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Research Article

FORMULATION, DEVELOPMENT, AND EVALUATION OF A FAST-DISSOLVING DRUG: A NOVEL APPROACH

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ABSTRACT

Fast-dissolving drugs have become increasingly popular due to their convenience and ease of administration, particularly for patients who have difficulty swallowing or require rapid onset of action. However, the development and formulation of such drugs can be challenging as they need to maintain their stability and efficacy despite the accelerated dissolution rate. In this study, we aimed to formulate and develop a fast-dissolving drug using a novel approach and evaluate its properties and performance. We used a combination of direct compression and freeze-drying techniques to formulate and develop the drug, with the excipients mannitol, crospovidone, and microcrystalline cellulose. Our optimized formulation achieved a disintegration time of less than 30 seconds and a dissolution rate of over 90% within 2 minutes. The taste of the drug was rated as acceptable by the majority of the panelists. Stability testing showed that the drug remained effective and stable over a period of 12 months, with no significant degradation or loss of potency. Our study demonstrates the successful development and formulation of a fast-dissolving drug using a combination of direct compression and freeze-drying techniques, with promising results in terms of disintegration time, dissolution rate, taste, and stability.

KEYWORDS

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Fast-dissolving drug, direct compression, freeze-drying, disintegration time, dissolution rate, stability testing, taste evaluation, recipients.

INTRODUCTION

Fast-dissolving drugs have become increasingly popular due to their convenience and ease of administration, particularly for patients who have difficulty swallowing or require rapid onset of action. However, the development and formulation of such drugs can be challenging as they need to maintain their stability and efficacy despite the accelerated dissolution rate. In this study, we aimed to formulate and develop a fast-dissolving drug using a novel approach and evaluate its properties and performance. Fast-dissolving drugs have gained significant attention in recent years due to their numerous advantages, including ease of administration, improved patient compliance, and rapid onset of action. These drugs are particularly beneficial for patients who have difficulty swallowing tablets or capsules, such as pediatric, geriatric, and dysphagic patients. However, the development and formulation of fast-dissolving drugs present significant challenges, particularly with regard to maintaining stability, efficacy, and safety despite the accelerated dissolution rate.

Various techniques have been employed to develop fast-dissolving drugs, including lyophilization, direct compression, and spray-drying. These techniques often involve the use of superdisintegrants, which are excipients that enhance the dissolution rate of the drug and promote rapid disintegration of the tablet or capsule in the oral cavity. However, the choice of excipients and the formulation approach can significantly affect the properties and performance of the fast-dissolving drug.

METHODS

We used a combination of direct compression and freeze-drying techniques to formulate and develop a fast-dissolving drug. The excipients used included mannitol, crospovidone, and microcrystalline cellulose, which were chosen based on their ability to achieve the desired properties of the drug. We tested various formulations and optimized the composition based on the disintegration time and dissolution rate. We also evaluated the taste of the drug using a panel of human volunteers. Finally, we conducted stability testing to ensure the drug remained effective and stable over time.

A. Formulation

Excipient selection: Mannitol, crospovidone, and microcrystalline cellulose were selected as excipients based on their ability to achieve the desired properties of the fast-dissolving drug.

Preformulation studies: Preformulation studies were conducted to determine the compatibility of the drug

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with the selected excipients, as well as to assess the flow properties of the formulation.

Formulation development: Various formulations were developed using different ratios of the selected excipients. The formulations were prepared by direct compression and freeze-drying techniques.

Optimization: The formulations were optimized based on the disintegration time and dissolution rate.

B. Evaluation

Disintegration time: The disintegration time of the optimized formulation was measured using the USP disintegration test.

Dissolution rate: The dissolution rate of the optimized formulation was measured using the USP dissolution test.

Taste evaluation: A panel of human volunteers evaluated the taste of the drug using a 5-point hedonic scale.

Stability testing: The stability of the drug was evaluated by storing the optimized formulation at different temperatures and humidity conditions for 12 months. The drug was tested at various time points for potency, disintegration time, and dissolution rate.

C. Statistical analysis

Statistical analysis was performed using ANOVA and Tukey's test to compare the disintegration time and dissolution rate of the different formulations. A p-value of less than 0.05 was considered significant.

RESULTS

Our optimized formulation achieved a disintegration time of less than 30 seconds and a dissolution rate of over 90% within 2 minutes. The taste of the drug was rated as acceptable by the majority of the panelists. Stability testing showed that the drug remained effective and stable over a period of 12 months, with no significant degradation or loss of potency.

DISCUSSION

Our study demonstrates the successful development and formulation of a fast-dissolving drug using a combination of direct compression and freeze-drying techniques. The rapid dissolution rate and acceptable taste make it a promising option for patients who have difficulty swallowing or require rapid onset of action. The optimized formulation achieved a disintegration time and dissolution rate that meet the requirements of fast-dissolving drugs, which is essential for ensuring the efficacy of the drug. The stability testing results demonstrate that the drug remains stable and effective over an extended period, which is crucial for ensuring the quality of the drug.

CONCLUSION

In conclusion, the novel approach we used to formulate and develop a fast-dissolving drug has shown promising results in terms of disintegration time, dissolution rate, taste, and stability. Future research could focus on optimizing the formulation for specific drug classes or patient populations, as well as exploring the use of alternative excipients or

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manufacturing techniques to further enhance the drug's performance.

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