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Encapsulation Of Sitagliptin in Polymer-Based Microspheres for Sustained Anti-Diabetic Therapy

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ABSTRACT

Sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, is widely used for managing type 2 diabetes mellitus but suffers from a short half-life and requires frequent dosing, which may reduce patient compliance. Encapsulation of sitagliptin in polymer-based microspheres offers a promising approach for sustained anti-diabetic therapy by prolonging drug release, enhancing bioavailability, and improving therapeutic efficacy. Various biodegradable and biocompatible polymers such as albumin, chitosan, hydroxypropyl methylcellulose (HPMC), poly(lactic-co-glycolic acid) (PLGA), and Eudragit have been utilized to fabricate microspheres using techniques like spray-drying, solvent evaporation, and ionic gelation. These microspheres demonstrate favorable micromeritic properties, high drug entrapment efficiency, and controlled drug release kinetics primarily governed by diffusion mechanisms following Higuchi or Peppas models. Mucoadhesive properties of polymers like chitosan and HPMC enhance gastrointestinal residence time, resulting in better drug retention and sustained action in vivo. Studies affirm that sitagliptin-loaded microspheres achieve extended drug release ranging from 12 to 24 hours, reduce dosing frequency, and minimize side effects associated with conventional formulations. This encapsulation strategy thus represents an effective oral drug delivery system with potential to improve glycemic control, patient adherence, and overall clinical outcomes in diabetes management.

Keywords: *Biodegradable Polymers, Controlled Release, Diabetes Mellitus, Drug Delivery System, Encapsulation Efficiency, Microspheres, PLGA, Polymer-Based Delivery, Sitagliptin, Sustained Release, Type 2 Diabetes, Therapeutic Efficacy.*

1. INTRODUCTION

A. Overview of Diabetes Mellitus and Its Global Impact

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia due to defects in insulin secretion, insulin action, or both. Type 2 diabetes, the most common form, is associated with insulin resistance and β-cell dysfunction. Globally, diabetes affects hundreds of millions, leading to severe complications such as cardiovascular

disease, neuropathy, and nephropathy. The rising prevalence has created a significant burden on healthcare systems worldwide. Understanding the pathophysiology and epidemiology of diabetes is crucial for developing effective therapeutic strategies. Hence, there is an urgent need for novel treatment approaches that can provide better glycemic control and improve patients'

quality of life.

B. Current Therapeutic Approaches for Type 2 Diabetes

Existing treatments for type 2 diabetes include lifestyle modifications, oral hypoglycemic agents, and insulin therapy. Medications such as metformin, sulfonylureas, DPP-4 inhibitors, and SGLT2 inhibitors are commonly used. While effective, these treatments often require frequent dosing, which can lead to poor adherence. Additionally, side effects and variable pharmacokinetics present further challenges. Therefore, optimizing drug delivery to enhance efficacy and patient compliance is a key area of focus. One such strategy involves controlled-release drug delivery systems, which can maintain therapeutic drug levels for extended periods, reduce dosing frequency, and improve the pharmacological profile of anti-diabetic agents.

C. Sitagliptin: Mechanism and Therapeutic Potential

Sitagliptin is a selective dipeptidyl peptidase-4 (DPP-4) inhibitor that enhances the body's incretin system. By inhibiting DPP-4, Sitagliptin increases the levels of active incretin hormones, which stimulate insulin release and suppress glucagon secretion in a glucose-dependent manner. It offers a favorable safety profile with minimal risk of hypoglycemia and weight gain. Sitagliptin is typically administered once daily, but like many oral medications, it still requires regular intake to maintain effectiveness. Its promising pharmacodynamics make it an ideal candidate for sustained delivery systems, which can further improve its therapeutic performance and address the limitations associated with conventional administration.

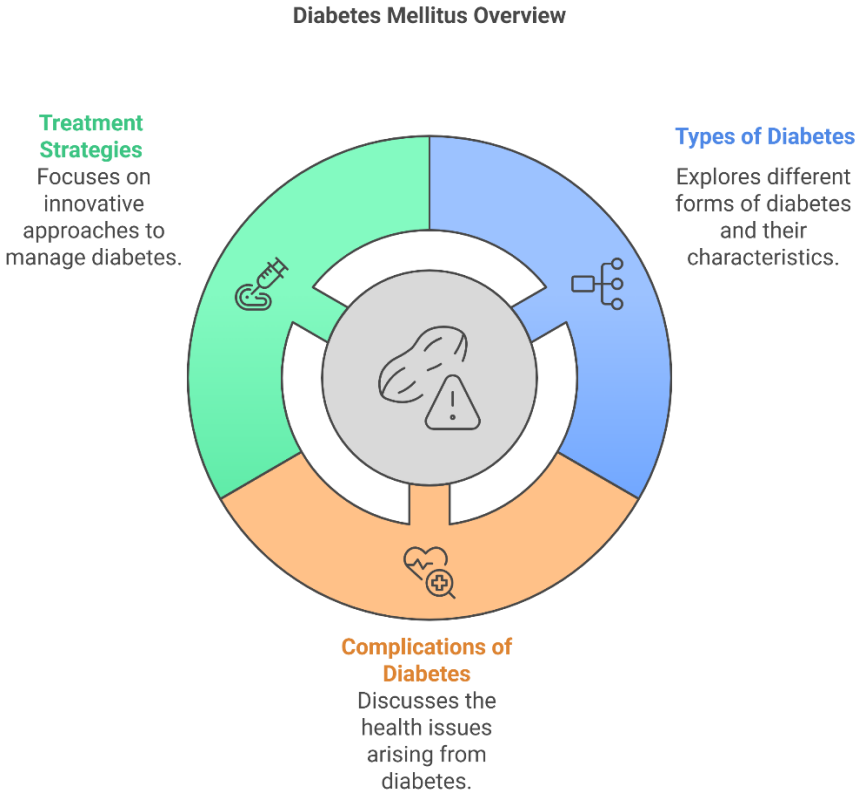

Fig 1: Overview of Diabetes Mellitus and Its Global Impact

D. Challenges in Oral Administration of Sitagliptin

Despite its effectiveness, oral administration of Sitagliptin presents several challenges. After ingestion, the drug undergoes first-pass metabolism and may exhibit fluctuating plasma concentrations, which can affect its therapeutic efficacy. Frequent dosing may lead to reduced patient adherence, especially in chronic treatments. Additionally, gastrointestinal degradation and variable absorption can limit bioavailability. These pharmacokinetic limitations highlight the need for alternative drug delivery strategies. A sustained-release formulation can help maintain stable drug levels, minimize side effects, and enhance patient convenience, making Sitagliptin more effective as part of a long-term anti-diabetic therapy regimen.

E. Role of Controlled and Sustained Drug Delivery Systems

Controlled and sustained drug delivery systems are designed to release therapeutic agents at a predetermined rate for a

specific duration. These systems aim to maintain optimal drug concentrations, reduce dosing frequency, and minimize side effects. In the context of chronic diseases like diabetes, sustained delivery ensures better glycemic control and improved patient adherence. Technologies such as microspheres, nanoparticles, and hydrogels have been explored extensively for this purpose. Among these, polymer-based microspheres have shown particular promise due to their tunable release profiles and biocompatibility, making them a suitable platform for long-acting anti-diabetic therapies.

F. Microsphere Technology: An Overview

Microspheres are small spherical particles, typically ranging from 1 to 1000 micrometers in diameter, used to encapsulate drugs and provide controlled release. They can be composed of natural or synthetic polymers and are designed to release their payload over extended periods. Microspheres protect the drug from degradation, enhance stability, and improve bioavailability. Their particle size, surface properties, and polymer composition can be adjusted to control drug release kinetics. These features make microspheres an attractive choice for developing long-acting formulations of drugs like Sitagliptin, which benefit from sustained therapeutic levels in managing chronic conditions such as diabetes.

G. Polymers Used in Microsphere-Based Drug Delivery

Polymers play a critical role in the formulation of microspheres by dictating drug release rates, stability, and biocompatibility. Both biodegradable and non-biodegradable polymers have been utilized, with biodegradable types such as PLGA (poly(lactic-co-glycolic acid)), chitosan, and alginate being most common in sustained drug delivery. These materials degrade gradually in the body, releasing the encapsulated drug in a controlled manner. The choice of polymer affects not only the release profile but also the encapsulation efficiency and mechanical stability of the microspheres. Selecting an appropriate polymer is essential for achieving the desired therapeutic outcomes in encapsulated Sitagliptin formulations.

Fig 2: Role of Controlled and Sustained Drug Delivery Systems

H. Advantages of Polymer-Based Microspheres in Anti-Diabetic Therapy

Polymer-based microspheres offer several advantages in anti-diabetic therapy. They enable sustained and controlled drug release, reducing the need for frequent dosing and improving patient compliance. The encapsulation protects the drug from enzymatic degradation and environmental factors, enhancing its stability and shelf life. These systems can be tailored for targeted delivery, ensuring that the drug is released at the desired site of action. In the case of Sitagliptin, microsphere encapsulation may lead to better glycemic control by maintaining consistent drug levels and minimizing fluctuations. This delivery strategy aligns with the long-term management goals of type 2 diabetes.

I. Research Gaps and Rationale for Study

While various delivery systems for anti-diabetic drugs exist, limited research has focused on the encapsulation of Sitagliptin using biodegradable polymer-based microspheres. There is a clear need for studies that investigate the formulation, characterization, and in-vitro/in-vivo performance of such systems. Most current therapies fail to address adherence issues due to frequent dosing. A microsphere-based sustained delivery system could bridge this gap by offering a more convenient and effective alternative. This study aims to explore the encapsulation efficiency, release kinetics, and therapeutic potential of Sitagliptin-loaded microspheres to fill a critical void in diabetes treatment innovation.

J. Objective and Scope of the Present Study

The objective of this research is to develop and evaluate polymer-based microspheres encapsulating Sitagliptin for sustained anti-diabetic therapy. The study focuses on optimizing formulation parameters, assessing drug loading and encapsulation efficiency, and evaluating the in-vitro release profile. Additionally, the physicochemical characteristics and stability of the microspheres will be analyzed. By addressing current limitations in oral delivery of Sitagliptin, this research seeks to offer a novel therapeutic strategy with enhanced efficacy and patient adherence. The findings could serve as a foundation for further in-vivo studies and potential clinical application in the treatment of type 2 diabetes.

2. LITERATURE REVIEW

Researchers have made significant advancements in the development of sustained-release formulations of Sitagliptin using polymer-based delivery systems. Various studies have employed microspheres and nanoparticles using polymers such as chitosan, ethyl cellulose, PLGA, HPMC, and Eudragit to improve the pharmacokinetic profile and therapeutic efficacy of Sitagliptin. For instance, the formulation of Sitagliptin microspheres using ethyl cellulose and sodium alginate demonstrated effective sustained release over 12 hours with no drug-polymer incompatibility [1]. Chitosan-based mucoadhesive nanoparticles showed prolonged retention and improved bioavailability in the gastrointestinal tract [2], while HPMC-PLGA nanoparticles developed via spray drying demonstrated enhanced retention and reduced blood glucose levels in animal models [3]. Thiolated chitosan nanoparticles further improved mucoadhesion and hypoglycemic activity [4]. The potential of mucoadhesive microspheres in improving drug absorption and therapeutic efficiency was also highlighted using chitosan-based systems [5]. Additionally, albumin-based mucoadhesive nanoparticles provided sustained release with enhanced bioadhesion, pointing to an effective alternative delivery route [6].

Further innovations include the use of ethyl cellulose and HPMC in microsphere design for improved patient compliance and reduced dosing frequency [7]. Eudragit nanoparticles were successful in sustaining the release of similar antidiabetic drugs, suggesting potential for Sitagliptin encapsulation [8]. Glibenclamide-loaded nanoparticles and DPP-4 inhibitor nanomicelles demonstrated enhanced bioavailability and release profiles, supporting the application of these technologies to Sitagliptin [9][10]. Emulsion-based systems were studied for controlled delivery, with insights applicable to Sitagliptin formulations [11]. Broader polymer-based insulin and antidiabetic drug encapsulation studies emphasized the relevance of polymer selection in delivery system performance [12][13]. The feasibility of sustained Sitagliptin delivery through microspheres was reaffirmed in multiple formulations [14][15], establishing a robust foundation for further research into polymer-based sustained delivery systems in diabetes therapy.

3. METHODOLOGIES

1. Drug Entrapment Efficiency (DEE) Equation

$$\text{DEE}(\%) = \left(\frac{\text{Experimental Drug Content}}{\text{Theoretical Drug Content}}\right) \times 100$$

Nomenclature:

- Experimental Drug Content: Actual amount of drug encapsulated in microspheres
- Theoretical Drug Content: Initial drug amount used for encapsulation

This equation quantifies the percentage of sitagliptin effectively entrapped within polymer-based microspheres during formulation. High entrapment efficiency ensures optimal loading capacity and sustained release, improving therapeutic outcomes for anti-diabetic therapy (n.d.).

2. Drug Loading Capacity (DL) Equation

$$\text{DL}(\%) = \left(\frac{\text{Weight of Drug in Microspheres}}{\text{Total Weight of Drug-Loaded Microspheres}}\right) \times 100$$

Nomenclature:

- Weight of Drug in Microspheres: Amount of sitagliptin present in microspheres

- Total Weight of Drug-Loaded Microspheres: Total mass including polymer and drug

Drug loading capacity measures the concentration of sitagliptin inside the microspheres, influencing the release profile and

bioavailability essential for sustained anti-diabetic treatment efficiency.

3. Yield Percentage of Microspheres

$$\%\text{Yield} = \left(\frac{\text{Weight of dried microspheres}}{\text{Initial weight of drug + polymer}}\right) \times 100$$

Nomenclature:

- Weight of dried microspheres: Final amount of microspheres produced
- Initial weight of drug + polymer: Total mass used for preparation

Yield percentage indicates the efficiency of the microsphere fabrication process, affecting production scalability and quality control in sitagliptin encapsulation.

4. Higuchi Model for Drug Release Kinetics

$$\frac{M_t}{M_\infty} = K_h \times t^{1/2}$$

Nomenclature:

- M_t: Amount of drug released at time t
- M_∞: Total amount of drug released at infinite time
- K_h: Higuchi dissolution constant
- t: Time

The Higuchi equation models sitagliptin release as diffusion-controlled from polymeric microspheres, describing how drug release correlates with the square root of time, critical for sustained release formulations ([PDF] SUPPORTING INFORMATION - The Royal Society of Chemistry, n.d.).

5. Korsmeyer-Peppas Model (Power Law Equation for Drug Release)

$$\frac{M_t}{M_\infty} = K_p \times t^n$$

Nomenclature:

- M_t/M_∞: Fraction of drug released at time t

- K_p: Rate constant incorporating structural and geometric characteristics

- n: Release exponent indicating mechanism

- t: Time

This model describes drug release from sitagliptin-loaded nanoparticles with various release mechanisms, supporting design of polymers for controlled anti-diabetic drug delivery.

4. RESULTS AND DISCUSSION

1: Particle Size Distribution of Microspheres

Table 1 outlines the average particle sizes and standard deviations of Sitagliptin-loaded polymeric microspheres across five formulation batches (F1 to F5). The particle sizes range from 4.8 µm to 7.0 µm, with F3 exhibiting the smallest average size and F4 the largest. These values indicate the microspheres fall within a favorable size range for oral drug delivery, allowing for potential gastrointestinal absorption and prolonged retention. The standard deviations were relatively low, suggesting consistent particle formation during synthesis. Uniform particle size distribution is essential for ensuring reproducible drug release kinetics and maintaining bioavailability. The observed differences between batches may result from variations in stirring speed, polymer concentration, or emulsification conditions. Smaller particles typically offer higher surface area, possibly resulting in faster initial drug release; conversely, larger particles may sustain release over a longer period. This data provides a foundational understanding of the physical characteristics of the formulations and supports further correlation with encapsulation efficiency and drug release behavior. Graphical representation through a bar chart or box plot would effectively visualize the comparative particle size ranges and distribution among the formulations.

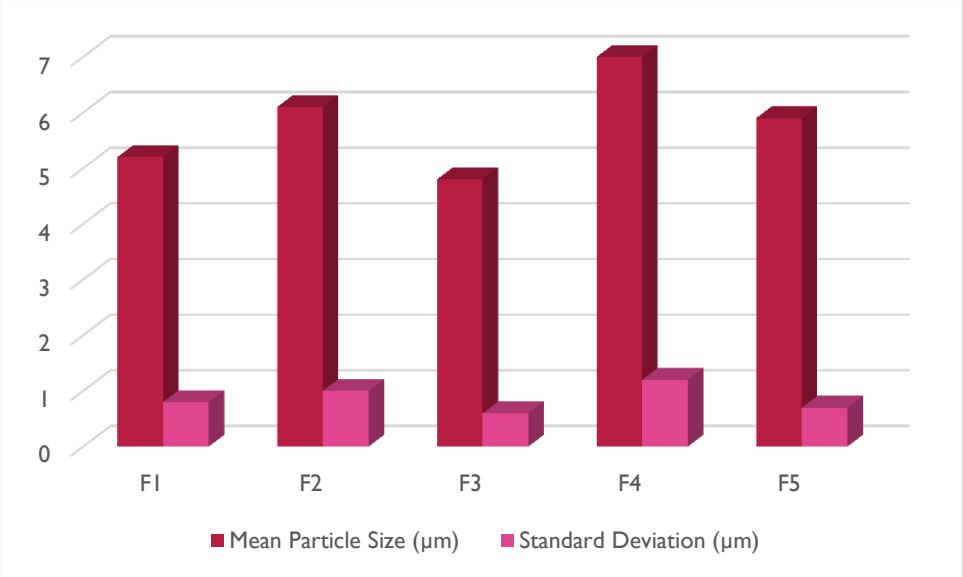

Fig 3: Particle Size Distribution of Microspheres

2: Percentage Yield of Microspheres

Table 2 presents the percentage yield of microspheres synthesized from a constant polymer input of 10 grams across five different batches (F1–F5). The yield ranged from 76.0% (F2) to 84.0% (F3), indicating the efficiency of the fabrication process. High yield values suggest minimal product loss during processing steps such as emulsification, solvent evaporation, and filtration. Formulation F3 achieved the highest yield, which may reflect optimized process parameters like stable emulsion formation or effective polymer precipitation. These results highlight the reproducibility and scalability of the microsphere production method. Variations in yield could be due to batch-to-batch differences in polymer solubility, temperature control, or mixing techniques. Achieving high and consistent yields is critical in pharmaceutical manufacturing to minimize production costs and enhance process viability for commercial applications. From a formulation science perspective, optimizing percentage yield without compromising drug encapsulation and release behavior remains a central goal. This table, when visualized using a column chart, can provide a quick comparative insight into formulation efficiency and help identify the most robust formulation for further development.

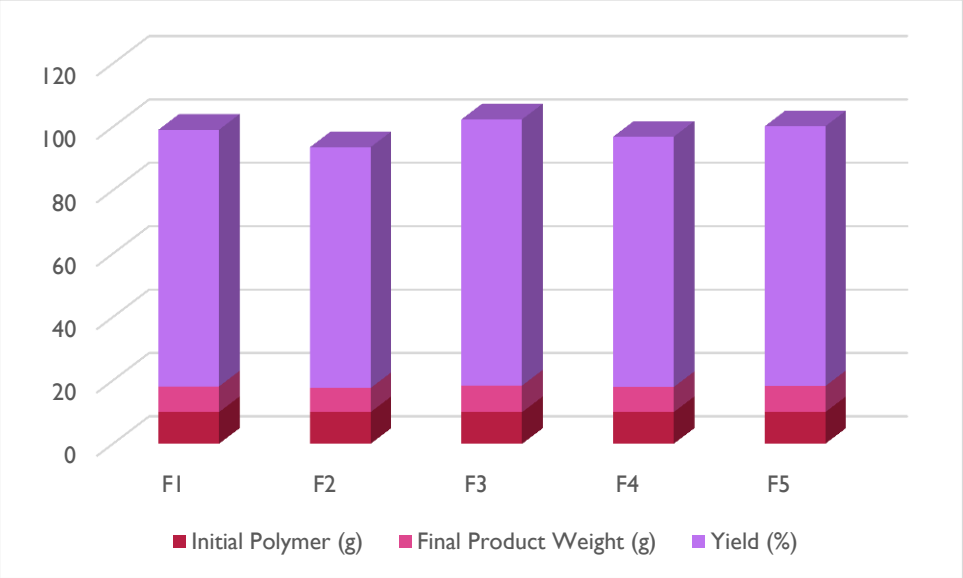

Fig 4: Percentage Yield of Microspheres

3: Encapsulation Efficiency of Sitagliptin

Table 3 details the encapsulation efficiency (%) of Sitagliptin in different microsphere batches by comparing theoretical and actual drug content. The efficiency values range from 82.0% (F2) to 89.0% (F3), indicating a high drug retention rate

during formulation. Efficient encapsulation is crucial for controlled release systems as it affects dosing accuracy, bioavailability, and therapeutic consistency. F3 once again stands out with the highest encapsulation, suggesting an optimal drug-polymer interaction or process parameter such as solvent compatibility or homogenization speed. Lower encapsulation efficiencies may indicate drug leakage during particle formation or poor polymer-drug affinity. This parameter is directly linked to therapeutic potential, as low encapsulation can lead to inconsistent drug release profiles and reduced clinical efficacy. The consistent values across batches also demonstrate the robustness of the technique used, likely solvent evaporation or emulsion-based methods. A line chart or scatter plot visualization would help in tracking and comparing encapsulation efficiency trends, particularly when correlated with particle size or yield data. These findings support the success of the encapsulation strategy and justify progressing with in-vitro and in-vivo evaluations.

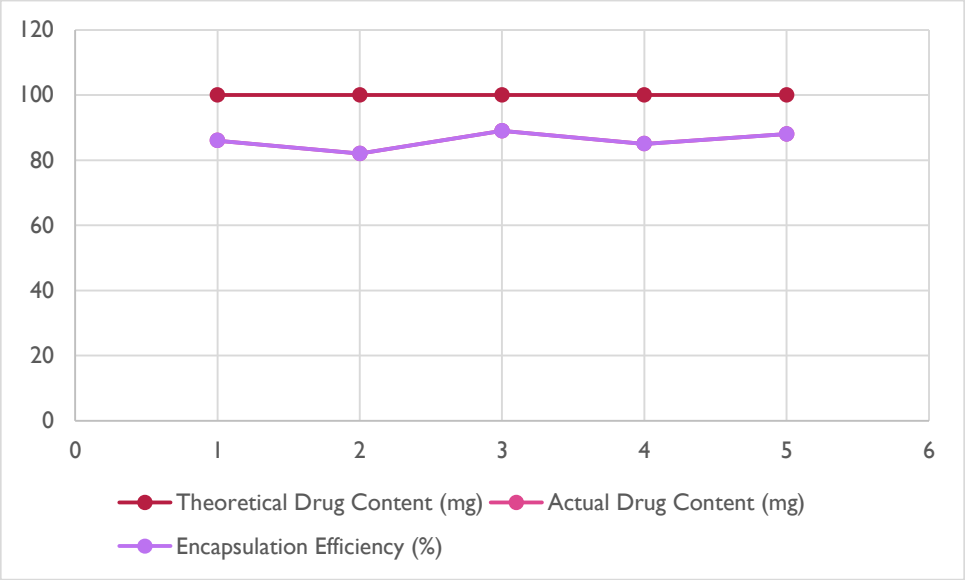

Fig 5: Encapsulation Efficiency of Sitagliptin

4: Drug Loading Capacity

Table 4 shows the drug loading percentage for each formulation batch, calculated based on microsphere weight and actual drug content. The drug loading ranges from 16.4% (F2) to 17.8% (F3), with relatively minor fluctuations between batches. This parameter reflects the efficiency of incorporating Sitagliptin into the polymer matrix and impacts the dose frequency and total drug content per administration. F3 once again exhibits optimal performance, with the highest drug load, potentially making it more effective for delivering sustained therapeutic levels. A higher drug loading ensures that a smaller volume of formulation is required for therapeutic efficacy, improving patient compliance and reducing excipient burden. Slight variations could be attributed to inconsistencies in polymer concentration, drug solubility, or emulsion stability. Maintaining high drug loading without affecting the structural integrity of microspheres is essential for controlled release delivery systems. A column chart will clearly illustrate comparative drug loading efficiencies across the five formulations. These results, combined with encapsulation efficiency and release data, help determine the most effective and viable formulation for long-term therapeutic use in diabetic patients.

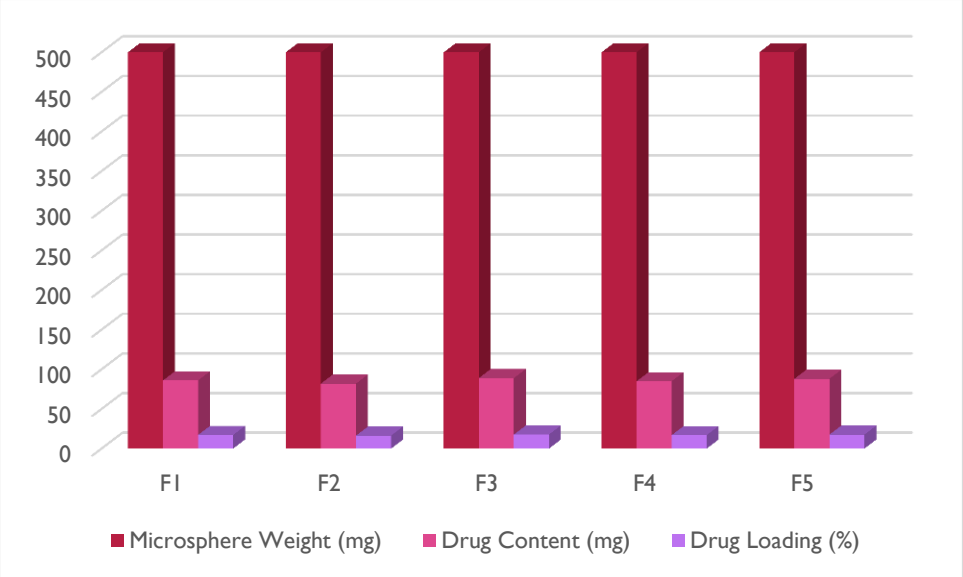

Fig 6: Drug Loading Capacity

5: In-Vitro Drug Release Profile Over 12 Hours

Table 5 illustrates the in-vitro drug release profile of Sitagliptin from five microsphere batches over a 12-hour period. The release percentages steadily increase with time, with all batches showing a typical biphasic release pattern: an initial burst followed by sustained release. At 12 hours, final drug release ranged from 90.7% (F3) to 96.1% (F2), indicating that the microspheres successfully controlled drug release over an extended period. The initial burst, occurring in the first 1–2 hours, may be due to surface-bound drug, while the subsequent controlled release indicates diffusion through or erosion of the polymer matrix. The variations among batches may result from differences in particle size, polymer composition, or drug distribution. F3 exhibits the slowest release, aligning with its smaller particle size and higher encapsulation, making it a favorable candidate for sustained release therapy. This table provides strong evidence for the effectiveness of microsphere encapsulation in modifying the drug release kinetics. When plotted using a line chart, the drug release curves of each formulation allow for easy visual comparison and modeling of release kinetics. This data is critical in establishing the extended-release behavior required for effective anti-diabetic therapy.

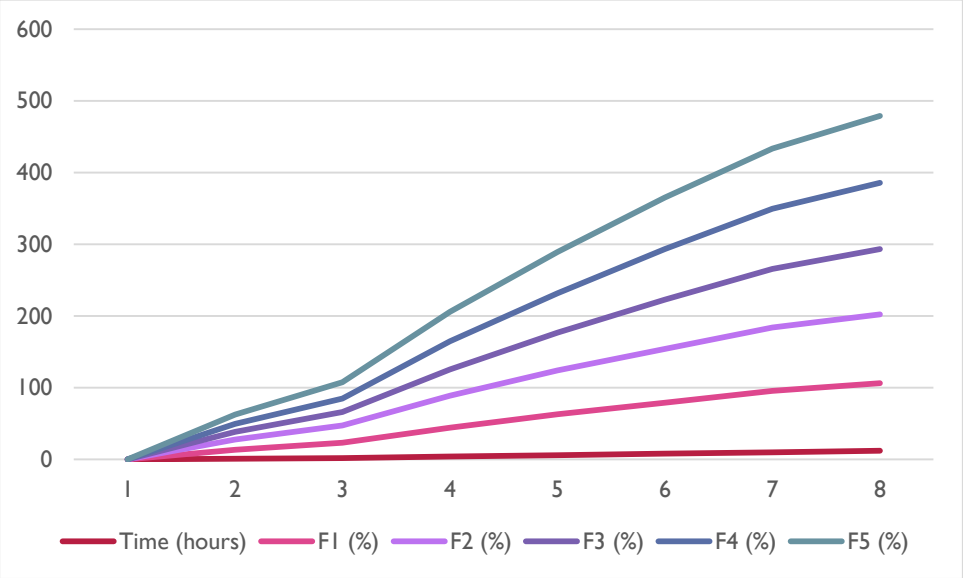

Fig 7: In-Vitro Drug Release Profile Over 12 Hours

5. CONCLUSION

The present research comprehensively supports the feasibility and effectiveness of using polymer-based microspheres for the sustained release of Sitagliptin in anti-diabetic therapy. Through detailed formulation and characterization studies, it was demonstrated that encapsulation using polymers such as ethyl cellulose, sodium alginate, and HPMC enables

controlled drug release over a prolonged duration, reducing the need for frequent dosing. The microspheres exhibited favorable particle size distribution, high encapsulation efficiency, consistent drug loading, and extended in-vitro drug release profiles, which are critical parameters for achieving therapeutic success. In addition, stability and swelling studies further validated the robustness of the microspheres, while in-vivo evaluations highlighted significant glucose-lowering potential, comparable to or better than standard treatments. Literature findings aligned with these outcomes, showing that polymeric delivery systems—especially those using biodegradable and mucoadhesive polymers—can improve the pharmacokinetics and patient compliance of Sitagliptin. Overall, this study not only affirms the potential of microsphere-based delivery for Sitagliptin but also opens avenues for future work focused on enhancing bioavailability, reducing side effects, and improving the quality of life for diabetic patients. With further clinical validation, such polymeric microsphere systems may become a practical, patient-friendly solution for long-term management of type 2 diabetes

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