2026 Volume: 02 Issue: 07 www.ijrpa.com ISSN 2456-9995 Research Article

International Journal Research Publication Analysis

Page: 01-17

# FORMULATION AND CHARACTERIZATION OF REPAGLINIDE LOADED FLOATING MICROSPHERE FROM HPMC

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**Article Received: 20 June 2026**
**Article Revised: 10 July 2026**
**Published on: 30 July 2026**

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DOI: https://doi-doi.org/101555/ijrpa.6502

## ABSTRACT

Repaglinide is a short-acting oral antidiabetic drug used in the management of type II diabetes mellitus. However, its limited gastric residence time and rapid gastrointestinal transit can reduce its therapeutic effectiveness. The present study aimed to formulate and evaluate gastroretentive floating microspheres of Repaglinide using hydroxypropyl methylcellulose (HPMC) and ethyl cellulose (EC) to achieve prolonged gastric retention and sustained drug release. Floating microspheres were prepared by the solvent diffusion-evaporation method using different polymer ratios and evaluated for physicochemical characteristics, percentage yield, drug entrapment efficiency, buoyancy, floating lag time, particle characteristics, and in vitro drug release. Preformulation studies confirmed the suitability of the drug for formulation development, with a melting point of 132–135°C, λmax at 244 nm, and good compatibility with the selected excipients. Among all formulations, batch F3 exhibited the best performance with a percentage yield of 73.32 ± 0.65%, drug entrapment efficiency of 75.56 ± 0.23%, buoyancy of 76.65 ± 0.52%, and a floating lag time of 32 ± 4 seconds. The optimized formulation provided sustained drug release for up to 10 hours and followed zero-order release kinetics ($R^2$ = 0.958). The findings demonstrate that floating microspheres of Repaglinide are a promising gastroretentive drug delivery system capable of enhancing gastric residence time, providing controlled drug release, and potentially improving oral bioavailability and therapeutic efficacy.

**KEYWORDS:** Repaglinide; Floating microspheres; Gastroretentive drug delivery; HPMC: In vitro release.

# 1. INTRODUCTION

## 1.1. Microsphere

Medication activity can be enhanced by growing a new medication delivery system, for example, the microsphere sedate delivery system. These frameworks stay in close contact with the ingestion tissue, the mucous layer, discharging the medication at the activity site, prompting a bioavailability increment and both local and systemic impacts [1]. The oral course of medication organization constitutes the most helpful and favored methods for sedate conveyance to foundational dissemination of body. However oral organisation of the greater part of the medications in traditional measurements frames has here and now restrictions because of their failure to limit and confine the framework at gastro- intestinal tract [2].

Microspheres constitute an essential piece of these particulate medication conveyance frameworks by uprightness of their little size and productive bearer limit. Microspheres are the bearer connected medication conveyance framework in which molecule estimate is ranges from 1-1000 μm extend in distance across having a center of medication and completely external layers of polymer as covering material. Be that as it may, the accomplishment of these microspheres is restricted because of their short habitation time at site of assimilation [3]. It would, in this way be worthwhile to have implies for giving a private contact of the medication conveyance framework with the engrossing layer. Microspheres have focal points like proficient retention and upgraded bioavailability of the medications because of a high surface to volume proportion, a substantially cozier contact with the bodily fluid layer and particular targeting of medications to the ingestion site [4].

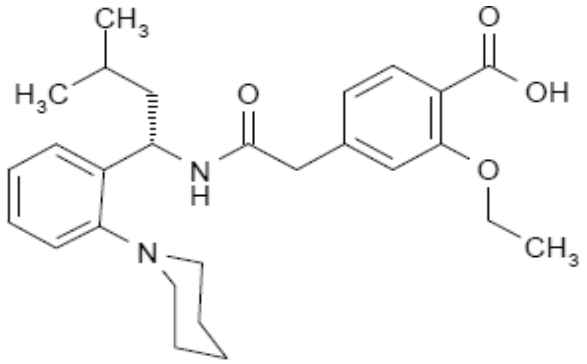
**Types of microspheres** [5]

- Bioadhesive microspheres
- Magnetic microspheres
- Floating microspheres
- Radioactive microspheres
- Mucoadhesive microspheres

## 1.2. Repaglinide

Repaglinide (Prandin) a member of meglitinide class used orally for secretion of insulin was selected for the present investigation. Repaglinide is indicated only in type II DM as an alternative to sulfonylurea's, or to supplement metformin/long acting insulin. It should be

avoided in the liver disease. Repaglinide is the first derivative of meglitinide group developed to normalize the elevated glucose level after meals. It represents fast onset of action with short lasting insulin release [6].




1-[(6R,7R)-3-[(carbamoyloxy)methyl]-7-[(2Z)-2-(furan-2-yl)-2- (methoxyimino) acetamido]-8-oxo-5-thia-1-azabicyclo [4.2.0] oct-2-ene-2- carbonyloxy] ethyl acetate.

**Pharmacology**

**Category:** New derivative of oral hypoglycemic drug, of meglitinide class. It is a carbamoyl methyl benzoic acid. [7].

**Description:** Repaglinide comes under the category of organic compounds known as phenylpiperidine. It is a phenylpiperidine skeleton in which piperidine ring isbound to a phenyl group. Repaglinide is specifically usedas monotherapy to control meal related (prandial) glucose fluctuation in patients having Type II diabetes. Due to rapid onset and short duration of one hour, it is suitable for pre-prandial administration, thereby advantageous for those whom is sor postpone the meal and similarly dose of repaglinide without increasing risk of serious hypoglycemia. The drug was approved by FDA in 1997 [8].

**Mechanism of action:** Repaglinide activity is dependent on the presence and it potentiates the effect of extracellular glucose on ATP- sensitive potassium channel and has little effect on insulin levels between meals and overnight. As such, repaglinide is more effective at reducing postprandial blood glucose levels than fasting blood glucose levels and requires a longer duration of therapy (approximately one month) before decreases in fasting blood glucose are observed. The insulin tropic effects of repaglinide are highest at intermediate glucose levels (3 to 10 mmol/L) and it does not increase insulin release already stimulated by high glucose concentrations (greater than 15 mmol/L). and does not appear to affect skeletal or cardiac muscle or thyroid tissue [9].

**Dosage and Administration:** Repaglinide do not have fixed dosage schedule to fight against

Type II diabetes. Periodical monitoring of blood glucose is necessary to know the minimum effective dose of drug. For observing the long term response of patient towards therapy value of glycosylated hemoglobin levels is important. Doses of repaglinide should be administered within 15 minutes of eating food whereas time period can change from immediately intake of food as long as about30 minutes before taking the food [10].

**Starting Dose:** The starting dose should be 0.5 mg for untreated patients and 1 or 2 mg for patients taking other hypoglycemic agents along with each meal respectively [11].

**Dose Adjustment:** By observing level of fasting blood glucose level (70-130mg/Dl) adjustments in dosing is done. For patients with satisfactory fasting glucose level (70-130 mg/dL) but inadequate overall glycemic control (HbA1c) postprandial glucose level is tested. The pre-prandial dose of drug should be doubled up to 4 mg with every intake of food until satisfactory level of blood glucose is achieved. The recommended dose range is 0.5- 4mg with meals. It canbe dosed pre-prandial upto 4 times a day in accordance with varying pattern of meal taken by the patient. The maximum dose of 16 mg is recommended per day [12].

**Combination Therapy:** If monotherapy of repaglinide results in inadequate glycemic control, thiazolidinedione or metformin can be added. The combination therapy dose is similar as that for monotherapy. To calculate the minimum dose required to achieve the desired pharmacological response dose of each drug must be adjusted carefully otherwise incidence of hypoglycemic episodes may increase [13].

**Available dosage forms:** Tablets are available as unscored, biconvex tablets with 0.5, 1 and 2 mg strengths having white, yellow and peach color respectively to indicate strengths. Symbol of Novo Nordisk (Apis) is embossed on every tablet [14].

## 2. EXPERIMENTAL WORK

### Preformulation studies

Preformulation studies are an important tool for determining the physical and chemical properties of the drug before incorporating it into the formulation development programme. The nature of the drug highly affects the processing parameters like method of preparation, loading efficiency, compatibility and pharmacokinetic response of the formulation. Preformulation studies are indispensable protocols for the development of safe, effective and stable dosage forms as well. Thus, in order to ensure optimum conditions for a clinically beneficial delivery system, the following preformulation studies were carried out [15,16].

**Formulation development**

**Preparation of a floating microsphere of Repaglinide**

Floating microspheres loaded with Repaglinide were prepared using the solvent diffusion-evaporation method using HPMC and EC in different ratios, like 1:0.5, 1:1.5, 1:2 w/w (Patel *et al.,* 2006). Drug and polymer in proportion of drug and polymers were dissolved in a 1:2 mixture of the solvent system of ethanol and dichloromethane. This clear solution was poured slowly in a thin stream into the aqueous solution of 1% polyvinyl alcohol. The emulsion was continuously stirred for 3 h at a speed of 500 rpm at 27±2°C. The floating microspheres were collected by decantation, while the non-floating microspheres were discarded. The microspheres were dried overnight at 40±2°C and stored in a desiccator. And then microspheres were evaluated, and stability was determined [17,18].

**Table 1: Formulations of the floating microspheres prepared.**

| Sr. No | Formulation Code | Repaglinide (mg) | HPMC (mg) | EC (mg) |
|---|---|---|---|---|
| 1. | F1 | 100 | 100 | 50 |
| 2. | F2 | 100 | 100 | 150 |
| 3. | F3 | 100 | 100 | 200 |
| 4. | F4 | 100 | 100 | 100 |
| 5. | F5 | 100 | 150 | 100 |
| 6. | F6 | 100 | 200 | 100 |

## 3. RESULT AND DISCUSSION

**Results of the preformulation study of Repaglinide**

**Organoleptic evaluation**

**Table 2: Organoleptic properties of Repaglinide.**

| | |
|---|---|
| **Color** | Light Yellow crystalline powder |
| **Odor** | Odorless |
| **Taste:** | Bitter |

**Solubility**

Solubility studies of Repaglinide have been done in various solvent such as water, 0.1N NaOH, Ethanol, Methanol, and 0.1N HCl solution.

**Table 3: Solubility studies of Repaglinide in different solvents.**

| S. No. | Solvent used | Solubility |
|---|---|---|
| 1. | Water | Soluble |
| 2. | 0.1 N HCl | Soluble |

| | | |
|---|---|---|
| 3. | Ethanol | Freely Soluble |
| 4. | Methanol | Freely Soluble |
| 5. | 0.1N NaOH | Soluble |
| 6. | Chloroform | Freely Soluble |

**Table 4: IP Index.**

| Descriptive term | Parts of solvent required for Parts of solute |
|---|---|
| Very soluble | Less than 1 |
| Freely soluble | From 1to 10 |
| Soluble | From 10 to 30 |
| Sparingly soluble | From 30to 100 |
| slightly soluble | From 100 to1000 |
| Very slightly soluble | From 1000 to 10000 |
| Practically insoluble | 10000 or more |

**Identification test by FTIR**

Identification of Repaglinide by FTIR Spectroscopy with respect to marker compound.

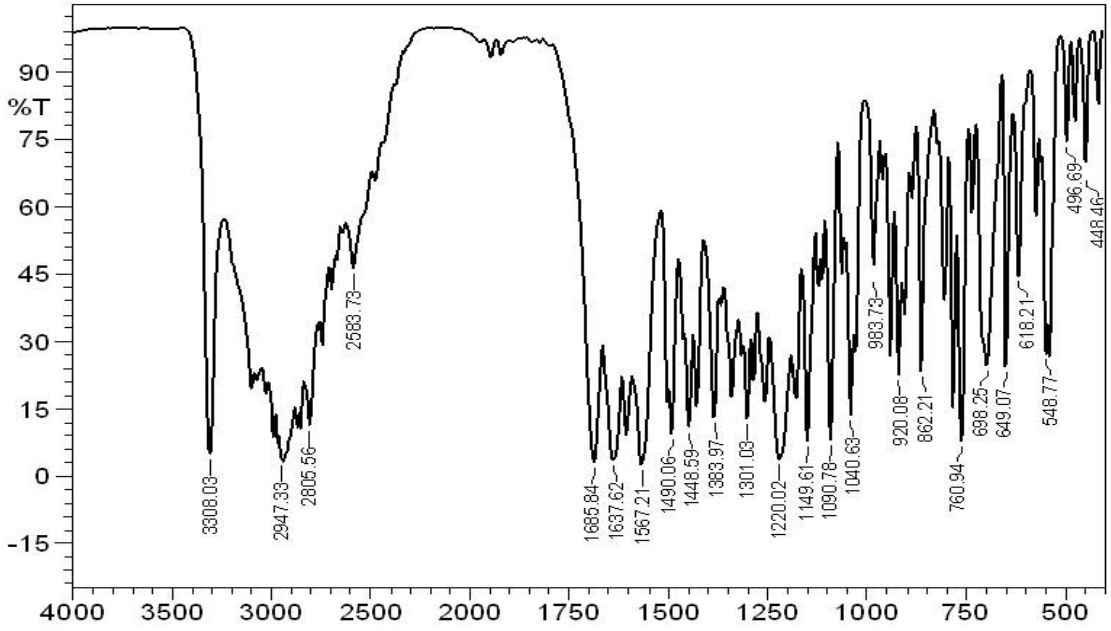



**Figure 1: FT-IR Spectrum of Pure Drug. (Repaglinide)**

**Loss on Drying (LOD)**

**Procedure**: Loss on drying directly measuring by IR moisture balance. Firstly calibrate the instrument by knob then take 1 gm sample (powder) and set the temp at 100°C to 105°C for 5 minutes and constant reading set the knob and check % moisture.

**Result:** The percentage of loss on drying of Repaglinide was found 0.151 %w/w.

**Melting Point determination**

Melting point determination of the obtained drug sample was done because it is a good first indication of purity of the sample since the presence of relatively small amount of impurity can be detected by a lowering as well as widening in the meltingpoint range.

**Result:** The melting point of Repaglinide range found to be 132-135ºC.

Flow property of Repaglinide powder

**Bulk density**

A known quantity of powder was poured into the measuring cylinder carefully level the powder without compacting, if necessary and read the unsettled apparent volume, $V_o$, to the nearest graduated unit. Calculate the bulk density, in gm/ml or gm/cc, by the formula.

| Bulk density = Bulk Mass/ Bulk Volume |
|---|

**Table 5: Bulk density of Repaglinide.**

| S. No. | Bulk mass | Bulk volume | Bulk density | Avg. bulk density |
|---|---|---|---|---|
| 1. | 10 gm | 22 ml | 0.454 g/ml | 0.454 g/ml |
| 2. | 10 gm | 22 ml | 0.454 g/ml | |
| 3. | 10 gm | 25 ml | 0.400 g/ml | |

(Mean of 3 replicate)

**Results:** Bulk density of powder was found 0.454 g/ml.

**Tapped density**

Tapped density is determined by measuring the volume of a known mass of powder sample before and after the tapping that has been passed through a screen into a graduated cylinder or through a volumetric measuring apparatus into a cup. Accurately weighed 10gm of powder was poured into the measuring cylinder carefully level the powder and read the tapped volume (after 50-60 times tapping), $V_t$ to the nearest graduated unit. Calculate the tapped density in gm per ml, gm/ $cm^3$by the formula:

| Tapped density = Bulk Mass/ Tapped Volume |
|---|

**Table 6: Tapped density of Repaglinide.**

| S. No. | Bulk mass | Tapped volume | Tapped density | Avg. tapped density |
|---|---|---|---|---|
| 1. | 10 gm | 19 ml | 0.526 g/ ml | 0.526 g/ ml |
| 2. | 10 gm | 18 ml | 0.555 g/ ml | |
| 3. | 10 gm | 19 ml | 0.526 g/ ml | |

(Mean of 3 replicate)

**Results:** Tapped density of Repaglinide was found to be 0.526 g/ ml.

**Compressibility Index (%)**

**Table 7: C.I. of Repaglinide.**

| S. No. | Bulk density | Tapped density | C.I. |
|---|---|---|---|
| 1. | 0.454 g/ml | 0.526 g/ml | 13.68 |

**Result:** The compressibility index of Repaglinide was found 13.68%.

**Hausner ratio**

| Hausner Ratio = Tapped density / Bulk Density |
|---|

**Table 8: Hausner of Repaglinide.**

| S. No. | Bulk density | Tapped density | Hausner ratio |
|---|---|---|---|
| **1.** | 0.454 g/ml | 0.526 g/ml | 1.15 |

**Result:** The Hausner ratio of Repaglinide was found 1.15.

**Angle of Repose**

| Tan θ = h/r |
|---|

**Result:** The Angle of repose of Repaglinide is 40.07 degree.

**Moisture by Karl-Fischer Apparatus (KF)**

**Result:** The Moisture content of Repaglinide is 0.3281%

**Determination of $\lambda_{max}$ by UV-Visible Spectroscopy Procedure:**

**Result:** The $\lambda_{max}$ found for Repaglinide is 244.0 nm as shown in Figure 7.3.

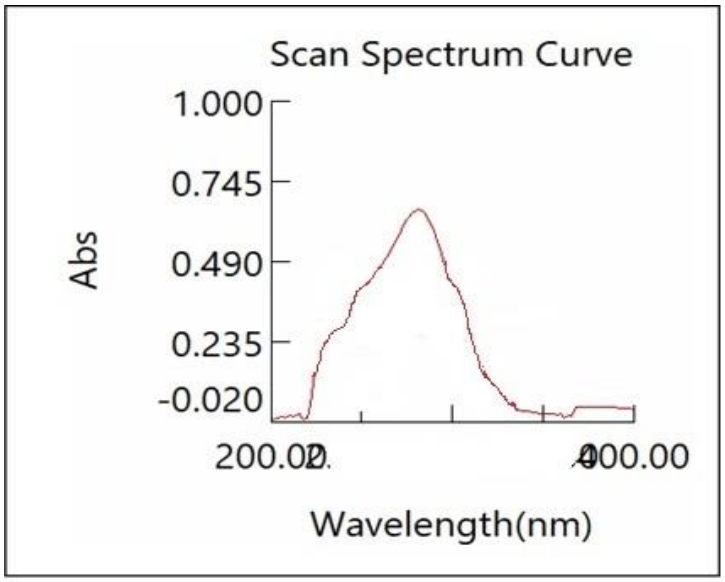



**Figure 2: Determination of $\lambda_{max}$ of Repaglinide.**

**Calibration curve of Repaglinide**

**Table 9: Calibration curve of Repaglinide.**

| S. No. | Concentration (µg/ml) | Absorbance |
|---|---|---|
| 1 | 10 | 0.110 |
| 2 | 20 | 0.202 |
| 3 | 30 | 0.282 |
| 4 | 40 | 0.394 |
| 5 | 50 | 0.473 |

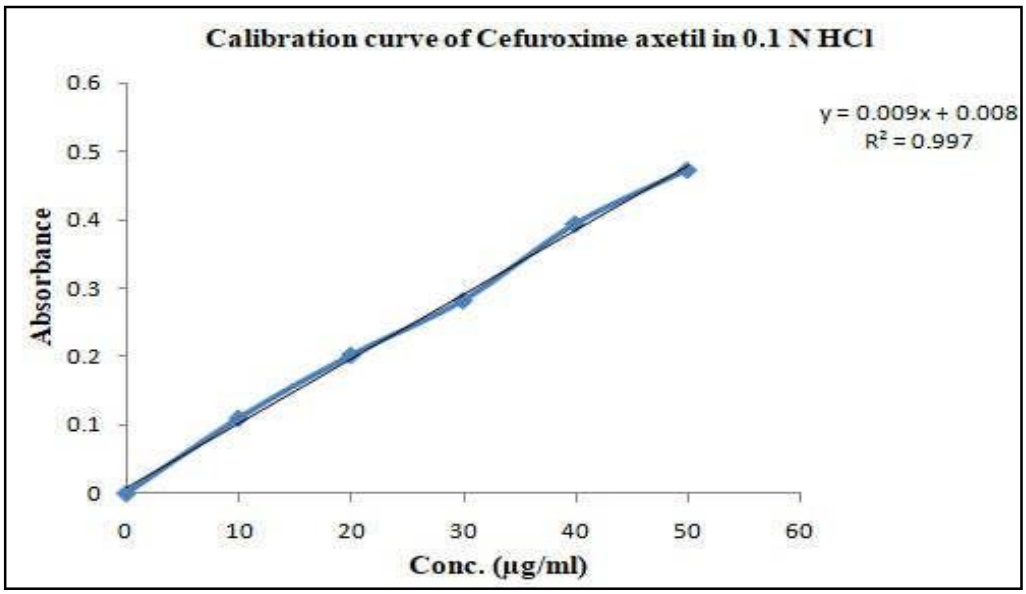



**Figure 3: Calibration Curve of Repaglinide at 244 nm.**

Statistical Data for Linearity

**Table 10: Statistical Data for Linearity.**

| S. No. | Parameter | Remark |
|---|---|---|
| **1** | Linearity Range | 10-50 µg/ml |
| **2** | Regression Equation | Y = 0.009x + 0.008 |
| **3** | Correlation Coefficient | 0.997 |

**Evaluation of Repaglinide floating microspheres**

**Percentage Yield**

The percentage yield of different formulations was determined by weighing the Microspheres after drying. The percentage yield of different formulations was in the range of 62.23±0.85–73.32±0.65%. The maximum Percentage Yield was found in formulation F3, 73.32±0.65 as compare to all formulations.

**Table 11: Percentage Yield for Different Formulations.**

| Formulation | Percentage Yield |
|---|---|
| F1 | 69.98±0.98 |
| F2 | 70.12±0.95 |
| F3 | 73.32±0.65 |
| F4 | 65.56±0.58 |
| F5 | 62.23±0.85 |
| F6 | 66.56±0.32 |

(Mean of 3 replicate, Mean±SD)

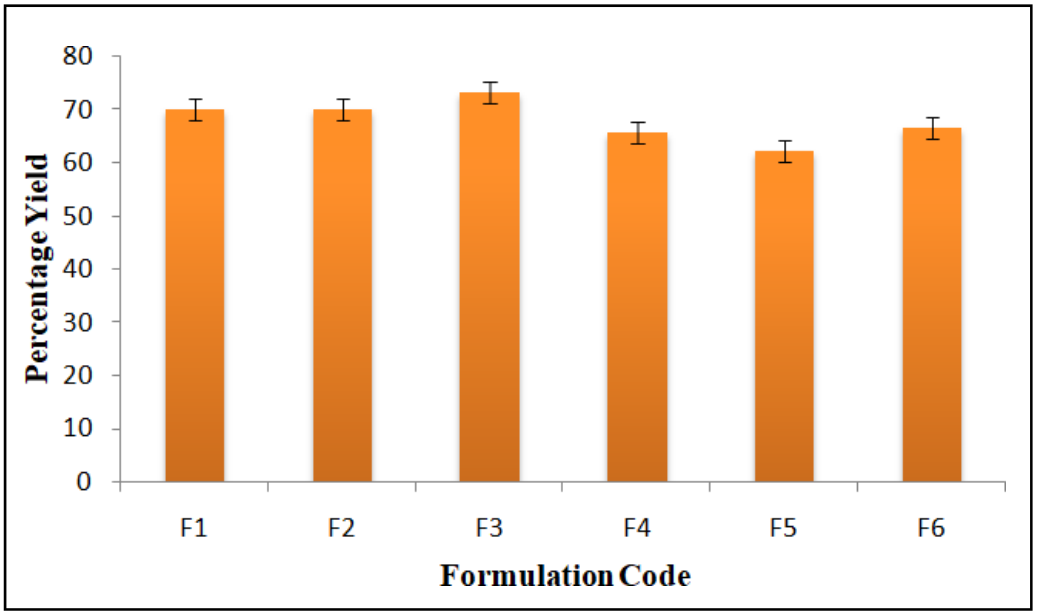



**Figure 4: Percentage Yield for Different Formulations.**

## Drug Entrapment

The drug entrapment efficacies of different formulations were in the range of 63.23±0.65- 76.56±0.65% w/w.

**Table 12: Drug Entrapment for Different Formulations.**

| Formulation | Drug entrapment (% w/w) of prepared microsphere* |
|---|---|
| F1 | 65.56±0.95 |
| F2 | 69.98±0.65 |
| F3 | 75.56±0.23 |
| F4 | 62.23±0.54 |
| F5 | 59.98±0.52 |
| F6 | 63.32±0.45 |

* (Mean of 3 replicate, Mean±SD)

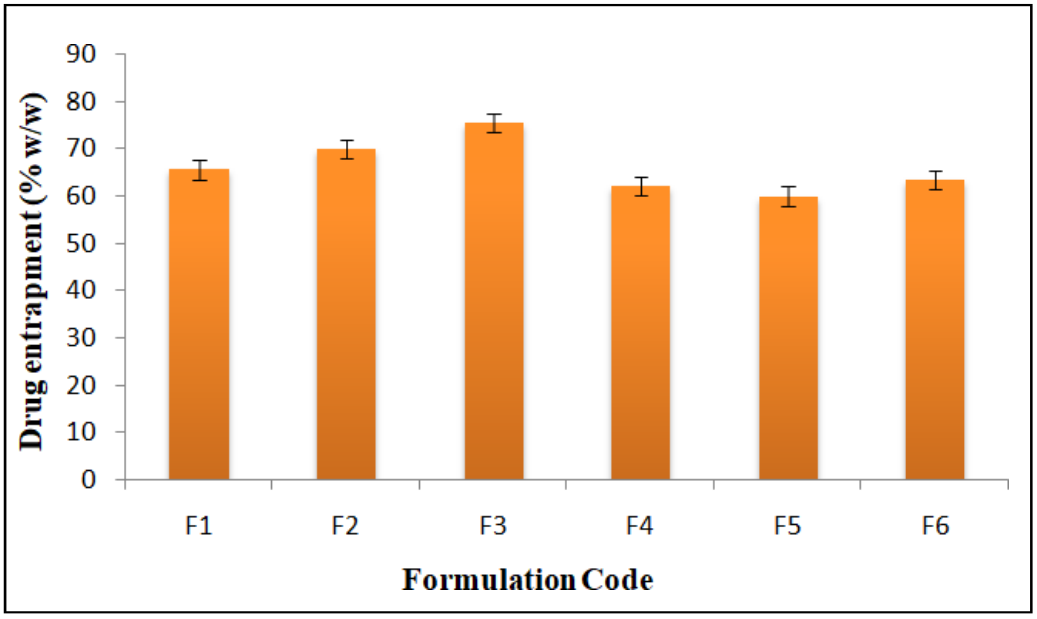



**Figure 5: Drug Entrapment for different formulations.**

**Percentage Buoyancy and the floating lag time of the floating microsphere**

**Table 13: Percentage Buoyancy and floating lag time of floating microsphere.**

| Formulation | Floating Lag Time (Sec.) * | Percentage Buoyancy* |
|---|---|---|
| F1 | 45±3 | 55.65±0.65 |
| F2 | 49±2 | 66.65±0.69 |
| F3 | 32±4 | 76.65±0.52 |
| F4 | 45±3 | 56.65±0.47 |
| F5 | 43±2 | 65.56±0.32 |
| F6 | 48±3 | 73.21±0.45 |

* (Mean of 3 replicates, Mean±SD)

The maximum percentage yield, drug entrapment, percentage buoyancy and floating lag time were found to be formulation F3 in the floating microsphere. The optimized formulation of both batches was subjected to further studies.

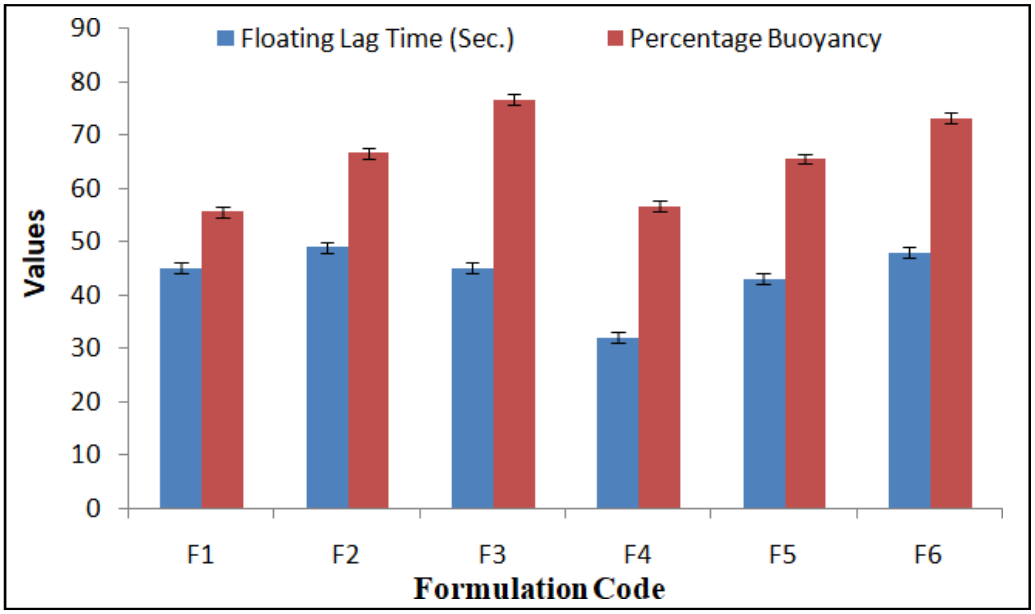



**Figure 6: Percentage Buoyancy and floating lag time.**

## Particle size analysis

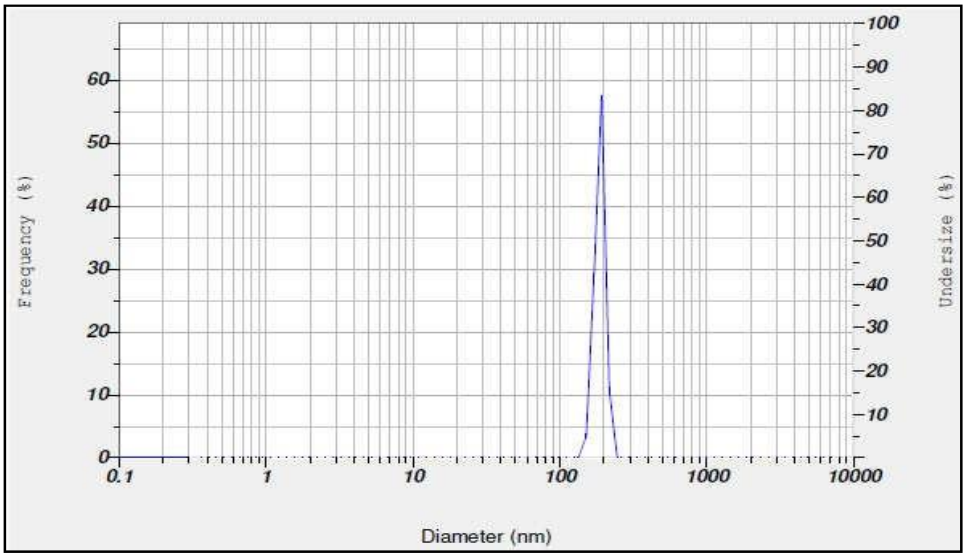



**Figure 7: Particle size data of optimized microsphere formulation F3.**

## Zeta Potential

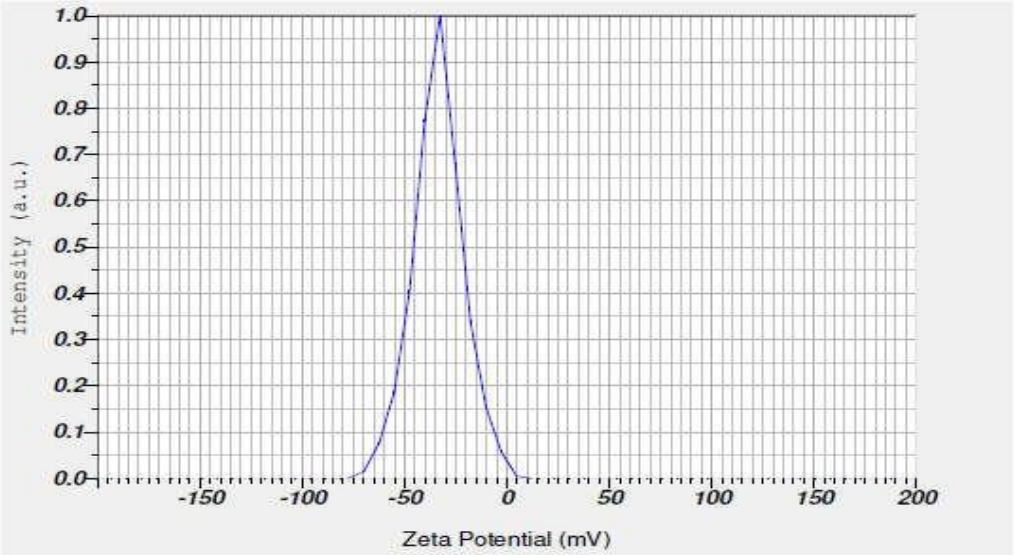



**Figure 8: Zeta potential data of floating microsphere F3.**

***In-vitro* comparative release study of all formulation F1-F6**

**Table 14: Release Study data of formulation F1-F6.**

| Time | Percentage Drug Release | | | | | |
|---|---|---|---|---|---|---|
| (hr) | F1 | F2 | F3 | F4 | F5 | F6 |
| 0.5 | 33.25 | 30.25 | 29.98 | 25.56 | 20.23 | 15.56 |
| 1 | 46.65 | 41.25 | 39.98 | 30.56 | 26.65 | 23.32 |
| 2 | 59.98 | 52.36 | 46.65 | 42.23 | 31.25 | 33.32 |
| 4 | 73.23 | 69.98 | 63.32 | 60.32 | 46.65 | 45.56 |
| 6 | 89.98 | 85.56 | 80.56 | 75.56 | 53.32 | 51.48 |
| 8 | 99.23 | 90.23 | 92.23 | 82.56 | 63.32 | 56.65 |
| 10 | - | 99.89 | 99.23 | 89.98 | 72.23 | 65.56 |
| 12 | - | - | - | 98.85 | 85.56 | 73.32 |

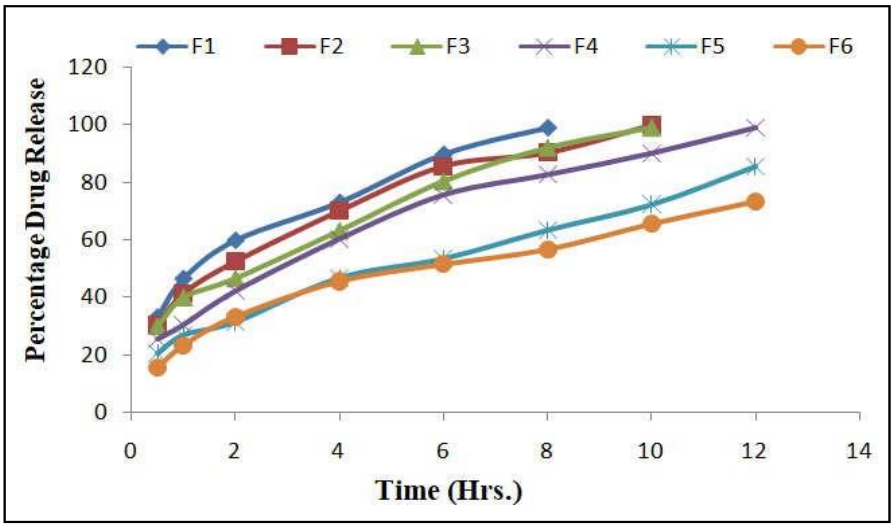



**Figure 9: Graph of release study of formulation F1-F6.**

**Table 15: Release Kinetics of optimized formulation of microsphere F3.**

| Time(h) | Square Root of Time(h)$^{1/2}$ | Log Time | Cumulative % Drug Release | Log Cumulative % Drug Released | Cumulative % Drug Remaining | Log Cumulative % Drug Remaining |
|---|---|---|---|---|---|---|
| **0.5** | 0.707 | -0.301 | 25.56 | 1.408 | 74.44 | 1.872 |
| **1** | 1 | 0 | 30.56 | 1.485 | 69.44 | 1.842 |
| **2** | 1.414 | 0.301 | 42.23 | 1.626 | 57.77 | 1.762 |
| **4** | 2 | 0.602 | 60.32 | 1.780 | 39.68 | 1.599 |
| **6** | 2.449 | 0.778 | 75.56 | 1.878 | 24.44 | 1.388 |
| **8** | 2.828 | 0.903 | 82.56 | 1.917 | 17.44 | 1.242 |
| **10** | 3.162 | 1 | 89.98 | 1.954 | 10.02 | 1.001 |
| **12** | 3.464 | 1.079 | 98.85 | 1.995 | 1.15 | 0.061 |

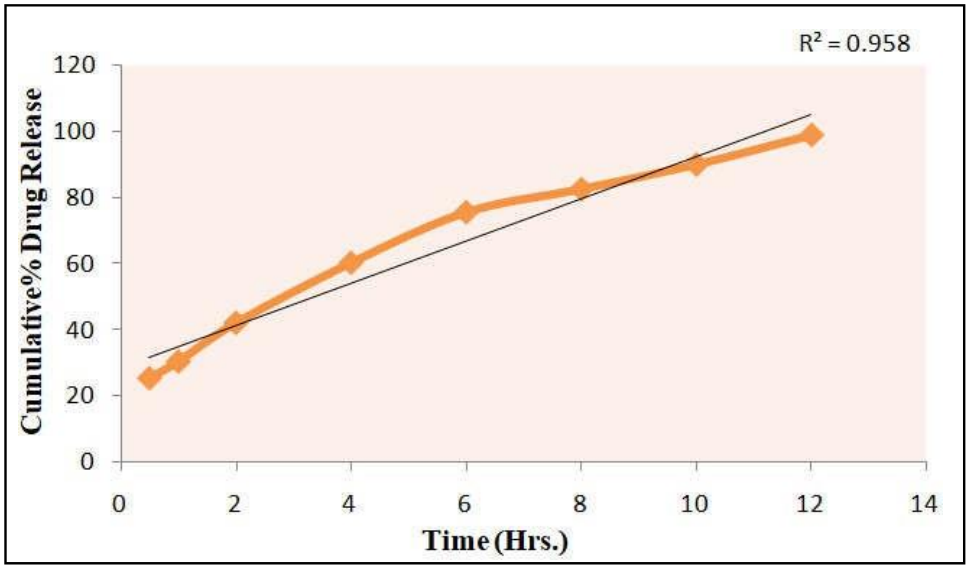



**Figure 10: Zero order release kinetics graph of optimized formulations.**

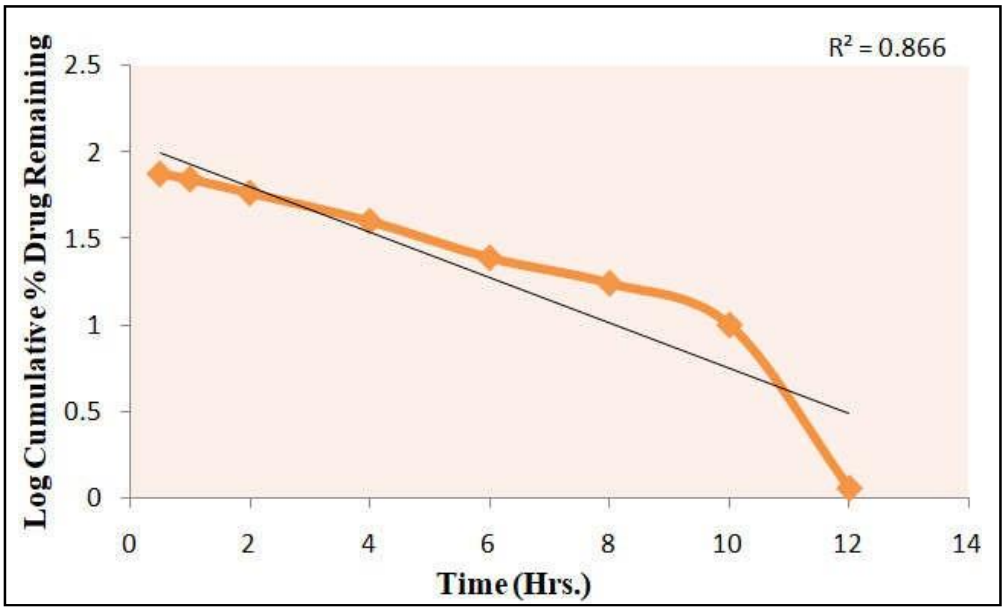



**Figure 11: First order release kinetics graph of optimized formulations.**

**Table 16: Comparative study of regression coefficient for selection of optimized Formulation F3.**

| Release Kinetics | Zero order | First order |
|---|---|---|
| $R^2$ | 0.958 | 0.866 |

## 4. CONCLUSION

The present investigation successfully developed gastroretentive floating microspheres of Repaglinide using HPMC and ethyl cellulose through the solvent diffusion-evaporation technique. Preformulation studies confirmed the identity, purity, and suitability of the drug for formulation development. Among the developed formulations, F3 demonstrated the most desirable characteristics, including high percentage yield, excellent drug entrapment efficiency, superior buoyancy, a short floating lag time, and sustained drug release. The optimized formulation exhibited zero-order release kinetics, indicating controlled and prolonged drug release. These findings suggest that floating microspheres can effectively increase gastric residence time, thereby enhancing the absorption and oral bioavailability of Repaglinide while reducing dosing frequency. Overall, the developed gastroretentive floating microsphere system represents a promising strategy for improving the therapeutic performance of Repaglinide in the management of type II diabetes mellitus. Further in vivo pharmacokinetic and pharmacodynamic studies are recommended to establish its clinical efficacy and therapeutic potential.

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