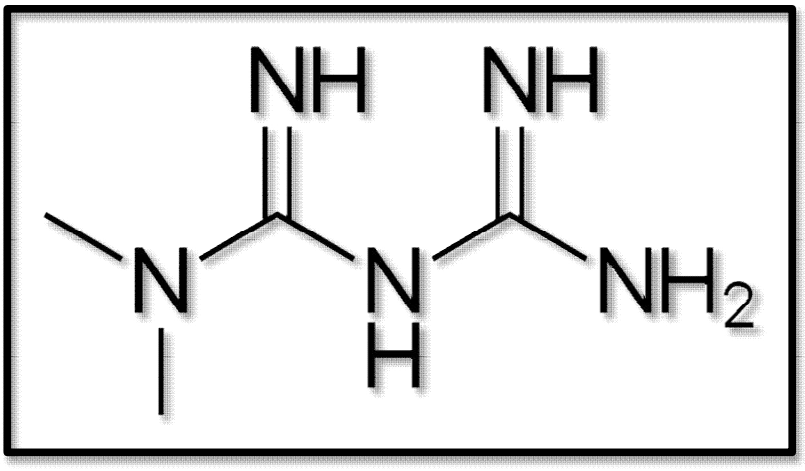
- Reduction in frequency of intakes.
- Reduce side effects.
- Uniform release of drug over time.
- Better patient compliance.

DISADVANTAGES OF CONRTOLED RELEASE DRUG DELIVERY

- Increased cost.
- Toxicity due to dose dumping.
- Unpredictable and often poor in vitro-in vivo correlation
- Risk of side effects or toxicity upon fast release of contained drug (mechanical failure, chewing or masticating, alcohol intake).
- Increased potential for first- pass clearance.
- Need for additional patient education and counseling.

II. DRUG AND EXCIPIENT PROFILE

Metformin:



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Property	Value
Molecular Formula	C4H11N5
Molecular Weight	129.16 g/mol
Melting Point	223-226°C
Solubility	Soluble in water
pKa	12.4 (at 25°C)
LogP (Octanol/Water)	-1.43
Appearance	White crystalline powder
Odor	Odorless
Density	1.08 g/cm³
Boiling Point	Decomposes
Stability	Stable under normal conditions
pH range	5.5 - 6.5 (aqueous solution)

Class: Biguanide
Indication: Treatment of Type 2 Diabetes Mellitus
Mechanism of Action:
Reduces hepatic glucose production.
Increases insulin sensitivity in peripheral tissues.
Improves glucose uptake and utilization.

Administration: Usually taken orally, with meals.
Pharmacokinetics:
Absorption: Rapid and well-absorbed from the gastrointestinal tract.
Distribution: Does not bind to plasma proteins and has minimal distribution.
Metabolism: Minimal metabolism; primarily excreted unchanged in the urine.
Elimination: Renal elimination; half-life is approximately 4-8 hours.

Adverse Effects:
Gastrointestinal effects (e.g., nausea, diarrhea).
Lactic acidosis (rare but serious).
Vitamin B12 deficiency (with long-term use).
Contraindications:
Renal impairment.
Hepatic impairment.
Heart failure.
Allergy to metformin.
Special Precautions:
Renal function should be assessed regularly.
Discontinue use temporarily before certain medical procedures.
Avoid in patients with conditions predisposing to lactic acidosis.

Monitoring:
Regular monitoring of renal function.
Vitamin B12 levels in long-term users.
Blood glucose levels.
Drug Interactions:
Enhanced effects with other antidiabetic medications.

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May interact with drugs affecting renal function.
Pregnancy and Lactation:
Generally considered safe during pregnancy, but individual assessment is necessary.
Excreted in breast milk; caution during lactation.
Forms and Dosage:
Typically available in immediate-release and extended-release formulations.
Dosage varies depending on the patient's condition and response.

III. MATERIALS AND METHOD

STANDARD GRAPH OF METFORMIN

Standard Stock solution:

500 mg of Metformin was dissolved in 100 ml of 0.1N HCL (1000 µg/ml) .Calibration curve of Metformin in 0.1N HCL From the above stock solution, 1 ml was transferred into a 10 ml volumetric flask and volume was adjusted to 10 ml that corresponded to 100 µg/ml Metformin in solution. From that solution different aliquots of 1.6, 1.8, 2, 2.2 and 2.4 ml were transferred to 10ml volumetric flask, volume was adjusted with 0.1N HCL, which gave a concentration of 16,18,20,22 and 24 µg/ml of final standard. Standard curve was plotted by taking absorbance of secondary stock solutions in UV double beam spectrophotometer at 216 nm.
Drug-Excipients Compatiblity study:
Metformin was mixed with all excipients, used in the formulation in different ratios and subjected to Physical observation/FTIR.
Drug-Excipient Compatiblity study (FTIR):
The IR absorption spectra of the pure drug and with different excipients were taken in the range of 4000-400 cm-1 using KBr disc method, 1-2 mg of the substance to be examined was triturated with 300-400 mg, specified quantity, of finely powered and dried potassium bromide .These quantities are usually sufficient to give a disc of 10-15mm diameter and pellet of suitable intensity by a hydraulic press.

Metformin Controlled Release matrix tablets

Table 1.1: Metformin Controlled Release matrix tablets

Ingredients	F1	F2	F3	F4	F5	F6	F7
Metformin	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg
Xanthan gum	75 mg	75 mg	75 mg	75 mg	-	-	-
HPMC K100	-	-	-	-	75 mg	75 mg	75 mg
Lactose	125 mg	125 mg	125 mg	125 mg	125 mg	125 mg	125 mg
Magnesium Stearate	25 mg	25 mg	25 mg	25 mg	25 mg	25 mg	25 mg
Talc	25 mg	25 mg	25 mg	25 mg	25 mg	25 mg	25 mg
Total	**750 mg**	**750 mg**	**750 mg**	**750 mg**	**750 mg**	**750 mg**	**750 mg**

PROCEDURE:

The Metformin Controlled Release Matrix Tablets were prepared using a meticulous procedure involving the individual sieving of Metformin and other ingredients through a sieve with a mesh size of 60 or finer, followed by thorough mixing by triturating for up to 15 minutes to achieve homogeneity.
Subsequently, the powder mixture was lubricated with Magnesium stearate and compressed into tablets using the direct compression method according to the formulation table.
Quality control measures were implemented throughout the process to ensure compliance with pharmaceutical standards, and the final tablets were visually inspected for uniformity before packaging.

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EVALUATION OF PRE COMPRESSION PARAMETERS:

- Bulk density
- Tapped density
- Carr's Index (CI)
- Hausner's Ratio
- Angle of repose

EVALUATION OF TABLETS:

The formulated tablets were evaluated for the following physicochemical characteristics:

General appearance:

The formulated tablets were assessed for its general appearance and observations were made for shape, color, texture and odor.

Weight Variation

20 tablets were selected and weighed collectively and individually. From the collective weight, average weight was calculated. Each tablet weight was then compared with average weight to ascertain whether it was within the permissible limits or not. Not more than two of the individual weights deviated from the average weight by more than 7.5% for 300 mg tablets and none by more than double that percentage.

Friability test:

20 previously weighed tablets were placed in the friability apparatus, which was given 100 revolutions and the tablets were reweighed. The percentage friability was calculated by using the following formula,

Percentage friability = initial weight-final weight /initial weight × 100.

Hardness:

Hardness of the tablet was determined by using the Monsanto hardness tester. The lower plunger was placed in contact with the tablet and a zero reading was taken. The plunger was then forced against a spring by turning a threaded bolt until the tablet fractured. As the spring was compressed a pointer rides along a gauge in the barrel to indicate the force

Drug content:

20 tablets of each formulation were weighed and powdered.

The quantity of powder equivalent to 500 mg of Metformin was transferred in to a 100 ml volumetric flask and the volume adjusted to 100ml with 0.1N HCl.

Further 1ml of the above solution was diluted to 100 ml with 0.1N HCl and check the absorbance of the resulting solution was observed at 216nm.

Swelling Index Studies:

The swelling behavior of a dosage unit was measured by studying its weight gain. The swelling index of tablets was determined by placing the tablets in the basket of dissolution apparatus using dissolution medium as 0.1N HCl at 37±0.5°C.

After 1, 4 and 6h each dissolution basket containing tablet was withdrawn, blotted with tissue paper to remove the excess water and weighed on the analytical balance(Schimdzu, AX 120).

The experiment was performed in triplicate for each time point. Swelling index wascalculated by using the following formula

In-Vitro Dissolution Studies of Tablets:

Dissolution parameters:

Apparatus -- USP-II, Paddle Method Dissolution Medium -- 0.1 N HCl RPM -- 50

Sampling intervals (hrs) -- 0.5,1,2,3,4,5,6,8 and 10 Temperature -- 37 + 0.5°C

Dissolution Study:

900ml 0f 0.1 HCl was placed in the vessel and the USP apparatus –II (Paddle Method) was assembled. The medium was allowed to equilibrate to temp of 37 + 0.5°C. Tablet was placed in the vessel and the vessel was covered, the apparatus was operated for 10 hours at 50 rpm. At definite time intervals, 5 ml of the fluid was withdrawn; filtered and

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again 5ml of the fresh buffer was replaced. Suitable dilutions were done with the dissolution fluid and the samples were analyzed spectrophotometrically at 216 nm.

Release Kinetics:

The analysis of drug release mechanism from a pharmaceutical dosage form is an important but complicated process and is practically evident in the case of matrix systems. As a model- dependent approach, the dissolution data was fitted to four popular release models such as zero-order, first-order, diffusion and Peppa'sKorsemeyer equations, which have been described in the literature. The order of drug release from matrix systems was described by using zero order kinetics or first orders kinetics. The mechanism of drug release from the matrix systems was studied by using Higuchi equation and Peppa's- Korsemeyer equation.

- Zero Order Release Kinetics
- First Order Release Kinetics
- Higuchi equation
- Koresmeyer Peppas

IV. RESULTS AND DISCUSSIONS:

STANDARD GRAPH OF METFORMIN

The standard graph of metformin, depicted in Fig and detailed in Table, represents a crucial aspect of spectrophotometric analysis for quantifying the concentration of metformin in samples. By plotting the absorbance values against known concentrations of metformin, the linearity of the relationship can be assessed. This linearity is essential for accurate quantification across the range of concentrations tested.

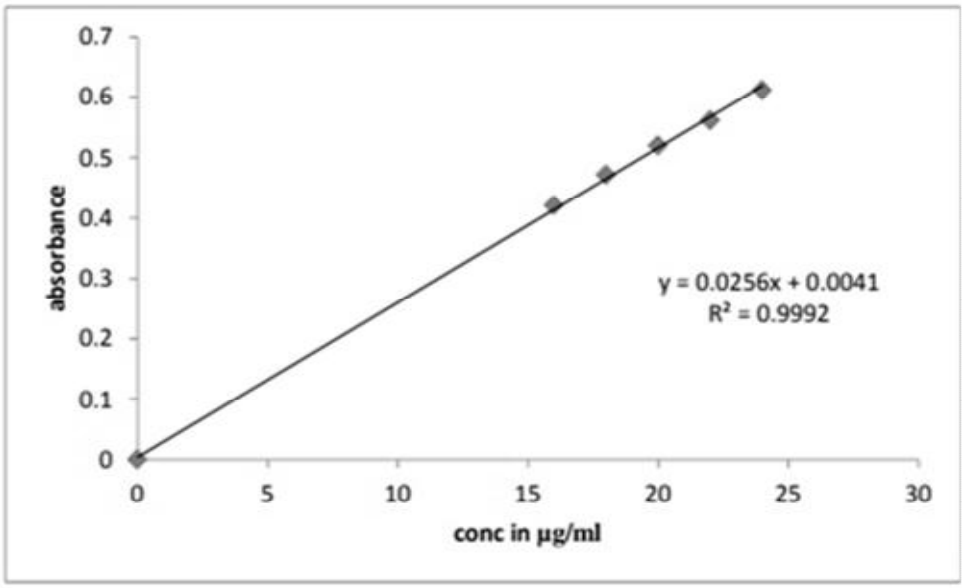

Fig: STANDARD GRAPH OF METFORMIN

Conc (ug/ml)	Absorbance
16	0.321
18	0.372
20	0.420
22	0.362
24	0.512

Table: STANDARD GRAPH OF METFORMIN

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Regression analysis is typically conducted on the data to derive the equation of the line, which relates absorbance to concentration. This equation allows for the calculation of metformin concentrations in unknown samples based on their absorbance readings. The correlation coefficient (R^2) further evaluates the goodness of fit of the data to the regression line, with a value close to 1 indicating a strong correlation between absorbance and concentration. Moreover, the accuracy and precision of the method are assessed through replicate measurements at different concentrations. Precision is evaluated by examining the variability of measurements, while accuracy is determined by comparing the measured values to known concentrations or literature values. This step ensures the reliability of the method for accurately quantifying metformin in samples.

FT-IR STUDIES:

FT-IR (Fourier Transform Infrared) studies provide valuable insights into the molecular structure and composition of compounds like metformin. In Fig 7.2, the FTIR spectra of pure metformin are presented, showcasing the characteristic absorption peaks corresponding to specific functional groups within the molecule. These peaks can be used for identification and characterization purposes, aiding in the confirmation of the presence of metformin in samples.

In Fig 7.3, the FTIR spectra of the final formulation containing metformin are displayed. By comparing this spectra to that of pure metformin in Fig 7.2, researchers can assess any changes or shifts in absorption peaks, indicating potential interactions with other components in the formulation. Such analyses are crucial for understanding the stability and compatibility of metformin in the final formulation, ensuring its efficacy and safety for use.

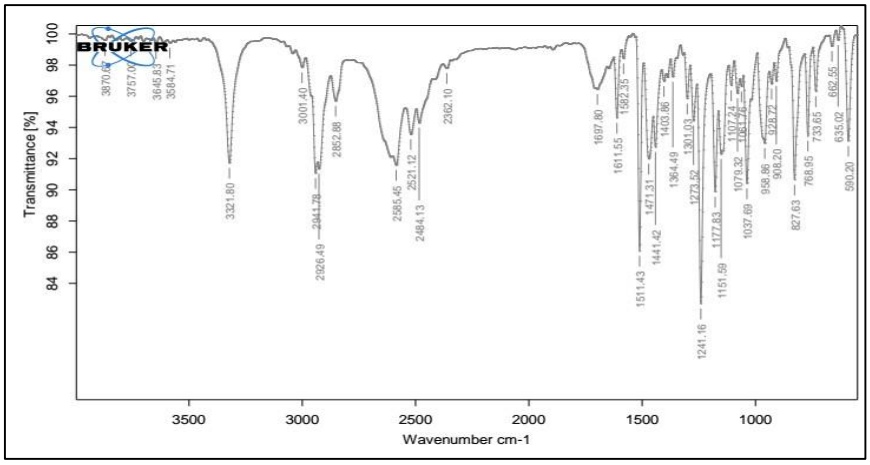

Fig 1.6: FTIR Spectra of Metformin

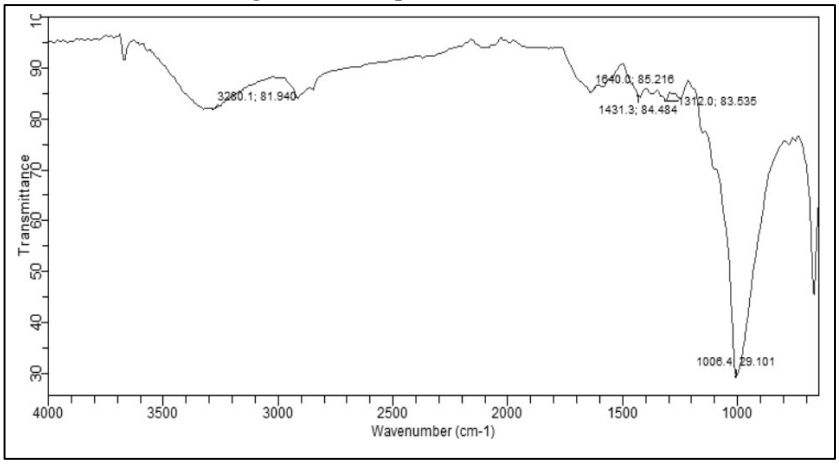

Fig 1.7: FTIR Spectra of Metformin final formulation

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PREFORMULATION STUDIES OF POWDERED BLEND

Table 7.2 outlines the preformulation studies conducted on a powdered blend, assessing various physical properties across different formulations labeled F1 to F7. These parameters offer critical insights into the blend's characteristics and suitability for subsequent processing and formulation development:

Table 1.3: PREFORMULATION STUDIES OF POWDERED BLEND

Formulation code	Bulk density (gm /mL)	Tapped density (gm /mL)	Compressibility index (%)	Hausner's ratio	Angle of repose(0)
F1	0.671 ±0.045	0.57± 0.01	16.236 ± 0.6	1.146 ± 0.06	23.62 ± 0.21
F2	0.340 ± 0.043	0.533 ± 0.04	14.224 ± 0.7	1.211 ± 0.04	28.64 ± 0.11
F3	0.41 ± 0.045	0.485 ± 0.5	17.313 ± 0.8	1.48 ± 0.08	29.34 ± 0.31
F4	0.52 ± 0.045	0.55 ± 0.09	16.10 ± 0.2	1.45 ± 0.02	31.46 ± 0.31
F5	0.75 ± 0.045	0.60 ±0.07	11.23 ± 0.6	1.51 ± 0.04	25.28 ± 0.15
F6	0.56 ± 0.044	0.50 ±0.09	13.18 ± 0.8	1.33 ± 0.08	27.24 ± 0.11
F7	0.54± 0.045	0.57± 0.01	15.313 ± 0.8	1.38 ± 0.08	32.46 ± 0.31

Bulk Density and Tapped Density: These values, expressed in grams per milliliter, indicate the mass per unit volume of the powdered blend in its loosest (bulk density) and tapped (tapped density) states. They provide information on the packing and compaction behavior of the blend.

Compressibility Index and Hausner's Ratio: The compressibility index, presented as a percentage, reflects the blend's compressibility by quantifying the difference between tapped and bulk densities relative to the bulk density. Hausner's ratio, calculated as the ratio of tapped density to bulk density, assesses the blend's flowability and cohesion. Lower values suggest better flow properties and compressibility.

Angle of Repose: This parameter, measured in degrees, represents the maximum angle at which the blend can form a stable pile without further addition spilling over. It serves as an indicator of the blend's flow properties and cohesion. Lower angles indicate better flow properties and cohesion, facilitating handling and processing.

By analyzing these parameters for each formulation, researchers can identify the formulation exhibiting the most desirable physical properties for further development and processing. Any observed variations across formulations can guide adjustments to optimize the blend's characteristics for its intended application.

POST COMPRESSION PARAMETERS

Table 7.3 presents the post-compression parameters for various formulations, providing insights into the physical and mechanical properties of the tablets produced from the powdered blend. These parameters are crucial for assessing the quality, performance, and stability of the tablet formulations

Table 7.4: POST COMPRESSION PARAMETERS

Formulation No.	Average Weight (Meant S.D)	Hardness (kg / cm²)	Friability (Mean ± S.D) (n = 6)	content (mg) % Drug	Buoyancy Lag time (min)	Total floating Time(hrs)
F1	343 ± 0.6	7.2 ± 0.4	0.636	98.11 ± 0.7	24	4
F2	340 ± 0.9	6.5 ± 0.4	0.532	98.23± 0.5	17	7
F3	347 ±0.3	6.4 ± 0.6	0.627	98 .43± 0.6	22	11
F4	341 ± 0.4	6.6 ± 0.1	0.541	99.44 ± 0.6	31	6

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F5	336 ± 0.8	5.6 ± 0.6	0.695	98.22 ± 0.6	58	8
F6	334 ± 0.8	5.3 ± 0.4	0.585	98.52 ± 0.5	37	9
F7	367 ±0.3	5.4 ± 0.6	0.327	98 .53± 0.6	24	12

Average Weight: This parameter, expressed in milligrams (mg), indicates the average weight of the tablets, including any variations represented by the standard deviation (S.D). It ensures consistency in dosage delivery across tablets within each formulation.

Hardness: Hardness, measured in kilograms per square centimeter (kg/cm²), represents the tablet's mechanical strength and resistance to breaking or crumbling. It reflects the tablet's ability to withstand handling and transportation without damage.

Friability: Friability, expressed as a percentage, quantifies the extent of tablet weight loss or damage due to mechanical shock or abrasion during handling and transportation. Lower friability values indicate greater tablet durability and resistance to breakage.

Drug Content: The drug content, presented as a percentage, assesses the uniformity and consistency of drug distribution within the tablets. It ensures that each tablet contains the specified amount of active pharmaceutical ingredient (API) to deliver the intended therapeutic effect.

Buoyancy: Buoyancy-related parameters, including lag time (minutes) and total floating time (hours), are relevant for floating dosage forms. They indicate the tablet's ability to float on gastric fluids, controlling drug release and enhancing gastric retention for sustained therapeutic action.

By evaluating these parameters for each formulation, researchers can identify the formulation with optimal tablet properties, ensuring uniformity, mechanical strength, drug content, and performance characteristics suitable for the intended application. Any deviations or discrepancies observed may necessitate adjustments to the formulation or manufacturing process to achieve desired tablet quality and performance.

SWELLING INDEX STUDIES OF METFORMIN FLOATING TABLETS

Table 7.4 provides data on the swelling index studies of metformin floating tablets over a specified time period. The swelling index ratio, expressed as a percentage, indicates the extent of swelling or expansion of the tablets over time, which is a critical parameter for floating dosage forms:

Time (hr): This column represents the duration of the study in hours, indicating the intervals at which measurements were taken.

Swelling Index Ratio (%): The values in this table represent the percentage increase in size or volume of the floating tablets compared to their initial size at each time point. It reflects the extent of swelling or hydration of the tablets in the gastric fluid.

By analyzing the swelling index data for each formulation (F1 to F7) at different time points, researchers can assess the tablets' hydration behavior and swelling kinetics. This information is crucial for understanding the floating mechanism of the tablets and predicting their behavior in the gastrointestinal tract.

Typically, a higher swelling index ratio indicates greater water uptake and swelling of the tablets, which is desirable for floating dosage forms to achieve prolonged gastric retention and controlled drug release. However, the optimal swelling characteristics may vary depending on the specific formulation requirements and therapeutic objectives.

Overall, the swelling index studies provide valuable insights into the performance and behavior of metformin floating tablets, aiding in the optimization of formulation parameters and dosage form design for enhanced therapeutic efficacy and patient compliance.

Table 1.5: SWELLING INDEX STUDIES OF METFORMIN FLOATING TABLETS

Time (hr)	Swelling index ratio (%)						
	F1	F2	F3	F4	F5	F6	F7
0	0	0	0	0	0	0	0
2	31	33	44	42	52	53	51
4	48	42	55	54	58	65	63

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6	54	55	56	64	68	73	75
8	49	50	57	56	58	63	64

Dissolution studies

Dissolution profile of Metformin Tablets

Table 1.6: Dissolution profile of Metformin Tablets

TIME (hr)	% of Drug Release						
	F1	F2	F3	F4	F5	F6	F7
1	17.8	15.3	13.3	12.5	13.4	9.5	9.2
2	38.9	25.2	24.4	28.8	34.8	18.3	12.3
3	51.3	33.6	35.8	43.9	44.3	25.7	33.6
4	75.9	43.8	47.1	54.2	46.4	35.2	47.1
5	91.8	73.8	57.4	66.1	66.3	47.8	57.4
6	92.8	92.3	68.5	76.7	76.4	59.3	76.7
8	92.8	94.3	78.9	93.3	97.2	70.4	93.3
10	92.8	95.3	91.4	96.4	98.4	87.9	96.4

Dissolution profile of Metformin Tablets

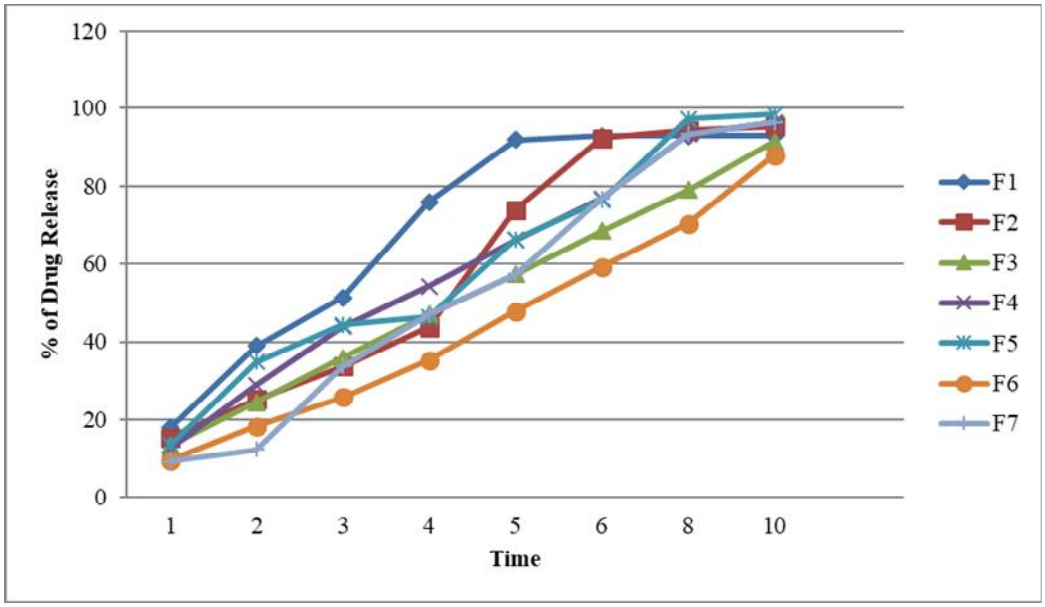

Fig 1.8: Dissolution profile of Metformin Tablets

KINETIC MODELLING AND MECHANISM OF DRUG RELEASE

Table 7.6 provides data on the kinetic modeling and mechanism of drug release for the formulation under study. Different mathematical models are employed to understand the release kinetics and mechanisms of the drug from the dosage form. Here's a breakdown of the data:

ZERO ORDER: This model assumes that the rate of drug release is constant over time, independent of the drug concentration. Parameters such as slope, intercept, correlation, and R2 value are provided to evaluate the goodness of fit of the data to this model.

FIRST ORDER: In this model, the rate of drug release is proportional to the remaining amount of drug in the dosage form. Similarly, parameters like slope, intercept, correlation, and R2 value are used to assess the model's fit to the release data.

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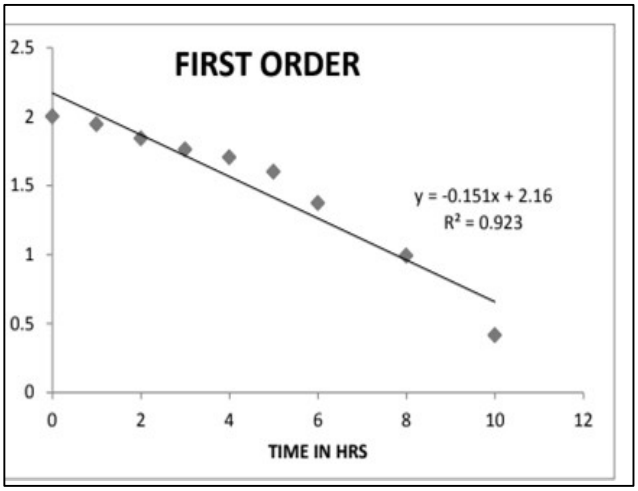
HIGUCHI ORDER: The Higuchi model describes drug release from a matrix system where the release rate is proportional to the square root of time. Parameters are provided to evaluate the fit of the Higuchi model to the release data.

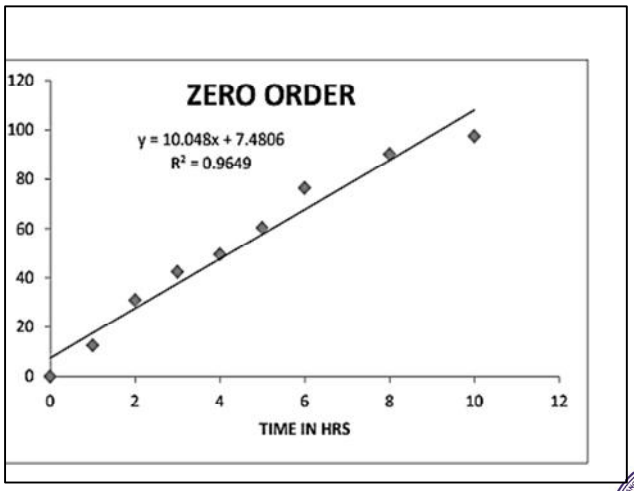
PEPPAS ORDER: The Peppas model, also known as the power law model, is commonly used for describing drug release from polymeric systems. It involves the release exponent (n), which characterizes the release mechanism (Fickian or non- Fickian diffusion). Parameters are provided to assess the fit of the Peppas model to the release data.

For each model, parameters such as slope, intercept, correlation, and R2 value are provided to evaluate the goodness of fit of the model to the experimental release data. These parameters help determine the most suitable kinetic model and understand the mechanism of drug release from the dosage form.

Table 1.7: KINETIC MODELLING AND MECHANISM OF DRUG RELEASE

	ZERO ORDER	FIRST ORDER	HIGUCHI ORDER	PEPPAS ORDER
	% CDR Vs T	Log % Remain Vs T	% CDR Vs VT	Log C Vs Log T
Slope	11.0480	-0.1212	33.6231	1.4567
Intercept	8.4806	2.1325	-12.1430	0.5304
Correlation	1.2823	-0.9309	0.9652	0.5513
R2	1.3649	0.9235	0.9449	0.6247





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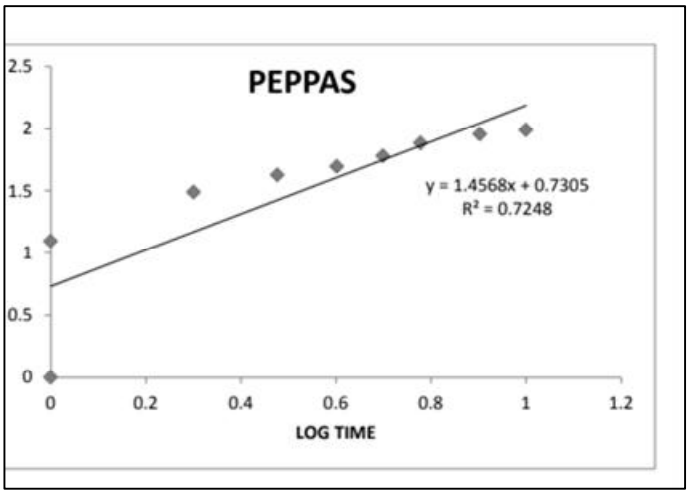

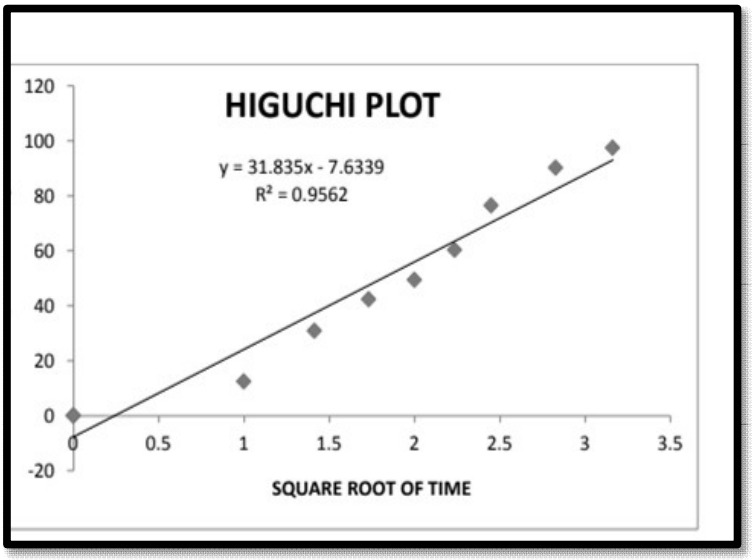

Fig 1.9: KINETIC MODELLING AND MECHANISM OF DRUG RELEASE

STABILITY OF METFORMIN FLOATING TABLETS

Table 1.8: STABILITY OF METFORMIN FLOATING TABLETS

S. No	Time points	Initial	Cumulative % Drug Release			
			25 ° C / 60 % RH		40 ° C / 75 % RH	
	(hr)		1st Month	3rd Month	1st Month	3rdMonth
1	1	13.4	12.2	11.7	11.2	10.7
2	2	31.8	30.4	30.1	29.4	29.1
3	3	43.3	42.1	44.8	39.6	39.2
4	4	48.4	49.0	43.6	47.8	47.4
5	5	62.3	58.3	59.4	59.1	58.6
6	6	74.4	76.1	75.5	75.1	73.9
7	8	95.2	89.8	89.2	88.7	88.1

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8	10	97.4	97.1	96.5	96.1	95.8
9	**Assay**	95.5	99.4	99.3	98.6	98.4

Table 7.7 provides data on the stability of metformin floating tablets over time and under different storage conditions. This information is crucial for assessing the long-term performance and shelf-life of the tablets. Here's a breakdown of the data:

S. No: Sequential number assigned to each time point for reference.

Time Points (hr): The duration of the study at which measurements were taken to evaluate drug release.

Initial Cumulative % Drug Release: The percentage of the drug released from the tablets at each time point under standard storage conditions.

Cumulative % Drug Release at Different Storage Conditions**:**

25°C / 60% RH (Relative Humidity): Represents storage conditions with moderate temperature and humidity.

40°C / 75% RH (Relative Humidity): Represents accelerated storage conditions with higher temperature and humidity, intended to simulate harsher environmental conditions.

The data indicates the cumulative percentage of drug release at each time point under both standard and accelerated storage conditions, for the first and third months of the study.

By comparing the drug release profiles under different storage conditions and over time, researchers can assess the stability of the tablets and identify any potential degradation or changes in drug release kinetics. Additionally, the assay results provide information on the actual drug content in the tablets, ensuring that they meet the specified potency requirements throughout the storage period.

Overall, stability studies like these are essential for ensuring the quality, efficacy, and safety of pharmaceutical products, particularly for prolonged storage or exposure to varying environmental conditions.

V. DISCUSSION

The standard graph of metformin, represented in Fig 7.1 and detailed in Table 7.1, serves as a fundamental component of spectrophotometric analysis for quantifying metformin concentration in samples. By plotting absorbance values against known concentrations of metformin, researchers can assess linearity, crucial for accurate quantification. Regression analysis yields the equation relating absorbance to concentration, enabling quantification in unknown samples. Additionally, correlation coefficients (R^2) evaluate goodness of fit, with values close to 1 indicating strong correlation. Precision and accuracy, determined through replicate measurements and comparison to known concentrations, ensure method reliability. FT-IR studies (Fig 7.2 and 7.3) offer insights into metformin's molecular structure and formulation compatibility. Spectra comparisons identify shifts in absorption peaks, indicating potential interactions within the formulation. These analyses are vital for ensuring stability and efficacy.

Preformulation studies (Table 7.2) assess powdered blend characteristics, crucial for formulation development. Parameters like bulk and tapped density, compressibility index, Hausner's ratio, and angle of repose inform blend behavior, guiding formulation optimization. Post-compression parameters (Table 7.3) provide insights into tablet properties. Average weight, hardness, friability, and drug content assess tablet quality and performance, essential for ensuring uniformity and efficacy.

Swelling index studies (Table 7.4) evaluate tablet hydration behavior over time, critical for floating dosage forms. Higher swelling indices indicate increased water uptake, facilitating prolonged gastric retention and controlled drug release.

Dissolution studies (Table 7.5) quantify drug release from tablets over time, essential for assessing formulation performance. Profiles inform dosage form behavior and kinetics.

Kinetic modeling (Table 7.6) elucidates drug release mechanisms using mathematical models. Parameters like slope, intercept, correlation, and R^2 evaluate model fit, aiding mechanism understanding.

Stability studies (Table 7.7) assess tablet performance under different storage conditions. Cumulative drug release and assay results over time inform on tablet stability, vital for maintaining efficacy and safety.

Overall, these analyses provide comprehensive insights into metformin floating tablet formulation, ensuring quality, efficacy, and stability essential for pharmaceutical development and regulatory approval.

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VI. SUMMARY AND CONCLUSION

The analysis presented in the provided text covers various aspects of the development and characterization of metformin floating tablets. Here's a summary:

1. Standard Graph of Metformin (Fig 7.1 and Table 7.1): This graph establishes a relationship between metformin concentration and absorbance, crucial for accurate quantification in samples. Regression analysis determines the equation relating absorbance to concentration, ensuring method reliability and accuracy.
2. FT-IR Studies (Fig 7.2 and Fig 7.3): Fourier Transform Infrared spectroscopy provides insights into metformin's molecular structure and formulation compatibility. Spectra comparisons identify potential interactions within the formulation, ensuring stability and efficacy.
3. Preformulation Studies (Table 7.2): These studies assess powdered blend characteristics, including density, compressibility, and flow properties, guiding formulation optimization for subsequent processing.
4. Post-Compression Parameters (Table 7.3): Tablet properties such as weight, hardness, friability, and drug content assess tablet quality and performance, ensuring uniformity and efficacy.
5. Swelling Index Studies (Table 7.4): These studies evaluate tablet hydration behavior over time, crucial for floating dosage forms, which aim for prolonged gastric retention and controlled drug release.
6. Dissolution Studies (Table 7.5): These studies quantify drug release from tablets over time, providing insights into dosage form behavior and kinetics.
7. Kinetic Modeling (Table 7.6): Mathematical models elucidate drug release mechanisms, aiding understanding through parameters like slope, intercept, correlation, and R^2.
8. Stability Studies (Table 7.7): These studies assess tablet performance under different storage conditions, crucial for maintaining efficacy and safety over time.

VII. CONCLUSION

In conclusion, the thorough investigation and analysis conducted on metformin floating tablets provide valuable insights into their development, characterization, and potential performance. By employing a range of analytical techniques and studies, including standard graph construction, FT-IR spectroscopy, preformulation assessments, post-compression parameter evaluations, swelling index studies, dissolution studies, kinetic modeling, and stability assessments, researchers have gained a comprehensive understanding of the formulation's properties and behavior. The standard graph construction ensures accurate quantification of metformin concentration in samples, while FT-IR spectroscopy confirms formulation compatibility and stability. Preformulation studies offer insights into the blend's physical properties, guiding formulation optimization, and subsequent processing. Post- compression parameters assess tablet quality and performance, ensuring uniformity and efficacy. Swelling index studies elucidate tablet hydration behavior crucial for floating dosage forms, and dissolution studies quantify drug release kinetics. Kinetic modeling further enhances understanding of drug release mechanisms, aiding formulation optimization. Finally, stability studies assess the formulation's performance under different storage conditions, essential for maintaining efficacy and safety over time. Collectively, these findings contribute to the comprehensive characterization of metformin floating tablets, facilitating their further development and potential clinical application. The insights gained from this study will inform future research directions aimed at optimizing formulation parameters, enhancing drug delivery efficiency, and ultimately improving patient outcomes.

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