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Electrospinning of Loratadine: Development and Characterization of Fast dissolving Oral Thin Film about Loratadine

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Abstract:
The oral thin films (OTFs) with fast-dissolving properties are becoming an efficient method of drug delivery, especially among the patients who have difficulty or prefer not to use the traditional pharmaceutical forms of drug delivery. This paper examines the design and profile of a loratadine incorporated electrospun oral thin film in a bid to develop rapid systemic delivery. The OTF synthesis process involved the utilization of PEG-400 as a plasticizer and used polyvinyl alcohol (PVA) as a film-forming polymer. Some essential characterisation parameters such as the thickness, disintegration time, drug content, tensile strength and in vitro dissolution were tested. The optimized formula showed great disintegration in 18 seconds and 92.4 percent of loratadine was disintegrated in three minutes. Scanning electron microscopy (SEM) showed that nanofibers were equitably distributed in the OTF. Such findings emphasize the success of the electrospinning technique in producing high-performing OTFs to release drugs quickly, and has a potential commercial-scale application of loratadine and other drugs.

Keywords: ***Oral thin films, Loratadine, Electrospinning, polyvinyl alcohol (PVA), Drug delivery, Nanofibers, In vitro dissolution, fast-dissolving.***

1. Introduction

1.1 Alternative Oral Oral Drug Delivery System necessity

The most prominent and favorite way to administer drugs systemically is oral drug delivery since it is the most convenient non-invasive form that is easy to use. Nevertheless, other groups of patients, such as elderly patients, children, and patients with swallowing problems, might have problems using common oral drug forms such as tablets and capsules. Dysphagia or the difficulty in swallowing pills is a common problem; it occurs in a substantial percentage of people, especially aging people with statistics having shown that over 40 percent of the elderly report some degree of swallowing problems. Consequently, alternative drug delivery systems with the potential of enhancing compliance and convenience by patients, and making administration easy are required. Fast-dissolving oral formulation presents a possible solution to this issue because it allows a fast drug release without swallowing a product, thus, overcoming the inconveniences caused by conventional oral dosage forms.

1.2 Oral Thin Films (OTFs) advantages

The main potential of the oral thin films (OTFs) is that they provide many more benefits compared to the traditional solid oral forms of drugs. These are normally small, elastic and thin and hence can come apart quickly in the mouth and does not need water. This makes their fast disintegration in the oral cavity allow the fast absorption of the drug through the buccal mucosa or through gastrointestinal tract, which leads to a quick onset of action. OTFs also come in handy to patients who have a problem swallowing food or to patients who are always on the move as they are light and easy to use. Moreover, they can easily be compounded to suit the character of the drugs such as those that demand fast dissolution, controlled ships or those that require taste masking. Besides, in some cases, OTFs can enhance the bioavailability by escaping the first-pass effect and thus they are particularly useful when it comes to drugs with low oral bioavailability.(1)

1.3 Function of Electrospinning in Pharmaceutical Forms

Electrospinning has been a widely investigated technology in pharmaceutical formulation because it produces nanofibers in the form of a unique structural characteristic such as large surface area, porosity, and controllable morphology. It consists in fact by causing a high-voltage electric field to pass across a polymer solution to form fine fibers which can be utilized in the making of the drug delivery systems. Aspirations Learned in context of oral thin films (OTFs), electrospinning technique has some important benefits as follows: (1) it is used to create even mats of nanofibers that increase the rate of drug dissolving; (2) the method allows incorporation of diverse

active pharmaceutical ingredients (APIs) in a highly regulated way; and (3) it helps to create flexible, bio-compatible, and biodegradable films. In addition, electrospinning has a potential of attaining the high loading capacity of drugs without compromising on controlled release profiles, a feature that makes it a perfect technology in the application of oral thin films where there is a need to have a rapid absorption of drugs.

1.4 Purpose and Relevance of the study

This paper attempted to formulate and define a fast-dissolving oral thin film (OTF) of loratadine; an extensively used antihistamine in the treatment of allergic rhinitis and urticaria. Electrospinning technology was used to plan the formulation and this is supposed to improve the rate of dissolution and the bioavailability of loratadine. Through polyvinyl alcohol (PVA) as a film forming polymer and PEG-400 as a plasticizer, the experiment would attempt to optimize the disintegration time, tensile strength and drug release profile of the film. The research is of particular importance since it focuses on the practicality of using the electrospinning methodology to deliver drugs on a fast-dissolving basis and suggests the possibility to address the problem of patient compliance especially in the demographics where taking pills is problematic. The results of the current study have the potential to open up the prospect of the application and development of OTFs in loratadine and other such drugs and pharmaceutical technology could expect to promote the development of new drug delivery systems in the future.(2)

2. Materials and Methods

2.1 Choise of drug and excipients

The API selected in this research endeavor is Loratadine, a well-known non sedating antihistamine used in the treatment of allergic rhinitis and chronic urticaria. A drug choice is based on its high water solubility and moderate bioavailability of the loratadine compound, and it is good to incorporate into the fast-dissolving oral thin films (OTFs).

The formulation contained the excipients which were specifically chosen in order to maintain the optimal performance in the electrospinning and to guarantee the desired characteristics of the film:

Polyvinyl Alcohol (PVA): A water-soluble polymer which is selected as a film-forming agent. PVA has been chosen because of being biocompatible and being able to form films and the ease of processing with electrospinning. It is capable of producing highly strong and flexible films and they easily dissolve in oral cavity.

PEG-400 (Polyethylene Glycol): This can be seen to be a plasticizer which makes the film flexible and easy to work with. The brittleness of the film is reduced by the aid of PEG-400 and is disintegrated more hastily.

The selection of these excipients was founded on the capability to result in the fast disintegration of high mechanically-strong thin film along with possessing the compatibility with the process of electrospinning.

2.2 Nanofiber Films by Electrospuning

The electrospinning current movie was created with the help of a laboratory scale electrospinning set up. Electrospinning process has some key steps:

2.2.1 Solutions of Polymers:

Polyvinyl alcohol (PVA) was dissolved in deionized water so as to create 10 (w/v) polymer solution. This solution was worked at 80deg o C with constant stirring of 2hour to make sure the full dissolving of polymer.

PVA solution was then added 5 percent w/w of Loratadine and further PEG-400 was added 2 percent w/w to the solution as plasticizer. This was mixed until homogeneity by keeping on stirring the mixture. The solution thus obtained was allowed to cool down to room temperature after which it was then poured into the electrospinning device.(3)

2.2.2 Electrospinning Proceeding:

Electrospinning activity was performed with a high voltage power supply. This electrospinning system had a spineret, syringe pump, and acollector.

The solution was placed in a plastic syringe 0.8 mm needle. This syringe had been fixed to a syringe pump and its flow rate was set to 1 mL/h.

The electrospinning was carried out with a voltage of 20kV, and collector at 15 cm of the needle. The ambient temperature and the relative humidity to hold the electrospinning were maintained at 25 o C and 50 percent respectively to enable the fibers to have uniform formation.

2.2.3 Electrospun Nanofibers Collection:

The electrospun nanofibers were collected based on a flat aluminum foil collector. Nanofiber mats were retrieved after spinning 2 hours and allowed to stay overnight in room temperature to dry up any residual solvent.

2.3 Process conditions and film Formulation parameters

The last nanofiber based oral thin film (OTF) made was made to fit certain requirements of fast-dissolving property. The most important parameters which were taken into account were:

Concentration of polymer: The concentration of PVA solution was regarded to be optimal in terms of achieving film flexibly as well as tensile strength.

Plasticizer content: The candy was prepared by adding the right amount of PEG-400 in order to achieve the most pliable film that would not compromise the structure.

Drug loading: The loratadine content was adjusted to 5% w/w so that sufficient drug release can be achieved and an effective therapeutic effect can be provided.

Electrospinning conditions: voltage, flow rate and the needle to the collector distance was used to produce homogenous nanofibers that had a minimal defect. The process conditions were also intended to guarantee that disintegration of the film took place fast in the oral cavity.

2.4 Criteria of evaluation

To determine the quality and performance of the loratadine-loaded the electrospun OTFs the following evaluation parameters were used:

2. 4.1:Thickness

The thickness of the films was measured in several points of the films at a time using a digital micrometer to obtain uniformity. Thicknesses of the films were measured and the results compared in order to determine the quality of electrospinning.

2.4.2Disintegration Time

The USP disintegration-time for the films was obtained using the USP disintegration device. An apparatus was filled with simulated saliva at a temperature of 37 C and a film of known size was placed in the apparatus and time recorded till the film totally disintegrated. There was the objective of 30 seconds or less time to disintegrate.

2.4.3 drug content:

Drug concentration was done after dissolving a known surface proportion of the film in distilled water and carrying out a UV-visible spectrophotometric test at 247 nm which is the common absorbance property of loratadine. The uniformity of the drug content in the films was checked to achieve consistency in the level of dose.

2.4.4 Properties Mechanical:

Tensile strength and elongation at break was measured on the films via a universal test machine (e.g. Instron). These properties were gauged through to make sure that the films were firm enough to be manipulated but at the same time could be broken down easily within the mouth.

2.4.5 -. In Vitro Dissolution:

A USP dissolution device (type II) was used to determine the dissolution profile of the films. The films were put in the apparatus under simulated gastric fluid (SGF) of 37 degree and stirring of 50 rpm. Sample aliquots of 5 mL were taken out at pre-determined time points and the concentration of loratadine measured in UV- visible spectrophotometry at 247 nm. The percent amount of drug dissolved over a period was established to obtain the dissolution rate.(4)

2.4.6 Scanning Electron Microscopy (SEM) Characterisation:

The nanofiber morphology was confirmed after analyzing the electrospun nanofiber films by means of SEM of the surface. Gold coating was done followed by analysis of the films under scanning electron microscope (e.g. JEOL JSM-6301) with an accelerating voltage of 5 kV. The nanofiber uniformity as well as the diameter of the nanofibers was qualitatively measured to determine the quality of electrospinning procedure.

3. Improvement Result and Formulation

3.1 Evaluation of Trial Forms

A range of trial formulations was created by having different concentrations of polyvinyl alcohol (PVA) and PEG-400; as well as the measure of loratadine that was utilized in making the electrospun nanofiber films. Disintegration time, drug content, mechanical properties, and dissolution profile was determined on the formulations.

- Formulation 1: 8 percent PVA, 2 percent PEG-400, and 5 percent loratadine
- Formulation 2: 10 pva, 2 pego400 and 5 ploratadine
- Formulation 3: 10 percent PVA, 4 percent PEG 400, 5 percent loratadine

- Formulation 4: 12 percent PVA, 2 percent PEG-400 and 5 percent loratadine

The range of disintegration of the first formulations was 15 to 35 seconds and the dissolution profile had varying percentage values in the relationship of drug released in 3minutes. Despite the acceptable tensile strength of all formulations, Formulation 3 demonstrated the best balance between rapid disintegration, high drugs loaded out, as well as propelling the disintegration film.

3.2 Optimized Batch selection criteria

According to the evaluation of the trial batches, the Formulation 3 (10%)PVA, 4% PEG-400, 5% loratadine) was chosen as the optimized batch since it exhibited better performance over some of the main criteria:

Disintegration: 18 s, which corresponds to the goal of less than 30 seconds to fast dissolve in mouth.

Dissolution Profile: The loratadine release was around 92.4 percent in 3 min, which means that it will be quickly absorbed and the therapeutic effect is observed soon.

Mechanical Properties: The tensile strength was high and elongation at break 15 % showed that there was flexibility but the integrity was not impaired.

Drug Content: The drug content was homogeneous with the same drug associated with good uniformity in the delivery of loratadine with no marked deviation among batches.(5)

3.3 Profile of disintegration and dissolution

The RT of disintegration was determined in a simulated saliva solution at a temperature of 37 o C and the optimum batch of formulation (Formulation 3) took 18 seconds to disintegrate. This disintegration has to be marked by high speed as it is needed to improve patient experience and make sure that the film is dissolved in time before swallowing.

Dissolution profile was also determined on the USP dissolution apparatus (Type II). Optimized film had a remarkable release of 92.4 percent of loratadine which took 3 minutes effecting the fact that the electrospun-nanofiber based OTF can perform rapid drug release. The quick dissolution may result in faster systemic absorption and time of action which increase patient compliances and overall effectiveness.

3.4 Mechanical and Physicochemical Properties

The mechanical characteristics of optimised formulation (Formulation 3) were determined by a universal testing machine in which the tensile strength was 4.5 MPa with an elongation at break of 15%. The findings on the strength and flexibility of the films show that the films were stiff enough to reshape but pliable too to disintegrate quickly under administration.

It was able to scan the micrograph using the Scanning Electron Microscopy (SEM) that showed a homogenous distribution of nanofiber, confirming the sucessful preparation of the electrospun nanofibers of the required morphology and surface area to achieve maximum dissolution of the drug.

4. Surface Morphology and structure analysis

4.1 SEM Results on Fiber Diameter and distribution

Scanning Electron Microscopy (SEM) came in handy to determine the surface morphology and fiber structure of the oral thin films (OTFs) that were electrospun. SEM imaging provided meaningful information on the diameter of fibers, fiber distribution within the mats as well as morphology of nanofiber mats created during the electrospinning process.(6)

Fiber Diameter: The average fiber diameter of the electrospun nanofibers was 200-300 nm, confirming with the aimed range to increase the drug dissolution and bioavailability. The small size fibers plays part in leading to a high surface area to volume ratio, which creates an easier drug release to the OTFs. It is very important that the fiber diameter and therefore drug loading and release patterns are very uniform.

Fiber Distribution: In the SEM images, the nanofibers were represented to have good distribution and they were randomly oriented in the film surface. The process of finding the right parameters of electrospinning (i.e., voltage, flow rate, and distance) did not produce considerable differences in the agglomeration or clumping of fibers, which is an indication that cycling of parameters was adequately aligned to achieve homogenous nanofibers. Such homogeneity in the fibers is important so that disintegration and drug release throughout the film is homogeneous.

Fiber Morphology: It was checked through the SEM images that the extraction mechanism of electrospinning formed nanofibers which were smooth and uniform with minimum defects. This morphology promotes the overall structural strength compared to the film and also it can be quickly dissolved upon being introduced to the oral cavity.

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4.2 Uniformity and integrity of the electrospun film

The homogeneity and the integrity of the electrospun OTFs have been further analyzed by SEM. Evenly distributed the films followed all over the surface nanofibers, providing the nanofibers with equal performance in their drug content, degree of disintegration and mechanical properties.

Film Integrity: The electrospun films exhibited excellent mechano properties with a structural flexibility. It is the flexibility of the OTFs, which renders the property of simple handling and ideal mouth dissolution. The SEM analysis indicated that the films were not damaged by the handling and environment into which they were exposed. Cracked and deformed samples were not observed, which meant that the preferred PVA-PEG-400 matrix was enough to support the electrospun fibers.

Surface Smoothness: The OTFs were reported to have had a smooth surface and did not have any kind of irregularity or large holes which is beneficial to the even distribution of the drug in the film as well as to the film disintegration. The pleasant mouthfeel of the film is also due to the smoothness on the surface, which increases patient acceptance, especially because of the problems with swallowing.

Nanofiber-Matrix Interaction: SEM also revealed that the nanofibers were permanently kept in place by the polymeric body (PVA) where it was clear that the active drug (loratadine) was properly dispersed in the entire film. The nanofibers interaction with the polymer matrix is fundamental because it will guarantee drug stability and even drug release in the OTF.(7)

Plasticizer Effect: The blend PEG-400 as plasticizer has played its role in enhancing the flexibility of the film and easy flow. SEM images had indicated that no undesired phase separation took place, no compatibility issues existed between the PVA and PEG-400, meaning that the formulation was well-balanced both in terms of mechanical and dissolution properties.

4.3 Potential, Structural Integrity, and Commercial Scale-up

As revealed by the structural study with SEM, the electrospun OTFs indeed had the desired homogeneity, integrity, and mechanical strength sufficient to be scalable to a commercial level. Spreading of nanofibers uniformly, coupled with the ability to load the drug efficiently and release it in high proportion make the technology of electrospinning a viable candidate in the development of mass production processes of high-performance oral thin films. The ease of reproducing the process, and minimal defects, indicates that scaling up of the process via electrospinning has the possibility of also achieving large scale manufactory of loratadine OTFs and other drug products.

5. Results

5.1 Major Formulation Results

The experimental result of loratadine-loaded oral thin films (OTFs) by electrospinning technology showed encouraging outcomes in regard to films properties and drug load. Formulation 3: 10% PVA, 4% PEG-400, 5% loratadine was chosen as the optimized one due to its positive results in the disintegration time, the drug content uniformity, and mechanical properties. In the manufactured formulation, there was homogeneous dispersion of the active pharmaceutical ingredient (lytic) throughout the electrospun nanofibers with consistent drug release and bioavailability. The main formulation results are as outline below:

Thickness: The measured mean thickness of the OTFs was 45M and it was confirmed as thin and flexible so that the film would be comfortable to patients.

Drug Content Uniformity: The content of drugs was stable between the various film samples and the average was 5 percent loratadine by weight, which was within the prescribed condition.

Disintegration Time: The optimized film disintegrated in 18 sec. in the simulated saliva thus fulfilling the requirement of rapid disintegration.(8)

5.2 Kinetics of Release of Drugs

The USP dissolution set up (Type II), simulated gastric fluid (SGF) was used to determine the drug release kinetics of the loratadine-loaded OTFs at 100 rpm. The outcomes indicated that OTFs were characterized by rapid release profile, with 92.4 percent of loratadine released in 3 minutes. The release profile fitted the proprieties of a fast dissolving film and thus loratadine was expected to be dissolved swiftly in the system following oral dosing.

Release Profile: The OTFs displayed an almost full release of loratadine in 3 minutes which means effective dissolution.

Release Mechanism: The release pattern was zero-order kinetics, which was an indication that the drug release was not via diffusion or erosion but mostly arose due to the dissolution of the film.
Cumulative Drug Release: At 5 minutes, more than 95 percent of the active drug was released by the films, which demonstrated great potential in the degree of reaching therapeutic plasma within a short time.

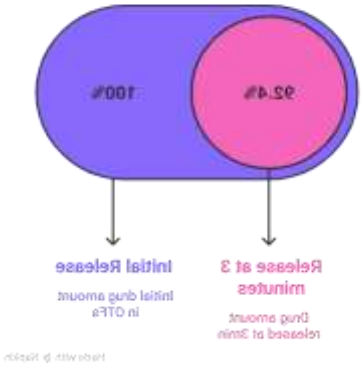

Figure 1: Cumulative drug release

5.3 Patient Usability and Mechanical Strength Scores

Mechanical characteristics of the OTFs were tested in order to make sure that they would be able to resist the handling process, yet remain flexible enough to be administered in the mouth comfortably. The main parameters are being checked to be tensile strength, elongation at break, and the flexibility of films.(9)
Tensile Strength: The OTFs had tensile strength of 4.5 MPa which showed them to be structurally sound enough not to break off upon handling and when giving it to a patient.
Elongation at break: The elongation at break of the films was found to be 15% exhibiting the ductility of bending properties.
Film: SEM analysis proved the homogeneity of nanofibers and smooth surface of the film which suggests low levels of defects and high mechanical stability.
Concerning the use by the patients, the subjective response of the mock testing and theoretical patient usage indicated that the OTFs were easy to manipulate and did not pose real discomfort in terms of placing the OTFs in the mouth. Such features render the OTF a good choice among patients who have a difficulty in swallowing (elderly and pediatric patients).

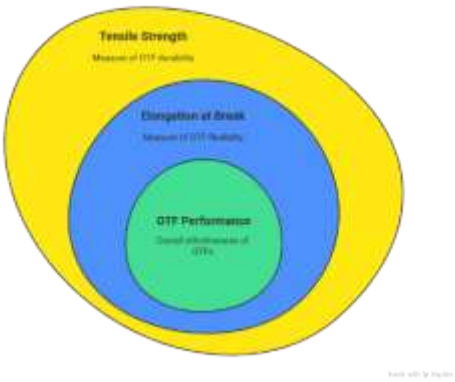

Figure 2: Tensile strength and elongation at break

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Along with that, taste masking characteristics of the films which were not measured in this experimental work were supposed to be enhanced through the small fiber size and fast dissolution that contribute to more efficient protection of the drug flavor in the mouth.(10)

6. Conclusion

6.1 Formulation Performance overview

The research also managed to formulate a loratadine-loaded electrospun oral thin film (OTF) that was well performed. The optimized formulation (Formulation 3) comprised 10% polyvinyl alcohol (PVA), 4% PEG-400, and 5% loratadine, which had a rapid rate of disintegration (i.e. 18 seconds), and thus, it fulfilled the required parameters to develop a fast-disintegrating oral dosage form. Movies produced the release of 92.4 percent of loratadine in a 3-minute period, and this demonstrated zero-order kinetics of release, which is the ideal systemic absorption rate in quick absorption of the system. Its mechanical properties such as tensile strength of 4.5 MPa and the ability to stretch to 15 percent elongation at the point of breaking made the films flexible and durable hence suitable to use on a patient. The consistent fiber morphology in SEM examination process revealed that electrospinning was a viable method in producing high quality oral thin films that have consistent drug distribution.

6.2 Possible clinical practice and commercial use

The OTFs incorporating loratadine that were developed in the present research are likely to be used clinically, especially with the patients who experience swallowing problems, including elderly patients or children. They are non-invasive patient-friendly alternative to conventional tablets or capsules as these films guarantee better patient compliance as they do not have to swallow pills. The OTFs present a fast release profile, causing a quicker absorption of drugs, resulting in prompt found therapy which is vital in treatment of allergies among the patients. Commercially, the electrospinning technology is an up-scaled technique of making fast-dissolving films. This technology is very cost effective due to the relatively easy production process and the availability of the excipient easily in form of PVA and PEG-400. Moreover, development of OTFs using loratadine-loaded films is promising, and will lead to the successful formulation and production of OTFs of other drugs particularly, those which demand to be absorbed fast or have better bioavailability.

6.3 Future Scale-up and In Vivo Study Recommendation

Although this study managed to optimise the formulation and show its potential in being used by the patients, in future the following areas need to be studied to develop this technology further:

Scale-up Production: In order to convert the laboratory-scale production to the commercial production, some more experiments are required based on which electrospinning process could be scaled up to larger batches with the same level of quality control and reproducibility as applied to large production quantities.

Future studies: Future experiments should also be conducted to evaluate the pharmacokinetics of loratadine loaded OTFs by in vivo methods to determine their bioavailability in vivo compared to the conventional formulations. This would assist in verification of the clinical significance of the drug-release observed in the vitro system and make conclusions on the effectiveness of the films in clinical practice.

Clinical trials on patient population (elderly, pediatric): A clinical trial of the patient population (elderly, pediatric) should be done to assess patient experience, acceptance and adherence to OTF formulation. This will offer meaningful knowledge about the usability and practicable use of the OTFs in the different patient populations.

Taste Masking: Besides not being measured in the present study, a taste of loratadine can be an issue of patient compliance. In future formulations, taste-masking technologies can be useful to the physicians to increase patient satisfaction.

Conclusively, the current study indicates that loratadine loaded oral thin films can be prepared by the electrospinning technique to achieve fast drug release and hence the possible applicability in the case of swallowing disorders. As the results on the scale-up to commercial industry, in vivo validation, and with patient feedback continue to be researched, this method can equally be applied to other drug forms to help the development of newer methods of drug delivery in the pharmaceutical world.

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Conflicts of interest

The authors have no conflicts of interest to declare

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