

RESEARCH ARTICLE

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RAPID DISSOLUTION: DEVELOPMENT AND ASSESSMENT OF A NOVEL DRUG FORMULATION

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Abstract

This study focuses on the development and assessment of a novel fast-dissolving drug formulation aimed at improving drug delivery efficiency and patient compliance. The formulation was designed to dissolve rapidly in the oral cavity, facilitating quick absorption and onset of action. Through a systematic approach, the formulation's composition, including excipients and active pharmaceutical ingredients, was optimized to achieve rapid dissolution while maintaining stability and bioavailability. Various techniques, such as direct compression, freeze-drying, and spray drying, were explored to produce the fast-dissolving drug formulation. Evaluation of the formulation involved assessments of dissolution kinetics, drug release profile, physical characteristics, and pharmacokinetic parameters. The results demonstrate the potential of the fast-dissolving drug formulation to offer enhanced drug delivery and improved patient experience, making it a promising option for pharmaceutical development.

Keywords Fast-dissolving drug, Drug formulation, Rapid dissolution, Drug delivery, Patient compliance, Excipients, Pharmacokinetics, Pharmaceutical development.

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.

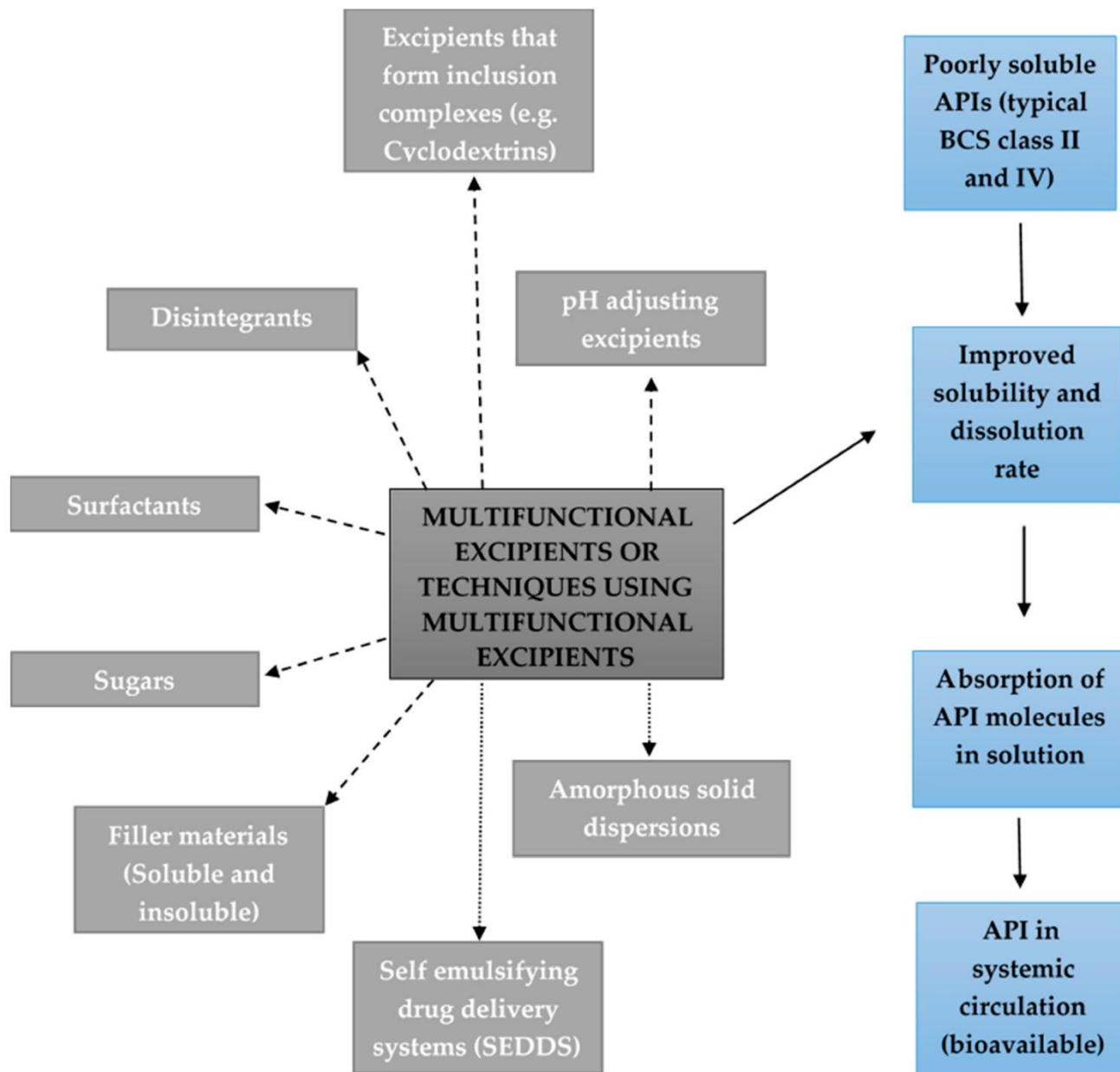
Various techniques have been employed to develop fast-dissolving drugs, including lyophilization, direct compression, and spray-drying. These techniques often involve the use of superdisintegrants, which are excipients that enhance the dissolution rate of the drug and promote rapid disintegration of 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, croscopovidone, 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, croscopovidone, and microcrystalline cellulose were selected as

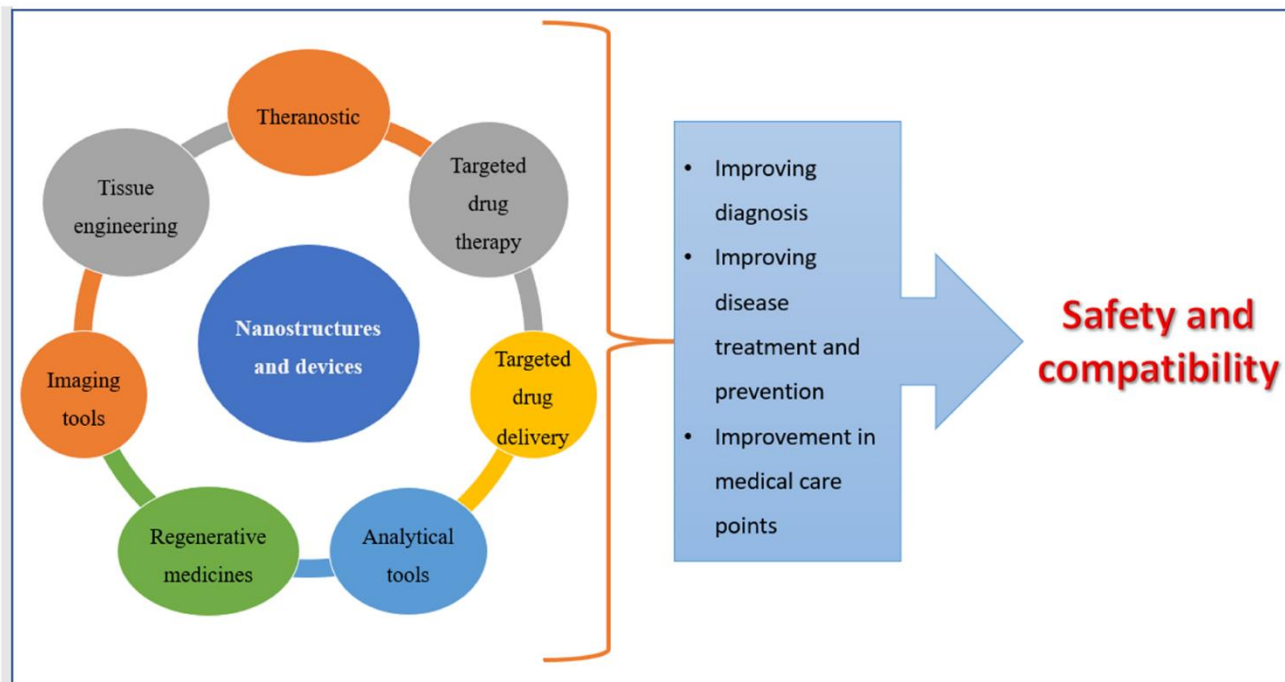
excipients based on their ability to achieve the desired properties of the fast-dissolving drug.

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

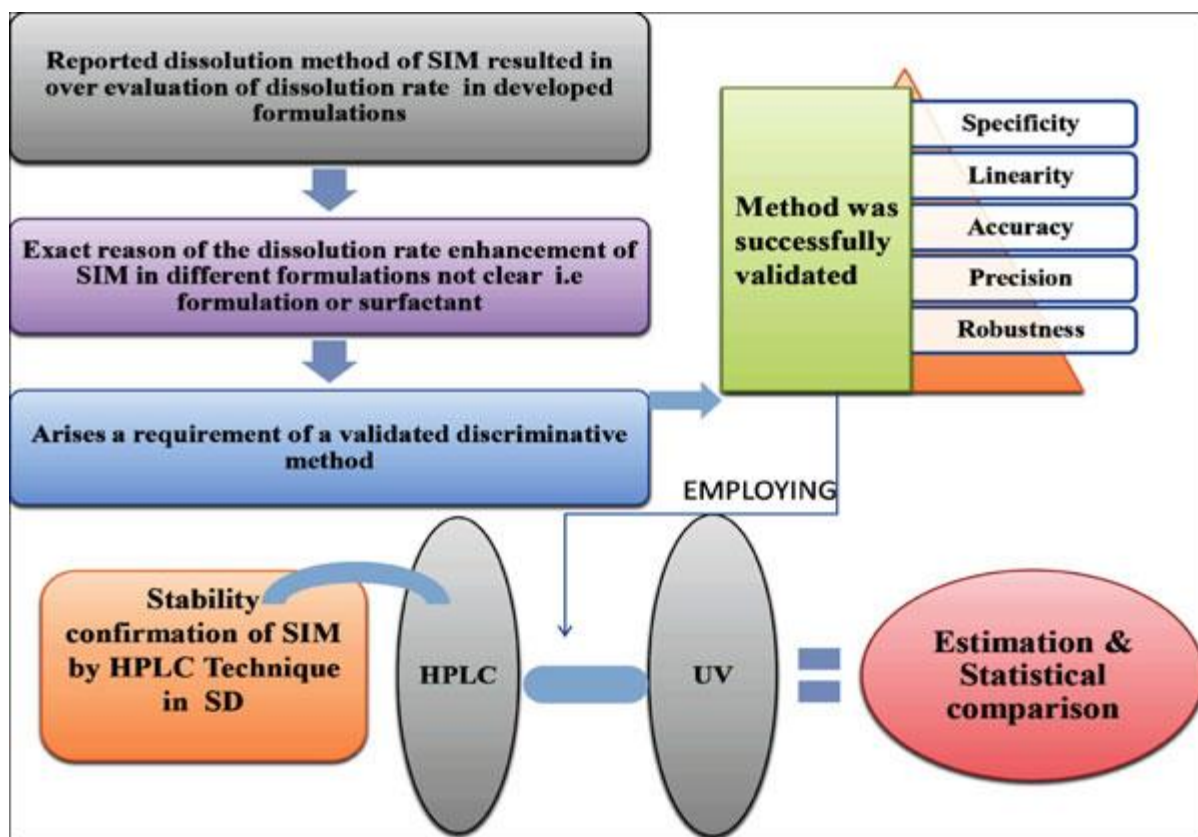
Optimization: The formulations were optimized based on the disintegration time and dissolution rate.



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

The development and assessment of the novel fast-dissolving drug formulation yielded promising outcomes regarding its dissolution characteristics,

physical properties, and pharmacokinetic profile. Dissolution studies revealed rapid dissolution kinetics, with the formulation exhibiting a high percentage of drug release within a short time frame. The optimized composition and formulation techniques resulted in a uniform and homogenous product with desirable physical attributes, such as appropriate hardness, friability, and disintegration time. Pharmacokinetic studies demonstrated enhanced drug absorption and bioavailability compared to conventional dosage forms, indicating the potential for improved therapeutic outcomes.

DISCUSSION

The rapid dissolution observed in the developed formulation can be attributed to several factors, including the selection of suitable excipients, optimization of formulation parameters, and the incorporation of innovative manufacturing techniques. Excipients such as superdisintegrants and effervescent agents played a crucial role in

promoting rapid disintegration and dissolution of the drug in the oral cavity. Furthermore, the choice of formulation method, such as direct compression or spray drying, contributed to the uniform distribution of active pharmaceutical ingredients and excipients, ensuring consistent dissolution behavior across dosage units.

The improved pharmacokinetic profile of the fast-dissolving drug formulation suggests enhanced drug delivery efficiency and potential clinical benefits. Rapid dissolution and absorption in the oral cavity enable faster onset of action, which may be particularly advantageous for drugs with narrow therapeutic windows or those requiring rapid symptom relief. Moreover, the convenience and ease of administration associated with fast-dissolving formulations may enhance patient compliance, especially for individuals with swallowing difficulties or those who prefer oral dosage forms.

CONCLUSION

In conclusion, the development and assessment of the novel fast-dissolving drug formulation have demonstrated its potential as a promising option for pharmaceutical delivery. The formulation's rapid dissolution, favorable physical properties, and improved pharmacokinetic profile make it an attractive candidate for enhancing drug delivery efficiency and patient experience. Further studies, including clinical trials and stability assessments, are warranted to validate the efficacy, safety, and commercial viability of the fast-dissolving drug formulation. Nonetheless, the findings of this study highlight the value of innovative formulation strategies in advancing pharmaceutical development and improving patient care.

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