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Research Paper

Formulation And Evaluation of Pellets

Anisha Kohale, Dr. A. V. Chandewar, Dr. S. R. Gawande, Abhay Dhakare, Anjali Bhansali, Ashwini Warankar

P. Wadhawani college of pharmacy, Yavatmal 445001

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ABSTRACT

The present study focuses on the formulation and evaluation of Esomeprazole-coated sustained release pellets using various polymers in different ratios. Esomeprazole, a proton pump inhibitor, is acid-labile and requires protection from gastric acid for effective intestinal absorption. In this research, non-pareil (NP) seeds were prepared using the extrusion-spheronization process and subsequently coated with Esomeprazole and sustained release polymers through the pan coating method. Various polymer ratios were applied to assess their effect on drug release behavior. The formulated pellets were evaluated for physical properties such as size, flow properties, and friability, along with in-vitro drug release studies under simulated gastrointestinal conditions. The influence of different polymer types and coating levels on the drug release profile was systematically analyzed. The optimized formulation exhibited controlled and sustained drug release with improved stability compared to conventional dosage forms.

INTRODUCTION

Oral drug delivery systems remain the most preferred route for drug administration due to patient compliance, ease of administration, and cost-effectiveness. Among these, sustained release dosage forms have gained significant attention as they offer controlled drug release, maintain plasma drug levels for prolonged periods, and minimize dosing frequency, improving therapeutic outcomes.

Esomeprazole, a proton pump inhibitor, is widely prescribed for the treatment of acid-related disorders such as gastroesophageal reflux disease (GERD), peptic ulcers, and Zollinger–Ellison syndrome. However, it is highly acid-labile and requires protection from gastric acid to ensure its stability and effective absorption in the intestine. Therefore, formulating Esomeprazole in a sustained release pellet form can enhance its therapeutic efficiency by providing prolonged release and targeted delivery to the intestinal region.

***Corresponding Author:** Anisha Kohale
Address: *P. Wadhawani college of pharmacy, Yavatmal 445001*
Email ✉: kohaleanisha@gmail.com

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Pelletization is a versatile technique in pharmaceutical formulation, offering several advantages such as uniform drug distribution, reduced dose dumping risk, and improved bioavailability. Non-pareil (NP) seeds, commonly used as inert cores, serve as carriers for drug layering and sustained release coating. In this study, NP seeds were formulated using the extrusion-spheronization process, a reliable method for producing uniform, spherical pellets with good mechanical strength and flow properties.

The coated pellets were prepared by applying Esomeprazole and various sustained release polymers in different ratios using the pan coating technique. This method ensures even distribution of coating material, uniform pellet size, and efficient drug release control. The prepared pellets were evaluated for physical parameters such as particle size, flow properties, friability, and in-vitro drug release profiles under simulated gastrointestinal conditions.

The primary aim of this study was to optimize the polymer coating ratios and assess their effect on the sustained release behavior of Esomeprazole pellets, along with stability evaluation as per ICH guidelines. The findings of this research may contribute to the development of an effective and reliable sustained release oral dosage form of Esomeprazole with enhanced stability and therapeutic performance.

AIM, OBJECTIVES AND NEED OF STUDY

Aim: To Formulate and Evaluate Pellets.

Objective:

1. To remove excess moisture from the material to prevent caking, spoilage and microbial growth.
2. To enhance material flow ability for efficient processing and pellet formation.
3. To achieve a uniform particle size distribution for consistent pellet quality.
4. To prevent degradation or oxidation of the material during processing.
5. To ensure pellets are durable, dense, and have a uniform texture.

DRUG PROFILE

1. ESOMEPRAZOLE:

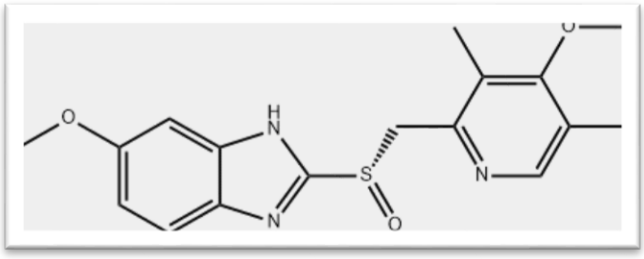

Fig. 1. Chemical structure of Esomeprazole

- Molecular Formula: C17H19N3O3S
- Molecular Weight: 345.42
- Solubility: Very slightly soluble in water
- Melting point: 155 °C

Uses:

Esomeprazole is a proton pump inhibitor (PPI) used to:

1.Treat GERD (acid reflux)
2. Heal erosive esophagitis
3. Manage peptic ulcers (including with H. pylori therapy)
4. Prevent NSAID-induced ulcers
5. Control acid in Zollinger-Ellison syndrome.

EXCIPIENT PROFILE

1. HPMC

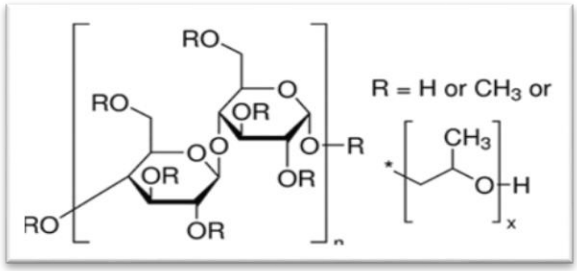

Fig. 2. Chemical structure of HPMC

- Chemical Name: Hydroxypropyl methyl cellulose
- Synonyms HPMC: HYPROMELLOSE
- Molecular Formula: C3H7O
- Molecular Weight: 59.08708
- Melting Point: 225-230 °C

Uses:

1. Sustained/controlled release polymer in drug formulations.
2. Film coating agent for tablets and capsules.
3. Binder in tablet formulations.
4. Thickener and stabilizer in liquids, emulsions, and eye drops.

2. HPMC K4M

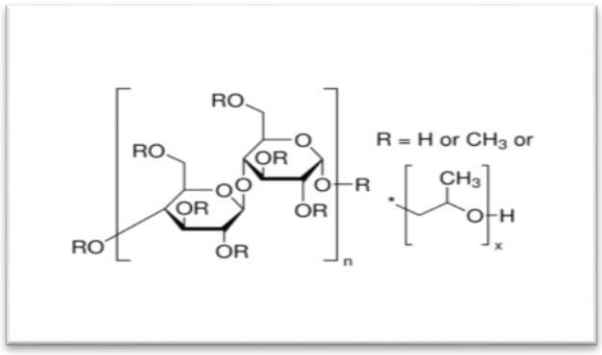

Fig. 3. Chemical structure of HPMC K4M

- HPMC K4M, or Hydroxypropyl Methyl Cellulose K4M, is a water-soluble, semisynthetic polymer derived from cellulose.
- It's a white to cream-colored powder with a viscosity of 3,500-5,600 cP at 2% concentration in water at 20°C.
- It's commonly used in various applications, including pharmaceuticals, food, and cosmetics, due to its thickening, stabilizing, and film-forming properties.

Solubility:

- It's readily soluble in water.

MATERIAL AND METHOD

1. Preformulation Studies:

Preformulation studies are the first step in rational development of dosage form of a drug substance Preformulation study is the process of optimizing the delivery of the drug through the determination of the physicochemical properties of the new compound that affect the drug performance and development of an efficacious, safe and stable dosage form. It gives the information needed to define the nature of the drug substance and provide a framework for the drug combination with the pharmaceutical excipients in the dosage form. Hence, these studies were performed for the obtained sample of drug for identification and compatibility studies.

1.1. Organoleptic Properties

1) Colour: A small quantity of Quetiapine fumarate powder was taken on a butter paper and was viewed in a well illuminated place.
2) Taste and Odour: Very less quantity of Quetiapine fumarate was tasted and smelled to get odour.

1.2. Calibration curve of Esomeprazole:

Calibration curve of Esomeprazole was carried out in Phosphate buffer of pH 6.8 and absorbance was taken by using UV spectrophotometer

Preparation of Phosphate buffer of pH 6.8.

- Preparation of 0.2M sodium hydroxide:

Dissolve about 8 g of sodium hydroxide in sufficient quantity of distilled water and made up to 1000ml with distilled water.

- Preparation of 0.2M potassium dihydrogen phosphate:

Dissolve potassium phosphate about 27.218g in sufficient quantity of distilled water and made up to 1000ml with distilled.

- Preparation of Phosphate buffer of pH 6.8:

Take about 50ml of potassium dihydrogen phosphate in a 200ml volumetric flask and add

22.4ml of 0.2M Sodium hydroxide and made up to 200ml with distilled water. Check the pH of resulting solution and adjust to pH 6.8 by using 0.2M sodium hydroxide solution.

➢ Calibration curve of Esomeprazole in pH 6.8:

100 mg of drug Esomeprazole was dissolved in 0.5 ml methanol(cosolvent) and volume was make up to 100ml using phosphate buffer 6.8 to make stock solution of concentration 200µg/ml. Then 2 ml of stock solution was taken and diluted upto 100ml with the buffer of pH 6.8 and to get concentration of 2µg/ml and in similar way dilution were made as 2, 4, 6, 8 and 10 µg/ml respectively and absorbance measured at 300nm by UV visible spectrophotometer. The absorbance values were plotted against concentration (µg/ml) to obtain the standard calibration curve.

2. Preparation of Drug and Polymer Coated Pellets:

The drug and polymer coated pellets were prepared by using synthetic polymer like HPMC, HPMC K4M, Ethyl cellulose.

Table no.1: Formulation Table Of Sustained Release Coated Pellets

Ingredients	F1 (1:8)	F2 (1:6)	F3 (1:4)	F4 (1:4)	F5 (1:6)	F6 (1:6)	F7 (1:4)
Esomeprazole (gm)	250	250	250	250	250	250	250
HPMC (mg)	2000	_	_	_	_	_	_
HPMC K4M (mg)	_	1500	750	500	1000	750	800
Ethyl Cellulose (mg)	_	_	250	500	500	750	200
Ethanol (ml)	50	50	50	50	50	50	50
Total (gm)	2.25	1.75	2	1.25	2	1.25	1.25

3. Evaluation of Esomeprazole Pellets:

3.1. Micromeritic Properties:

Bulk density:

Weighed quantity of 10 gm pellets was transferred into a 100 inl recasuring cylinder without tapping, during transfer the volume occupied by pellets was measurer. Bulk density was measured by using formula.

Bulk density was calculated by using following formula,

$$\textbf{Bulk Density} = \frac{\textbf{Weight of sample in gm}}{\textbf{Bulk volume(Vo)}}\ \textbf{gm/ml}$$

Tapped Density:

Weighed quantity of 10 gm pellets was taken into graduated cylinder, volume occupied by granules was noted down. Then cylinder was subjected to 100 taps in tapped density tester (Electro Lab USP II), the % Volume variation was calculated by following formula.

$$\textbf{Tapped Density} = \frac{\textbf{Weight of sample in gm}}{\textbf{Volume after tapping}}\ \textbf{gm/ml}$$

Carr's/compressibility index

Compressibility is the ability of pellets to decrease in volume under pressure. Using untapped density and tapped density the percentage compressibility of pellets was determined, which is given as Carr's compressibility index.

$$\textbf{Carr's index} = \frac{\textbf{Tapped density} - \textbf{Bulk density}}{\textbf{Tapped density}} \times \mathbf{100}$$

Hausner's ratio

It is measurement of frictional resistance of the drug, it was determined by the ratio of tapped density and bulk density.

Hausner's ratio = $\frac{\text{Tapped Density}}{\text{Bulk Density}}$

Table no. 2: Scale of Flowability

Compressibility Index	Flow Characters	Hausner's Ratio
<10	Excellent	1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very Poor	1.46-1.59
>38	Very Very Poor	>1.60

Angle of repose:

Angle of repose is the maximum angle formed between the surface of pile of powder and horizontal plane. It is usually determined by fixed funnel method and is the ability to measure the flowability of powder

$$\textbf{Angle of Repose (0)} = \tan^{-1}\frac{h}{r}$$

Where,
h = height of the heap of the pile
r = radius of the base of the pile

Table No. 3 : Flow Properties And Corresponding Angle Of Repose

Flow property	Angle of Repose
Excellent	<20
Good	20-30
Passable	30-40
Poor	>40

Percentage yield:

The yield was determined by weighing the pellets and then, finding out the percentage yield with respect to the weight of the input materials. The formula for caleulation of percentage yield is

$$\textbf{Percentage yield (\%)} = \frac{\text{Weight of Pellets}}{\text{Weight of drug + Weight of polymers}} \times 100$$

Friability Test:

From each batch, sieved 2 gm pellets were accurately weighed and placed in the friability test apparatus (Roche friabilator). Apparatus was operated at 25 rpm for 4 minutes. pellets were then taken after 100 rotations, seived and reweighed. The friability was calculated as the percentage weight loss.
% friability was calculated as follows;

$$\textbf{\% friability} = \frac{(W1 - W2)}{W1} \times 100$$

Where,
W = Initial weight of pellets
W2 = Final weight of pellets after testing.

Particle Size Analysis:

The pellets were then subjected sieving (Mechanical Sieve Shaker, Jayant Scientific, India) using a nest of standard sieves (4, 10, 20, 25, 40, 60) shaken for 10 min on a sieve shaker The pellets retained on each sieve were used to construct frequency distribution. The size range of 500-1500 um was considered appropriate, and the weight of pellets in this range is reported as yield of pelletization. The same set of sieves was used for size distribution analysis. The mean diameter was calculated according to the Equation:

$$\textbf{d} = \frac{\text{PXifi}}{\text{Pfi}}$$

Where,
Pxifi = the weight size
Pfi = the percentage weight retain

Table no. 4 : Sieve Size Analysis Properties

Sieve No.	Opening (mm)	Sieve No.	Opening (mm)
4	4.75	20	0.85
6	3.35	25	0.71
8	2.36	40	0.425
10	2.00	60	0.250
14	1.40	80	0.180
18	1.00	100	0.150

Drug Content:

Pellets were weighed and taken into a mortar and crushed into fine powder. An accurately weighed portion of the powder equivalent to about 40 mg of Esomeprazole was transferred to a 100 ml volumetric flask containing 100 ml of phosphate buffer pH 6.8. This forms 100 µg/ml of solution. It was filtred through a Whatman filter paper (No. 1) absorbance was measured against blank at 300 nm.

In-Vitro drug release studies:

In-vitro release studies of ODPs of Esomeorazole was carried out using USP 'TDT-08L rotating paddle apparatus (type II). The dissolution medium consisted of 900 ml of phosphate buffer pH 6.8. The release study was performed at 37°C ±0.5°C with a rotation speed of 50 rpm. The sample 1 ml was withdrawn at a time intervals of 1hr, 2hr... up to 12hr. and replaced with 1 ml of dissolution media to maintain the sink condition The amount of Esomeprazole released was determined spectrophotometrically at 300nm.

RESULT AND DISCUSSION

1. Physical Characteristics

Table No. 5. Physical characteritics of Esomeprazole

Sr. No.	Content	Observation
1.	Colour	Yellow
2.	Odour	Odourless
3.	Taste	Bitter
4.	Melting Point	155^0C

1.1. Solubility study:

Table No. 6. Solubility study

Sr.No.	Solvent	Solubility of Esomeprazole
1.	Water	Insoluble
2.	Ethanol	Slightly soluble
3.	Methanol	Soluble
4.	DMF	Soluble
5.	Acetone	Slightly soluble
6.	DMSO	Soluble

1.2. Analyatical Characterization of Drug Sample

Standard Curve of Esomeprazole:

Table no. 7. Calibration of Esomeprazole in pH 6.8 Phosphate buffer

Sr.No.	Volume Of stock Solution	Concentration (ug/ml)	Absorbance
1.	0.2	2	0.065
2.	0.4	4	0.114
3.	0.6	6	0.177
4.	0.8	8	0.233
5.	1.0	10	0.290

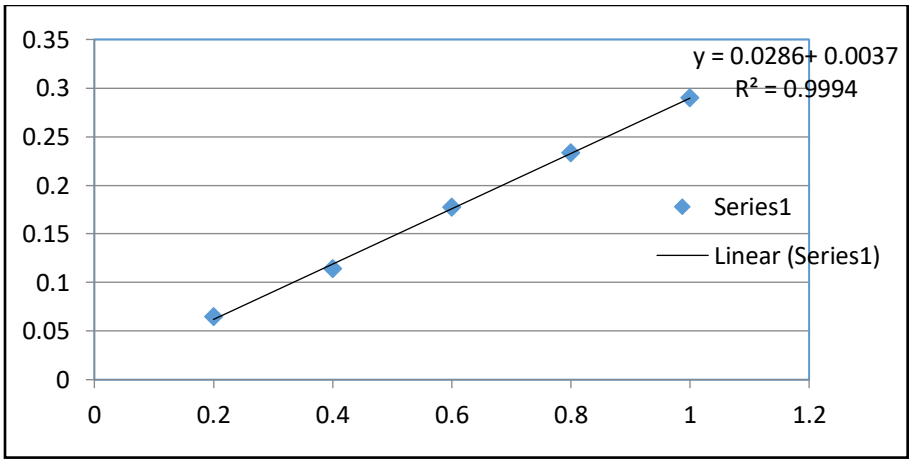

Fig. 4. Calibration curve of Esomeprazole

2. Evaluation of Esomeprazole Pellets:

2.1. Micromeritic Properties of Pellets

Table no. 8

Batches	Bulk Density gm/ml Mean ± SD	Tapped Density gm/ml Mean ±SD	Angle of Repose Mean ±SD	Carr's Index % Mean±SD	Hausner's Ratio Mean±SD
F1	0.5482 ± 0.004	0.7169 ± 0.06	22.27 ± 1.97	23.53 ± 1.21	1.30 ± 0.46
F2	0.6239 ± 0.055	0.7487 ± 0.08	24.82 ± 1.12	16.66 ± 1.17	1.20 ± 0.47
F3	0.5467 ± 0.045	0.6560 ± 0.10	23.76 ± 0.12	16.66 ± 0.74	1.19 ± 0.49
F4	0.5570 ± 0.65	0.6189 ± 0.10	23.076 ± 1.41	10.00 ± 1.52	1.11 ± 0.40
F5	0.5577 ± 0.37	0.6458 ± 0.12	24.57 ± 0.47	13.64 ± 0.79	1.15 ± 0.58
F6	0.6233 ± 0.05	0.6993 ± 0.07	25.04 ± 1.34	11.09 ± 0.74	1.12 ± 0.74
F7	0.6026 ± 0.10	0.7156 ± 0.16	25.08 ± 0.54	15.74 ± 1.71	1.18 ± 0.68

The result of angle repose is less than 30 indicate good flow properties of sustained release pellets. This was further supported by lower Carr's index value. Carr's index value up to 11.09% resulted in excellent flow properties. Thus, all the obtimized formulation was found to exhibit good to excellent flow properties.

Table no. 9. Percent Yield, Percent Friability & Particle size

Sr. no.	Batches	% Yield	Friability (%)	Particle size(mm)
1.	F1	47.05	0.16	0.72
2.	F2	57.33	0.13	0.73
3.	F3	66.15	0.25	0.71
4.	F4	64.61	0.15%	0.71
5.	F5	59.46	0.14	0.69
6.	**F6**	**62.93**	**0.17**	**0.68**
7.	F7	67.38	0.15	0.75

2.3. Drug Content

Table no. 10. Drug Entrapment Efficiency, % Drug Loading

Sr.No.	Batch	Drug: Polymer Ratio	Therotical loading %	Actual loading%	Drug entraptment efficiency (%)
1.	F1	1:8	11.11	4.589	41.30
2.	F2	1:6	14.28	5.204	36.44
3.	F3	1:4	20	15.358	76.79
4.	F4	1:4	20	8.96	44.8
5.	F5	1:8	11.11	6.896	62.07
6.	F6	1:8	11.11	10.25	92.25
7.	F7	1:4	20	7.407	37.038

2.4. In-vitro Percent drug release

Table no. 9.

Time (hr)	F1	F2	F3	F4	F5	F6	F7
1	109.25%	48%	76.21%	36.87%	45%	47.36%	52.08%
2	98.76%	52.5%	87.74%	35.30%	48%	50.51%	54.18%
3	99.82%	67.5%	68.86%	37.40%	87.74%	55.85%	58.90%
4		75.68%	54.18%	35.82%	99.81%	57.85%	69.39%
5		92.47%	55.75%	41%	101.91%	58.52%	74.63%
6		100.86%	61.52%	43%		61.52%	86.70%
7			89.4%	47.36%		65.72%	101.91%
8			99.82%	56.80%		72.53%	
9				63.62%		84.07%	
10				72.01%		**97.19%**	
11				80.93%			
12				94.56%			

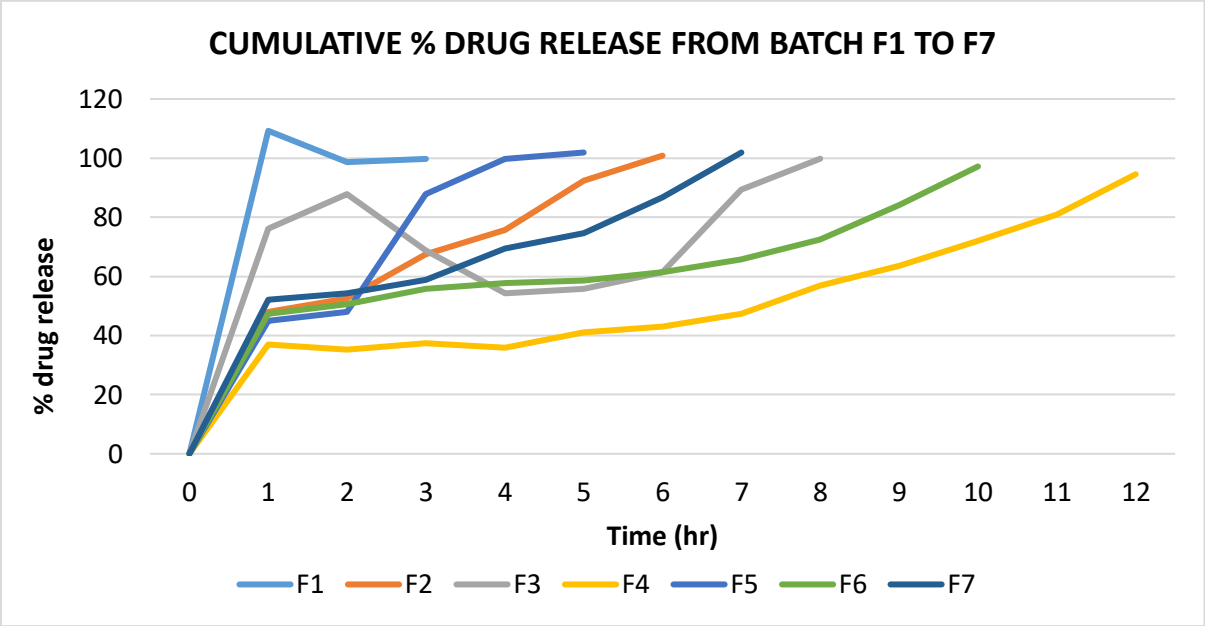

Fig. Cumulative % drug release from batch F1 to F7

SUMMARY

The present study was undertaken to develop and evaluate sustained release coated pellets of Esomeprazole using various polymers. Esomeprazole, a proton pump inhibitor with a short half-life, benefits from sustained release formulations to prolong therapeutic action and improve patient compliance. The pellets were prepared by using different concentrations and combinations of hydrophilic and hydrophobic polymers, including Hydroxypropyl Methylcellulose (HPMC), HPMC K4M, and Ethyl Cellulose. A total of seven formulations (F1–F7) were prepared by varying the ratios of polymers and evaluated for their micromeritic properties, bulk density, tapped density, and drug release profile. The drug release was studied in phosphate buffer pH 6.8 using UV spectrophotometry at 300 nm. The results revealed that the combination of hydrophilic and hydrophobic polymers influenced the drug release rate effectively. Formulations containing only HPMC or HPMC K4M exhibited faster release compared to those containing Ethyl Cellulose. Among all, Formulation F6 (containing 750 mg HPMC K4M and 750 mg Ethyl Cellulose)

demonstrated an optimal sustained release profile, releasing 97.19% of the drug over a period of 10 hours, with desirable micromeritic and physical characteristics.

CONCLUSION

The study successfully developed Esomeprazole sustained release coated pellets using a combination of HPMC K4M and Ethyl Cellulose as polymeric coating agents. The in-vitro drug release studies confirmed that the combination of hydrophilic and hydrophobic polymers effectively controlled the release of Esomeprazole, achieving prolonged release over a 10-hour period. Formulation F6 emerged as the most promising formulation, providing controlled and sustained drug release with favorable physical properties. The results demonstrate that adjusting the ratio of HPMC K4M and Ethyl Cellulose offers a simple and efficient method to modulate drug release rates for Esomeprazole. This approach can be considered for the development of sustained release oral formulations of Esomeprazole, potentially improving therapeutic efficacy and patient compliance.

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