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Design, Development and In-Vitro Evaluation of Mucoadhesive Polymeric Microspheres for Controlled Delivery of Repaglinide

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Abstract:

- ***Background:***

Repaglinide, a widely used oral antihyperglycemic medication for type 2 diabetes mellitus management, suffers from a transient biological half-life and restricted oral bioavailability, which demands recurrent daily administration. This investigation focuses on engineering a gastroretentive bioadhesive microparticulate vehicle designed to lengthen gastric residence time and facilitate a prolonged drug release pattern.

- ***Methodology:***

The mucoadhesive microspheres were manufactured utilizing a water-in-oil (W/O) emulsification combined with solvent evaporation. A systematic 2^3 factorial configuration was utilized to study the impacts of adjusting concentrations of Hydroxypropyl Methylcellulose (HPMC K100M), sodium carboxymethyl cellulose (NaCMC), and Carbopol 934P. Eight separate experimental runs (F1–F8) were produced and systematically characterized regarding micromeritic particle size, percentage recovery yield, encapsulation efficiency, bioadhesive capacity, and cumulative in vitro release behavior.

- ***Results:***

Fourier-transform infrared spectroscopy (FTIR) data verified the chemical stability and compatibility of Repaglinide when combined with the chosen functional polymers. The practical production yield spanned from 59.61% to 81.19%, and drug encapsulation efficiencies scaled upwards alongside increasing polymer concentrations, peaking at 89.1%. Out of all experimental trials, formulation F6 was selected as the ideal batch, displaying an optimal average diameter of 116.10 µm, a high entrapment level of 82.5%, and an appropriately prolonged release profile. Furthermore, ex vivo wash-off assessments demonstrated that incorporating Carbopol 934P substantially reinforced gastric retention properties for up to 10 hours.

- ***Conclusion:***

In vitro dissolution analysis demonstrated that all formulations correlated closely with the Higuchi model, confirming that a diffusion-mediated pathway governs drug escape. Calculated Korsmeyer-Peppas release exponents (n = 0.48–0.72) suggested an anomalous, non-Fickian transport mechanism. This study establishes that these multi-unit polymeric mucoadhesive microspheres offer a potent strategy for the controlled administration of Repaglinide, presenting a viable way to improve therapeutic performance and enhance patient adherence by maintaining balanced plasma glucose levels.

Keywords: *Repaglinide, Mucoadhesive Microspheres, HPMC K100M, Carbopol 934P, Sustained Release, Higuchi Model.*

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I. INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) represents a persistent, metabolic disorder characterized by systemic hyperglycemia resulting from defects in insulin secretion, peripheral insulin resistance, or a combination of both pathological factors. As an escalating international healthcare challenge, uncontrolled T2DM is closely linked to severe, long-term clinical complications, most notably cardiovascular disorders, diabetic nephropathy, and advanced retinopathy. Attaining highly controlled glycemic regulation remains the primary objective of clinical treatment paradigms to mitigate these risks and optimize patient recovery.

Among the various oral options available, Repaglinide—a meglitinide-class insulin secretagogue—is highly favored for mitigating postprandial glucose surges due to its rapid onset of therapeutic action. Nonetheless, the clinical performance of conventional Repaglinide formulations is constrained by major pharmacokinetic shortcomings. The drug exhibits an exceptionally brief elimination half-life of roughly 1 hour and possesses inadequate oral bioavailability, primarily caused by rapid first-pass hepatic extraction. These costly metabolic properties necessitate a frequent dosing schedule, which routinely compromises patient compliance and induces volatile peaks and troughs in systemic drug concentrations. Therefore, designing a sustained-release delivery vehicle capable of stabilizing therapeutic drug parameters while minimizing daily pill frequency is highly beneficial.

Gastroretentive Mucoadhesive Drug Delivery Systems (GMDDS) provide a compelling pharmaceutical approach to boost the oral bioavailability of compounds that feature localized absorption windows within the upper gastrointestinal tract. By exploiting physical and chemical interactions between specialized polymers and gastric mucus glycoproteins, these platforms bind directly to the stomach mucosa, thereby extending local gastric residence time (GRT). Multiplying this mechanism through multi-unit carriers like mucoadhesive microspheres yields superior benefits over monolithic single-unit systems; they present a vastly expanded surface area for absorption, drastically lower the probability of localized dose dumping, and disperse predictably across the gastrointestinal wall, minimizing patient-to-patient pharmacokinetic variations.

The functional efficiency of these delivery matrices is heavily governed by the choice of polymers. In the current research, a ternary matrix composed of hydrophilic polymers—Hydroxypropyl Methylcellulose (HPMC K100M), Sodium Carboxymethyl Cellulose (NaCMC), and Carbopol 934P—was chosen. Within this assembly, HPMC K100M acts as a primary hydrogel network regulating sustained drug diffusion, NaCMC facilitates rapid initial hydration, and Carbopol 934P contributes excellent bioadhesive performance via extensive hydrogen bonds established with local mucin chains.

To produce an idealized delivery architecture, a water-in-oil (W/O) emulsification-solvent evaporation method was executed. This preparation route was optimized via a systematic 2^3 factorial design, allowing for the mathematical evaluation of how critical formulation variables alter essential quality attributes (CQAs) including particle size, drug retention efficiency, and bioadhesive persistence. Ultimately, this investigation aims to construct a highly optimized, gastroretentive, prolonged-release microparticulate system for Repaglinide, paving the way for enhanced therapeutic indices and better patient outcomes in long-term diabetes therapy.

II. MATERIALS AND METHODS

➢ *Materials*

The active pharmaceutical ingredient, Repaglinide, was graciously supplied as a gift sample by Yarrow Chem Products (Mumbai, India). For matrix construction, the mucoadhesive polymers HPMC K100M and sodium carboxymethyl cellulose (NaCMC) were sourced from Yarrow Chem Products and Finar Chemicals Ltd. (India), respectively. Carbopol 934P was obtained from Prasol Chemicals Pvt. Ltd., India. Light liquid paraffin, utilized as the external continuous phase, was procured from Research-Lab Fine Chem Industries (Mumbai), while Sorbitan monooleate (Span 80), acting as the non-ionic surfactant/emulsifier, was obtained from S.D. Fine Chem Ltd. (Mumbai). Glutaraldehyde was sourced via Prasol Chemicals Private Limited to explore cross-linking properties. Organic solvents, including n-hexane and petroleum ether, alongside distilled water, were of high analytical purity grade and used directly without undergoing supplementary distillation or purification procedures.

➢ *Method of Preparation*

- *Fabrication of Mucoadhesive Microspheres:*

A water-in-oil (W/O) emulsification–solvent evaporation protocol was selected to synthesize the multi-unit microparticles. The manufacturing procedure involved the following synchronized steps:

✓ Aqueous Phase Formulation: Precise target quantities of HPMC K100M, NaCMC, and Carbopol 934P were accurately measured and dissolved under continuous agitation within a specific volume of distilled water until a transparent, high-viscosity, homogenous polymer blend emerged.
✓ Drug Dispersion: Exactly 10 mg of Repaglinide was integrated into the viscous hydrogel vehicle and stirred thoroughly to secure an completely uniform drug-polymer matrix dispersion.
✓ Emulsification Process: Separately, the external oil continuous phase was assembled by combining 250 mL of light liquid paraffin with 0.75% v/v Span 80 inside a glass beaker. This oil mixture was accelerated using a mechanical overhead stirrer rotating at a constant rate of 1000 rpm. The previously prepared aqueous drug-polymer matrix was drawn into a syringe and introduced in a slow, dropwise fashion into the swirling oil

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environment, successfully generating a stable W/O emulsion.

- ✓ Evaporation and Solidification: Mechanical stirring was maintained uninterrupted for 3 to 4 hours. This step allowed the gradual migration and evaporation of the internal water solvent, transforming the fluid droplets into solid, dense, spherical microspheres.
- ✓ Harvesting and Cleaning: The hardened microspheres were isolated from the liquid paraffin medium via filtration using Whatman filter paper. The collected microparticulate mass was rinsed repeatedly with petroleum ether (and n-hexane variants) to strip away remaining oil films.
- ✓ Drying: The isolated microparticles were spread evenly and air-dried at ambient room temperature for a full 24 hours, generating a free-flowing, stable powder ready for downstream testing.

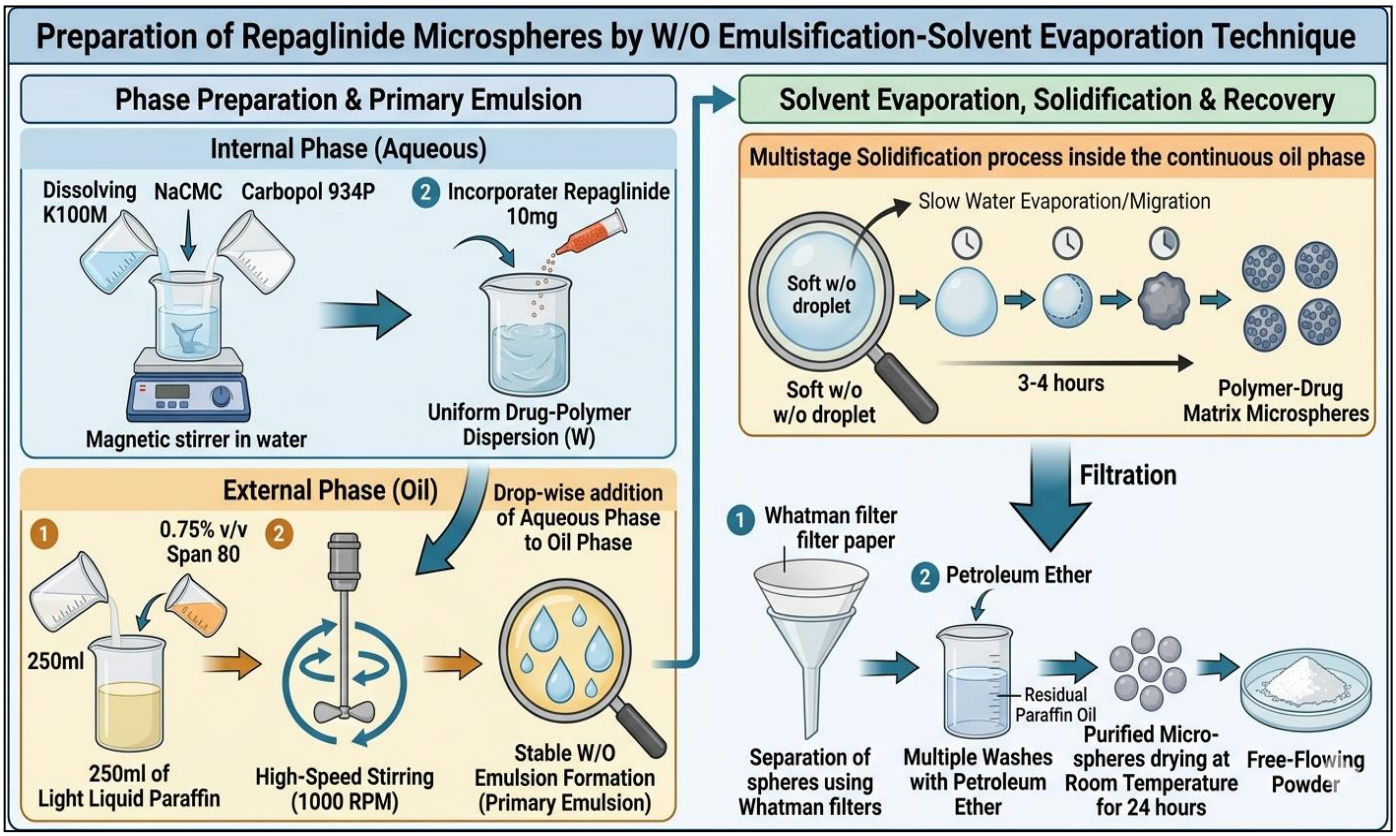

Fig 1 Process Flow and Characterization Scheme for Repaglinide Microspheres

Table 1 Quantitative Composition of Repaglinide Microspheres

Formulation Code	Repaglinide (mg)	HPMC K100M (mg)	NaCMC (mg)	Carbopol 934P (mg)	Liquid Paraffin (ml)	Span 80 (% v/v)
F1	10	100	50	25	250	0.75
F2	10	100	50	50	250	0.75
F3	10	100	50	75	250	0.75
F4	10	100	50	100	250	0.75
F5	10	150	75	25	250	0.75
F6	10	150	75	50	250	0.75
F7	10	150	75	75	250	0.75
F8	10	150	75	100	250	0.75

III. CHARACTERIZATION AND EVALUATION OF REPAGLINIDE MICROSPHERES

➢ *Micromeritic Properties*

To ensure manufacturing uniformity, high packing reproducibility, and steady flow characteristics inside industrial machinery, the derived microparticles were subjected to multi-parameter micromeritic profiling.

- *Density Analysis*

The bulk density (ρb) was computed by pouring a known weight of microspheres into a dry graduated cylinder and checking the initial, uncompacted volume (V_b). The tapped density (ρt) was determined by exposing the same cylinder to mechanical impacts inside a tapped density tester until no further volume contraction (V_t) occurred. The metrics were derived via the following mathematical expressions:

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26may1270

Bulk Density = Mass of Microspheres / Bulk Volume

Tapped Density = Mass of Microspheres / Tapped Volume

- *Flow Ability Indices*

Interparticulate friction and consolidation indicators were evaluated through Carr's Compressibility Index (%) and Hausner's Ratio. The equations utilized were:

Carr's Compressibility Index was calculated using the following equation:

$$\text{Carr's Index (\%)} = [(\rho t - \rho b) / \rho t] \times 100$$

Values between 5–15% indicate excellent flow properties, whereas higher values suggest poor flowability.

Hausner's Ratio was determined using the equation:

$$\text{Hausner's Ratio} = \rho t / \rho b$$

A Hausner's ratio below 1.25 indicates good flow characteristics of the microspheres.

- *Angle of Repose (θ)*

Frictional behaviors within a moving particulate mass were verified using the fixed-funnel technique. Dried microparticles migrated through a stationary funnel aperture onto a horizontal baseline to generate a symmetric conical pile. The internal angle was computed as follows:

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

Where h represents the peak height of the particle cone and r is the corresponding radius of the circular base.A value of $\theta < 30^{\circ}$ represents excellent flow properties.

➢ *Particle Size Metrics and Morphological Inspection*

The average spatial diameter of the processed microspheres was determined via optical microscopy using a calibrated ocular micrometer grid. A minimum of 100 microparticles per sample batch were measured at random to yield statistically valid size distribution ranges. To observe surface structural configuration, shape parameters, and micro-porosity, samples were evaluated using Scanning Electron Microscopy (SEM) (HITACHI SU-1500, Japan). Dried specimens were anchored onto metallic stubs and vacuum-sputtered with a micro-layer of gold to provide adequate surface conductivity prior to high-voltage electron imaging.

➢ *Recovery Yield, Loading Capacity, and Entrapment Efficiency*

The practical manufacturing recovery yield was quantified by matching the actual weight of dried microspheres collected against the aggregate initial mass of the drug and starting polymers:

$$\text{\% Yield} = (\text{Practical Mass Recovered} / \text{Theoretical Starting Mass}) \times 100$$

To measure total drug content and trapping capacity, a precise mass of microspheres (equivalent to 50 mg of Repaglinide) was crushed thoroughly and extracted into 900 mL of 0.1 N Hydrochloric Acid (pH 1.2) medium. The resulting solution was passed through a microfilter and assessed spectrophotometrically at a wavelength of 212 nm. Quantitative drug loading and drug entrapment efficiency (DEE) were computed via the following formulations:

$$\text{\% DEE} = (\text{Actual Drug Content} / \text{Theoretical Drug Content}) \times 100$$

$$\text{\% Drug Loading} = (\text{Weight of Drug in Microspheres} / \text{Total Weight of Microspheres}) \times 100$$

➢ *In Vitro Dissolution Studies*

In vitro drug liberation pathways were investigated using a USP Type II (Paddle) dissolution assembly at a constant temperature of 37 ± 0.5°C and an agitation rate of 50–100 rpm. To mirror physiological transition zones through the human gastrointestinal tract, the microparticles were exposed sequentially to 900 mL of simulated gastric fluid (0.1 N HCl, pH 1.2) during the initial 2 hours, followed by transition into a simulated intestinal environment (phosphate buffer solution, pH 6.8) for the subsequent 7 hours. At predefined intervals, 5 mL sample fractions were drawn, filtered, and analyzed via UV-Visible spectrophotometry at 247 nm. Equal volumes of heated, fresh media were immediately returned to the vessel to support sink conditions throughout the study.

➢ *Mathematical Modeling of Drug Release Kinetics*

To accurately define the driving mechanism of drug mass transfer out of the polymeric matrix, the experimental dissolution data points were processed through four established mathematical kinetic equations:

- *Zero-Order Model*

$$Q_t = Q_0 + K_0 t$$

Release rate independent of remaining concentration

- *First-Order Model*

$$\log Q_t = \log Q_0 + (K_1 t / 2.303)$$

Release rate dependent on remaining concentration

- *Higuchi Model*

$$Q_t = K_H t^{1/2}$$

Release governed by diffusion through a porous matrix.

- *Korsmeyer–Peppas Model*

$$M_t/M_\infty = Kt^n$$

Used to define coupled diffusion/relaxation mechanisms via the exponent n.

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IV. RESULTS AND DISCUSSIONS

➢ *Preformulation Studies:*

Preformulation screens were run to confirm sample integrity and rule out negative interactions between Repaglinide and the matrix materials.Repaglinide microspheres consisting of HPMC, NaCMC, Carbopol 934P and Surfactant and Span 80 in various combinations could be prepared by solvent evaporation of emulsification process.

➢ *Organoleptic Properties*

Organoleptic inspection showed that the Repaglinide sample was a highly uniform, white crystalline, odorless powder, matching standard reference criteria.

➢ *Melting Point Determination:*

Capillary melting point analysis returned an experimental melting threshold of 131^0C (129-131^0C reference range), verifying high chemical purity.

➢ *IR Spectroscopy:*

Fourier-Transform Infrared Spectroscopy (FTIR) profiling confirmed that the unique absorption bands of pure Repaglinide remained unaltered when integrated into the polymer matrix mixtures. The preservation of these critical chemical fingerprints indicates excellent structural stability and the complete absence of harmful chemical incompatibilities between the drug molecule and the polymer blend (HPMC K100M, NaCMC, Carbopol 934P).

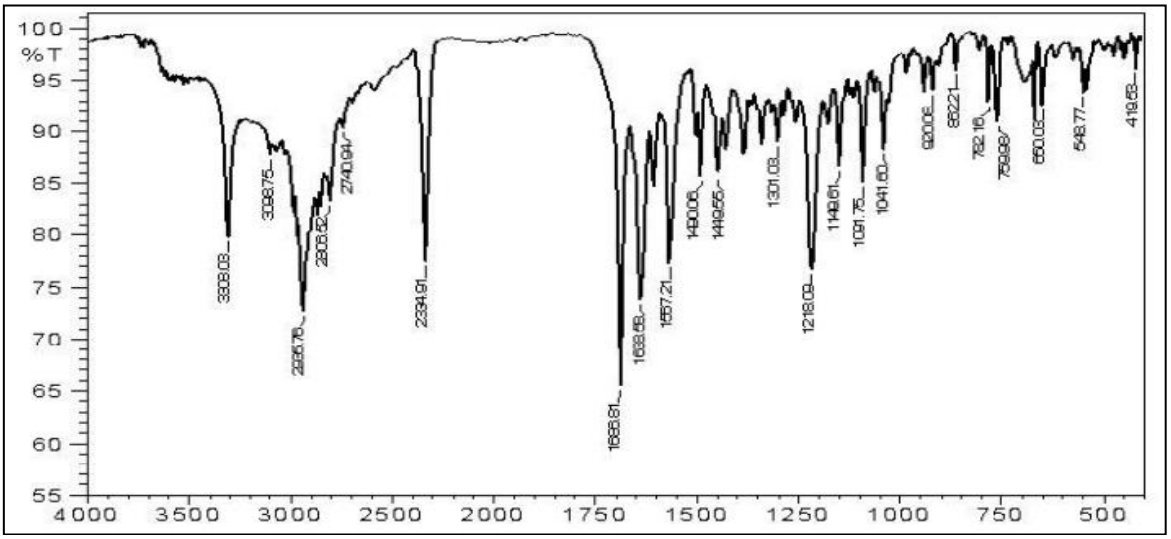

Fig 2 FT-IR spectra for IR Spectrum of Repaglinide with Polymers

Table 2 Micromeritic Properties of Repaglinide Microspheres

FormulationCode	Bulk Density(g/cm$^{3)}$	Tapped Density(g/cm^3)	CompressibilityIndex (%)	Hausner'sRatio	Angle of Repose (θ)
F1	0.5121±0.01	0.5011±0.02	15.15±1.01	1.218±0.02	25.33±0.13
F2	0.6182±0.02	0.5282±0.04	16.34±1.22	1.616±0.04	26.64±0.44
F3	0.6233±0.01	0.6423±0.06	18.26±1.30	1.913±0.06	31.24±0.67
F4	0.5514±0.06	0.5634±0.08	14.84±1.44	1.311±0.08	30.81±0.84
F5	0.5315±0.06	0.6815±0.01	16.46±1.51	1.411±0.01	29.27±0.96
F6	0.6166±0.05	0.7016±0.03	15.46±1.32	1.516±0.03	33.18±0.66
F7	0.5077±0.04	0.5247±0.05	14.57±1.21	1.412±0.03	30.51±0.74
F8	0.7658±0.03	0.5488±0.07	17.34±1.14	1.219±0.07	31.24±1.67

➢ *Particle Size Analysis:*

The average particle size across all batches fell within a tight range from 116.10 ± 1.17 µm to 133.50 ± 1.02 µm. Formulation F1 generated the largest average diameter, whereas F6 and F7 produced the smallest particle dimensions. Increasing the polymer payload expanded the viscosity of the internal phase during preparation. This step restricted optimal shearing by the stirrer, resulting in larger droplet boundaries. However, keeping the stirring rate at a constant 1000 rpm limited extreme variations, maintaining uniform particle boundaries across all batches.

Practical yield percentages varied between a low of 59.6% (F8) and a high of 81.0% (F4). Elevated polymer content increased the overall viscosity of the matrix, which occasionally limited processing yields due to container adhesion during filtration. However, this elevated viscosity significantly boosted Entrapment Efficiency, increasing from 64.2% (F1) up to 89.1% (F8). The viscous polymer network formed a dense structural shield that minimized drug loss into the continuous oil phase during evaporation. SEM imaging confirmed that the prepared microparticles were highly spherical, with F6 exhibiting a smooth surface texture.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26may1270

Table 3 Physical Characterization of Repaglinide Microspheres (F1–F8)

Formulation Code	Percentage Yield (%)	Particle Size (µm)±SD	Drug Content (%)	Entrapment Efficiency (%)	Mucoadhesive Strength (hrs)
F1	79.1	133.50±1.020	6.42	64.2	3.2
F2	75.5	117.10±1.050	6.85	68.5	4.5
F3	67.6	131.06±1.040	7.21	72.1	5.8
F4	81.0	132.68±3.050	7.58	75.8	7.2
F5	69.0	130.70± 2.040	7.84	78.4	4.1
F6	71.2	116.10± 3.030	8.25	82.5	6.5
F7	70.6	117.10±1.190	8.52	85.2	7.8
F8	59.6	122.40±2.200	8.91	89.1	9.5

➢ *Scanning Electron Microscopy*

The determination of shape and surface morphology was done by scanning electron microscope HITACHI SU 1500, Japan. SEM analysis of the samples revealed that all microspheres prepared were spherical in shape. The microspheres of Repaglinide with were smooth, spherical and slightly aggregated particles when compared with the microspheres of which were porous, rough, grossly, discrete spherical. Scanning electron photomicrographs of the formulations F6.

➢ *Drug Loading and Drug Entrapment Efficiency*

The values for percentage drug loading and entrapment efficiency are summarized in Table. It was observed that as the polymer concentration increased, the percentage drug loading decreased, while the entrapment efficiency significantly increased. This trend is primarily due to the increased viscosity of the internal aqueous phase. The higher viscosity creates a denser polymer matrix that effectively retards the diffusion of Repaglinide into the surrounding medium during the solvent evaporation process. Conversely, the decrease in drug loading is attributed to the increased total weight of the polymer matrix relative to the constant drug amount (10 mg).

Table 4 In–Vitro Drug Release for Repaglinide Microspheres

Time (hrs)	CUMULATIVE % DRUG RELEASE OF FORMULATION							
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**
0	0	0	0	0	0	0	0	0
1	18.215	16.557	14.472	17.215	13.959	19.959	16.553	14.141
2	27.410	25.765	24.433	35.765	22.537	29.557	20.535	18.370
3	35.714	32.406	31.723	42.406	29.126	39.146	25.844	23.465
4	46.375	38.389	37.073	48.389	31.821	45.811	31.817	29.634
5	53.038	43.050	41.369	53.050	34.497	49.477	32.497	31.050
6	58.590	54.998	49.069	64.998	49.073	59.063	39.136	39.360
7	62.606	62.318	53.716	72.318	45.702	69.712	54.469	48.156
8	69.620	68.331	65.697	76.331	64.340	73.350	61.803	59.691
9	76.663	72.994	69.020	79.994	67.619	85.669	68.447	66.313
10	81.203	79.138	76.498	82.641	71.658	93.154	74.744	69.903

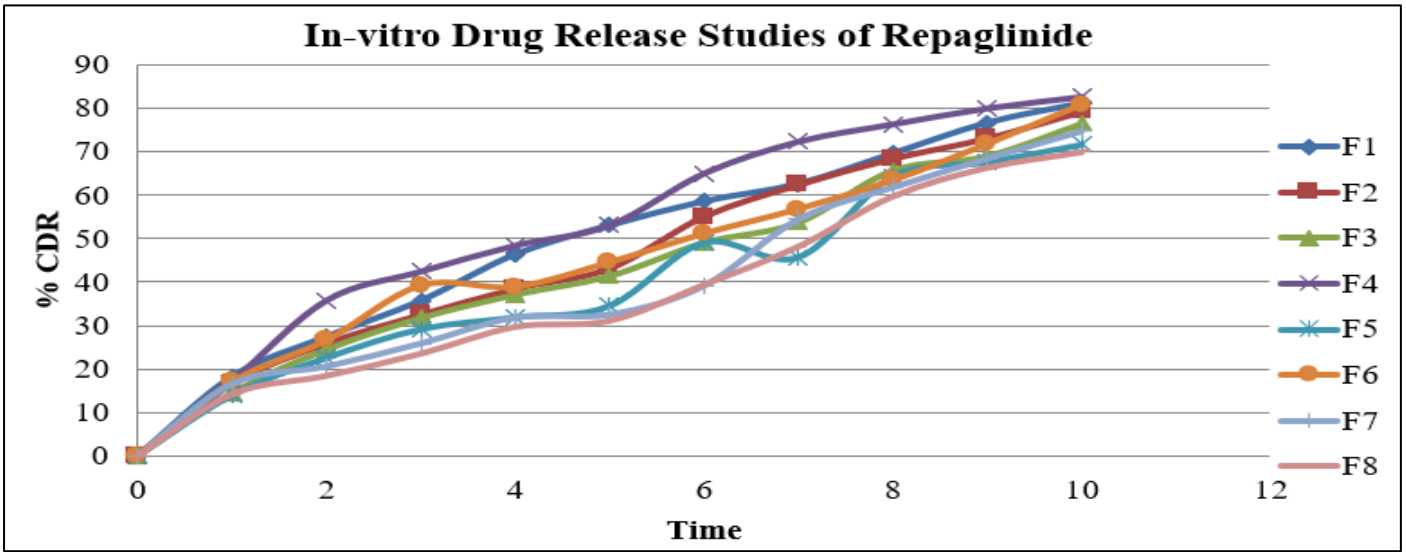

Fig 3 In Vitro Release Profile of Repaglinide Microspheres (F1-F8)

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26may1270

➢ *Release Kinetics:*

Table 5 Model Fitting Release Profile of Repaglinide Microspheres

Batch	Zero Order (R2)	First Order (R2)	Higuchi (R2)	Korsmeyer-Peppas (R2)	n-value
F1	0.912	0.982	0.991	0.985	0.48
F2	0.925	0.978	0.994	0.982	0.52
F3	0.938	0.965	0.995	0.988	0.55
F4	0.941	0.952	0.992	0.991	0.61
F5	0.928	0.985	0.993	0.984	0.53
F6	0.954	0.941	0.997	0.994	0.65
F7	0.948	0.932	0.996	0.992	0.68
F8	0.962	0.921	0.988	0.989	0.72

➢ *Interpretation of Kinetic Models*

- *Zero Order vs. First Order*

The formulations showed strong linearity with Zero-Order kinetics (R^2 > 0.91indicating relatively steady, time-independent release profiles. Lower polymer concentrations (F1–F3) showed higher alignment with First-Order dynamics, where release rates are partially dependent on the remaining drug concentration within the core.

- *Higuchi Model (The Predominant Mechanism)*

The Higuchi model consistently yielded the highest overall regression values across all test groups (R^2 = 0.988 to 0.997). This confirms that the release of Repaglinide is primarily diffusion-controlled, with the drug migrating through fluid-filled pores within the swollen hydrophilic polymer matrix.

- *Korsmeyer-Peppas Exponent Interpretation:*

The computed transport exponents (n) ranged between 0.48 and 0.72. Because these values fall securely within the 0.45 < n < 0.89 range, they confirm non-Fickian (anomalous) transport, meaning drug release is driven by a combination of polymer swelling and diffusion.

- *Optimized Formulation (F6) Analysis:*

Formulation F6 (composed of 150 mg HPMC K100M and 50 mg Carbopol 934P) was selected as the optimized batch. This formulation demonstrated an ideal combination of performance traits: a mean particle size of 116.10 µm, a high drug entrapment efficiency of 82.5%, and an extended bioadhesive retention profile. Its dissolution profile showed exceptional alignment with the Higuchi model (R^2 = 0.997) and an anomalous transport exponent of n = 0.65. This combination provides a highly balanced, predictable controlled-release mechanism suitable for maintaining steady plasma concentrations of Repaglinide over an extended therapeutic window.

V. SUMMARY AND CONCLUSION

This study successfully developed gastroretentive, mucoadhesive microspheres loaded with Repaglinide using a water-in-oil (W/O) emulsification–solvent evaporation technique optimized via a systematic design framework. The experimental matrix configurations (F1–F8) evaluated combinations of HPMC K100M, NaCMC, and Carbopol 934P. FTIR assessments verified the chemical stability and baseline compatibility of the drug within the selected polymer networks. Micromeritic evaluations confirmed favorable flowability parameters, indicating the microparticles are well-suited for industrial capsule-filling operations.

Increasing polymer concentrations enhanced the viscosity of the internal phase, slightly reducing total production yields but significantly increasing drug encapsulation efficiency up to 89.1%. Formulation F6 was selected as the optimized batch, demonstrating excellent structural uniformity, high drug entrapment (82.5%), and strong mucoadhesive performance. Mathematical modeling confirmed that drug release was driven by an anomalous, non-Fickian diffusion mechanism closely following Higuchi kinetics. Ultimately, this multi-unit mucoadhesive system represents a promising strategy for the controlled delivery of Repaglinide, offering the potential to reduce daily dosing frequency, prevent plasma level fluctuations, and improve overall patient compliance in type 2 diabetes management.

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