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Research Article

DEVELOPMENT OF FAST DISINTEGRATING FILMS AND TABLETS OF VALSARTAN: FORMULATION, CHARACTERIZATION, AND EVALUATION

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ABSTRACT

The development of fast disintegrating films and tablets for the delivery of Valsartan, an angiotensin II receptor antagonist used in the treatment of hypertension, aims to improve patient compliance, especially for those with difficulty swallowing conventional tablets. This study focuses on the formulation, characterization, and evaluation of fast disintegrating films and tablets of Valsartan using various excipients such as superdisintegrants, polymers, and other film-forming agents. The fast disintegrating films were prepared using solvent casting techniques, while tablets were formulated through direct compression. The formulations were evaluated for disintegration time, drug release profile, mechanical strength, and stability under various conditions. The Valsartan-loaded films and tablets exhibited rapid disintegration, with improved drug release kinetics compared to traditional tablet formulations. Additionally, the film dosage form demonstrated excellent patient acceptability due to its ease of administration. In vitro drug release studies showed that both the films and tablets achieved complete release within 10–15 minutes, ensuring fast onset of action. Stability studies indicated that the formulations remained stable under accelerated conditions, ensuring the feasibility of these fast-dissolving forms for clinical application. This research highlights the potential of fast disintegrating films and tablets

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as an effective alternative to conventional Valsartan formulations, offering benefits in terms of ease of administration, improved bioavailability, and enhanced patient compliance.

KEYWORDS

Valsartan, Fast disintegrating films, Fast disintegrating tablets, Formulation development, Drug delivery systems, Superdisintegrants.

INTRODUCTION

Valsartan, a widely prescribed angiotensin II receptor antagonist, plays a critical role in the management of hypertension, heart failure, and post-myocardial infarction. Despite its effectiveness, the conventional tablet formulations of Valsartan may pose challenges for certain patient populations, particularly elderly patients or those with swallowing difficulties. These difficulties can lead to poor patient compliance and hinder the therapeutic outcomes of the drug. To address this issue, the development of fast disintegrating films and tablets has emerged as a promising solution. Fast disintegrating dosage forms offer significant advantages, including ease of administration, rapid onset of action, and improved patient compliance, especially in individuals with dysphagia or cognitive impairments.

Fast disintegrating films and tablets are designed to disintegrate rapidly in the mouth, enabling quicker drug absorption and enhanced bioavailability. The formulation of such dosage forms requires a careful selection of excipients, such as superdisintegrants, polymers, and other film-forming agents, to ensure that the final product meets the desired characteristics of rapid disintegration, high drug loading, and stability. Moreover, the preparation of fast disintegrating films through solvent casting techniques and fast disintegrating tablets via direct compression can be optimized to provide effective delivery of Valsartan with improved therapeutic outcomes.

This study focuses on the development, characterization, and evaluation of fast disintegrating films and tablets of Valsartan. The aim is to explore how the formulation of these

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dosage forms can enhance the therapeutic efficacy of Valsartan, ensure ease of administration, and improve overall patient satisfaction. The work includes detailed formulations, evaluation methods for drug release, mechanical properties, disintegration time, and stability studies, providing a comprehensive analysis of the potential benefits of fast disintegrating Valsartan films and tablets. Ultimately, the study seeks to demonstrate that fast disintegrating dosage forms can serve as a viable alternative to conventional tablet forms, offering a patient-friendly approach to managing cardiovascular diseases effectively.

METHOD

Formulation of Fast Disintegrating Films:

Fast disintegrating films of Valsartan were formulated using a solvent casting technique. Various film-forming polymers, such as hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), and chitosan, were selected for their ability to provide rapid disintegration upon contact with saliva. Superdisintegrants, including sodium starch glycolate and croscarmellose sodium, were incorporated to enhance the disintegration rate of the films. The films were prepared by dissolving the selected polymers and superdisintegrants in an appropriate solvent mixture (e.g., ethanol and water), followed by the addition of Valsartan. The solution was then cast onto a flat glass surface and dried under controlled conditions at room temperature to form thin, flexible films. The films were cut into uniform sizes for further evaluation.

Formulation of Fast Disintegrating Tablets:

Valsartan fast disintegrating tablets were formulated using the direct compression method. The active pharmaceutical ingredient, Valsartan, was mixed with excipients such as microcrystalline cellulose (MCC) as a diluent, sodium starch glycolate and croscarmellose sodium as superdisintegrants, and magnesium stearate as a lubricant. The powder blend was prepared by dry mixing the ingredients in a geometrical fashion to ensure uniform distribution of Valsartan and excipients. The prepared blend was then directly compressed into tablets using a rotary tablet machine. Different compression forces and tablet weights were tested to determine the optimal formulation for fast disintegration and adequate mechanical strength.

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Characterization of Fast Disintegrating Films and Tablets:

The prepared fast disintegrating films and tablets were subjected to several characterization tests to evaluate their physical and functional properties.

Thickness and Uniformity: The thickness of the films and tablets was measured using a digital micrometer, ensuring uniformity in size and thickness. For films, the average thickness of each sample was calculated from several points, and for tablets, uniformity of weight was assessed according to pharmacopoeial standards.

Disintegration Time: The disintegration time of both films and tablets was evaluated using a disintegration tester. For films, disintegration was assessed by placing them in a small volume of simulated saliva (pH 6.8) at 37°C. The time taken for the films to completely disintegrate was recorded. For tablets, the disintegration was tested using a similar method in a basket-rack assembly, monitoring the time required for complete disintegration.

Drug Content and Uniformity: The drug content in the films and tablets was analyzed by dissolving the films and tablets in an appropriate solvent, followed by UV spectrophotometric analysis at the maximum absorption wavelength of Valsartan. The uniformity of the drug distribution in the dosage forms was also checked by evaluating the variation in drug content across different samples.

In Vitro Drug Release Studies: The drug release profiles of the films and tablets were assessed using the USP dissolution apparatus. The films were placed in a dissolution medium (simulated gastric fluid, pH 1.2) and the tablets were placed in the dissolution apparatus at 37°C. The amount of drug released at different time intervals was determined by collecting samples of the dissolution medium and analyzing them spectrophotometrically.

Mechanical Properties of Films: The mechanical strength of the films was assessed by measuring their tensile strength, elongation, and modulus of elasticity using a texture analyzer. These properties are important to ensure the films maintain their structural integrity during handling and administration.

Stability Studies:

To evaluate the stability of the fast disintegrating films and tablets, accelerated stability testing was

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performed according to ICH guidelines. The formulations were stored at 40°C and 75% relative humidity for a specified period, and then evaluated for any changes in physical appearance, drug content, disintegration time, and dissolution profile. The formulations were also examined for any signs of degradation or color changes during the stability study.

Statistical Analysis:

All data obtained from the characterization tests, including disintegration time, drug release, mechanical properties, and drug content uniformity, were analyzed using statistical methods. The data were compared for the different formulations using analysis of variance (ANOVA) to determine the significance of the differences in performance. The results were expressed as mean ± standard deviation, and a p-value of less than 0.05 was considered statistically significant.

This methodical approach ensured the development of Valsartan-loaded fast disintegrating films and tablets with optimized formulation parameters, offering rapid disintegration, improved drug release, and good mechanical stability.

Results

The developed fast disintegrating films and tablets of Valsartan exhibited satisfactory characteristics in terms of disintegration time, drug content uniformity, mechanical strength, and drug release profile.

Film Formulations: The fast disintegrating films prepared using hydroxypropyl methylcellulose (HPMC) and polyvinyl alcohol (PVA) exhibited rapid disintegration times ranging from 15 to 30 seconds in simulated saliva (pH 6.8). The films with higher concentrations of superdisintegrants (sodium starch glycolate and croscarmellose sodium) showed faster disintegration and enhanced drug release profiles. The tensile strength and mechanical properties of the films were optimal, with no significant deformation or tearing during handling.

Tablet Formulations: The fast disintegrating tablets, formulated using sodium starch glycolate and croscarmellose sodium as superdisintegrants, showed disintegration times ranging from 30 to 60 seconds in the dissolution medium (simulated gastric fluid, pH 1.2). The drug content in both tablets and films was uniform, with the percentage of Valsartan content

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in each formulation falling within the acceptable pharmacopoeial limits (95–105%). In vitro drug release studies indicated that both films and tablets provided complete drug release within 10–15 minutes, with no significant lag time.

Stability Studies: Accelerated stability studies indicated that both the films and tablets remained stable under conditions of 40°C and 75% relative humidity for 6 months. No significant changes in physical appearance, disintegration time, or drug release were observed, suggesting that the formulations are stable and suitable for long-term storage.

DISCUSSION

The results from this study indicate that fast disintegrating films and tablets of Valsartan can be effectively developed to enhance the patient experience, particularly for those with difficulty swallowing conventional tablets. The choice of polymers (HPMC, PVA) and superdisintegrants (sodium starch glycolate, croscarmellose sodium) was key in achieving the desired rapid disintegration times and maintaining the stability of the formulations. These excipients facilitated the rapid breakdown of the films and tablets in the oral cavity, ensuring the fast onset of action of Valsartan.

The fast disintegration times of the formulations were in line with the ideal properties of fast disintegrating dosage forms, which are designed to dissolve quickly in the mouth, promoting rapid absorption and improving bioavailability. The uniformity of drug content, coupled with the excellent in vitro drug release profiles, indicates that the formulations are capable of delivering Valsartan effectively to achieve therapeutic levels quickly.

Additionally, the mechanical strength of the films was sufficient to prevent breakage or damage during handling, while the tablet formulations demonstrated good hardness and friability, ensuring their integrity during storage and transportation. The stability data further confirmed the suitability of these formulations for long-term use without significant degradation or loss of efficacy.

CONCLUSION

The development and evaluation of fast disintegrating films and tablets of Valsartan have shown that these novel dosage forms can provide

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an effective alternative to traditional tablet formulations. The formulations developed in this study exhibit rapid disintegration, uniform drug distribution, and excellent drug release profiles, making them suitable for improving patient compliance, particularly for individuals who have difficulty swallowing tablets. The fast disintegrating films, in particular, offer the added advantage of ease of administration and faster onset of action.

Further optimization of these formulations can be explored by incorporating additional excipients or modifying the processing conditions to improve the mechanical properties and stability even further. Additionally, clinical studies could be conducted to assess the bioavailability and therapeutic efficacy of these fast disintegrating formulations in comparison to conventional tablet forms of Valsartan.

In conclusion, the research demonstrates that fast disintegrating films and tablets of Valsartan are promising formulations that can improve patient compliance, enhance bioavailability, and provide an alternative to traditional oral dosage forms, ultimately leading to better management of cardiovascular diseases such as hypertension.

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