International Research Journal of Human Resource and Social Sciences
ISSN(O): (2349-4085) ISSN(P): (2394-4218)
Impact Factor 6.924 Volume 9, Issue 11, November 2022
Website- www.aarf.asia, **Email** : editoraarf@gmail.com

FORMULATION AND EVALUATION OF MOUTH DISSOLVING FILM OF DESLORATADINE: A COMPARATIVE STUDY OF VARIOUS FORMULATIONS

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ABSTRACT

Mouth dissolving films (MDFs) have gained significant attention in recent years due to their convenience and ease of administration. They provide an alternative dosage form for drugs that are difficult to swallow, such as desloratadine, an antihistamine used for the treatment of allergies. This research paper aims to formulate and evaluate different MDF formulations of desloratadine and compare their characteristics, including disintegration time, drug release profile, mechanical properties, and taste masking. The study will explore various polymers, plasticizers, and other excipients to optimize the formulation of MDFs, focusing on factors like film thickness, drug content uniformity, and stability. The comparative analysis of different formulations will provide insights into the effect of formulation variables on the performance of MDFs. The findings of this research will contribute to the development of an effective and patient-friendly dosage form of desloratadine, improving medication adherence and patient satisfaction.

Keywords: Mouth dissolving film, Desloratadine, Formulation, Evaluation, Comparative study.

I. INTRODUCTION

Mouth dissolving films (MDFs) have emerged as an innovative drug delivery system that offers numerous advantages over traditional dosage forms. These films, also known as oral thin films or oral strips, are designed to rapidly disintegrate and dissolve in the oral cavity, allowing for convenient administration without the need for water. The formulation and evaluation of MDFs have gained significant interest in recent years due to their potential to enhance patient

compliance, especially for individuals who have difficulty swallowing tablets or capsules, such as pediatric, geriatric, and bedridden patients.

Desloratadine, a second-generation antihistamine, is widely used for the management of allergic rhinitis and chronic idiopathic urticaria. It exhibits potent anti-allergic and anti-inflammatory properties by selectively antagonizing peripheral histamine H1 receptors. However, conventional oral dosage forms of Desloratadine, such as tablets or syrups, may pose challenges in terms of administration and patient acceptance. The development of a mouth dissolving film of Desloratadine presents an attractive alternative that can overcome these limitations and offer several additional benefits.

The objective of this research paper is to formulate and evaluate a mouth dissolving film of Desloratadine. By incorporating Desloratadine into a polymeric matrix, the film can rapidly disintegrate upon contact with saliva, facilitating the absorption of the drug through the oral mucosa. The use of MDFs for Desloratadine delivery aims to improve patient convenience, enhance drug bioavailability, and potentially lead to improved therapeutic outcomes.

This study will explore the selection of appropriate polymers, plasticizers, and other excipients for the formulation of Desloratadine mouth dissolving films. The films will be prepared using a suitable technique, such as solvent casting or hot melt extrusion, and evaluated for various parameters, including physical characteristics, thickness, weight variation, folding endurance, disintegration time, drug content uniformity, and in vitro drug release. The results will be analyzed and discussed in relation to the desired drug release profile and therapeutic efficacy.

The successful formulation and evaluation of a mouth dissolving film of Desloratadine hold promise in terms of improving patient compliance, especially for individuals with swallowing difficulties. Additionally, the use of MDFs may provide faster onset of action, better drug absorption, and potentially reduced side effects associated with higher systemic drug concentrations. The findings of this research can contribute to the development of innovative drug delivery systems and offer a valuable alternative for the administration of Desloratadine.

Overall, this research paper aims to explore the formulation and evaluation of a mouth dissolving film of Desloratadine, highlighting its potential benefits and implications in improving patient care and therapeutic outcomes.

II. FORMULATION OF MOUTH DISSOLVING FILM OF DESLORATADINE

The formulation of a mouth dissolving film of Desloratadine involves the selection of suitable polymers, plasticizers, and other excipients that enable rapid disintegration and dissolution of the film in the oral cavity. The choice of these ingredients plays a crucial role in achieving the desired characteristics, drug release profile, and patient acceptability. The following steps outline the formulation process:

1. **Selection of Polymers:**

- Polymers used in mouth dissolving films should possess good film-forming properties, rapid disintegration, and excellent mouthfeel.
- Commonly employed polymers include hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), sodium carboxymethyl cellulose (NaCMC), and pullulan.
- The selection of a polymer depends on factors such as film stability, flexibility, and drug-polymer compatibility.

2. **Selection of Plasticizers:**

- Plasticizers are incorporated into the film formulation to improve flexibility, elasticity, and mechanical properties.
- Commonly used plasticizers include polyethylene glycol (PEG), glycerol, propylene glycol, and sorbitol.
- The plasticizer concentration should be optimized to maintain film integrity while allowing rapid disintegration upon contact with saliva.

3. **Drug-Polymer Compatibility:**

- Evaluate the compatibility between Desloratadine and selected polymers to ensure drug stability and uniform drug distribution within the film.
- Techniques such as differential scanning calorimetry (DSC) and Fourier-transform infrared spectroscopy (FTIR) can be employed to assess compatibility.

4. **Film Preparation Techniques:**

- Solvent Casting: Dissolve the polymer in an appropriate solvent (e.g., ethanol, water) and add the plasticizer and Desloratadine.
- Stir the mixture until homogenous and pour it onto a clean glass or metal surface.
- Allow the solvent to evaporate, resulting in the formation of a thin film.
- Cut the film into appropriate sizes or shapes for subsequent evaluation.

5. Evaluation of Mouth Dissolving Films:

- Physical Appearance: Assess the visual characteristics, color, and transparency of the film.
- Thickness: Measure the thickness of the film using a micrometer or a suitable instrument.
- Weight Variation: Weigh individual films and calculate the average weight to ensure uniformity.
- Folding Endurance: Repeatedly fold the film at the same spot until it breaks to determine its flexibility and durability.
- Disintegration Time: Place a film in a suitable dissolution apparatus or in a simulated saliva solution and measure the time taken for complete disintegration.
- Drug Content Uniformity: Analyze the amount of Desloratadine in the film using a validated analytical method.
- In Vitro Drug Release: Conduct dissolution studies using a suitable apparatus to determine the release profile of Desloratadine from the film.

The formulation process should be optimized by systematically varying the concentrations of polymers, plasticizers, and other excipients to achieve the desired characteristics and drug release profile. It is important to consider the compatibility between Desloratadine and the selected materials to ensure stability and efficacy.

III. EVALUATION OF MOUTH DISSOLVING FILM OF DESLORATADINE

The evaluation of mouth dissolving films (MDFs) of Desloratadine involves assessing various parameters to ensure their quality, performance, and suitability for oral administration. The following are the commonly performed evaluations:

1. Physical Appearance:

- Observe the films visually for their color, transparency, and any signs of defects or impurities.

2. Thickness:

- Measure the thickness of the film using a micrometer or a suitable instrument at multiple points and calculate the average thickness.

3. Weight Variation:

- Weigh individual films using a calibrated balance and calculate the average weight to ensure uniformity.

4. Folding Endurance:

- Assess the flexibility and durability of the films by repeatedly folding them at the same spot until they break or show signs of damage. Note the number of folds required for the film to break.

5. Disintegration Time:

- Place a film in a suitable disintegration apparatus or in a simulated saliva solution and measure the time taken for complete disintegration. The film should disintegrate rapidly in the oral cavity.

6. Drug Content Uniformity:

- Analyze the amount of Desloratadine present in the film using a validated analytical method such as high-performance liquid chromatography (HPLC) or UV spectrophotometry. Ensure that the drug content is uniform throughout the film.

7. In Vitro Drug Release:

- Perform dissolution studies using a suitable apparatus (e.g., USP apparatus) in a dissolution medium simulating saliva or other appropriate media.

- Collect samples at specific time intervals and analyze the released Desloratadine using an appropriate analytical method.

- Plot a drug release profile and compare it with the desired release pattern, such as immediate or sustained release.

8. Moisture Uptake:

- Assess the ability of the film to resist moisture uptake by storing it under controlled humidity conditions and measuring the weight gain over time.

9. Surface pH:

- Determine the pH of the film surface using a suitable pH meter to ensure that it is within the acceptable range for oral mucosal application.

10. Mechanical Strength and Elasticity:

- Perform tensile strength and elongation tests using a suitable instrument to evaluate the mechanical properties of the film, including its strength and elasticity.

11. Stability Studies:

- Conduct stability studies under controlled temperature and humidity conditions to assess the physical, chemical, and drug release stability of the MDFs over an extended period.

These evaluations provide valuable information on the physical characteristics, drug content uniformity, disintegration time, drug release profile, and overall quality of the mouth dissolving films of Desloratadine. The results of these evaluations help in determining the suitability of the formulation for further development, optimization, and potential commercialization.

IV. CONCLUSION

In conclusion, the formulation and evaluation of a mouth dissolving film (MDF) of Desloratadine offer a promising alternative for the convenient and effective delivery of the drug. The development of MDFs addresses the challenges associated with conventional oral dosage forms, particularly for patients with swallowing difficulties, such as pediatric, geriatric, and bedridden individuals.

The formulation process involves the careful selection of polymers, plasticizers, and excipients to achieve the desired characteristics, rapid disintegration, and drug release profile. Polymers such as hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), sodium carboxymethyl cellulose (NaCMC), and pullulan have shown potential as film-forming agents. Plasticizers like polyethylene glycol (PEG), glycerol, propylene glycol, and sorbitol contribute to the flexibility and mechanical properties of the films.

Evaluation of the MDFs includes assessing parameters such as physical appearance, thickness, weight variation, folding endurance, disintegration time, drug content uniformity, in vitro drug release, moisture uptake, surface pH, mechanical strength, and stability. These evaluations ensure the quality, uniformity, and performance of the MDFs.

The formulation and evaluation of Desloratadine MDFs have the potential to enhance patient compliance, improve drug bioavailability, and possibly lead to enhanced therapeutic outcomes. The rapid disintegration and absorption in the oral cavity can provide faster onset of action and potentially reduce side effects associated with higher systemic drug concentrations. Moreover, the ease of administration without the need for water makes MDFs particularly suitable for patients with specific needs or preferences.

Further optimization and development of Desloratadine MDFs can be explored, considering factors such as taste masking, stability under various storage conditions, and patient acceptability. Additionally, clinical studies to assess the bioequivalence, safety, and efficacy of Desloratadine MDFs compared to conventional dosage forms would be valuable.

Overall, the formulation and evaluation of a mouth dissolving film of Desloratadine present an innovative approach in drug delivery, offering a convenient, patient-friendly, and potentially effective alternative for the administration of Desloratadine.

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