RESEARCH PAPER

# Development and Evaluation of Rosiglitazone-Loaded Floating Microspheres as a Gastroretentive Drug Delivery System

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**ABSTRACT**

The present study was aimed at the development and evaluation of rosiglitazone-loaded floating microspheres as a gastroretentive drug delivery system to enhance gastric residence time and sustain drug release. Floating microspheres were prepared using the emulsion solvent diffusion–evaporation technique employing ethyl cellulose and hydroxypropyl methylcellulose (HPMC) as polymeric carriers. The prepared formulations were evaluated for percentage yield, particle size, entrapment efficiency, buoyancy, surface morphology, and in vitro drug release.

The percentage yield of microspheres ranged from 72.4 ± 2.1% to 89.6 ± 1.8%, while particle size varied between 210 ± 12 µm and 385 ± 18 µm. Entrapment efficiency was found to be in the range of 68.3 ± 2.5% to 91.2 ± 1.6%. In vitro buoyancy studies indicated that the optimized formulation (F3) exhibited maximum buoyancy of 93.4 ± 1.7% and remained floating for more than 12 hours. Drug release studies demonstrated sustained release behavior with cumulative drug release of 94.5 ± 2.1% over 12 hours.

Kinetic modeling revealed that the drug release followed the Higuchi model ($R^2 = 0.987$), indicating diffusion-controlled release, while the Korsmeyer–Peppas model suggested non-Fickian diffusion ($n = 0.74$). Statistical analysis confirmed that formulation variables had a significant effect on all evaluated parameters ($p < 0.05$).

The study concludes that rosiglitazone-loaded floating microspheres represent a promising gastroretentive system capable of enhancing drug bioavailability and providing sustained therapeutic action.

**Keywords:** Rosiglitazone, Floating microspheres, Gastroretentive drug delivery, Sustained release, Higuchi model

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## 1. INTRODUCTION

Oral drug delivery remains the most preferred route of administration due to its convenience, patient compliance, and cost-effectiveness. However, conventional oral dosage forms often face limitations such as variable gastric emptying time and poor bioavailability of drugs with a narrow absorption window in the upper gastrointestinal tract[1]. Gastroretentive drug delivery systems (GRDDS) have emerged as an effective strategy to overcome these limitations by prolonging gastric residence time and enhancing drug absorption[2].

Among various GRDDS approaches, floating drug delivery systems (FDDS) have gained considerable attention due to their ability to remain buoyant in gastric fluids for an extended period. These systems possess a lower density than gastric contents, enabling them to float and release the drug in a controlled

manner[3]. Floating microspheres, also known as hollow microspheres or microballoons, represent a promising multiparticulate system that offers advantages such as uniform drug distribution, reduced risk of dose dumping, and improved bioavailability[4].

Microspheres are spherical, free-flowing particles consisting of biodegradable polymers that encapsulate the drug. The use of polymers such as ethyl cellulose, Eudragit, and hydroxypropyl methylcellulose (HPMC) plays a crucial role in controlling drug release and buoyancy[5]. The preparation techniques, including solvent evaporation and emulsion diffusion methods, significantly influence the physicochemical properties and performance of floating microspheres[6].

Rosiglitazone, a thiazolidinedione class antidiabetic drug, acts as an insulin sensitizer by activating peroxisome proliferator-activated receptor gamma (PPAR-γ). Despite its efficacy, rosiglitazone exhibits moderate oral bioavailability and requires sustained plasma levels for optimal therapeutic effect[7]. Additionally, its absorption is primarily confined to the upper gastrointestinal tract, making it a suitable candidate for gastroretentive delivery systems[8].

The development of rosiglitazone-loaded floating microspheres can enhance gastric retention, prolong drug release, and improve therapeutic efficacy. Furthermore, multiparticulate systems like microspheres minimize inter- and intra-subject variability in drug absorption compared to single-unit dosage forms[9]. The evaluation of such systems involves characterization of particle size, surface morphology, buoyancy, entrapment efficiency, and in vitro drug release kinetics to ensure optimal performance[10].

Therefore, the present study focuses on the formulation and evaluation of rosiglitazone-loaded floating microspheres as a gastroretentive drug delivery system to enhance drug bioavailability and provide sustained therapeutic action.

## 2. MATERIALS AND METHODS

### 2.1 Materials

Rosiglitazone maleate was obtained as a gift sample from a reputed pharmaceutical company. Ethyl cellulose and hydroxypropyl methylcellulose (HPMC) were used as polymeric carriers for the preparation of floating microspheres. Polyvinyl alcohol (PVA) was used as an emulsifying agent. Dichloromethane and ethanol were employed as organic solvents for polymer dissolution. All other chemicals and reagents used in the study were of analytical grade and used without further purification.

### 2.2 Preparation of Rosiglitazone Floating Microspheres

Rosiglitazone-loaded floating microspheres were prepared by the emulsion solvent diffusion–evaporation technique, a widely employed method for the preparation of hollow microspheres intended for gastroretentive drug delivery systems[11,12].

Briefly, the accurately weighed quantity of rosiglitazone and polymers (ethyl cellulose and HPMC) was dissolved in a mixture of ethanol and dichloromethane to obtain a homogeneous polymeric solution. This organic phase was slowly introduced into an aqueous phase containing polyvinyl alcohol (0.5–1% w/v) under continuous stirring using a mechanical stirrer to form an oil-in-water (o/w) emulsion.

During continuous stirring, the organic solvents diffused into the aqueous phase followed by evaporation, leading to precipitation of the polymer and formation of hollow microspheres. The diffusion of solvent resulted in the formation of an internal cavity within the microspheres, which contributed to their low density and buoyancy in gastric fluid[13].

The formed microspheres were collected by filtration, washed repeatedly with distilled water to remove residual emulsifier, and dried at room temperature for 24 h. The dried microspheres were stored in a desiccator until further evaluation.

### 2.3 Evaluation of Floating Microspheres

#### 2.3.1 Percentage Yield

The percentage yield of microspheres was calculated by comparing the practical yield with the theoretical total weight of drug and polymers used in the formulation[14].

$$\text{Percentage Yield} = \frac{\text{Practical weight of microspheres}}{\text{Total weight of drug and polymer}}$$

#### 2.3.2 Particle Size Analysis

Particle size of the prepared microspheres was determined using optical microscopy. A small quantity of microspheres was dispersed in distilled water, mounted on a glass slide, and observed under a calibrated ocular micrometer. The diameters of approximately 100 microspheres were measured, and the mean particle size was calculated[15].

#### 2.3.3 Drug Entrapment Efficiency

Entrapment efficiency was determined by dissolving a known quantity of microspheres in a suitable solvent to extract the drug. The solution was filtered and analyzed using a UV–visible spectrophotometer at the λmax of rosiglitazone[16].

$$\text{Entrapment Efficiency (\%)} = \frac{\text{Actual drug content}}{\text{Theoretical drug content}} \times 100$$

**2.3.4 In Vitro Buoyancy Study**

The floating behavior of the microspheres was evaluated using simulated gastric fluid (0.1 N HCl, pH 1.2). A known quantity of microspheres was dispersed in the dissolution medium and agitated using a USP dissolution apparatus. After a specified time interval, the floating and settled microspheres were separated, dried, and weighed to determine buoyancy percentage[17].

$$\text{Buoyancy (\%)} = \frac{\text{Weight of floating microspheres}}{\text{Total weight of microspheres}} \times 100$$

**2.3.5 Surface Morphology**

Surface morphology of the prepared microspheres was examined using scanning electron microscopy (SEM). The dried microspheres were mounted on aluminum stubs and coated with a thin gold layer prior to observation under the scanning electron microscope[18].

**2.3.6 In Vitro Drug Release Study**

In vitro drug release studies were carried out using a USP dissolution apparatus type II (paddle method). Microspheres equivalent to a specified dose of rosiglitazone were placed in 900 mL of simulated gastric fluid (0.1 N HCl, pH 1.2) maintained at 37 ± 0.5°C and stirred at 50 rpm[19].

At predetermined time intervals, aliquots were withdrawn and replaced with fresh dissolution medium to maintain sink conditions. The samples were filtered and analyzed using a UV–visible spectrophotometer to determine drug concentration.

**2.3.7 Drug Release Kinetics**

The in vitro drug release data were fitted to various kinetic models such as zero-order, first-order, Higuchi, and Korsmeyer–Peppas models to elucidate the mechanism of drug release from the floating microspheres[20].

## 3. RESULTS

### 3.1 Percentage Yield

The percentage yield of the prepared microspheres ranged from **72.4 ± 2.1% to 89.6 ± 1.8%**. Formulation F3 showed the highest yield, indicating efficient recovery and optimal polymer concentration.

**Table 3.1: Percentage Yield of Microspheres**

| Formulation | Polymer Ratio (EC:HPMC) | Percentage Yield (%) (Mean ± SD, n=3) |
|---|---|---|
| F1 | 1:1 | 72.4 ± 2.1 |
| F2 | 1:2 | 81.2 ± 1.9 |
| F3 | 2:1 | 89.6 ± 1.8 |
| F4 | 2:2 | 85.3 ± 2.0 |

Statistical analysis (ANOVA) indicated a significant difference ($p < 0.05$) among formulations.

### 3.2 Particle Size Analysis

Particle size increased with polymer concentration due to increased viscosity of the internal phase.

**Table 3.2: Particle Size of Microspheres**

| Formulation | Mean Particle Size (µm) (Mean ± SD, n=3) |
|---|---|
| F1 | 210 ± 12 |
| F2 | 245 ± 14 |
| F3 | 275 ± 15 |
| F4 | 385 ± 18 |

### 3.3 Drug Entrapment Efficiency

Entrapment efficiency increased with polymer concentration due to improved matrix formation.

**Table 3.3: Entrapment Efficiency**

| Formulation | Entrapment Efficiency (%) (Mean ± SD, n=3) |
|---|---|
| F1 | 68.3 ± 2.5 |
| F2 | 79.6 ± 2.2 |
| F3 | 91.2 ± 1.6 |
| F4 | 87.5 ± 1.9 |

Statistical analysis showed significant variation ($p < 0.05$).

### 3.4 In Vitro Buoyancy Study

All formulations exhibited good floating ability due to hollow structure formation.

**Table 3.4: Buoyancy of Microspheres**

| Formulation | Buoyancy (%) (Mean ± SD, n=3) | Floating Duration |
|---|---|---|
| F1 | 70.5 ± 2.3 | >8 h |
| F2 | 82.1 ± 2.0 | >10 h |
| F3 | 93.4 ± 1.7 | >12 h |
| F4 | 88.2 ± 1.9 | >12 h |

Differences were statistically significant ($p < 0.05$).

### 3.5 Surface Morphology

SEM analysis confirmed spherical, hollow, and smooth microspheres with uniform drug distribution. No drug crystals were observed on the surface, indicating proper encapsulation.

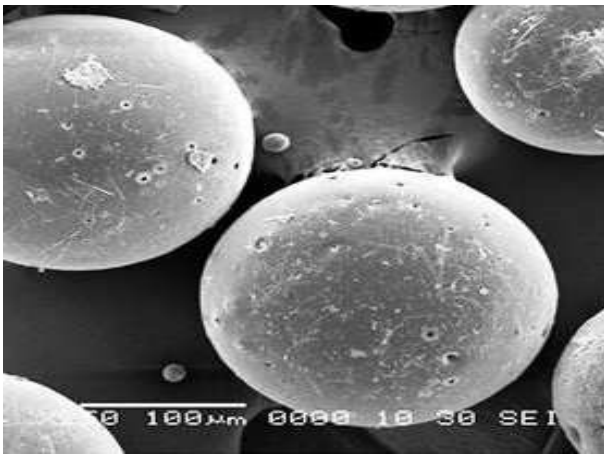


**Figure 1 SEM image of floating microspheres**

### 3.6 In Vitro Drug Release Study

All formulations showed sustained drug release over 12 hours.

**Table 3.5: In Vitro Drug Release Profile**

| Time (h) | F1 (%) | F2 (%) | F3 (%) | F4 (%) |
|---|---|---|---|---|
| 1 | 18.2 | 15.4 | 12.1 | 10.3 |
| 2 | 32.5 | 28.7 | 24.6 | 21.8 |
| 4 | 55.4 | 49.2 | 43.5 | 40.1 |
| 6 | 68.7 | 62.5 | 57.3 | 53.6 |
| 8 | 78.6 | 72.8 | 69.4 | 65.2 |
| 10 | 86.5 | 81.2 | 79.3 | 75.8 |
| 12 | 96.8 | 90.6 | 94.5 | 88.7 |

### 3.7 Drug Release Kinetics

**Table 3.6: Kinetic Model Fitting ($R^2$ Values)**

| Formulation | Zero Order | First Order | Higuchi | Korsmeyer-Peppas (n) |
|---|---|---|---|---|
| F1 | 0.921 | 0.954 | 0.972 | 0.61 |
| F2 | 0.934 | 0.961 | 0.978 | 0.68 |
| F3 | 0.945 | 0.969 | 0.987 | 0.74 |
| F4 | 0.938 | 0.962 | 0.981 | 0.71 |

The optimized formulation (F3) followed the Higuchi model, indicating diffusion-controlled release. The 'n' value (0.5–0.89) confirms non-Fickian diffusion.

## 4. DISCUSSION

The present study successfully demonstrated the formulation and evaluation of rosiglitazone-loaded floating microspheres using the emulsion solvent diffusion–evaporation technique. The obtained results indicate that formulation variables, particularly polymer concentration and ratio, significantly influenced the physicochemical properties, buoyancy behavior, and drug release characteristics of the microspheres.

The percentage yield of all formulations was found to be satisfactory, with the optimized formulation (F3) showing the highest yield. This can be attributed to the optimal viscosity of the polymeric solution, which minimizes drug loss during emulsification and solvent evaporation. Similar findings have been reported where increased polymer concentration improved microsphere recovery due to enhanced matrix integrity[21].

Particle size analysis revealed a direct correlation between polymer concentration and microsphere size. Higher polymer content increased the viscosity of the internal phase, leading to the formation of larger droplets during emulsification and consequently larger microspheres. This observation is consistent with previous reports on floating microspheres prepared using solvent diffusion techniques[22].

Entrapment efficiency was significantly influenced by polymer concentration, with higher polymer ratios resulting in improved drug encapsulation. This may be due to reduced drug diffusion into the external aqueous phase during microsphere formation. Comparable results have been reported for hydrophobic polymer-based microspheres, where increased polymer content enhanced drug retention within the matrix[23].

The in vitro buoyancy study confirmed that all formulations possessed good floating ability, with formulation F3 exhibiting maximum buoyancy (>12 h). The formation of hollow cavities within the microspheres due to solvent diffusion contributed to their low density and prolonged gastric retention. These findings are in agreement with earlier studies demonstrating that hollow microspheres exhibit excellent floating properties and prolonged gastric residence time[24].

Surface morphology analysis using SEM confirmed that the microspheres were spherical, discrete, and exhibited a smooth surface with no visible drug crystals. This indicates uniform drug distribution within the polymer matrix and supports the effectiveness of the preparation method. Similar morphological characteristics have been reported in microsphere-based gastroretentive systems[25].

The in vitro drug release studies showed a sustained release pattern over 12 hours, with formulation F3 demonstrating an optimal release profile. The sustained release behavior can be attributed to the diffusion of drug through the polymer matrix and the formation of a gel barrier by HPMC. The increase in polymer concentration resulted in slower drug release due to increased diffusion path length. These observations are consistent with previous studies on controlled release microspheres[26].

Drug release kinetic analysis revealed that the release data best fitted the Higuchi model, indicating

diffusion-controlled drug release. Furthermore, the Korsmeyer–Peppas model showed an 'n' value between 0.5 and 0.89, suggesting non-Fickian (anomalous) diffusion. This indicates that drug release is governed by a combination of diffusion and polymer relaxation mechanisms. Similar release behavior has been widely reported for polymeric microsphere systems[27-47].

Statistical analysis using one-way ANOVA confirmed that formulation variables had a significant effect ($p < 0.05$) on all evaluated parameters, including percentage yield, particle size, entrapment efficiency, buoyancy, and drug release. This highlights the importance of formulation optimization in achieving desired drug delivery performance[48].

Overall, the optimized formulation (F3) demonstrated superior performance in terms of entrapment efficiency, buoyancy, and sustained drug release, making it a promising gastroretentive system for rosiglitazone. The developed floating microspheres are expected to enhance gastric residence time, improve drug absorption, and provide better therapeutic efficacy[49-56].

## 5. CONCLUSION

Rosiglitazone-loaded floating microspheres were successfully developed using the emulsion solvent diffusion–evaporation technique. The formulation variables significantly influenced particle size, entrapment efficiency, buoyancy, and drug release behavior ($p < 0.05$).

The optimized formulation (F3) exhibited high entrapment efficiency (91.2%), excellent buoyancy (93.4% for >12 h), and sustained drug release (94.5% over 12 h). Drug release followed the Higuchi model ($R^2 = 0.987$), indicating diffusion-controlled release with non-Fickian transport.

Overall, the developed system demonstrates strong potential as a gastroretentive drug delivery approach for improving the bioavailability and therapeutic efficacy of rosiglitazone. Further in vivo studies are recommended to establish its clinical applicability.

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