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A REVIEW ON DIFFERENT FORMULATION OF ANTI-ASTHMATIC STRIPS

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ABSTRACT:

The development of oral spray formulations has revolutionized drug delivery across various therapeutic categories, including antihistamines, asthma medications, and treatments for erectile dysfunction. Rapid drug delivery systems, pioneered in the 1970s, have paved the way for the creation of oral strips—a unique dosage form distinct from traditional capsules, syrups, and tablets. Oral strips offer unparalleled advantages, particularly in patient populations with swallowing difficulties such as dysphagia, as well as in pediatric and geriatric patients. The ease of self-administration without the need for water or chewing significantly enhances patient compliance, thereby improving treatment outcomes. Moreover, oral strips provide rapid absorption and bypass the first-pass metabolism, leading to rapid onset of action and achieving therapeutic concentrations more efficiently. This comprehensive review elucidates the selection of polymers for formulating asthma strips, delves into the intricacies of the manufacturing process, and outlines the critical parameters for final evaluation. By exploring these aspects, this review aims to provide insights into the development and optimization of oral strip formulations for the effective management of asthma and other respiratory conditions, ultimately enhancing patient care and treatment efficacy.

KEYWORDS: Asthma, Anti-asthmatic strips, anti-asthamatic drugs.

INTRODUCTION:

Asthma, a prevalent chronic respiratory condition affecting individuals worldwide, presents a significant health burden, with an estimated 262 million diagnosed cases and 461,000 associated deaths reported in 2019 alone. Its multifaceted nature encompasses diverse manifestations, including allergic asthma triggered by environmental allergens like pollen, non-allergic asthma influenced by stress or air irritants, exercise-induced bronchoconstriction (EIB), and occupational asthma stemming from workplace exposures. The interplay of genetic predispositions, such as family history and specific gene variants, alongside environmental factors, including early-life infections and air quality, contributes to its complex etiology. The classification of asthma into various stages, ranging from mild intermittent to severe persistent, provides a framework for tailoring treatment strategies to individual patient needs, based on the severity and frequency of symptoms. Amidst this landscape, asthmatic strips emerge as indispensable tools for asthma management, offering a portable and user-friendly means of monitoring lung function, particularly through peak flow measurement. Their utility lies in facilitating quick assessments, enabling continuous monitoring of respiratory status, guiding personalized treatment adjustments, empowering individuals for self-care, aiding in early issue detection to prevent exacerbations, ensuring portability for use in diverse settings.

Thus, asthmatic strips play a pivotal role in enhancing the quality of life for asthma patients by providing valuable insights into their respiratory health and facilitating proactive management approaches.

IDEAL PROPERTIES OF ORAL FILMS:

- Pleasant mouth feel and taste for patient comfort and acceptance
- High mechanical strength to withstand post-production handling without breakage
- Drug stability and solubility in both water and saliva for effective delivery
- Minimal residue in the mouth after administration for enhanced patient comfort
- Rapid dissolution upon contact with saliva to facilitate swift drug release
- Compatibility among all ingredients to maintain integrity and uniform drug distribution

ADVANTAGES OF ANTI-ASTHMATIC STRIPS:

- Avoiding the risk of choking during administration.
- Bypassing first-pass metabolism, leading to quicker onset of action even at lower doses.
- Palatable taste enhances patient acceptance and compliance.
- Good stability of the drug within the film matrix.
- No requirement of water for administration, increasing convenience and accessibility.
- Large surface area of the film allows for rapid disintegration and dissolution in the oral cavity, facilitating quick drug release.
- Ease of administration for patients with conditions such as dysphagia, repeated emesis, motion sickness, and mental disorders.
- Dose precision ensures accurate dosing, promoting therapeutic efficacy and safety.

DISADVANTAGES OF ANTI-ASTHMATIC STRIPS:

- High doses cannot be included in the film due to limitations in film size and drug loading capacity.
- Expensive packaging is required for the film, potentially increasing overall production costs.
- Drugs that cause mucosal irritation are not suitable for administration via oral films due to the direct contact with the oral mucosa.
- Fragility of the film necessitates protection from exposure to water, which may affect stability and integrity.
- Specialized packaging is required to protect the fragile films, adding to the complexity and cost of production and storage.

FORMULATION TECHNIQUES OF ANTI-ASTHMATIC STRIPS :

1. **Solvent Casting Method:** The solvent casting method represents a cornerstone in the fabrication of Anti-asthmatic Strips, offering a versatile approach to incorporate both film-forming polymers and active pharmaceutical ingredients (APIs). This technique begins with the dissolution of polymers such as hydroxypropyl methylcellulose (HPMC) in solvents like water or ethanol, forming a homogeneous solution. The addition of APIs to this solution allows for precise control over dosage and therapeutic efficacy. The resultant mixture is then carefully poured into molds and subjected to a drying process, yielding uniform films with desirable characteristics such as flexibility and drug release kinetics. However, meticulous attention to solvent selection and concentration is paramount to ensure product uniformity and stability. Moreover, optimization of drying parameters is essential to mitigate issues such as film cracking or inconsistency.
2. **Hot Melt Extrusion (HME):** Hot Melt Extrusion (HME) emerges as a sophisticated and continuous manufacturing process for Anti-asthmatic Strips, particularly favored for its ability to precisely modulate drug release kinetics. This method involves the controlled heating and extrusion of a blend comprising polymers and APIs, typically thermoplastic polymers like polyethylene oxide (PEO). Through precise manipulation of temperature and pressure, pharmaceutical scientists can tailor the properties of the resulting films, including their mechanical strength and drug release profiles. However, HME demands a thorough understanding of polymer behavior under varying processing conditions, necessitating extensive experimentation and optimization. Additionally, careful consideration of polymer compatibility and degradation kinetics is imperative to ensure the stability and efficacy of the final formulation.
3. **Spray Coating:** Spray coating stands out as a versatile and scalable technique for manufacturing Anti-asthmatic Strips, offering precise control over film thickness and uniformity. This method involves atomizing polymer and API solutions onto substrates using specialized equipment, facilitating the deposition of thin, homogeneous films. Polymers such as hydroxypropyl cellulose (HPC) or polyvinylpyrrolidone (PVP) are commonly employed due to their film-forming properties and compatibility with various APIs. Spray coating is particularly advantageous for formulating taste-masked or rapidly dissolving medications, as it ensures uniform drug distribution within the film matrix. However, optimization of spraying parameters, including nozzle size and spray rate, is essential to achieve consistent film quality and reproducibility across manufacturing batches.
4. **Printing:** Printing methodologies, encompassing techniques such as inkjet and screen printing, offer unparalleled precision in drug deposition and dosage control for Anti-asthmatic Strips. This enables the formulation of personalized or pediatric medications tailored to individual patient needs. By utilizing polymers like hydroxypropyl methylcellulose (HPMC), pharmaceutical scientists can design films with customizable drug release profiles and enhanced patient compliance. Printing also facilitates the incorporation of multiple APIs within a single dosage form, allowing for combination therapies and synergistic therapeutic effects. However, the

implementation of printing technologies requires specialized equipment and expertise, along with meticulous optimization of ink formulations and printing parameters to ensure product uniformity and stability.

5. **Freeze-Drying (Lyophilization):** Freeze-drying, or lyophilization, offers a unique approach to the formulation of Anti-asthmatic Strips, particularly beneficial for preserving heat-sensitive drugs and achieving rapid dissolution profiles. This method involves freezing polymer and API solutions followed by sublimation of the solvent under vacuum conditions, resulting in the formation of porous films with enhanced surface area and solubility. Polymers such as gelatin or pullulan are commonly employed due to their compatibility with the freeze-drying process and ability to form stable matrices. Freeze-drying is well-suited for formulating fast-dissolving medications, as it allows for the incorporation of high drug loads while maintaining uniform drug distribution. However, the lyophilization process requires careful optimization of freezing and drying parameters to prevent structural collapse or loss of pharmaceutical activity.
6. **Rolling Method:** The rolling method offers a straightforward and scalable approach to manufacturing Anti-asthmatic Strips, involving the mechanical rolling out of polymer and API mixtures between rollers to form uniform films. This method is characterized by its simplicity and cost-effectiveness, making it suitable for large-scale production of pharmaceutical dosage forms. Polymers such as polyvinyl alcohol (PVA) or hydroxypropyl methylcellulose (HPMC) are commonly utilized due to their film-forming properties and compatibility with various APIs. The rolling method enables the fabrication of films with desirable characteristics such as flexibility, mechanical strength, and controlled drug release profiles. However, optimization of roller geometry and processing parameters is essential to ensure consistent film quality and reproducibility across manufacturing batches.
7. **Compression Molding:** Compression molding emerges as a robust and high-throughput method for manufacturing Anti-asthmatic Strips, particularly suitable for sustained-release formulations. This technique involves compressing polymer and API mixtures between heated molds, resulting in the formation of dense and uniform films with controlled drug release kinetics. Polymers such as hydroxypropyl cellulose (HPC) or polyethylene oxide (PEO) are commonly employed due to their thermoplastic properties and compatibility with compression molding processes. Compression molding offers advantages such as high production throughput, low manufacturing costs, and scalability to meet commercial demands. However, careful optimization of molding parameters, including temperature, pressure, and dwell time, is essential to ensure uniform drug distribution and mechanical integrity of the final dosage form.

STANDARD COMPOSITION OF ANTI-ASTHMATIC STRIPS:

1. **Drug (Active Pharmaceutical Ingredient):** Anti-asthmatic Strips, designed to provide rapid and effective relief from asthma symptoms, are formulated with carefully selected active pharmaceutical ingredients (APIs) at concentrations typically ranging from 1-25% w/w. These APIs are meticulously chosen based on their proven efficacy in managing asthma exacerbations and improving respiratory function. To ensure optimal drug delivery and bioavailability, micronized forms of APIs are often preferred, as they exhibit enhanced texture and dissolution properties, facilitating rapid absorption and onset of action. Moreover, given the potential bitterness associated with certain APIs, taste masking techniques are employed, involving the incorporation of pleasant-tasting excipients or flavoring agents to enhance patient acceptability and compliance, particularly in pediatric and geriatric populations.
2. **Film Forming Polymer:** Integral to the structural integrity and performance of Anti-asthmatic Strips are film-forming polymers such as hydroxypropyl methylcellulose (HPMC) or polyvinyl alcohol (PVA). These polymers serve as the backbone of the strips, providing mechanical strength, flexibility, and uniformity. Depending on the desired characteristics of the final product, polymers may be used alone or in combination to optimize properties such as mouthfeel, solubility, and drug release kinetics. Through their film-forming properties, HPMC and PVA ensure uniform drug dispersion within the strip matrix, facilitating consistent dosage delivery and therapeutic efficacy.
3. **Plasticizer:** Plasticizers are essential additives in Anti-asthmatic Strips formulations, designed to enhance flexibility, elasticity, and overall performance. Commonly employed plasticizers include glycerol or propylene glycol, which effectively soften the polymer matrix, allowing the strips to conform to mucosal surfaces within the oral cavity upon administration. By improving the strips' pliability and conformability, plasticizers contribute to patient comfort and ease of use, while also promoting uniform drug release and absorption. Furthermore, plasticizers play a crucial role in preventing strip brittleness and ensuring product stability throughout its shelf life.
4. **Saliva Stimulating Agent:** Accelerating strip dissolution and onset of action, saliva stimulating agents such as citric acid or malic acid are incorporated into Anti-asthmatic Strips formulations. These agents work by triggering the production of saliva upon contact with the oral mucosa, promoting rapid hydration and disintegration of the strip matrix. By facilitating faster drug release and absorption, saliva stimulating agents enhance the strips' efficacy in providing prompt relief from asthma symptoms, including bronchospasm and respiratory distress.
5. **Sweetening Agent:** Enhancing palatability and masking the potential bitterness of certain APIs, sweetening agents play a vital role in improving patient acceptance and compliance with Anti-asthmatic Strips. Sucralose, mannitol, or other non-nutritive sweeteners are commonly employed to impart a pleasant taste to the strips without compromising their therapeutic efficacy. Especially in pediatric formulations, where taste preferences significantly influence medication adherence, sweetening agents contribute to a positive patient experience and ensure consistent treatment outcomes.
6. **Flavouring Agent:** Adding an extra dimension to the sensory experience of Anti-asthmatic Strips, flavouring agents are incorporated to enhance taste and overall acceptability. A wide range of flavors, from fruity to minty, are utilized to cater to diverse patient preferences and age groups. By providing a pleasant and enjoyable administration experience, flavouring agents promote patient

satisfaction and adherence to treatment regimens, thereby optimizing therapeutic outcomes in asthma management. Additionally, flavouring agents serve to mask any residual medicinal taste, further improving the palatability of the strips.

7. **Surfactant:** Essential for ensuring rapid and uniform drug release from Anti-asthmatic Strips, surfactants such as polysorbates are included in formulations to enhance wetting properties and dissolution rates. These agents reduce the surface tension between the strip matrix and saliva, facilitating rapid hydration and dispersion of the drug throughout the oral cavity. By promoting efficient drug absorption and onset of action, surfactants play a critical role in optimizing the therapeutic efficacy of Anti-asthmatic Strips, ensuring consistent and predictable treatment outcomes for patients.
8. **Colouring Agent:** Beyond their aesthetic appeal, colouring agents serve important functional roles in Anti-asthmatic Strips formulations, aiding in product identification and differentiation. By imparting distinct hues to the strips, colouring agents enable patients and healthcare providers to easily distinguish between different formulations and dosages, minimizing the risk of medication errors and improving overall safety. Additionally, colouring agents contribute to the overall branding and marketing of the product, enhancing its recognizability and appeal to consumers. Through careful selection and incorporation of colouring agents, Anti-asthmatic Strips manufacturers can ensure product consistency, compliance with regulatory requirements, and enhanced patient satisfaction.

EVALUATION PARAMETERS FOR ANTI-ASTHMATIC STRIPS:

1. Morphology Study:

1. This assesses the physical characteristics of the strips, including their shape, size, and surface features.
2. Techniques such as microscopy are employed to discern even the minutest details.
3. It provides crucial insights into the overall quality and uniformity of the strips' physical attributes.

2. Weight Variation:

1. Determines the uniformity of weight among individual strips.
2. Ensures consistency in drug content and dosage accuracy across the entire batch.
3. Fundamental for reliable therapeutic outcomes and compliance with regulatory standards.

3. Thickness:

1. Measures the thickness of the strips to ensure uniformity and adherence to specifications.
2. Crucial for dosage accuracy and maintaining stringent manufacturing quality control standards.
3. Variations in thickness can impact drug release kinetics and therapeutic efficacy.

4. Surface pH:

1. Evaluates the acidity or alkalinity of the strip's surface.
2. Impacts drug stability, skin irritation potential, and overall product effectiveness.
3. Ensures patient safety and satisfaction by maintaining optimal pH conditions.

5. Dissolution Test:

1. Examines the rate and extent of drug release from the strips under standardized conditions.
2. Provides insights into their performance and bioavailability.
3. Crucial for optimizing therapeutic outcomes and ensuring consistent drug delivery.

6. Disintegration Time:

1. Determines the time taken for the strips to break down or dissolve completely.
2. Influences drug absorption kinetics and onset of action.
3. Essential for predicting clinical efficacy and patient adherence.

7. Folding Endurance:

1. Assesses the flexibility and durability of the strips by measuring their ability to withstand folding.
2. Indicates mechanical strength and reliability during handling and administration.
3. Ensures product integrity and patient convenience.

8. Tensile Strength:

1. Measures the maximum stress a strip can withstand before breaking.
2. Reflects structural integrity and suitability for practical use.
3. Crucial for ensuring product reliability and minimizing the risk of damage during handling.

9. Percent Elongation:

1. Evaluates the ability of the strips to stretch without breaking.
2. Provides insights into flexibility and resilience to deformation.
3. Ensures patient comfort and compliance during administration.

10. In vitro Drug Release:

1. Investigates the release of the drug from the strips in simulated physiological conditions.
2. Essential for predicting drug behavior and optimizing formulations.
3. Provides crucial data for regulatory submissions and ensuring therapeutic efficacy.

11. Swelling Property:

1. Assesses the extent to which the strips absorb fluid and swell over time.
2. Impact drug release kinetics, stability, and patient comfort upon application.
3. Understanding swelling properties is crucial for optimizing formulation parameters and predicting in vivo behavior.
4. Ensures consistency in drug delivery and minimizes variations in therapeutic outcomes.

12. Storage and Packaging:

1. Considers factors such as packaging materials, labeling, and storage conditions.
2. Ensures product stability, integrity, and compliance with regulatory requirements throughout its shelf life.
3. Proper storage and packaging mitigate risks of degradation, contamination, or tampering.
4. Crucial for maintaining product quality and safety until the point of administration.

List of Anti-asthmatic strips available in the market:

Sr no.	Product	Manufactured by
1	Dextromethorphan HBr (cough suppressant) Diphenhydramine citrate (cough and cold)	MonoSolRx
2	Doneprezil rapid dissolving film, ondansetron Rapid dissolving film.	Labtech pharma
3	Diphenhydramine HCL fast dissolving film, folic acid 1mg fast dissolving film, caffeine fast Dissolving films	Hughes medical corporation
4	Altoid cinnamon strips, cool shock peppermint strips, benzocaine films,	Dow chemical company
5	Listerine pocket paks breath freshening strips	Pfizer's warner-lambert Consumer healthcare division
6	Energy strips- caffeine 20mg, acetyl salicylic acid (ASA) ondansetron HCL, Dexamethason,	ODF technologies Inc.
7	Caffeine films	Dow chemical company
8	Triaminic thin strips	Novartis pharmaceutical
9	Methylcobalamin fast dissolving film	Hughes medical corporation
10	Diphenyhydramine hydrochloride film	MonosolRX
11	Life-saving rotavirus vaccine to infants	Johns Hopkins undergraduate Biomedical engineering student
12	Suppress	InnoZen, inc

CONCLUSION:-

Anti-asthmatic strips are a cutting-edge trend, and the majority of pharmaceutical companies in this industry are still researching and developing ways to modify their products across a range of categories to work with this technology. For patients of all ages who have difficulty swallowing, this technology offers an inventive method of delivering medication, particularly for younger and older patients. In addition, it has various benefits over the other dosage forms, including increased bioavailability and quicker onset of action. When a quick onset impact is necessary and in an emergency, it is one of the most significant oral dosage forms that can be used. Thus, it can be said that Anti-asthmatic strips with superior patient compliance and numerous benefits have cutting-edge, forward-thinking prospects.

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