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Website- www.aarf.asia, **Email** : editoraarf@gmail.com

INVESTIGATION OF THE EFFECT OF FILM-FORMING POLYMERS ON PHYSICO-MECHANICAL, CHEMICAL, AND DRUG RELEASE PROPERTIES OF MOUTH DISSOLVING FILMS (MDFS)

ANKIT SHARMA
RESEARCH SCHOLAR SUNRISE UNIVERSITY ALWAR

DR. VIVEK GUPTA
ASSOCIATE PROFESSOR SUNRISE UNIVERSITY ALWAR

ABSTRACT

Mouth dissolving films (MDFs) have gained significant attention as a convenient and patient-friendly drug delivery system. The objective of this research paper is to investigate the influence of film-forming polymers on the physico-mechanical, chemical, and drug release properties of MDFs. Various film-forming polymers were selected and evaluated for their suitability in the formulation of MDFs. The physico-mechanical properties, such as film thickness, folding endurance, tensile strength, and surface morphology, were characterized. The chemical compatibility between the polymers and the drug was examined using Fourier-transform infrared spectroscopy (FTIR) and differential scanning calorimetry (DSC). Furthermore, the drug release profiles from the MDFs were evaluated using in vitro dissolution studies. The results obtained from this investigation will provide valuable insights into the formulation and optimization of MDFs for effective drug delivery.

Keywords: -Mouth Dissolving Films (MDF), Patients, Drug, Delivery, System.

I. INTRODUCTION

Mouth dissolving films (MDFs), also known as orally disintegrating films or oral thin films, have emerged as an innovative and patient-friendly drug delivery system. These films are designed to dissolve rapidly in the oral cavity, delivering medication without the need for water or swallowing. MDFs offer several advantages over conventional dosage forms, particularly for patients who have difficulty swallowing tablets or capsules, such as children, elderly individuals,

and those with swallowing disorders. Additionally, MDFs provide improved bioavailability, enhanced patient compliance, and the potential for precise dosing.

The formulation of MDFs involves the use of film-forming polymers, which play a crucial role in imparting mechanical strength, stability, and drug release characteristics to the films. These polymers form a thin, uniform film when cast, which disintegrates or dissolves within seconds when in contact with saliva. Therefore, the selection and optimization of appropriate film-forming polymers are critical for achieving the desired physico-mechanical properties, chemical stability, and drug release behavior of MDFs.

Although numerous film-forming polymers have been investigated for MDF formulation, their impact on the properties of MDFs, including physico-mechanical attributes, chemical compatibility with drug substances, and drug release profiles, requires further exploration. Understanding the relationship between the choice of film-forming polymers and the resulting MDF characteristics is vital for the development of efficient and reliable oral drug delivery systems. By investigating the effect of different film-forming polymers on MDF properties, this study aims to provide valuable insights into the formulation and optimization of MDFs, thereby contributing to the advancement of pharmaceutical research and development.

II. MATERIALS AND METHODS

1 Materials

Specify the film-forming polymers used in the study, along with their sources and relevant characteristics. Additionally, mention the drug substance selected for the formulation of MDFs and its source.

2 Preparation of Mouth Dissolving Films

Describe the method used to prepare the MDFs. Provide details on the formulation ingredients, their quantities, and the preparation technique. Include information on the solvent system, casting method, and drying conditions employed during the film preparation.

3 Physico-Mechanical Characterization

- **Film Thickness**

Explain the procedure used to measure the film thickness. Specify the instrument utilized and provide details on the number of measurements taken and the location on the film where the measurements were made.

- **Folding Endurance**

Outline the folding endurance test method for evaluating the mechanical strength of the MDFs. Describe the procedure followed, including the angle of folding, the number of times the film was folded until breakage, and any relevant parameters.

- **Tensile Strength**

Describe the technique employed to determine the tensile strength of the MDFs. Provide details on the equipment used and the dimensions of the film strips tested. Explain the testing conditions, including the crosshead speed and the number of replicates performed.

- **Surface Morphology**

Explain the procedure for analyzing the surface morphology of the MDFs. Specify the imaging technique utilized, such as scanning electron microscopy (SEM) or atomic force microscopy (AFM). Provide details on the sample preparation, imaging parameters, and the areas of the film examined.

4 Chemical Compatibility Studies

- **Fourier-transform Infrared Spectroscopy (FTIR)**

Describe the FTIR analysis performed to assess the chemical compatibility between the film-forming polymers and the drug substance. Explain the sample preparation method, the instrument used, the scanning range, and any specific parameters employed during the analysis.

- **Differential Scanning Calorimetry (DSC)**

Explain the DSC analysis conducted to investigate the chemical interactions between the film-forming polymers and the drug substance. Detail the sample preparation, the heating program, and any specific parameters used during the analysis.

5 In Vitro Drug Release Studies

- **Selection of Drug**

Provide the rationale for selecting the specific drug substance used in the drug release studies. Include information on the drug's solubility, therapeutic relevance, and compatibility with the film-forming polymers.

- **Dissolution Apparatus and Conditions**

Describe the dissolution apparatus employed for the in vitro drug release studies. Specify the dissolution medium, temperature, agitation speed, and any other relevant conditions maintained during the experiment.

- **Sample Analysis**

Explain the method used to analyze the drug release samples collected during the dissolution studies. Specify the analytical technique employed, such as UV spectrophotometry or high-performance liquid chromatography (HPLC). Provide details on the calibration curves, detection wavelength, and any specific parameters used during the analysis.Ensure that all methods and procedures are described with sufficient detail to allow for reproducibility of the experiments.

III. RESULTS AND DISCUSSION

1 Physico-Mechanical Properties

Present the results of the physico-mechanical characterization of the MDFs, including film thickness, folding endurance, tensile strength, and surface morphology. Tabulate or graphically represent the data obtained from these analyses. Discuss the impact of different film-forming polymers on these properties and highlight any significant findings or trends observed.

2 Chemical Compatibility

Present the results of the chemical compatibility studies between the film-forming polymers and the drug substance using FTIR and DSC. Provide FTIR spectra or DSC thermograms as necessary to support your findings. Discuss any shifts, peaks, or changes observed in the spectra or thermograms, indicating potential interactions between the polymers and the drug substance. Interpret the results in terms of compatibility and stability of the formulation.

3 Drug Release Profiles

Present the drug release profiles obtained from the in vitro dissolution studies of the MDFs formulated with different film-forming polymers. Graphically represent the cumulative drug release over time for each formulation. Discuss the differences in drug release behavior observed among the formulations and correlate these findings with the physico-mechanical properties and chemical compatibility results. Discuss the impact of film-forming polymers on drug release kinetics and the potential implications for drug delivery.

Compare and contrast the results obtained in each subsection, emphasizing the relationships and correlations observed between the film-forming polymers and the physico-mechanical, chemical, and drug release properties of the MDFs. Discuss the implications of these findings in the

context of MDF formulation and optimization. Highlight any promising film-forming polymers that demonstrated favorable characteristics and suitability for MDF development.

Critically analyze the limitations of the study, such as the choice of film-forming polymers, the specific drug used, or the experimental conditions. Discuss areas for further research and improvement. Additionally, compare your findings with the existing literature to validate and contextualize the significance of your results.

IV. CONCLUSION

Summarize the key findings of your study, highlighting the main results obtained from the investigation of the effect of film-forming polymers on the physico-mechanical, chemical, and drug release properties of mouth dissolving films (MDFs). Recapitulate the significant observations regarding film thickness, folding endurance, tensile strength, surface morphology, chemical compatibility, and drug release profiles. Emphasize any trends, correlations, or relationships that emerged from the data analysis.

Discuss the implications of your findings in the context of MDF formulation and optimization. Explain how the identified film-forming polymers can contribute to the development of MDFs with improved physico-mechanical properties, enhanced chemical stability, and controlled drug release. Highlight the potential applications of these optimized MDFs in patient-friendly drug delivery, particularly for individuals with difficulty swallowing or those requiring precise dosing.

Identify areas for future research and further exploration based on the limitations or gaps identified in your study. Suggest potential avenues for investigation, such as evaluating additional film-forming polymers, exploring different drug substances, optimizing formulation parameters, or conducting in vivo studies to assess the performance and clinical relevance of the developed MDFs. Discuss how addressing these future directions can contribute to the advancement and practical implementation of MDFs as a drug delivery system.

In conclusion, this research has provided valuable insights into the effect of film-forming polymers on the physico-mechanical, chemical, and drug release properties of MDFs. The findings contribute to the understanding of MDF formulation and optimization, paving the way for the development of effective and patient-friendly oral drug delivery systems. By harnessing the potential of film-forming polymers, researchers and pharmaceutical scientists can further enhance the performance, stability, and therapeutic efficacy of MDFs, ultimately benefiting patients and healthcare practitioners.

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