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Mouth-Dissolving Films: A Novel Approach for Oral Drug Delivery in Diabetic Management

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Abstract

For the administration of several pharmacological, the oral route is considered one of the most practical methods of drug administration, as it accommodates various dosage forms, including tablets, syrups, capsules, emulsions, and suspensions. Mouth Dissolving Drug Delivery Systems have created several fast-dissolving preparations, such as MDT and mouth dissolving film. The hydrophilic polymer makes oral thin films, an innovative dosage form designed to dissolve quickly in the buccal cavity. when it is placed in the mouth, because it is less expensive to produce, mouth dissolving film is better than mouth dissolving tablets. Oral films help overcome swallowing difficulties commonly experienced by both elderly and pediatric patients with tablets and capsules. It also has other benefits, including self-administration and rapid dissolution. This dosage form allows for rapid absorption, making it highly versatile. The current study aims to highlight various polymers, their concentrations, and their applications. Additionally, it explores the role of plasticizers, sweeteners, polymers, and different techniques used in the formulation of oral films, along with the key parameters for their evaluation.

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1. Introduction of Peptic Ulcer Disease

Mouth-dissolving films offer a sophisticated method of systemically delivering medications. Because of the rich vascular and lymphatic network, the increased permeability and avoidance of first-pass metabolism allow for the increased bioavailability. Furthermore, the oral mucosa is a perfect and targeted site for efficient systemic medication delivery due to its vast absorption surface, ease of intake and swallowing, and painless application.[1]. The oral route is a vital route for systemic and local drug delivery because of its high permeability, strong blood flow, and large surface area. Mouth-dissolving films are one of the most sophisticated oral dose forms available; they are more straightforward and convenient than other forms, such as sublingual or soluble tablets. In the 1970s, fast-dissolving drug delivery methods were created as an alternative to tablets, syrups, and capsules, especially for adults and teenagers who have difficulty swallowing conventional solid oral dosage forms. Without the need for water or chewing, oro-soluble films break down and disintegrate in the mouth in less than a minute. By avoiding first-pass metabolism, the medication's bioavailability is increased [2].

Diabetes is a metabolic disorder marked by high blood sugar levels resulting from impaired insulin secretion, action, or both. resulting in improper utilization of glucose. Gender, limited understanding about the disease and its management, lack of treatment adherence, and prolonged disease duration are common risk factors for complications. The hepatic and peripheral tissues' sensitivity to insulin is reduced by glucocorticoids via post-receptor mechanisms. Inadequate therapy, poor glycemic control, and a pessimistic outlook on diabetes all contribute to the disease's advancement [3]. Diabetes is a worldwide condition that results in increased urine production when the body is unable to control blood glucose levels, a form of sugar. This disorder develops when the body either uses insulin improperly or doesn't create enough of it. According to the WHO, the number of individuals with diabetes increased from 108 million in 1980 to 422 million in 2014. The prevalence of diabetes continues to increase rapidly in low- and middle-income countries.

Meanwhile, trends in high-income countries are different. An estimated 1.5 million fatalities in 2019 were directly attributed to diabetes, while 2.2 million deaths in 2012 were attributed to hyperglycemia [4].

2. Categories Of Diabetes

2.1 Diabetes Type 1

Type 1 diabetes is a long-term autoimmune disorder. is characterized by insufficient insulin production, leading to elevated blood sugar levels. The understanding of the disease, including its genetics, epidemiology, immune system and β-cell features, and overall impact, has advanced significantly during the last 25 years. Numerous approaches to enhance clinical management have been investigated, as well as a variety of therapies targeted at maintaining β-cells. Nonetheless, there are still many unanswered questions regarding type 1 diabetes, and there are still difficulties in standardizing clinical care and lowering the burden and problems associated with the condition. This session examines possible future routes for study and treatment while giving a summary of what is currently known about the illness [5].

2.2 Diabetes Type 2

Worldwide, the occurrence of type 2 diabetes mellitus (DM), a Long-term metabolic disease, has continuously increased. Owing to an aging population, the quantity of affected people is predicted to quadruple over the next decade, making it an epidemic in some countries. This will further put pressure on healthcare systems, especially in less developed nations. A thorough search of Medline, the Cochrane Library of Systematic Reviews, and the reference lists of pertinent papers served as the foundation for this evaluation. Type 2 diabetes mellitus, prevalence, current diagnosis, and current therapy were among the search phrases used [6].

3. Complications Of Diabetes

Retinopathy, nephropathy, neuropathy, and cardiovascular disorders are among the microvascular and macrovascular problems associated with diabetes. These problems arise from a complex interplay of Metabolic and hemodynamic imbalances, such as immune system dysfunction, insulin resistance, abnormal lipid levels, high blood pressure, and elevated blood sugar, which trigger harmful responses. including increased ischemia, inflammation, and reactive oxygen species (ROS) generation. The eyes, kidneys, and nerves are among the tissues that are most sensitive since these processes primarily harm the endothelium and nerve cells [7].

4. Symptoms Of Diabetes

Due to the slow progression of the disease, many people fail to notice the symptoms of diabetes. People tend to ignore hyperglycemia as a minor problem since, in contrast to other illnesses, its effects are not immediately noticeable. They are unaware that harm might start years before any obvious signs appear. This is regrettable because early symptom detection may improve disease management and avert major vascular consequences [8].

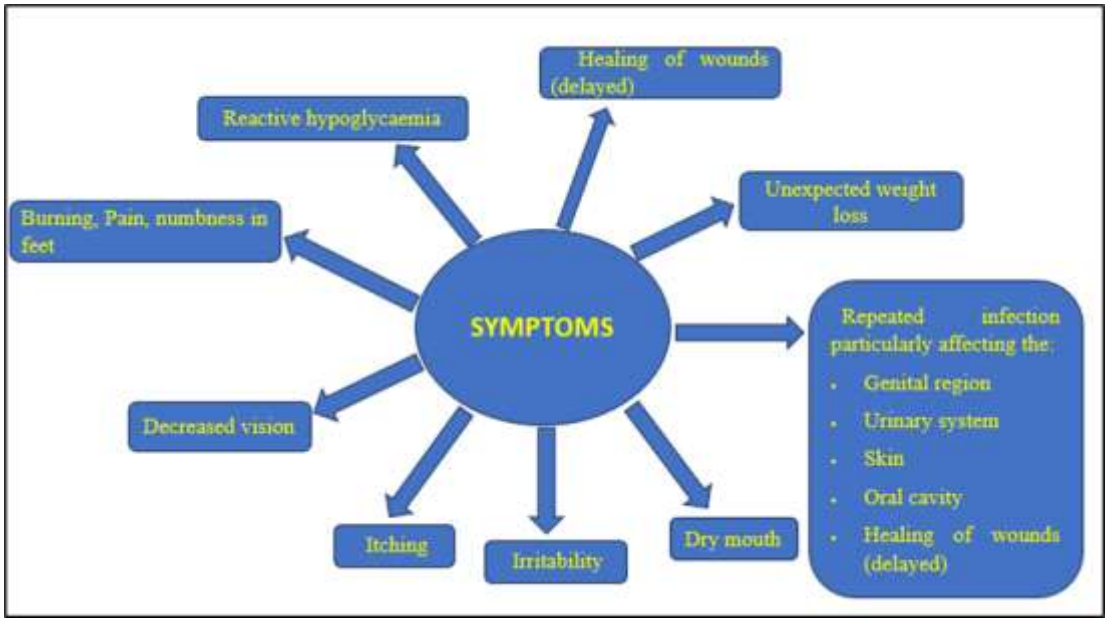

Figure 1: Common Symptoms Associated with Diabetes Mellitus

5. Treatment Of Diabetes

Diabetes is a persistent metabolic and endocrine disorder defined by elevated blood sugar levels. and several consequences. The most widely used treatments for diabetes nowadays include genetic-based therapies, non-insulin oral hypoglycemic medications, insulin, and insulin analogs. However, due to shortcomings in the drugs and delivery systems now in use, a comprehensive diabetes treatment plan is still elusive. Problems with oral administration, including enzymatic breakdown, chemical instability, and poor gastrointestinal absorption, and the negative effects of long-term subcutaneous insulin injections underscore these shortcomings. The development of efficient drug delivery methods and comprehensive treatment plans that are suited to the unique features of the medications and the illness is therefore imperative [9]. Drug delivery systems have the

potential to significantly improve the treatment of diabetes by increasing drug stability, increasing bioavailability by overcoming biological barriers, and offering intelligent, automated systems that can replicate the natural release of insulin while lowering the risk of hypoglycemia. This study aims to summarize recent advancements in diabetes treatment. the creation of novel delivery methods and their possible uses, all of which may influence future diabetes treatment strategies [10].

Table 1: Overview of Various Nanoparticle-Based Drug Delivery Systems for Diabetes Management.

S. No.	Delivery System	Drug	Route	*In Vivo* effect	References
1.	Dextran NPs	Insulin	SC	Sustained hypoglycaemia	[11]
2.	Liposomes	Complexes Cas9-RNP	SC	Improves insulin sensitivity, protects organs	[12]
3.	PLGA NPs	Insulin	Oral	Prolonged glucose reduction	[13]
4.	Chitosan NPs	Insulin	Oral	Enhances bioavailability, bypasses barriers	[14]
5.	SiO_2 NPs	Metformin	TD	Enhances glucose control, lowers risk	[15]
6.	PEG NPs	Insulin	Oral	Improves absorption, boosts effects	[16]
7.	Liposomes	BSA& Insulin	Oral	Overcomes mucus & epithelial barriers	[17]

5.1 Mouth Dissolving Film

Any drug delivery system's main goal is to efficiently administer the medication to the body while taking patient compliance into account. Fast-dissolving drug delivery systems, including mouth-dissolving films (MDF), provide a convenient dosage option for the general public as well as particular Individuals with swallowing difficulties, including children and older adults [18].

MDFs are cutting-edge dosage forms that dissolve and break down rapidly in the mouth. Bypassing the first-pass metabolism and enabling quick absorption, this lowers the dosage needed to achieve the desired therapeutic effect. This review provides an overview of the different polymers used in MDF formulation, along with an analysis of how these polymers and plasticizers affect the films' mechanical and physical characteristics. It also briefly discusses the formulation process of MDF and the challenges encountered during its manufacture [19].

Dissolving films offer several notable advantages in drug delivery. They provide an affordable dosage form that does not require water for administration, making them convenient for patients of all ages, especially those with swallowing difficulties. The risk of choking is significantly reduced, and the films are capable of masking unpleasant tastes, enhancing the overall patient experience. These films also exhibit better stability compared to some liquid formulations. Increased patient compliance is another major benefit due to their ease of use and portability. Importantly, drugs delivered via dissolving films enter the systemic circulation directly, reducing the impact of first-pass metabolism by the liver. Additionally, unlike syrups, dissolving films offer improved dose accuracy, ensuring consistent therapeutic effects [20].

Table 2: Components of Mouth-Dissolving Film.

S. No.	Ingredient	Amount (w/w)
1.	Therapeutic Active Component	7-35 %
2.	Film Forming Polymer	40-50 %
3.	Plasticizers	0-22%
4.	Surfactant	9.5 %
5.	Sweetener	4-7 %

6.	Saliva-Enhancing Agent	3-7 %
7.	Coloring Agent	1 %
8.	Flavoring Agent	1 %

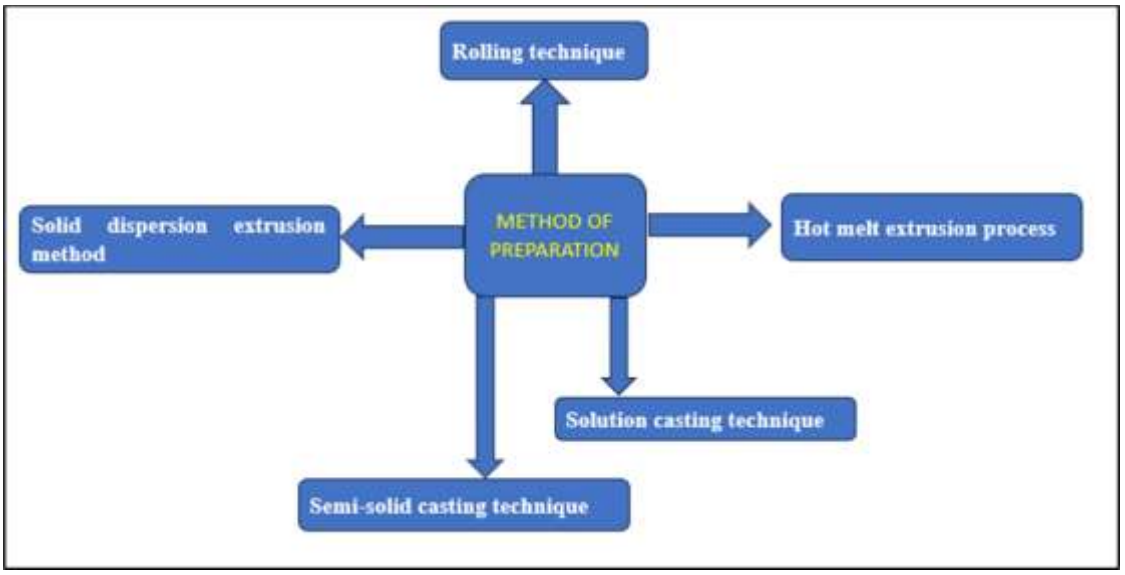

Figure 2: Method Of Preparation

6. Diabetes Management

Regular physical exercise participation has been linked to several health Advantages for individuals with diabetes in addition to influencing the development of type 2 diabetes. Insulin action, glycemic control, and metabolic abnormalities linked to type 2 diabetes seem to be positively impacted by physical activity on its own. However, the early stages of the disease's course seem to be when physical activity has the greatest positive metabolic effects. Diabetes patients' metabolic control and disease management practices can be influenced by a wide range of circumstances, both directly and indirectly. Along with individual elements, Family dynamics, broader social and cultural influences, and socioeconomic and healthcare system challenges all impact patient behavior. Diabetes self-management education has proven effective in promoting healthy lifestyle habits and, in certain situations, reducing hemoglobin A1c (HbA1c). Notably, less than 7% of individuals with private insurance obtain formal schooling within a year following their diagnosis [21].

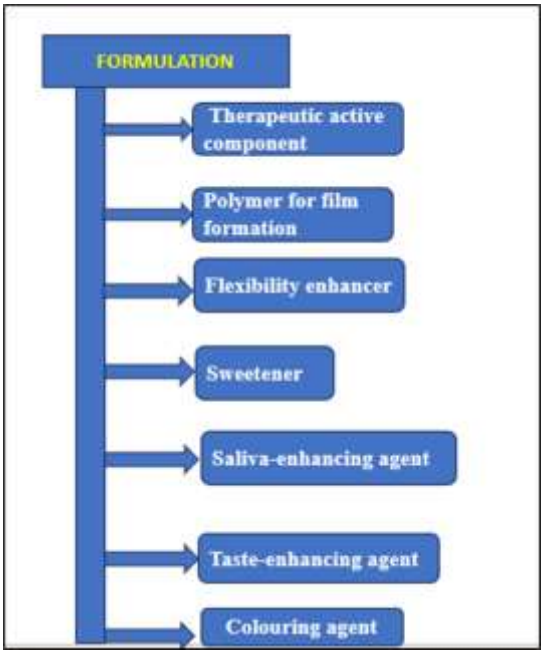

Figure 3: Key Components in the Formulation of Dissolving Films.

7. Regulatory Consideration

7.1 FDA Guidelines

The United States Food and Drug Administration (FDA) declared in March 2020 that it will be updating its 2008 Industry Guidelines for the Development of Diabetes Medications. Based on a vast amount of rigorous cardiovascular outcome trials (CVOTs) that have been carried out since 2008, the FDA released a preliminary version for public feedback. In this article, we outline the major moments in this 12-year medication development process, compare the 2008 and 2020 standards, and make recommendations for enhancements. We conclude by considering the lessons learnt for upcoming generations of clinicians, stakeholders in the industry, and legislators. Nevertheless, the necessity of evaluating every new antihyperglycemic drug through at least one large-scale, standardized randomized clinical outcomes trial should persist, ensuring that clinicians have confidence in the medication's efficacy and safety. The main criteria for approving T2 diabetes drugs that are meant to lower blood glucose levels are still reductions in HbA1c or glucose levels. Usually, just 300 to 600 patients must be subjected for six months, and only 100 must be exposed for a year, for trials intended to show the effect to last six to twelve months or less. [22].

7.2 Eu Regulation

Currently, limited data is available on the effectiveness and safety of mobile health applications, especially for diabetes management. Therefore, the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) collaboratively evaluated the current state of digital health technology for diabetes. Their review focused solely on standalone diabetes applications, excluding those integrated into regulated medical devices such as insulin pumps, continuous glucose monitors, and automated insulin delivery systems. The findings revealed that, unless these mobile applications meet the requirements for classification as medical devices intended for therapeutic or diagnostic purposes, they remain largely unregulated in both the United States and International organizations, such as the International Medical Device Regulators Forum and the World Health Organization, have made progress in categorizing various forms of digital health technology and incorporating them into the medical device sector [23].

8. Evaluation and Quality Control

Evaluation Parameter

Evaluation parameters are essential for maintaining the quality, effectiveness, and safety of MDFs. The following sections detail each parameter and its importance [24].

A. Disintegration Time

Disintegration time is a critical parameter for mouth dissolving films (MDFs) that measures the duration required for the film to break down upon contact with the oral cavity's saliva [25].

B. Physicochemical Properties

Physical characteristics are important as they are evaluated in the final dosage form, ensuring batch-to-batch consistency and preserving the visual appeal of the final formulation [26].

C. Variation in Weight

Weight variation is assessed by individually weighing 10 randomly chosen films and calculating their average weight. The deviation from the established weight variation limit should be minimal [27].

D. Assessment of Thickness

To maintain consistent drug distribution and, consequently, dose uniformity, there must be uniformity in terms of individual film thickness. Polymeric film thickness is measured with digital vernier calipers. To prevent measuring errors, the thickness is taken from a minimum of three locations on the film. Movies are chosen at random for this assessment, and the average reading with standard deviation is the result [28].

E. In Vitro Drug Release Test

Dissolution testing can be carried out using the conventional basket or paddle apparatus specified in pharmacopeial guidelines. The choice of dissolution medium depends on sink conditions and the maximum API dose. However, the test may present challenges, as the film strip often tends to float on the dissolution medium when using the paddle apparatus [29].

9. Quality Control Test

Structural Analysis: The morphological study of the oral strip is done by the scanning electron microscopy resulting solution is added to a solution of acid (SEM) at a definite magnification. Study refers to the insoluble polymer cellulose acetate butyrate) It also helps in the determination of the distribution of API [30].

A. Drying Evaluation/Film Integrity Test

The film drying process has been categorized into eight stages: set-to-touch, dust-free, track-free, dry-to-touch, dry-hard, dry-through, dry-to-recoat, and dry print-free. The assessment details for this parameter can be examined. Tack refers to the adhesion strength of the film to any surface it comes into contact with [31].

B. Stability Study Test

Stability study of mouth dissolving films is carried out for all the batches according to ICH guidelines. After predetermined time intervals, the films are evaluated for drug content, disintegration time, and physical appearance [32].

C pH of the Surface

The surface pH of mouth-dissolving films is assessed to determine the potential risk of side effects. Ideally, the film's surface pH should be close to the buccal cavity's pH, which is approximately 6.8. To measure

this, the film is slightly moistened with water, and the pH is recorded by placing the electrode in direct contact with its surface [33].

D. Dissolution Test

Dissolution testing may be carried out using the conventional basket or paddle apparatus specified in pharmacopeial standards. The choice of dissolution medium depends on sink conditions and the maximum API dose. However, conducting the test can be challenging as the strip tends to float on the dissolution medium [34].

Conclusion

In conclusion, mouth-dissolving films are a creative and effective way to administer medications for the treatment of diabetes. Among the many benefits of this innovative formulation are its quick absorption, non-invasive administration, and enhanced patient compliance, especially for people who have trouble swallowing conventional pills or capsules. These films could completely change the way diabetes is managed because of their quick onset of action and possibly improved bioavailability. As more research and development is conducted, mouth-dissolving films may play an important role in customized diabetes treatment, enhancing patient convenience and treatment results.

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Author Contributions

M.K.M. Conceptualized the study, **A.K.** Supervised the review, **T.S.** Prepared the manuscript draft**, S.H.M.** Reviewed the manuscript critically for intellectual content.

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Conflicts of Interest

No conflicts of interest are disclosed by the authors.

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