

Available online on 15.07.2025 at <http://jddtonline.info>

# Journal of Drug Delivery and Therapeutics

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Research Article

## Formulation and Evaluation of Gastroretentive Floating Tablets of Lovastatin Using Natural Polymers

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### Article Info:



### Article History:

Received 23 April 2025  
Reviewed 03 June 2025  
Accepted 29 June 2025  
Published 15 July 2025

### Cite this article as:

Kumar V, Sodavat RK, Rathore GS, Formulation and Evaluation of Gastroretentive Floating Tablets of Lovastatin Using Natural Polymers, Journal of Drug Delivery and Therapeutics. 2025; 15(7):71-79 DOI: <http://dx.doi.org/10.22270/jddt.v15i7.7280>

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### Abstract

**Background:** Lovastatin, a lipid-lowering agent, suffers from low bioavailability due to extensive first-pass metabolism and limited absorption in the gastrointestinal tract. A gastroretentive drug delivery system (GRDDS) offers a promising solution to enhance its therapeutic effectiveness.

**Objective:** The present study aims to formulate and optimize gastroretentive floating tablets of Lovastatin using various grades of hydroxypropyl methylcellulose (HPMC) and natural polymers to achieve sustained drug release.

**Methods:** Floating tablets were prepared by direct compression using HPMC K4M, HPMC K15M, and guar gum in varying ratios. The tablets were evaluated for pre-compression (bulk density, tapped density, Carr's index, Hausner ratio) and post-compression (thickness, hardness, friability, drug content, buoyancy) parameters. In vitro dissolution studies were conducted for 12 hours, and the data were fitted into kinetic models to determine the release mechanism.

**Results:** All formulations exhibited acceptable physicochemical characteristics. The optimized batch (F8) demonstrated more than 12 hours of buoyancy, high drug content (99.23%), and sustained release of 99.45% over 12 hours. Drug release followed first-order kinetics with Higuchi diffusion and non-Fickian transport mechanisms.

**Conclusion:** Floating tablets of Lovastatin prepared with HPMC K4M, K15M, and guar gum can effectively sustain drug release over 12 hours and improve gastric retention. This system holds potential for enhanced therapeutic efficiency in hyperlipidaemia treatment.

**Keywords:** Lovastatin, gastroretentive tablet, floating drug delivery, HPMC, sustained release, in vitro kinetics

## 1. INTRODUCTION

Oral drug delivery is the most common and convenient route for administering therapeutic agents, primarily due to its ease of use, cost-effectiveness, patient compliance, and flexibility in dosage form design. However, one of the significant challenges in oral drug administration is the limited gastric residence time of dosage forms. Drugs that are absorbed primarily in the upper part of the gastrointestinal tract (GIT), unstable in intestinal pH, or undergo extensive hepatic metabolism tend to have reduced bioavailability and therapeutic efficacy when administered through conventional dosage forms.

Lovastatin, a naturally occurring lipid-lowering agent belonging to the statin class, is widely used to manage hypercholesterolemia and prevent cardiovascular diseases. It acts by competitively inhibiting the enzyme HMG-CoA reductase, thereby decreasing cholesterol synthesis in the liver. Despite its clinical efficacy, Lovastatin exhibits poor oral bioavailability (<5%) due to its low aqueous solubility, poor permeability, and extensive first-pass metabolism. Moreover, Lovastatin is absorbed mainly in the upper GIT, making it a suitable

candidate for Gastroretentive drug delivery systems (GRDDS).

Gastroretentive systems are designed to retain the dosage form in the stomach for an extended period, thereby enhancing drug absorption, improving bioavailability, and reducing the need for frequent dosing. Among various GRDDS, floating drug delivery systems (FDDS) have gained significant attention. These systems are formulated to have a lower density than gastric fluids, allowing them to remain buoyant in the stomach for extended periods without affecting the gastric emptying rate. This buoyancy ensures better localization of drug release in the stomach, resulting in improved absorption and a more effective therapeutic effect.

To achieve sustained and controlled drug release, polymers play a pivotal role in modulating drug diffusion and erosion behavior. Hydroxypropyl methylcellulose (HPMC), a semisynthetic, inert, and hydrophilic polymer, is widely used in sustained-release formulations due to its swelling, gelling, and viscosity-enhancing properties. Various grades of HPMC such as K4M and K15M offer

different gel strengths and hydration rates. Additionally, natural polymers like guar gum can further enhance matrix integrity and modify drug release patterns through swelling and gel formation.

The rationale for developing a floating gastroretentive tablet of Lovastatin lies in enhancing its therapeutic effectiveness by:

- Increasing its residence time in the upper GIT
- Avoiding rapid clearance from the stomach
- Achieving sustained plasma concentration
- Reducing the frequency of administration and side effects

## 2. MATERIALS AND METHODS

**Table 1:** Materials used for the formulation of the Lovastatin tablet

| S.N. | Chemical/Excipient                                   | Source   |
|------|--|--|
| 1    | Lovastatin (API)                                     | Gift sample from Bio-plus Life Sciences, Bangalore |
| 2    | Hydroxypropyl methylcellulose (HPMC K15M & HPMC K4M) | Ozone International, Mumbai                        |
| 3    | Guar gum   | Analytical grade                                   |
| 4    | Lactose (filler)                                     | Loba Chemie Pvt. Ltd., Mumbai                      |
| 5    | Citric acid (gas-generating agent)                   | Qualigens Fine Chemicals, Mumbai                   |
| 6    | Sodium bicarbonate (gas-generating agent)            | Chempure Pvt. Ltd.                                 |
| 7    | Magnesium stearate (lubricant)                       | Jiangsu Huaxi International                        |
| 8    | Talc (glidant)                                       | Loba Chemie Pvt. Ltd., Mumbai                      |

### 2.1 Materials

The following materials were used in the formulation of Lovastatin floating tablets:

All materials used were of pharmaceutical grade and used without further purification.

### 2.2 Pre-formulation Studies

Preformulation studies are critical to understand the physical and chemical characteristics of

the drug and excipients, ensuring stability and compatibility prior to formulation development.

#### 2.2.1 Organoleptic Properties:

The physical appearance of Lovastatin was observed visually for color, texture, and odor.

#### 2.2.2 Melting Point Determination:

Melting point was determined using a digital melting point apparatus by the capillary tube method. The observed value was compared with standard reference.

#### 2.2.3 Solubility Studies:

Solubility was tested in various solvents including distilled water, ethanol, methanol, 0.1N HCl, and phosphate buffer (pH 6.8). Approximately 1–2 mg of drug was added to 5 mL of solvent in a test tube, shaken, and observed for solubility.

#### 2.2.4 Partition Coefficient (Log P):

The n-octanol/water partition coefficient was determined to assess the lipophilicity of Lovastatin, aiding prediction of its absorption behavior.

#### 2.2.5 Calibration Curve:

A stock solution of Lovastatin (1000 µg/mL) was prepared in 0.1N HCl. Serial dilutions (5, 10, 15, 20, 25 µg/mL) were scanned in UV spectrophotometer at  $\lambda_{max}$  = 228 nm to generate a standard curve.

### 2.3 Formulation Development

Floating tablets were formulated using the direct compression method. A total of nine formulations (F1–F9) were prepared using varying concentrations of HPMC K15M, HPMC K4M, and guar gum.

#### 2.3.1 Role of Key Ingredients:

- **HPMC K15M and K4M:** Serve as matrix-forming agents to control drug release.
- **Guar Gum:** Natural polymer added for additional swelling and gel-forming capacity.
- **Sodium Bicarbonate + Citric Acid:** Gas-generating agents to achieve buoyancy.
- **Lactose:** Used as a diluent to maintain tablet weight and compressibility.
- **Magnesium Stearate and Talc:** Used as lubricant and glidant respectively.

#### 2.3.2 Method:

1. All excipients and the API were passed through a 40-mesh sieve.
2. The weighed quantities were transferred into a polyethylene bag and mixed thoroughly.
3. Magnesium stearate and talc were added last to ensure uniform distribution.
4. The blend was compressed into tablets using a rotary tablet press with 9 mm flat-faced punches.

### 2.3.3 Formulation Composition:

Each tablet contained 20 mg Lovastatin with varying polymer ratios (see table in Results section for full composition)

**Table 2:** Formulation Composition of Lovastatin with varying polymer ratios

| Excipients(mg)   | F1  | F2  | F3  | F4  | F5  | F6  | F7  | F8  | F9  |
|--|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Lovastatin   | 20  | 20  | 20  | 20  | 20  | 20  | 20  | 20  | 20  |
| HPMC K 15  | 100 | 120 | 140 | -   | -   | -   | 50  | 60  | 70  |
| HPMC K 4   | -   | -   | -   | 100 | 120 | 140 | 50  | 60  | 70  |
| Gaur gum   | 15  | 15  | 15  | 15  | 15  | 15  | 15  | 15  | 15  |
| Citric acid  | 5   | 5   | 5   | 5   | 5   | 5   | 5   | 5   | 5   |
| NaHCO <sub>3</sub>   | 20  | 20  | 20  | 20  | 20  | 20  | 20  | 20  | 20  |
| Mg(C <sub>18</sub> H <sub>35</sub> O <sub>2</sub> ) <sub>2</sub> | 5   | 5   | 5   | 5   | 5   | 5   | 5   | 5   | 5   |
| Talc   | 5   | 5   | 5   | 5   | 5   | 5   | 5   | 5   | 5   |
| Lactose  | 80  | 60  | 40  | 80  | 60  | 40  | 80  | 60  | 40  |
| Total Weight   | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 |

### 2.4 Pre-compression Evaluation

The powder blend for each formulation was evaluated for:

- **Bulk Density and Tapped Density:** Measured using a 100 mL graduated cylinder.
- **Carr's Index and Hausner Ratio:** Calculated from bulk and tapped density to assess flowability.
- **Angle of Repose:** Determined by funnel method to evaluate the flow properties.

### 2.5 Post-compression Evaluation

After tablet compression, tablets were tested for:

- **General Appearance:** Visual inspection of colour, shape, and defects.
- **Tablet Thickness and Diameter:** Measured using Vernier callipers.
- **Hardness:** Tested using Monsanto hardness tester.
- **Friability:** 10 tablets were rotated at 25 rpm for 4 minutes using Roche friabilator.
- **Weight Variation:** 20 tablets weighed individually; average and % deviation calculated.
- **Drug Content Uniformity:** 10 tablets crushed, dissolved in 0.1N HCl, filtered, and analyzed spectrophotometrically at 228 nm.

### 2.6 In Vitro Buoyancy Test

Floating lag time (time to float) and total floating duration were determined by placing one tablet in 100 mL of 0.1N HCl (pH 1.2) maintained at  $37 \pm 0.5^\circ\text{C}$ . Time was recorded until the tablet rose to the surface (lag time) and remained floating (duration).

### 2.7 In Vitro Drug Release Study

Dissolution testing was performed using a USP Type II (paddle) apparatus at:

- **Medium:** 900 mL of 0.1N HCl
- **Speed:** 75 rpm
- **Temperature:**  $37 \pm 0.5^\circ\text{C}$

At specific intervals (0.5, 1, 1.5, 2, 3, 4, 6, 8, 12 hours), 5 mL samples were withdrawn and replaced with fresh medium. The samples were filtered and analyzed at 228 nm using a UV spectrophotometer. Drug release profiles were plotted.

### 2.8 Drug Release Kinetics

The dissolution data of the optimized formulation were fitted to the following kinetic models:

- **Zero-order kinetics:** Drug release vs. time
- **First-order kinetics:** Log % drug remaining vs. time
- **Higuchi model:** % drug release vs. square root of time
- **Korsmeyer-Peppas model:** Log % drug released vs. log time

The regression coefficient ( $r^2$ ) values were calculated to determine the best-fit model and drug release mechanism.

## 3. RESULTS

### 3.1 Pre-compression Parameters

The powder blends of all nine formulations (F1–F9) were evaluated for flow properties. The results indicate acceptable compressibility and flow, suitable for direct compression.

**Table 3:** Pre-compression properties of Lovastatin Gastroretentive tablet blends

| Formulation | Bulk Density (g/cm <sup>3</sup> ) | Tapped Density (g/cm <sup>3</sup> ) | Carr's Index (%) | Hausner Ratio |
|-------------|-----------------------------------|-------------------------------------|------------------|---------------|
| F1          | 0.456                             | 0.585                               | 22.05            | 1.283         |
| F2          | 0.459                             | 0.581                               | 21.00            | 1.266         |
| F3          | 0.462                             | 0.587                               | 21.30            | 1.271         |
| F4          | 0.461                             | 0.590                               | 21.86            | 1.280         |
| F5          | 0.465                             | 0.585                               | 20.51            | 1.258         |
| F6          | 0.469                             | 0.589                               | 20.37            | 1.256         |
| F7          | 0.468                             | 0.587                               | 20.27            | 1.254         |
| F8          | 0.452                             | 0.579                               | 21.93            | 1.281         |
| F9          | 0.461                             | 0.573                               | 19.55            | 1.243         |

### 3.2 Post-compression Parameters

All formulations passed pharmacopeial specifications for general appearance, weight variation, friability, and hardness.

**Table 4:** Post-compression evaluation of Lovastatin floating tablets

| Formulation | Thickness (mm) | Hardness (kg/cm <sup>2</sup> ) | Weight (mg) | Friability (%) | Drug Content (%) | Floating Duration (h) |
|-------------|----------------|--------------------------------|-------------|----------------|------------------|-----------------------|
| F1          | 3.22           | 5.1                            | 248         | 0.458          | 98.98            | >12                   |
| F2          | 3.25           | 5.2                            | 256         | 0.498          | 99.12            | >12                   |
| F3          | 3.26           | 5.1                            | 250         | 0.463          | 98.65            | >12                   |
| F4          | 3.21           | 5.3                            | 255         | 0.412          | 99.45            | >12                   |
| F5          | 3.20           | 5.2                            | 248         | 0.542          | 97.65            | >12                   |
| F6          | 3.25           | 5.4                            | 247         | 0.621          | 98.25            | >12                   |
| F7          | 3.24           | 5.2                            | 253         | 0.458          | 99.23            | >12                   |
| F8          | 3.25           | 5.1                            | 251         | 0.569          | 97.65            | >12                   |
| F9          | 3.26           | 5.2                            | 250         | 0.541          | 98.89            | >12                   |

### 3.3 In Vitro Buoyancy Study

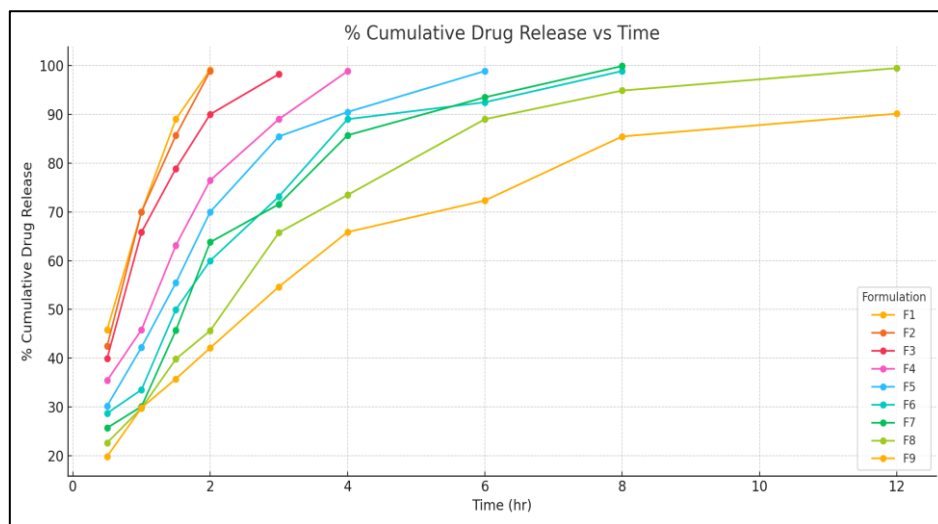
**Table 5:** Vitro Buoyancy Study

| Formulation | Floating Lag Time (sec) |
|-------------|-------------------------|
| F1          | 110                     |
| F2          | 120                     |
| F3          | 115                     |
| F4          | 123                     |
| F5          | 113                     |
| F6          | 112                     |
| F7          | 110                     |
| F8          | 129                     |
| F9          | 110                     |

### 3.4 In Vitro Drug Release Profile

**Table 6:** In Vitro Drug Release Profile

| Time (hr) | F1    | F2    | F3    | F4    | F5    | F6    | F7    | F8    | F9    |
|-----------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 0.5       | 45.85 | 42.54 | 39.98 | 35.45 | 30.25 | 28.74 | 25.74 | 22.69 | 19.89 |
| 1         | 69.98 | 69.98 | 65.84 | 45.85 | 42.25 | 33.56 | 30.12 | 29.78 | 29.85 |
| 1.5       | 88.98 | 85.65 | 78.85 | 63.12 | 55.45 | 49.98 | 45.71 | 39.84 | 35.78 |
| 2         | 99.12 | 98.85 | 89.98 | 76.45 | 69.98 | 59.98 | 63.78 | 45.65 | 42.12 |
| 3         | -     | -     | 98.22 | 88.98 | 85.45 | 73.12 | 71.56 | 65.74 | 54.65 |
| 4         | -     | -     | -     | 98.81 | 90.45 | 88.98 | 85.69 | 73.45 | 65.85 |
| 6         | -     | -     | -     | -     | 98.85 | 92.45 | 93.47 | 88.98 | 72.32 |
| 8         | -     | -     | -     | -     | -     | 98.85 | 99.87 | 94.85 | 85.45 |
| 12        | -     | -     | -     | -     | -     | -     | -     | 99.45 | 90.12 |



**Figure 1:** In-vitro drug release study of GRF tablets

### 3.5 Drug Release Kinetics of Optimized Batch (F8)

The drug release data of F8 was fitted to various kinetic models. The best fit was found with **First-order kinetics** with **Higuchi diffusion** and **non-Fickian (anomalous) transport**, indicating a combination of drug diffusion and polymer matrix erosion.

**Table 7:** In-vitro drug release data for optimized formulation F8

| Time (h) | Square Root of Time(h) <sup>1/2</sup> | Log Time | Cumulative* % Drug Release | Log Cumulative % Drug Release | Cumulative % Drug Remaining | Log Cumulative % Drug Remaining |
|----------|---------------------------------------|----------|----------------------------|-------------------------------|-----------------------------|---------------------------------|
| 0.5      | 0.707                                 | -0.301   | 22.69                      | 1.356                         | 77.31                       | 1.888                           |
| 1        | 1                                     | 0        | 29.78                      | 1.474                         | 70.22                       | 1.846                           |
| 1.5      | 1.225                                 | 0.176    | 39.84                      | 1.600                         | 60.16                       | 1.779                           |
| 2        | 1.414                                 | 0.301    | 45.65                      | 1.659                         | 54.35                       | 1.735                           |
| 3        | 1.732                                 | 0.477    | 65.74                      | 1.818                         | 34.26                       | 1.535                           |
| 4        | 2                                     | 0.602    | 73.45                      | 1.866                         | 26.55                       | 1.424                           |
| 6        | 2.449                                 | 0.778    | 88.98                      | 1.949                         | 11.02                       | 1.042                           |
| 8        | 2.828                                 | 0.903    | 94.85                      | 1.977                         | 5.15                        | 0.712                           |
| 12       | 3.464                                 | 1.079    | 99.45                      | 1.998                         | 0.55                        | -0.260                          |

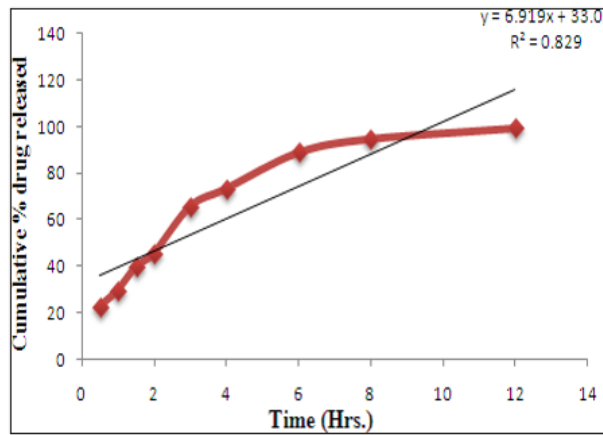


Figure 2: Zero order release Kinetics (Cumulative % drug released Vs Time)

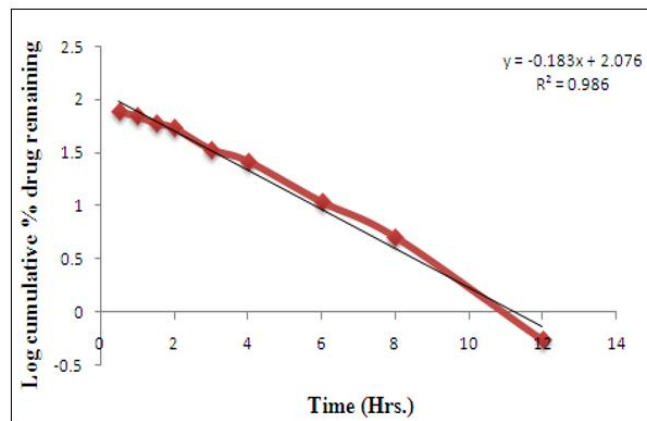


Figure 3: Zero order release Kinetics (Cumulative % drug released Vs Time)

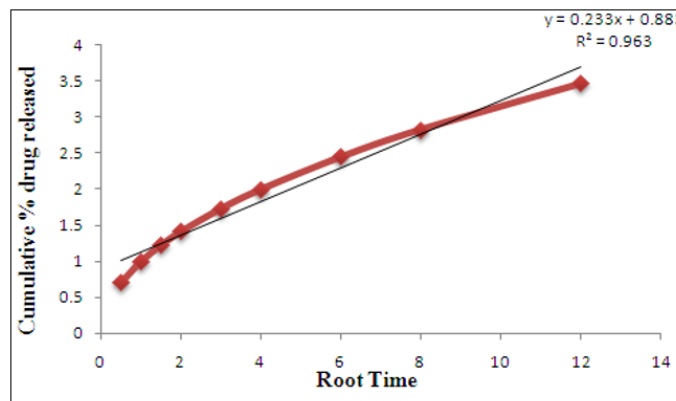


Figure 4: Higuchi release Kinetics (Cumulative % drug released Vs Root Time)

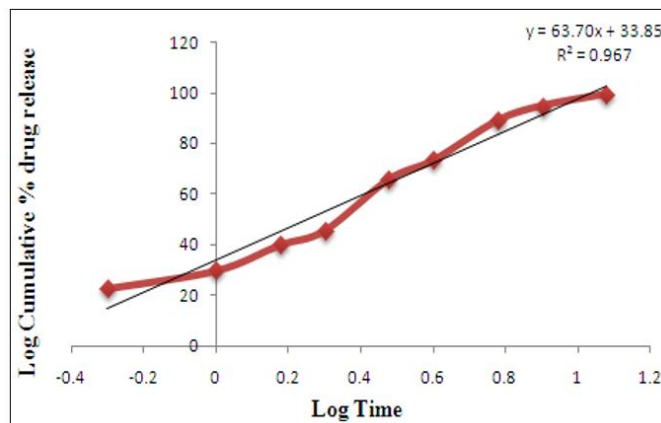


Figure 5: Korsmeyer-Peppas release Kinetics Log Cumulative % drug release Vs Log Time)

**Table 5: Regression coefficients ( $r^2$ ) of kinetic models for F8**

| Model            | Regression Coefficient ( $r^2$ ) |
|------------------|----------------------------------|
| Zero Order       | 0.829                            |
| First Order      | 0.986                            |
| Higuchi Model    | 0.963                            |
| Korsmeyer-Peppas | 0.967                            |

## 4. DISCUSSION

The present investigation focused on the formulation and optimization of Gastroretentive floating tablets of **Lovastatin**, a BCS Class II drug with limited bioavailability due to extensive first-pass metabolism and low aqueous solubility. Developing a floating drug delivery system allowed for prolonged gastric retention, facilitating localized drug release in the upper gastrointestinal tract (GIT) — a region where Lovastatin demonstrates optimal absorption.

### 4.1 Pre-compression and Blend Properties

The flow behavior of the powder blends was evaluated using parameters such as bulk density, tapped density, Carr's index, and Hausner ratio. All formulations exhibited Carr's index values between 19–22% and Hausner ratios under 1.3, indicating fair to good flowability, which is crucial for direct compression tablet formulation. These results ensured consistency in tablet weight and mechanical strength.

### 4.2 Physicochemical Evaluation

Post-compression parameters such as tablet hardness (5.1–5.4 kg/cm<sup>2</sup>) and friability (<0.7%) across all batches confirmed that the tablets had sufficient mechanical strength to withstand handling and transportation. Uniform drug content (97.65–99.45%) was observed, indicating homogeneous mixing and effective incorporation of Lovastatin during formulation. All tablets exhibited floating duration greater than 12 hours, suggesting that the effervescent system composed of sodium bicarbonate and citric acid was successful in generating CO<sub>2</sub> and creating buoyancy.

The floating lag time ranged between 110 to 129 seconds, which is acceptable and aligns with reported gastroretentive tablet benchmarks. Notably, the lag time for formulation F8 was slightly higher (129 seconds), possibly due to increased viscosity from polymer concentration delaying hydration.

### 4.3 In Vitro Drug Release and Optimization

The in vitro drug release profile revealed a strong influence of polymer type and concentration. Formulations F1–F3 containing HPMC K15M released drug rapidly (89–99% within 2 hours), whereas F4–F6 (HPMC K4M) showed more controlled release patterns extending up to 6–8 hours. Formulations F7–F9, incorporating both HPMC grades and guar gum, exhibited sustained release profiles over 12 hours, indicating

synergistic matrix-forming and swelling effects of polymer combinations.

Formulation F8 emerged as the optimized batch, exhibiting a drug release of 99.45% over 12 hours, ideal floating ability, and excellent mechanical properties. The sustained release achieved can be attributed to the gel-forming ability of HPMC K4M and K15M combined with guar gum, which enhanced matrix integrity and retarded drug diffusion.

### 4.4 Drug Release Mechanism

The drug release kinetics were evaluated using mathematical modelling:

- Zero-order showed a non-linear release, suggesting inconsistent drug release per unit time.
- First-order kinetics exhibited the highest regression value ( $r^2 = 0.986$ ), indicating that drug release was concentration-dependent.
- The Higuchi model ( $r^2 = 0.963$ ) suggested a diffusion-controlled release.
- The Korsmeyer-Peppas model ( $r^2 = 0.967$ ) confirmed anomalous (non-Fickian) transport, implying a combination of diffusion and polymer relaxation or erosion.

Such results are in line with sustained-release matrix systems, wherein both polymer swelling and drug solubilization contribute to the overall release.

### 4.5 Comparison with Existing Literature

The findings of this study align with previous investigations that have employed HPMC and natural polymers to sustain the release of poorly water-soluble drugs. For example, studies on Lovastatin-loaded floating matrices by Bommagani et al. (2013) and Saikrishna et al. (2014) reported similar drug release trends and buoyancy characteristics using HPMC and gas-generating systems.

Furthermore, the enhanced floating properties and controlled release behavior demonstrated in this study may offer improved therapeutic compliance, reduced dosing frequency, and enhanced patient outcomes, particularly for patients with hyperlipidemia who require chronic statin therapy.

## 5. CONCLUSION

In this study, gastroretentive floating tablets of Lovastatin were successfully formulated using a combination of HPMC K4M, HPMC K15M, and guar gum via the direct compression method. The primary goal was to prolong gastric residence time and sustain drug release in the upper gastrointestinal tract — thereby improving oral bioavailability, reducing dosing frequency, and enhancing patient compliance in the management of hypercholesterolemia.

Among all nine formulations, F8 was identified as the optimized batch based on its superior floating behavior, mechanical strength, and drug release profile. It exhibited:

- A total floating duration of over 12 hours
- A floating lag time of 129 seconds
- Drug content uniformity of 99.23%
- Complete drug release (99.45%) over 12 hours

Kinetic modeling revealed that drug release from the optimized formulation followed first-order kinetics, with diffusion-controlled release conforming to the Higuchi model. The Korsmeyer-Peppas exponent (n) indicated anomalous (non-Fickian) transport, signifying that both diffusion and polymer erosion governed the release mechanism.

These findings suggest that Lovastatin-loaded floating matrix tablets offer an effective strategy for sustained drug delivery. The formulation not only addresses the drug's bioavailability issues but also provides a robust platform for the delivery of other drugs with narrow absorption windows in the upper GIT.

**Acknowledgements:** The authors gratefully acknowledge Lal Bahadur Shastri College of Pharmacy, Jaipur, for providing necessary research facilities and infrastructure support. We also extend our appreciation to the laboratory staff for their technical assistance during the formulation and evaluation processes.

#### Author's Contributions

Dr. Vinesh Kumar: Conceptualization, methodology, supervision, and critical review of the manuscript.

Rakesh Kumar Sodavat: Experimental work, data collection, and primary manuscript drafting.

Dr. Garvendra Singh Rathore: Literature review, data analysis, and manuscript editing.

**Funding Source:** This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

**Conflicts of Interest:** The authors declare no conflicts of interest related to this study.

**Ethical Approval:** Not applicable. This study does not involve human or animal subjects.

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