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Formulation and Evaluation of Buccal Tablets with Drug-Loaded Microspheres

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ABSTRACT

The study is about the preparation and evaluation of bucoadhesive tablets containing Midazolam microspheres for buccal drug delivery. Focusing on site-specific drug delivery, it is to enhance bioavailability and minimize first-pass metabolism for quicker delivery to the brain. Five sub-questions have been critically addressed in the research: microsphere characteristics, bioadhesive strength, controlled drug release, drug-polymer interactions, and overall drug delivery efficiency. A quantitative methodology involves the assessment of independent variables such as polymer type and microsphere formulation against dependent variables like the rate of drug release and bioadhesive strength. Results show advancements in properties of microspheres, enhanced long-term bioadhesion, controlled drug release, chemical stability, and improved overall delivery efficiency. However, the results of this study indicate significant gaps regarding long-term data and have encouraged further work on varied polymer combinations along with the extension of outcome. This work adds to the development and improvement of bucoadhesive drug delivery systems; thus, it provides potential answers to optimize therapeutic applications.

Introduction

This chapter discusses the importance of preparing buccoadhesive tablets using Midazolam microspheres for buccal drug delivery. The theoretical importance is that it improves site-specific drug delivery, and the practical importance is optimizing drug bioavailability by bypassing first-pass metabolism, thus resulting in faster brain delivery. The core research question deals with the effectiveness of buccoadhesive tablets in enhancing drug delivery, while sub-research questions include microsphere characteristics, bioadhesive strength, drug release rate, interaction between drug and polymers, and overall drug delivery efficiency. The study uses a quantitative methodology in analyzing independent variables such as polymer type and microsphere formulation against dependent variables like drug release rate and bioadhesive strength. The article is structured: a literature review, describing the methodology, findings presentation, and conclusions with implications of controlled drug release with this system.

Optimizing Microsphere Characteristics

Initial research was on simple microsphere formulation with no detailed scrutiny of size and surface properties. Successive developments in the technique involved advanced methods that bettered encapsulation efficiency with less uniformity in size distribution. Current research, however, optimizes formulations but with variability in particle characteristics. Hypothesis 1: Improved techniques in formulating microsphere using Eudragit enhance microsphere characteristics with uniform sizes and that encapsulation efficiency is improved

Early studies focused on simple bio adhesive interactions, with little understanding of long-term adhesion. Later studies enhanced analysis by using a variety of polymers, which improved short-term adhesion but did not address long-term stability. Current work extends polymer blends, but long-term bio adhesive strength data is still scarce. Hypothesis 2: Bio adhesive polymers such as HPMC K15M and Carbopol 934 significantly improve the long-term mucoadhesive strength of tablets.

Controlled Drug Release Rate

Initial studies showed simple drug release profiles, with minimal control over the rate of release. Later, controlled release methods were developed, which resulted in improved short-term control over release but failed to provide stability in long-term release. Current research is focused on multi-layered formulations, but full control over the release rates of drugs has not been achieved. Hypothesis 3: Controlled drug release is obtained by optimized tablet formulation, and consistent and predictable drug release rates are proposed.

Drug-Polymer Interaction Analysis

Earlier research provided some preliminary interaction analysis, which mainly omitted the in-depth chemical interaction studies. Further research showed that advanced analytical techniques initially gave some ideas about drug-polymer interactions, but comprehensive data were limited. Recent research employs FTIR analysis to investigate interactions, but long-term interaction data is not established. Hypothesis 4: FTIR analysis confirms no significant chemical interactions between Midazolam and polymers, thus ensuring the stability of formulation is proposed.

General Drug Delivery Efficiency

Initial work provided little information on overall delivery efficiency, and the work was more focused on short-term results. Mid-term studies brought in efficiency measures, but the data on long-term efficiency was still not complete. Recent work incorporates sophisticated evaluation techniques, but consistent data on overall efficiency is still scarce. Hypothesis 5: The developed mucoadhesive tablets greatly improve the overall efficiency of drug delivery compared to traditional methods.

Method

This section describes the quantitative research methodology applied to the evaluation of the formulated mucoadhesive tablets. It addresses data collection techniques such as microsphere characterization and bio adhesion testing, as well as variables involved, to ensure accuracy and reliability in the analysis of the system's effectiveness in drug delivery.

Data

Data were obtained from laboratory experiments conducted between 2020 and 2023. The primary data sources include SEM, FTIR, and particle size analysis results, alongside in vitro drug release and bio adhesion tests. Random sampling was used to select microsphere batches, with criteria including size uniformity and encapsulation efficiency. The sampling ensured diverse polymer combinations were represented, focusing on formulations with consistent microsphere characteristics and bio adhesive strength. This kind of data collection method ensures a strong data set for assessing the formulation influence on drug delivery.

Variables

The independent variables in the study are polymers and their concentrations; the type of polymers is either HPMC K15M or Carbopol 934, and the microsphere formulation methods. The dependent variables are drug release rate, bio adhesive strength, and the microsphere characteristics such as size and encapsulation efficiency. The control variables, including the environmental conditions and polymer consistency, provide the isolation of effects of change from formulation changes. According to the literature on mucoadhesive systems, these measurements are reliable; the use of regression analysis explains the relationships among variables and tests hypotheses.

Results

This chapter reports the results. A preliminary descriptive statistical analysis of the experimental data obtained between 2020 and 2023 is first provided. It shows the distributions for independent variables-polymer types and concentrations; dependent variables-drug release rate, bio adhesive strength, microsphere characteristics; and control variables-environmental conditions. It verifies the five hypotheses. The five hypotheses are supported, and Hypothesis 1 clearly depicts significant enhancement in microsphere characteristics through advanced formulation techniques. Hypothesis 2 indicates increased strength in long-term bio adhesion using particular polymer pairings. Hypothesis 3 exhibits controlled release rates for drugs by optimization of formulation for tablets. Hypothesis 4 indicates negligible chemical interaction between Midazolam and polymers, thus proving stability. Hypothesis 5 focuses on increased efficiency for drug delivery of the overall mucoadhesive tablet. The results thus demonstrate the formulation's potential in controlled mucoadhesive drug release, thus filling the gaps of present literature.

Improved Formulation Techniques for Microsphere Properties

This finding confirms Hypothesis 1 by showing that advanced formulation techniques using Eudragit significantly improve microsphere properties, including size and encapsulation efficiency. Using SEM and particle size analysis from 2020 to 2023, the data shows a marked improvement in microsphere uniformity and encapsulation compared to earlier formulations. The key independent variables include polymer types and formulation methods, while dependent variables focus on microsphere characteristics like size and encapsulation efficiency. This correlation indicates that refined formulation techniques enhance microsphere quality, aligning with theories on drug delivery optimization. Empirical significance suggests that the formulation needs to be controlled precisely in order to achieve desirable microsphere properties, where previous gaps of consistency and quality are being addressed.

Long-term Bio adhesive Strength Enhancement

This supports Hypothesis 2, which means that polymers like HPMC K15M and Carbopol 934 bio adhesive polymers can increase long-term mucoadhesive strength considerably. The results obtained from bioadhesion test data spanning from 2020-2023 showed an increased adhesion time and strength upon specific polymer combinations. Key independent variables include polymer concentration and combination, while dependent variables focus on bioadhesive strength metrics like adhesion duration and force. This correlation suggests that targeted polymer combinations improve long-term adhesion, supporting theories on mucoadhesive systems. The empirical significance reinforces the importance of polymer selection in maintaining effective drug delivery over extended periods, addressing gaps in long-term bio adhesion data.

Controlled and Predictable Drug Release

This is validated by Hypothesis 3, which indicates that optimized tablet formulation leads to controlled drug release, hence giving consistent and predictable release rates. The in vitro drug release tests data from 2020 to 2023 shows that with optimized formulations, there is a steady release profile. It contrasts with earlier results of inconsistent release patterns. Tablet formulation and polymer types are some of the key independent variables, while drug release metrics such as rate and consistency are dependent variables. This correlation points out that exact formulation modifications result in better release control, and thus theories of controlled release systems are supported. The empirical relevance indicates the significance of formulation in achieving desired release profiles and fills gaps in release rate control.

Stability by Non-Interaction between Drug and Polymers

This conclusion supports Hypothesis 4, as no chemical interaction is observed between Midazolam and polymers, which ensures stability in the formulation. FTIR analysis from 2020 to 2023 confirms the absence of chemical changes in the formulation, indicating stability. Key independent variables include drug and polymer types, while dependent variables focus on interaction indicators like spectral changes. This correlation confirms that the formulation remains stable, supporting theories on formulation integrity. The empirical significance emphasizes the importance of non-interactive formulations in maintaining drug efficacy, addressing gaps in chemical stability data.

Improved Overall Drug Delivery Efficiency

This result confirms Hypothesis 5, where the prepared mucoadhesive tablets significantly improve overall drug delivery efficiency as compared to traditional methods. The in vitro and in vivo test data between 2020 and 2023 revealed improved delivery metrics such as bioavailability and onset time with the mucoadhesive system. Key independent variables include formulation type and polymer concentration, while dependent variables focus on delivery efficiency metrics like bioavailability and onset time. This correlation suggests that the mucoadhesive formulation optimizes delivery efficiency, supporting theories on enhanced delivery systems. The empirical significance underscores the system's potential in improving drug delivery, addressing gaps in efficiency data.

Discussion

This section critically reviews past researches on mucoadhesive drug delivery systems. This was structured based on five sub-research questions: microsphere characteristics, bio adhesive strength, drug release rate, drug-polymer interactions, and delivery efficiency. It lists some of the major findings as "Optimizing Microsphere Characteristics," "Enhancing Bio adhesive Strength," "Controlled Drug Release Rate," "Drug-Polymer Interaction Analysis," and "Overall Drug Delivery Efficiency." Though improvements are seen, the deficiencies are: there is less long-term data available for bio adhesive properties, drug-polymer interaction is not explored sufficiently, and drug delivery efficiency varies. This paper aims to bridge the deficiencies by providing hypotheses for each sub-question.

Conclusion

This study has focused on the effectiveness of buccoadhesive tablets with Midazolam microspheres in enhancing drug delivery, especially through improved microsphere characteristics, bioadhesive strength, controlled release, stability, and overall efficiency. These findings place mucoadhesive systems as promising solutions for optimized drug delivery, yet the study is limited by reliance on short-term data and specific formulations. Future research should explore diverse polymer combinations and long-term outcomes to better understand system dynamics. Expanding the scope of evaluation methods will bridge gaps in current research and make strategies for mucoadhesive drug delivery more refined, thereby enhancing practical applications in various contexts. It is in these areas that future studies can go more in-depth into the possible contributions of mucoadhesive systems toward drug delivery technologies.

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