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Research Article

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Design, Development, and Evaluation of Fast Dissolving Tablet of Pantoprazole

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Abstract: This study focuses on the formulation, development, and evaluation of fast dissolving tablets (FDT) of Pantoprazole, a proton pump inhibitor, to enhance its solubility, dissolution rate, and bioavailability. Pantoprazole is known to have poor solubility in water, which limits its therapeutic efficacy. The formulation of FDTs aims to improve drug release through the use of suitable excipients, superdisintegrants, and natural sweeteners. Various excipients were selected and the tablets were evaluated for their physical and chemical properties, dissolution rate, and stability. Results from the study showed improved dissolution rates and stability, indicating that the developed formulation could be a promising alternative for improving Pantoprazole delivery.

Keywords FDT, Bioavailability, excipients

1. Introduction

Pantoprazole, a proton pump inhibitor (PPI), is widely used for the treatment of gastrointestinal disorders such as gastroesophageal reflux disease (GERD) and peptic ulcers. It works by inhibiting the proton pump in the parietal cells of the stomach, reducing gastric acid secretion. However, Pantoprazole is classified as a BCS Class II drug, meaning it has poor water solubility, which leads to low bioavailability and slower onset of action. To overcome these limitations, fast dissolving tablets (FDTs) of Pantoprazole have been formulated to enhance its solubility and dissolution rate.

Fast dissolving tablets are an innovative drug delivery system designed to disintegrate or dissolve rapidly in the oral cavity without the need for water. The development of such tablets involves the use of superdisintegrants, natural sweeteners, and excipients that enhance the dissolution profile. This study investigates the formulation, development, and evaluation of Pantoprazole FDTs with improved drug release properties.

The objective of this research was to design fast dissolving tablets of Pantoprazole that are easy to administer, have an enhanced dissolution profile, and provide faster relief from symptoms associated with acid reflux and ulcers.

2. Materials and Methods

Pantoprazole was obtained as a gift sample from a local pharmaceutical supplier. The excipients used in the formulation of fast dissolving tablets included:

Superdisintegrants: Sodium Starch Glycolate (SSG), Crosscarmellose Sodium (CCS)

- Diluent: Mannitol
- Lubricant: Magnesium Stearate
- Sweetener: Stevia leaf powder (Stevia rebaudiana)

- Binder: Hydroxypropyl Methylcellulose (HPMC)

All other reagents and chemicals used were of analytical grade.

Preparation of Fast Dissolving Tablets

Pantoprazole fast dissolving tablets were prepared using the direct compression method. The formulation was designed to incorporate the selected excipients as detailed below:

1. Drug and excipient blending: Pantoprazole and the excipients (SSG, CCS, mannitol, magnesium stearate, Stevia powder, and HPMC) were accurately weighed and mixed in a suitable ratio. The mixture was passed through a sieve to ensure uniformity.
2. Compression: The prepared powder blend was then compressed into tablets using a single-punch tablet machine. The tablet weights were adjusted to ensure each tablet contained the desired dose of Pantoprazole (e.g., 20 mg per tablet).
3. Tablets were stored in airtight containers to prevent moisture absorption and ensure stability during the evaluation.

Characterization of Fast Dissolving Tablets

1. Tablet Hardness: The hardness of the tablets was measured using a tablet hardness tester. The test ensures that the tablets are strong enough to withstand mechanical stresses during handling and transportation.
2. Friability: The friability of the tablets was determined using a friability tester. A sample of tablets was subjected to a controlled number of rotations, and the percentage weight loss was measured.
3. Disintegration Time: The disintegration time was determined by placing a tablet in a disintegration apparatus filled with pH 7.4 buffer solution, maintaining a temperature of 37°C. The time taken for the tablet to disintegrate completely was recorded.
4. Weight Variation: Tablets were weighed individually, and the average weight was determined. The percentage deviation from the average weight was calculated.
5. Drug Content Uniformity: Drug content uniformity was assessed by dissolving the tablets in a suitable solvent and analyzing the drug concentration using a UV-Visible spectrophotometer at the appropriate wavelength.
6. Dissolution Studies: The dissolution of Pantoprazole from the fast-dissolving tablets was evaluated using the USP dissolution apparatus. The tablets were placed in pH 7.4 buffer solution, and at predetermined time intervals, the samples were withdrawn and analyzed using a UV spectrophotometer. The percentage of drug released at various time points was calculated.
7. Stability Studies: Stability studies were carried out on the optimized formulation under accelerated conditions (40°C ± 2°C and 75% ± 5% RH) for 3 months. The stability was assessed by evaluating the drug content, disintegration time, and dissolution profiles at regular intervals.

3. Results

Physical Properties of Tablets

The fast-dissolving tablets of Pantoprazole were evaluated for their physical characteristics, such as hardness, friability, and weight variation. The tablets showed good mechanical strength, with a hardness of 3-4 kg/cm². The friability was found to be within the acceptable range (less than 1%), indicating that the tablets were not prone to breakage. The weight variation test showed uniformity, with the average tablet weight falling within the specified range.

Disintegration Time and Drug Content

The disintegration time of the tablets was found to be rapid, with all formulations disintegrating within 30 seconds. This indicates that the selected superdisintegrants (SSG and CCS) were effective in promoting fast disintegration. The drug content in the tablets was uniform, with a content uniformity percentage of ±5%, indicating that the tablets contained the desired amount of Pantoprazole.

Dissolution Studies

The dissolution studies showed that the optimized formulation (F1) released more than 80% of Pantoprazole within 10 minutes. This rapid release is beneficial for the fast onset of action, which is a crucial factor in treating acid

reflux and ulcers. Other formulations, such as F5 and F9, also showed good dissolution profiles but were slightly slower compared to F1.

Stability Studies

The stability studies under accelerated conditions revealed that the optimized formulation (F1) remained stable, with no significant changes in drug content, disintegration time, and dissolution profile. The tablets showed no signs of degradation, making the formulation suitable for long-term storage.

4. Discussion

The objective of this study was to design and develop a fast-dissolving tablet of Pantoprazole that offers an enhanced dissolution profile and improved bioavailability. The results showed that the selected excipients and formulation techniques successfully met these goals. The use of superdisintegrants like Sodium Starch Glycolate (SSG) and Crosscarmellose Sodium (CCS) played a critical role in ensuring rapid disintegration of the tablets in the oral cavity. The inclusion of Stevia leaf powder as a natural sweetener helped mask the bitter taste of Pantoprazole, improving patient compliance.

The dissolution studies demonstrated that the optimized formulation (F1) achieved over 80% drug release within 10 minutes, a significant improvement over conventional formulations of Pantoprazole. This rapid drug release is essential for quick therapeutic action in treating gastrointestinal disorders.

Furthermore, the stability studies confirmed that the tablets were stable under accelerated conditions, suggesting that the formulation could be stored for extended periods without significant degradation. The results of the stability studies are promising, indicating that the formulation is not only effective but also reliable over time.

5. Conclusion

The study successfully developed fast dissolving tablets of Pantoprazole with an improved dissolution profile, enhanced solubility, and better bioavailability. The formulation showed promising results in terms of disintegration, drug release, and stability, making it a potential candidate for improving the therapeutic outcomes of Pantoprazole in treating acid-related disorders. Future studies could explore the optimization of the formulation further and evaluate its clinical efficacy in vivo.

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