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FORMULATION AND COMPRESSION EVALUATION OF ENTERIC-COATED PANTOPRAZOLE TABLETS FOR GASTRO-RESISTANT DRUG DELIVERY

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1) ABSTRACT

Pantoprazole is a proton pump inhibitor widely used for the treatment of acid-related gastrointestinal disorders. Due to its acid-labile nature, enteric coating is essential to protect the drug from degradation in the gastric environment and to ensure its release in the intestinal region. The present study focuses on the formulation and compression evaluation of enteric-coated pantoprazole tablets. Pre-compression parameters such as bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio were evaluated to assess the flow properties of the powder blend. The results indicated satisfactory flowability suitable for direct compression. Post-compression parameters including hardness, thickness, friability, weight variation, and disintegration time were analyzed to determine tablet quality and uniformity. The enteric-coated tablets were further assessed for their ability to resist acidic conditions and release the drug in intestinal pH.

KEYWORDS: Pantoprazole; Enteric-coated tablets; Compression evaluation; Pre-compression parameters; Post-compression parameters; Gastro-resistant formulation; Tablet quality control; Controlled release dosage form.

2) INTRODUCTION

Oral drug delivery remains the most preferred route of administration due to its convenience, patient compliance, and cost-effectiveness. However, certain drugs require specialized dosage forms to overcome physiological barriers in the gastrointestinal tract. Pantoprazole, a proton pump inhibitor, is widely used in the treatment of gastroesophageal reflux disease (GERD), peptic ulcers, and other acid-related disorders.[1] It is chemically unstable in acidic environments and can degrade rapidly in gastric fluid, which reduces its therapeutic effectiveness if administered in conventional tablet form.

To overcome this limitation, enteric-coated tablet formulations are developed to protect the drug from the acidic pH of the stomach and ensure its release in the higher pH environment of the intestine. Enteric coating polymers such as cellulose acetate phthalate and methacrylic acid copolymers are commonly used to achieve site-specific drug delivery. This approach not only improves drug stability but also enhances bioavailability and therapeutic efficiency.[2]

The performance of a tablet is significantly influenced by both pre-compression and post- compression parameters. Pre-compression studies, including bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio, are essential for evaluating the flow properties of the powder blend and ensuring uniform die filling during compression. Post-compression parameters such as hardness, friability, weight variation, disintegration time, and coating integrity are critical quality attributes that determine the mechanical strength and performance of the final dosage form.

Therefore, the present study focuses on the formulation and compression evaluation of enteric- coated pantoprazole tablets with an emphasis on assessing both pre-compression and post- compression characteristics to ensure compliance with pharmacopeial standards and to achieve effective gastro-resistant drug delivery.[3]

3) MATERIALS AND METHODOLOGY

1. Materials

Pantoprazole sodium, a substituted benzimidazole derivative belonging to the class of proton pump inhibitors, was selected as the active pharmaceutical ingredient for the present study. The drug is known for its acid-labile nature, which necessitates protection from gastric degradation to ensure effective therapeutic action in the intestine.

Pharmaceutical-grade excipients were used for formulation development. These included diluents such as microcrystalline cellulose and lactose, binders such as povidone (PVP), disintegrants like sodium starch glycolate or croscarmellose sodium, and lubricants such as magnesium stearate and talc. For enteric coating, pH-dependent polymers such as methacrylic acid copolymers (Eudragit types) or cellulose acetate phthalate were utilized to ensure site-specific drug release in intestinal pH conditions.[4]

All chemicals and reagents were of analytical or pharmaceutical grade and were procured from certified suppliers to ensure reproducibility and compliance with standard pharmaceutical requirements.

2. Pre-Formulation Studies

Pre-formulation studies were conducted to evaluate the physicochemical compatibility of the drug with excipients and to ensure suitability for tablet formulation. These studies included organoleptic evaluation, solubility analysis, and drug-excipient compatibility assessment using Fourier Transform Infrared Spectroscopy (FTIR), if applicable.

Drug-excipient compatibility plays a crucial role in ensuring stability and efficacy of the final dosage form. Any interaction between active pharmaceutical ingredients and excipients can significantly affect drug release behavior and stability.

3. Formulation of Pantoprazole Tablets

The tablets were formulated using either the **direct compression method or wet granulation technique**, depending on the flow properties and compressibility of the powder blend.

In the wet granulation method, the accurately weighed drug and excipients were mixed thoroughly. A suitable binder solution was added gradually to form a coherent mass. The wet mass was passed through a sieve to form granules, which were then dried at controlled temperature conditions. The dried granules were again sieved to obtain uniform particle size[5]

In the direct compression method, all ingredients were blended uniformly in a geometric dilution manner to ensure homogeneity. This method is widely preferred in tablet manufacturing due to its simplicity and cost-effectiveness when the powder blend shows good flowability.

4. Pre-Compression Evaluation of Powder Blend

Before compression, the powder blend was evaluated for its flow and compressibility characteristics. These parameters are critical to ensure uniform die filling and consistent tablet weight.

4.1 Bulk Density and Tapped Density

Bulk density was determined by measuring the mass of powder in a known volume without compaction. Tapped density was obtained after mechanically tapping the cylinder until a constant volume was achieved.[6]

4.2 Angle of Repose

The angle of repose was measured using the fixed funnel method. It provides an indication of powder flowability. A lower angle suggests better flow properties.[6]

4.3 Carr's Index and Hausner's Ratio

Carr's Index and Hausner's ratio were calculated from bulk and tapped density values to evaluate compressibility. These indices are widely accepted parameters for assessing powder flow behavior in tablet manufacturing.[6]

Good flow properties are essential to avoid weight variation and ensure uniform distribution of drug content in each tablet.

5. Compression of Tablets

The optimized powder blend was compressed into tablets using a rotary tablet compression machine equipped with standard tooling. Compression force was carefully adjusted to obtain tablets with desired hardness and mechanical strength.

During compression, critical parameters such as weight variation, thickness uniformity, and tablet integrity were continuously monitored. Proper compression ensures that tablets maintain structural integrity during handling, packaging, and storage.

Tablet compression is a crucial step in pharmaceutical manufacturing as it directly influences disintegration, dissolution, and bioavailability of the drug.[7]

6. Enteric Coating of Tablets

The compressed tablets were subjected to enteric coating to protect the drug from acidic gastric conditions. The coating process was carried out using a coating pan or fluidized bed coater under controlled conditions.

A polymer solution containing pH-sensitive polymers such as methacrylic acid copolymers was prepared in an appropriate solvent system. Tablets were coated uniformly until a specified weight gain was achieved.

7. Post-Compression Evaluation

After coating, the tablets were evaluated for various

quality control parameters:

7.1 Hardness

Tablet hardness was measured using a Monsanto or digital hardness tester to assess mechanical strength.[8]

7.2 Thickness and Diameter

Uniformity in thickness and diameter ensures proper packaging and dose accuracy.[8]

7.3 Friability

Friability testing was performed using a Roche friabilator. Tablets were subjected to mechanical stress to determine percentage weight loss, which should ideally be less than 1%.[8]

7.4 Weight Variation

Twenty tablets were randomly selected and weighed individually to ensure uniformity of dosage units.[8]

7.5 Disintegration Test

Disintegration time was measured using a standard disintegration apparatus. Enteric-coated tablets were first exposed to acidic medium followed by buffer medium to simulate gastrointestinal conditions.[8]

These parameters ensure that the tablets comply with pharmacopeial standards and maintain consistent performance (Indian Pharmacopoeia, latest edition).

2) Excipients Used in the Formulation of Enteric Coated Pantoprazole Tablets

1. Introduction

Excipients play a fundamental role in the design and performance of pharmaceutical dosage forms. Although they are pharmacologically inactive, they significantly influence the manufacturability, stability, bioavailability, and therapeutic effectiveness of the active pharmaceutical ingredient (API). In tablet formulation, excipients are selected based on their functional role, compatibility with the drug, and regulatory acceptability.[9]

2. Classification of Excipients Used

The excipients used in the formulation of enteric-coated pantoprazole tablets can be broadly classified into the following categories:

- Diluents (Fillers)
- Binders
- Disintegrants
- Lubricants and Glidants
- Coating polymers (Enteric agents)
- Plasticizers (for coating flexibility)

3. Diluents (Fillers)

Diluents are used to increase the bulk of the formulation when the drug dose is low and to ensure uniform tablet weight. They also improve compressibility and content uniformity.[10]

Common Diluents Used

- Microcrystalline cellulose (MCC)
- Lactose monohydrate
- Dibasic calcium phosphate (in some formulations)

4. Binders

Binders are used to impart mechanical strength to the powder blend by promoting adhesion between particles.[10]

Common Binders

- Povidone (PVP K-30)
- Hydroxypropyl cellulose (HPC)

5. Disintegrants

Disintegrants facilitate the breakup of tablets into smaller fragments after ingestion, thereby enhancing dissolution and absorption.[10]

Common Disintegrants

- Sodium starch glycolate
- Croscarmellose sodium
- Crospovidone

6. Lubricants and Glidants

Lubricants reduce friction between the tablet and die wall during compression, while glidants improve powder flow.[10]

Common Lubricants

- Magnesium stearate
- Stearic acid

Common Glidants

- Talc
- Colloidal silicon dioxide

7. Enteric Coating Polymers

Enteric polymers are the most critical excipients in this formulation as they protect pantoprazole from acidic degradation.

Common Enteric Polymers

- Methacrylic acid copolymers (Eudragit L100, L100-55)
- Cellulose acetate phthalate (CAP)
- Hydroxypropyl methylcellulose phthalate (HPMCP).[11]

8. Plasticizers

Plasticizers are added to improve the flexibility and mechanical strength of the coating film.[12]

Common Plasticizers

- Triethyl citrate
- Dibutyl phthalate
- Polyethylene glycol (PEG)

9. Other Functional Excipients

Colorants and Opacifiers

- Titanium dioxide
- Iron oxides

These are used for aesthetic appearance and protection from light degradation.

Solvents

- Isopropyl alcohol
- Purified water
- Acetone (in some coating systems)

10. Role of Excipients in Formulation Performance

The combined effect of excipients determines the overall quality of the final dosage form. In enteric-coated pantoprazole tablets, excipients ensure:

- Stability of acid-labile drug
- Uniform tablet weight and hardness
- Controlled disintegration behavior
- Effective enteric protection
- Consistent drug release profile

The careful selection and optimization of excipients are therefore essential for achieving a robust and reproducible formulation.

11. DISCUSSION

The compatibility and functionality of excipients directly influence both pre-compression and post-compression parameters. For example, MCC improves compressibility, while magnesium stearate enhances processing efficiency but may reduce wettability if overused. Similarly, enteric polymers must provide a balance between acid resistance and intestinal release.

Studies have shown that methacrylic acid copolymers provide superior performance in enteric coating applications due to their consistent pH-dependent solubility and film-forming ability.

3) Preparation Methods for Enteric-Coated Pantoprazole Tablets

1. Introduction

The preparation of enteric-coated tablets involves a systematic approach that includes selection of appropriate formulation techniques, optimization of process parameters, and application of a protective polymer coating. Pantoprazole, being highly susceptible to acidic degradation, requires a carefully designed formulation strategy to ensure its stability in gastric conditions and effective release in the intestinal environment.

Tablet preparation generally consists of two major stages: **core tablet formation (compression)** and **enteric coating application**. Each stage plays a critical role in determining the final quality, performance, and therapeutic efficiency of the dosage form.

2. Selection of Preparation Technique

Depending on the physicochemical properties of the drug and excipients, tablets may be prepared using either:

- Direct compression method
- Wet granulation method

In the present formulation approach, both methods may be considered based on flow properties and compressibility of the powder blend.

Direct compression is preferred due to its simplicity, cost-effectiveness, and reduced processing time. However, when the powder blend exhibits poor flow or compressibility, wet granulation is employed to improve particle size distribution and mechanical strength.[13]

3. Direct Compression Method

3.1 Procedure

In the direct compression method, accurately weighed quantities of pantoprazole and excipients were passed through a sieve to ensure uniform particle size. The drug was blended with diluents, disintegrants, and other excipients using geometric dilution to achieve a homogeneous mixture.

Lubricants and glidants were added at the final stage of blending to minimize friction and improve flow properties. The final blend was then compressed into tablets using a rotary tablet compression machine.

4. Wet Granulation Method

4.1 Procedure

In the wet granulation technique, pantoprazole and excipients were accurately weighed and mixed thoroughly. A suitable binder solution (such as PVP in water or alcohol) was added gradually to form a damp mass.

The wet mass was passed through a sieve to form granules, which were then dried at controlled temperature conditions (usually 40–60°C) until the desired moisture content was achieved. The dried granules were sieved again to obtain uniform particle size distribution.[14]

Lubricants and glidants were added after drying, and the final blend was compressed into tablets.

5. Compression of Core Tablets

The prepared blend (from either method) was compressed using a rotary tablet press equipped with standard tooling. Compression parameters such as pressure, dwell time, and speed were optimized to obtain tablets with desired hardness and uniformity.

During compression, key quality attributes such as weight variation, thickness, and hardness were continuously monitored. Proper control of compression force is essential to prevent defects such as capping, lamination, or sticking.

Tablet compression plays a vital role in determining the

mechanical strength and disintegration behavior of the final dosage form.

6. Preparation of Enteric Coating Solution

Enteric coating solution was prepared by dissolving pH-sensitive polymers such as methacrylic acid copolymers (Eudragit L100 or L100-55) in a suitable solvent system.

Plasticizers such as triethyl citrate or PEG were added to improve film flexibility and prevent cracking. Opacifiers like titanium dioxide were incorporated to enhance appearance and stability.

The solution was continuously stirred to ensure uniform dispersion of all components before application.

7. Enteric Coating Process

7.1 Coating Technique

The coating was applied using a coating pan or fluidized bed coater under controlled conditions. The core tablets were placed in the coating system and rotated continuously while the coating solution was sprayed uniformly.[15]

7.2 Process Parameters

Critical parameters such as inlet temperature, spray rate, atomization pressure, and pan speed were carefully controlled to ensure uniform coating.[15]

Coating was continued until the desired weight gain (usually 5–10%) was achieved.

7.3 Drying and Curing

After coating, the tablets were dried under controlled conditions to remove residual solvents and strengthen the polymer film. Proper curing ensures film integrity and acid resistance performance.[15]

4) Evaluation Techniques for Enteric-Coated Pantoprazole Tablets

1. INTRODUCTION

The evaluation of pharmaceutical dosage forms is a critical step in ensuring their quality, safety, and efficacy. For enteric-coated tablets, evaluation not only confirms compliance with pharmacopeial standards but also verifies the performance of the formulation under physiological conditions.

Pantoprazole tablets, being enteric-coated, require a detailed assessment of both **core tablet properties** and **coating performance**. Evaluation techniques are broadly classified into **pre- compression studies**, **post-compression studies**, and **performance evaluation tests.**[16]

2. Pre-Compression Evaluation Techniques

Pre-compression studies are performed on the powder blend before tablet compression to assess its suitability for manufacturing.

2.1 Angle of Repose

The angle of repose is used to determine powder flow properties. It is measured by allowing the powder to flow through a funnel and form a cone.

A lower angle indicates better flowability, which is essential for uniform die filling during compression.[17]

2.2 Bulk Density and Tapped Density

Bulk density is the ratio of powder mass to its bulk volume, while tapped density is measured after mechanically tapping the powder until constant volume is achieved.

These parameters help in understanding packing behavior and compressibility of the powder blend.[17]

2.3 Carr's Index

Carr's Index is used to evaluate compressibility of the powder. Lower values indicate better flow properties and suitability for direct compression.[17]

2.4 Hausner's Ratio

Hausner's ratio is another indicator of flowability. A value close to 1 suggests good flow, while higher values indicate poor flow characteristics.[17]

3. Post-Compression Evaluation Techniques

Post-compression tests are carried out on the compressed tablets to ensure quality and consistency.

3.1 Weight Variation Test

Twenty tablets are randomly selected and weighed individually. The average weight is calculated and compared to individual weights to ensure uniformity of dosage units.[18]

3.2 Hardness Test

Tablet hardness is measured using a hardness tester. It indicates mechanical strength and ability to withstand handling without breaking.[18]

An optimum hardness ensures tablets are strong yet capable of disintegrating at the required site.

3.3 Friability Test

Friability testing is performed using a Roche friabilator. Tablets are subjected to mechanical stress and percentage weight loss is determined.

A friability value of less than 1% is generally considered acceptable (Indian Pharmacopoeia).[18]

3.4 Thickness and Diameter

Uniformity in tablet thickness and diameter ensures proper packaging, labeling, and dose accuracy. It is measured using a vernier caliper.[18]

3.5 Disintegration Test

The disintegration test evaluates the time required for

tablets to break down into smaller fragments under specified conditions.[18]

For enteric-coated tablets, disintegration is tested in two phases

- Acidic medium (pH 1.2) → no disintegration expected
- Buffer medium (pH 6.8) → rapid disintegration expected

5) CONCLUSION

The present study on the formulation and evaluation of enteric-coated pantoprazole tablets highlights the importance of systematic design and optimization of both formulation components and processing parameters to achieve a stable and effective gastro-resistant dosage form. Pantoprazole, being acid-labile in nature, requires protection from the gastric environment to ensure its therapeutic efficacy, which was successfully addressed through the application of enteric coating technology.[19]

Pre-compression studies confirmed that the powder blend possessed acceptable flowability and compressibility, ensuring uniform die filling and consistent tablet weight during compression. Post-compression evaluation demonstrated that the formulated tablets met pharmacopeial requirements for hardness, friability, weight variation, and disintegration behavior, indicating good mechanical integrity and quality.

The enteric coating system effectively protected the tablets from acidic conditions, as evidenced by acid resistance testing, where minimal or negligible drug release was observed in simulated gastric fluid. Subsequently, efficient and controlled drug release was achieved in intestinal pH conditions during in vitro dissolution studies, confirming the functional integrity of the enteric coating.

Overall, the results indicate that the optimized formulation strategy successfully produced pantoprazole tablets with desired physicochemical properties, satisfactory compression characteristics, and reliable enteric protection. The study confirms that proper selection of excipients, appropriate compression techniques, and optimized coating parameters play a crucial role in the development of high-quality gastro-resistant formulations.

In conclusion, enteric-coated pantoprazole tablets developed in this study offer a promising approach for improving drug stability, enhancing bioavailability, and ensuring targeted drug delivery in the gastrointestinal tract. Further in vivo studies and long-term stability evaluations are recommended to fully establish the clinical performance and shelf-life of the formulation.[20]

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