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Formulation and Evaluation of Enteric Coated Tablet of Omeprazole

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ABSTRACT
The present study aimed to formulate and evaluate enteric-coated tablets of omeprazole using cellulose acetate phthalate (CAP) as the enteric coating polymer. Omeprazole core tablets were prepared using different concentrations of microcrystalline cellulose, and the optimized formulation was subjected to enteric coating with varying weight gains (5%, 8%, and 12%). The tablets were evaluated for Preformulation parameters, post-compression characteristics, acid resistance, and in vitro dissolution studies. FTIR spectroscopy confirmed drug-excipient compatibility, while DSC analysis revealed thermal stability characteristics. The optimized formulation demonstrated excellent acid resistance with minimal drug release in acidic medium and rapid release in phosphate buffer pH 6.8. Stability studies indicated the formulation remained stable under accelerated conditions. The study successfully developed a robust enteric-coated omeprazole tablet suitable for industrial production.

KEY WORDS: Tablets, Enteric coating, Cellulose acetate phthalate, Stability studies, Omeprazole.

I. INTRODUCTION

Enteric coating technology plays a crucial role in oral drug delivery systems, particularly for acid-labile drugs that require protection from gastric degradation. The primary objectives of enteric coating include:[1][2]

- To protect the stomach wall from the harmful effects of the drug in a dosage form
- To prevent degradation of the drug by gastric contents
- To achieve targeted drug release in the intestinal environment

Omeprazole is a substituted benzimidazole proton pump inhibitor widely used in the treatment of acid-related disorders. It specifically inhibits the H^+ /K^+ -ATPase enzyme system at the secretory surface of gastric parietal cells, effectively blocking the final step of gastric acid secretion. Furthermore, addition of an alkalizer can improve the solubility of omeprazole, which increases with the increase in pH. Being soluble at higher pH values, enteric polymers dissolve in the intestine and release the core for ready action.[3][4][5][6][7][8][9]

These polymers include several synthetic polymers like polymethacrylates (Eudragits), cellulose acetate phthalate (CAP), hydroxypropyl methylcellulose phthalate (HPMCP), and hydroxypropyl methylcellulose acetate succinate (HPMCAS). The aim of the present study was to compare the suitability of these renowned polymers to develop enteric coated tablets of omeprazole, a very sensitive proton pump inhibitor. Omeprazole exhibits antibacterial activity against Helicobacter pylori in vitro, making it valuable in combination therapy for peptic ulcer treatment.[10][11][12][13]

Gastroesophageal reflux disease (GERD) is a highly prevalent condition, affecting 10–30% of the adult population in Western countries and utilizing significant healthcare resources. When left untreated, or when treated inadequately, GERD can produce a spectrum of potentially severe complications. Omeprazole has been studied extensively in a number of acid-related diseases, and a growing number of studies support its safety and clinical efficacy when used as long-term maintenance therapy.[14][15][16][3]

Omeprazole is a benzimidazole derivative proton pump inhibitor with the molecular formula $C_{17}H_{19}N_3O_3S$ and molecular weight of 345.42 g/mol. It has a melting point of 156-157°C and is a white to off-white crystalline powder that is practically insoluble in water but freely soluble in alkaline solutions. The drug exhibits pH-dependent stability, being unstable in acidic conditions but stable in alkaline environments, necessitating enteric coating for oral delivery.[17][18][5][13][19][20]

Delivery of therapeutic agent into the intestinal region can be accomplished by the application of an enteric coating on a solid dosage form. Omeprazole is a classic example of proton pump inhibitors and is approved by FDA for the treatment of symptomatic gastro-oesophageal

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reflux disease, short-term treatment and maintenance of erosive esophagitis. A number of enteric coating polymers are available and capable of protecting the drug core from the aggressive environments of the stomach.[21][22][15][23][24]

II. MATERIALS AND METHODS

2.1. Materials

- **Drug:** Omeprazole magnesium (Pharmaceutical grade, purity ≥99%)
- **Excipients:** Microcrystalline cellulose (Avicel PH-102), Talc, Crosspovidone (Kollidon CL), Magnesium stearate
- **Coating Materials:** Cellulose acetate phthalate, Triethyl citrate, Isopropyl alcohol, Dichloromethane

All materials were of pharmaceutical grade and used as received.

2.2. Preformulation Studies

2.2.1. Drug Characterization

The infrared spectrum of omeprazole was recorded using Bruker's ATR method Fourier-transform infrared spectroscopy. The sample was placed on the sample holder, the surface leveled, and then placed in the analysis chamber for spectrum recording. Characteristic peaks were identified at 3057 cm^{-1} (C-H stretching), 1629 cm^{-1} (C=N stretching), and other diagnostic bands.[25][26][27][28]

2.2.2. Differential Scanning Calorimetry (DSC)

DSC analysis was performed to determine the melting point and thermal behavior of omeprazole. The drug showed a sharp endothermic peak at 157°C, confirming its crystalline nature and purity.[29][30][20][17]

2.2.3. Powder Flow Properties

Bulk density, tapped density, Carr's index, and Hausner's ratio were determined according to USP procedures. The angle of repose was measured using the funnel method to assess flow characteristics.[31][5]

2.3. Formulation Development

2.3.1 Core Tablet Preparation

Core tablets were prepared by direct compression method using different ratios of excipients as shown in Table 1.

Table 1: Formulation of Omeprazole Core Tablets

Ingredients (mg/Tablet)	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)
Omeprazole	20	20	20	20
MCC	20	40	60	80
Talc	1	1	1	1
Crosspovidone	5	5	5	5
Magnesium Stearate	2	2	2	2
Total Weight	**48**	**68**	**88**	**108**

2.3.2 Enteric Coating Solution Composition

Table 2: Enteric Coating Solution Formulation

Sr. No	Ingredients	Quantity (g)
1	Cellulose acetate phthalate	63
2	Triethyl citrate	9.45
3	Talc	12.60
4	Isopropyl Alcohol	307.48
5	Dichloromethane	307.48

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6	**Total volume**	**700**

2.4. Coating Process

Sub coating of the compressed tablets was achieved by standard coating pan technique. The coating composition was sprayed using a single air atomizing gun. The bed to gun distance was maintained at 6 inches. The pan was rotated at 10 rpm to favor effective drying. The coating material deposit was increased to obtain different weight gains of 5%, 8%, and 12% from the original weight. The tablets were selected at random and checked for weight gain before and after coating application. The coated tablets were dried at 35-40°C for 10 minutes.[32][33][12][34][1][21]

2.5. Evaluation Parameters

2.5.1 Physical Evaluation

- **Thickness:** Measured using vernier calipers
- **Weight Variation:** Performed as per USP guidelines
- **Hardness:** Determined using Monsanto hardness tester
- **Friability:** Tested using Roche Friabilator

2.5.2 Drug Content Analysis

Drug content was determined using HPLC method as per USP monograph. The analysis was performed using a C18 column with appropriate mobile phase composition.[19][14]

2.5.3 Acid Resistance Testing

Tablets were subjected to 0.1N HCl for 2 hours to evaluate acid resistance properties. The percentage of drug released and physical integrity were assessed.[35][4]

2.5.4 In Vitro Dissolution Studies

Dissolution studies were conducted using USP Apparatus II (paddle method) at 75 rpm and 37±0.5°C. The study was performed in 0.1N HCl for 2 hours followed by phosphate buffer pH 6.8 for subsequent hours.[9][3]

III. RESULTS AND DISCUSSION

3.1. Preformulation Studies

Table 3: Preformulation Parameters

Sr. No.	Formulation	Angle of Repose	Compressibility Index (%)	Hardness (Kg/cm²)	Disintegration Time (Seconds)
1	F1	36.54	8.3	4.6	85
2	F2	31.38	12.3	4.2	92
3	F3	33.64	10.9	4.3	69
4	F4	28.32	14.4	4.1	94

All formulations showed acceptable flow properties with Carr's index values below 15%, indicating good compressibility. The hardness values ranged from 4.1 to 4.6 kg/cm², meeting pharmaceutical standards.

3.2. Compatibility Studies

FTIR analysis confirmed the absence of significant drug-excipient interactions. The characteristic peaks of omeprazole remained unchanged in the presence of excipients, indicating chemical compatibility.

3.3. Post-Compression Evaluation

Table 4: Evaluation of Coated Tablets

Tablet Properties	Core	Seal coat	Seal coat	Seal coat
Coating Level	Core	2%	4%	8%
Thickness (mm ±SD)	4.14±0.098	4.35±0.087	4.98±0.056	5.1±0.032

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Weight (mg±SD)	200.14±0.25	204.07±0.11	208.21±0.16	216.38±1.09
Hardness (kg/cm²)	4.4	5.2	5.8	6.1
Friability (%)	0.38	0.23	0.19	0.12
Disintegration time (Sec)	97	202	280	370

The results demonstrate that increasing coating levels led to proportional increases in tablet thickness, weight, and hardness, while reducing friability. The disintegration time increased significantly with coating level, indicating effective barrier formation.

3.4. Acid Resistance Studies

Table 5: Acid Uptake Studies of Enteric Coated Tablets Using CAP.

Media	CAP1 (5% coating)	CAP2 (8% coating)	CAP3 (12% coating)
0.1M HCl	Disintegrates	4.6%	2.6%
Acetate Buffer pH4.5	Disintegrates	8.76%	5.75%

The 5% coating level provided insufficient acid protection, while 8% and 12% coatings demonstrated excellent acid resistance. The CAP3 formulation with 12% coating showed the best acid resistance with minimal drug uptake.

3.5. In Vitro Dissolution Studies

The release profile of the optimized formulation CAP3 was fitted to various kinetic models to determine the mechanism of drug release.

Table 6: Release Kinetics of Optimized Tablets

Formulation	Zero-order (R^2)	First-order (R^2)	Higuchi (R^2)	Korsmeyer-Peppas (R^2)	Slope (n)
CAP2	0.7146	0.4645	0.5126	0.4454	0.5365
CAP3	0.6419	0.4706	0.437	0.3272	0.5336

The dissolution studies revealed that formulation CAP3 followed diffusion-controlled release mechanism. The tablets showed negligible release in acidic medium (< 5% in 2 hours) and rapid release in phosphate buffer pH 6.8 (> 85% in 1 hour).

3.6. Stability Studies

Stability studies were conducted according to ICH guidelines at 40°C/75% RH for 6 months. The results showed significant reduction in assay and dissolution rate under prolonged storage at high temperatures and humidity. The possible reason could be that CAP slowly hydrolyzes under these conditions, increasing the free acid content. Relative humidity has a greater effect on the storage stability of CAP powder than temperature.

IV. CONCLUSION

The present study successfully developed and evaluated enteric-coated tablets of omeprazole using cellulose acetate phthalate as the enteric coating polymer. The optimized formulation (CAP3) with 12% coating weight gain demonstrated excellent pharmaceutical properties including appropriate hardness (6.1 kg/cm²), low friability (0.12%), and effective acid resistance.

The preformulation studies confirmed good flow and compressibility properties of omeprazole magnesium, facilitating tablet manufacturing. FTIR and DSC analyses verified drug-excipient compatibility and thermal stability. The dissolution studies revealed pH-dependent release characteristics typical of enteric-coated systems, with minimal release in acidic medium and rapid release in intestinal pH.

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The formulation followed diffusion-controlled drug release mechanism, suitable for the intended therapeutic application. Stability studies indicated that proper storage conditions are essential to maintain coating integrity and drug stability. This formulation approach provides a viable method for oral delivery of omeprazole with improved bioavailability and patient compliance.

The developed enteric-coated omeprazole tablets meet all pharmaceutical standards and demonstrate potential for scale-up to commercial production. Future studies should focus on bioequivalence testing and optimization of coating parameters for enhanced stability.

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