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(RESEARCH ARTICLE)

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Development and characterization of aloe vera–based herbal transdermal therapeutic systems for enhanced skin delivery

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Abstract

Transdermal drug delivery systems have become one of the new methods of enhancing the bioavailability and compliance of drugs in patients. The current research is dedicated to creating and testing herbal transdermal patches with Aloe vera extract by the solvent casting technique. Different polymers, such as hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), and chitosan were used to prepare various formulations with the help of appropriate plasticizers and permeation enhancers. The patches that were prepared were tested in terms of physicochemical parameters, i.e. thickness (0.21-0.29 mm), weight change (109-118 mg), folding strength (>250), surface pH (6.2-6.8), moisture content (3.8-5.1%), and uniform drug content (96.2-98.7%). The in vitro drug release test showed sustained release properties of up to 12 hours, with the highest release of the HPMC+PVA formulation (92.3%). The release kinetics was based on Higuchi diffusion model, which implies a controlled release of drugs. These findings indicate that the transdermal patches made of Aloe vera are a good platform of long-term drug delivery with a high degree of stability and adherence. The optimized formulation exhibited better performance of mechanical strength and drug release, which indicate its potentials in pharmaceutical use.

Keywords: Aloe Vera; Controlled Release; Herbal Drug Delivery; Polymer Matrix; Transdermal Patch

1. Introduction

Transdermal drug delivery systems (TDDS) have developed as an attractive substitute to the existing dosage form methods of delivery, with advantages like controlled drug release, enhanced patient compliance and prevention of first-pass metabolism. In recent decades, special emphasis has been placed on the inclusion of herbal therapeutics into the contemporary delivery systems in order to improve their bioavailability and therapeutic ability. Aloe vera is one of the most important medicinal plants in possession of a broad spectrum of pharmacological activities, such as anti-inflammatory, antimicrobial, wound-healing and antioxidant effects [1].

Transdermal applications Herbal extracts in transdermal patches are a new concept in the formulation of drugs, where old herbal wisdom is integrated with new drug delivery methodologies. The bioactive compounds present in aloe vera include polysaccharides, anthraquinones, vitamins and enzymes which add to its therapeutic potential. Nevertheless, traditional topical treatments of Aloe vera gel are usually characterized by low retention time and weak penetration of the gel through the skin barrier. This drawback leads to the creation of a more sophisticated delivery system that would be able to maintain the drug delivery and increase permeation [2].

The skin is the largest organ in the human body and it serves as a protective covering which limits the entry of outer substances. The stratum corneum is the outer layer which is very vital in resisting drug permeation. Hence, to overcome

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this barrier, the selection of polymers, plasticizers and permeation enhancers that are incorporated in designing an effective transdermal patch is done with care. The herbal transdermal patches have a controlled release system where a constant concentration of the active compound is released over a longer time with minimal side effects on the system [3].

The latest trends in research assert the significance of biodegradable and biocompatible polymers when preparing transdermal systems. Natural polymers like chitosan, gelatin, and derivatives of cellulose are also becoming more popular as they are non-toxic, and do not interfere with herbal constituents. Moreover, the use of Aloe vera extract as a part of such polymeric matrices also increases the therapeutic effect, such as an increased level of skin hydration and diffusion of drugs [4].

The invention of transdermal patches made out of Aloe vera is also in line with the increasing need of herbal and green healthcare products around the world. The patients are becoming more drawn to natural remedies as they are perceived to be not only safe, but also with minimum side effects. Moreover, transdermal delivery systems decrease the number of times one has to take a dose, thus enhancing compliance to treatment programs. All these benefits make herbal transdermal patches a promising research area of pharmaceutical sciences [5].

Here, the current research is based on the development and testing of herbal transdermal patches made out of Aloe vera. The study will be designed to design a stable, efficient and patient friendly delivery system to guarantee prolonged release and improved permeation of active constituents. Other physicochemical parameters are considered such as thickness, change in weight, folding endurance, moisture, drug content, uniformity of drug content and in vitro diffusion experiments are conducted to determine the quality as well as the performance of the developed patches.

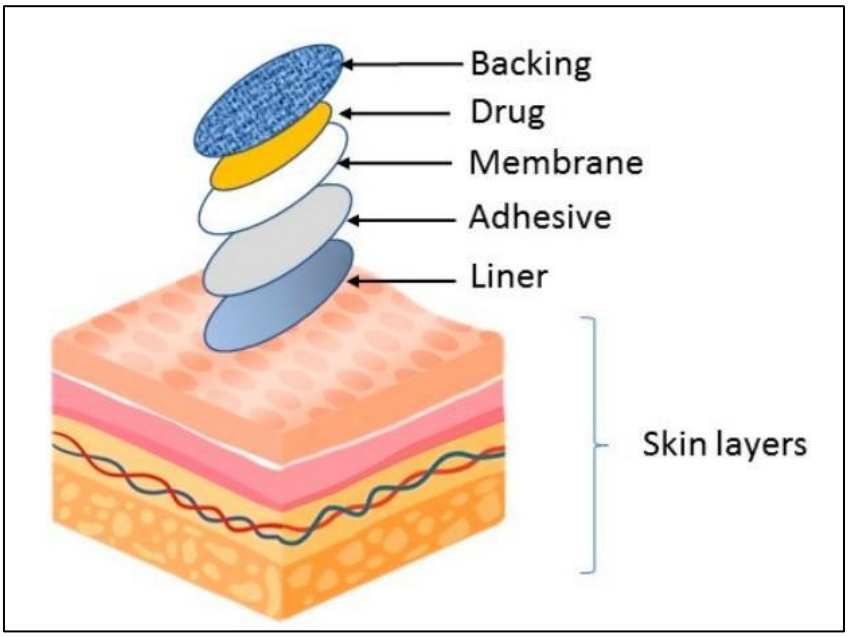

Figure 1 Structure of Transdermal Patch [6]

Figure 1 depicts the structural elements of a transdermal patch, which consist of the backing membrane, drug reservoir/matrix, adhesive layer, and release liner. All the layers are crucial to maintain controlled delivery of drugs. The system is covered by the support layer and the active ingredient is found in the drug matrix. The glue assures good adhesion to the skin and the release liner is peeled off prior to use. This structure is crucial in the design of effective Aloe vera-based patches with ideal drug release and stability.

2. Literature Review

Inclusion of herbal medicine in the current drug delivery systems has received a lot of interest within the recent times especially in the area of transdermal drug delivery. There has been a growing interest among researchers in coming up with plant-based formulations, which have greater therapeutic effects and less side effects. Aloe vera is one of these and

has proven to be one of the most researched herbal candidates with a broad pharmacological profile and good compatibility with polymeric systems [7], [8].

Initial research on transdermal drug delivery systems focused mainly on synthetic drugs but the drawbacks that were related to the toxicity, low adherence by the patient, and other side effects of the system prompted the use of herbs. Since herbal extracts are complex mixtures of bioactive compounds, they have synergistic effects as medicines. Here, Aloe vera has been extensively explored due to its wound-healing, anti-inflammatory and moisturizing effects, thus it is especially applicable in transdermal use [9], [10], [11].

A number of authors have investigated the preparation of Aloe vera in topical and transdermal systems. Early research was on simple gel formulations which showed good therapeutic results but was not long-lasting and dried on application. In order to eliminate these shortcomings, polymer-based film and patch were implemented. Incorporation of Aloe vera extract into polymeric materials like hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA) and chitosan have demonstrated better retention of drugs, controlled release and increased permeation [12], [13], [14].

Recent development in formulation strategies has put a focus on using natural and biodegradable polymers. Transdermal patches made of chitosan have been popular because of their biocompatibility, ability to make films, and in-built antimicrobial properties. Research has shown that Aloe vera-impregnated chitosan patches have enhanced mechanical strengths, and sustained profiles of drug release. On the same note, gelatin and sodium alginate have also been considered as alternative polymeric material, which is flexible and has higher moisture retention ability, which is essential to keep skin hydrated and facilitate diffusion of drugs [15], [16].

The rate of permeation is also a crucial consideration of transdermal drug delivery. Some literature has examined the addition of chemical enhancers like ethanol, propylene glycol and dimethyl sulfoxide (DMSO) to enhance the absorption of the drug to the stratum corneum. Interestingly, Aloe vera itself has been claimed to be a natural permeation enhancer as it is hydrating and skin softening. The two-fold functionality has made it a desirable transdermal formulation candidate [17], [18].

The use of in vitro and ex vivo evaluation methods has been very crucial in determining the performance of herbal transdermal patches. Franz diffusion cell has become a common technique to research the properties of drug release and permeation. Some studies have indicated that Aloe vera patches have a controlled release behavior, which follows the zero-order or Higuchi kinetic indicating that the release of medicines in patches is diffusion-controlled. These results demonstrate the possibility of Aloe vera preparations to attain longer-term therapeutic outcomes [19], [20], [21].

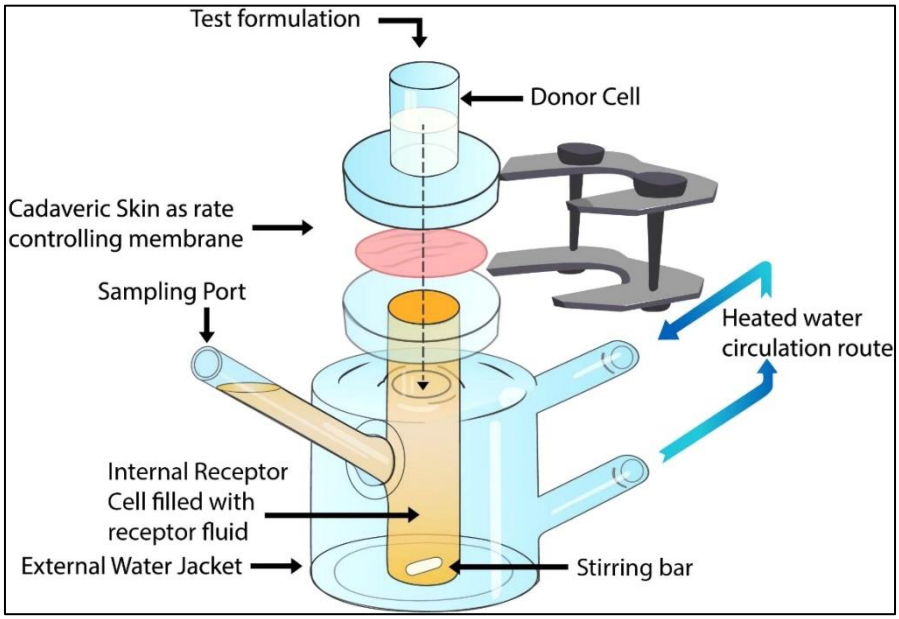

Figure 2 Franz Diffusion Cell Setup for In Vitro Study [24]

Another significant field that has been researched in the literature is mechanical and physicochemical characterization of transdermal patches. Thickness, tensile strength, folding endurance, moisture content, and uniform content of drugs

are the parameters that are essential in determining the quality and stability of the patches. Results of the research indicate that addition of plasticizers such as glycerol and polyethylene glycol increases the flexibility as well as durability of the films without affecting the release characteristics of the drugs [22], [23].

The figure 2 illustrates the Franz diffusion cell setup that is employed in the measurement of the skin or synthetic membrane permeation of drugs. The system comprises of donor and receptor compartments coupled with a membrane. The transdermal patch is laid in the donor compartment with a befitting buffer solution in the receptor compartment. Drug release is measured by taking samples at periodic times. It is a commonly employed system to investigate the release kinetics and permeation efficiency of transdermal patches made of Aloe vera.

Table 1 Summary of Previous Studies on Herbal Transdermal Patches

Author	Herbal Drug	Polymer Used	Key Findings
Sharma et al. [25]	Aloe vera	HPMC	Sustained release, good flexibility
Patel et al. [12]	Curcumin	PVA	Enhanced permeation
Singh et al. [11]	Neem extract	Chitosan	Antimicrobial effect
Kumar et al. [13]	Aloe vera	Gelatin	Improved skin hydration

Table 1 specifies some of the important research works associated with herbal transdermal patches. It emphasizes the kinds of herbal drugs, polymeric materials and key findings. Formulations of aloe vera are always associated with delayed release of drugs and enhanced skin hydration. Curcumin and neem are other promising herbal drugs that are used in transdermal applications. All these studies underscore the need to have proper polymer choice and formulation methods in order to have effective drug delivery.

3. Materials and Methods

The current paper is dedicated to systematic production of the Aloe vera-based herbal transdermal patches with the help of solvent casting method, and the thorough physicochemical and performance analysis. The methodology allows reproducibility, stabilization of formulation and ideal release properties of the drug.

3.1. Materials

Aloe vera fresh leaves were picked and authenticated to extract them. Hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA) and chitosan were chosen due to their ability to form films. Flexibility was added with the help of plasticizers such as glycerol and polyethylene glycol (PEG-400). Ethanol and distilled water were used as a solvent and propylene glycol was added as a permeation enhancer. The analysis of all reagents was of the analytical grade to allow consistency and reliability of the formulations.

3.2. Extraction of Aloe Vera Gel

The leaves of Fresh Aloe vera were cleaned with distilled water in order to get rid of impurities. A sterile knife was used to carefully scrape off the outer green rind and the inner mucilaginous gel was scraped off. The gel was mixed, and filtered using muslin cloth to extract a clear extract. To ensure that the active constituents are not degraded and to ensure that the extract is stable, filtered extract was kept at 40 degree centigrade. This extract was used as the active herbal ingredient of the formulation.

3.3. Formulation of Transdermal Patches

The solvent casting method was used in the preparation of the transdermal patches. Appropriate solvent system was used to dissolve selected polymers (HPMC, PVA or chitosan) and stir the solution continuously to create a uniform polymeric solution. The polymer matrix was then added along with plasticizers and permeation enhancers with aloe vera extract. The mixture thus formed was stirred to give a homogeneous solution.

The solution was added to a glass mold or petri dish and left to dry under controlled temperature conditions (4050 C) till a flexible film was formed. The patches were then dried and peeled off carefully and then cut in uniform sizes to be further evaluated. The ready-made patches were kept in desiccators to avoid being moist.

The figure shows the solvent casting technique that was applied in making transdermal patches. It consists of dissolving the polymers in an appropriate solvent, mixture of the drug and pouring the mix onto a surface. The solvent is then evaporated under a controlled environment in order to create a thin film. The technique guarantees that there is uniform distribution of drugs and uniform film thickness. It is common in that it is relatively simple and effective in making quality transdermal patches made of Aloe vera.

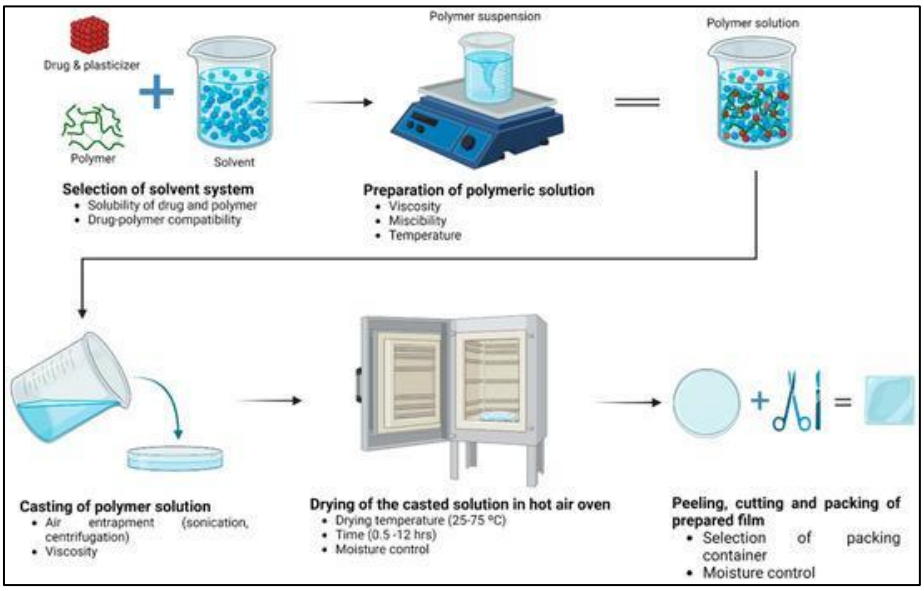

Figure 3 Solvent Casting Method for Patch Preparation

The figure 3 depicts the solvent casting technique in the making of transdermal patches. This is done by dissolving the polymers in a suitable solvent, adding the drug and pouring the solution on a flat surface. Then, the solvent is dried in controlled conditions to create a thin film. This process will guarantee the even distribution of drugs and the consistency of the film. It is commonly employed because it is easy and efficient in coming up with high quality Aloe vera-based transdermal patches.

3.4. Evaluation of Transdermal Patches

The ready patches were analyzed in terms of different physicochemical and mechanical characteristics in order to guarantee their quality and functionality.

3.4.1. Physical Evaluation

Parameters like thickness, weight change, folding endurance and surface pH were measured. Digital meter was used to measure the thickness and the change in weight was measured with an analytical balance. Mechanical strength was measured by folding the patch repeatedly at the same point until it broke giving the folding endurance.

3.4.2. Moisture Content and Moisture uptake

The content of moisture was calculated by putting the patches in a desiccator with calcium chloride and the uptake of moisture was measured by putting the patches in a high humidity environment. These parameters are important in assessing the stability and storing conditions of the patches.

3.4.3. Drug Content Uniformity

All the patches were dissolved in an appropriate solvent and the content of drugs was studied by the UV-visible spectrophotometry. Even distribution of drugs is crucial in obtaining uniform therapeutic effectiveness.

3.4.4. In Vitro Drug Release Study

The Franz diffusion cell was used to perform in vitro drug release experiments. The patch was inserted in the donor compartment, and separated with a semi-permeable membrane. The predetermined intervals saw the withdrawal of the samples and analysis performed spectrophotometrically to establish drug release kinetics. The receptor compartment was filled with phosphate buffer (pH 7.4) and the samples were held at 37C.

Table 2 Composition of Aloe Vera Transdermal Patch Formulation

Ingredient	F1	F2	F3
Aloe vera extract	2%	2%	2%
HPMC	3%	2%	—
PVA	—	2%	3%
Chitosan	—	—	2%
Glycerol	1%	1%	1%
Propylene glycol	0.5%	0.5%	0.5%

Table 2 shows various recipes of Aloe vera transdermal patches having different polymer combinations. All formulations will be aimed at assessing the impact of polymer type and concentration on patch behavior and drug release. HPMC based patches provide controlled release, and PVA increases mechanical strength. Chitosan offers antimicrobial properties and biocompatibility. Flexibility and enhanced diffusion of drugs in all formulations is maintained by the use of the same plasticizers and permeation enhancers.

Table 3 Evaluation Parameters and Methods

Parameter	Method Used
Thickness	Digital micrometer
Weight variation	Analytical balance
Folding endurance	Manual folding test
Drug content	UV spectrophotometry
Moisture content	Desiccator method
Drug release	Franz diffusion cell

Table 3 will indicate the parameters of evaluation and the analysis techniques applied in the research. All the parameters are very important in the determination of the quality and performance of the transdermal patches. As an example, thickness and weight variation provide consistency, whereas an analysis of drug content provides accuracy in the dosage. Moisture experiments show stability and diffusion experiments give an insight on the drug release kinetics. These approaches combined guarantee a thorough analysis of transdermal systems based on Aloe vera.

4. Results and Discussion

The Aloe vera-based transdermal patches developed were analyzed in terms of physicochemical characteristics, mechanical strength and drug release characteristics. The findings indicated that all formulations (F1–F3) formed smooth, flexible and uniform films free of noticeable air bubbles and cracks, which shows that the solvent casting technique was successful in formulating the films. Introduction of Aloe vera extract did not impact negatively on the film integrity and this indicates that it is compatible with the chosen polymers.

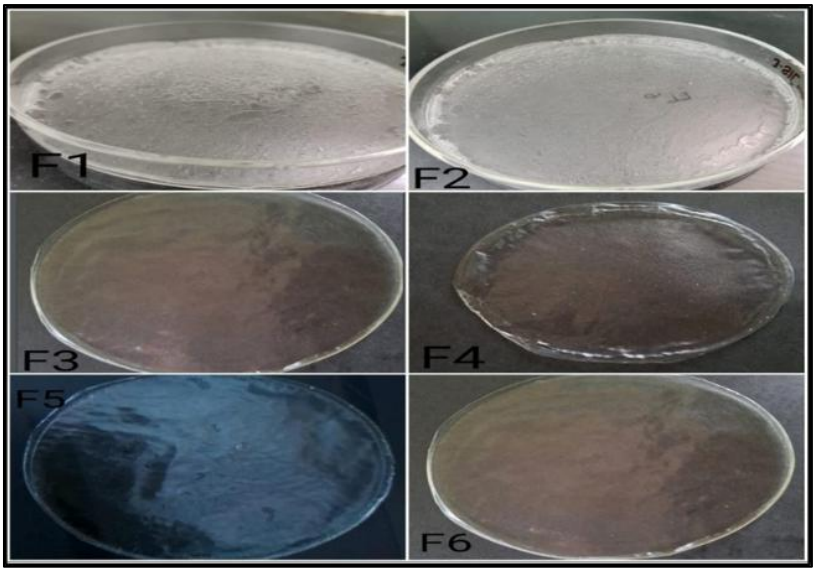

Figure 4 Visual Appearance of Prepared Aloe vera Transdermal Patch Formulations (F1–F6)

Figure 4 shows the physical appearance of six various transdermal patch formulations (F1-F6) made of Aloe vera extract in different polymer mixes with different proportions. The photos emphasize contrasts in the levels of transparency, smoothness of surfaces, and evenness. Formulations F1 and F2 seem more homogenous and transparent, which means that polymer distribution is more effective, whereas F3 to F6 are not very different in color and texture because the polymer type and its concentration can vary. Such visual attributes are significant signs of film quality, consistency and success in transdermal drug delivery systems overall formulation.

4.1. Physicochemical Properties

The thickness of the patches was between 0.21 ix 0.02 mm and 0.29 ix 0.01 mm, which meant that the film was uniformly formed. The low variation in thickness guarantees a steady distribution and release of drugs. The change of weight between the patches was observed to be within acceptable level indicating consistency in casting and drying. The pH of the surface was between 6.2 and 6.8 which is near the pH of the skin of the individuals, meaning that the patches would not irritate the skin when applied.

The values of folding endurance greater than 250 folds in all the formulations showed high mechanical strength and flexibility. The most stable formulation (F2 (HPMC + PVA combination)) had the highest folding endurance, which was due to synergistic polymer interaction. The moisture content and uptake analysis had established that the use of the chitosan (F3)-containing patches had slightly higher levels of moisture uptake because of its hydrophilic property that can help in increasing skin moisture levels and drug penetration.

Table 4 Physicochemical Evaluation of Transdermal Patches

Parameter	F1 (HPMC)	F2 (HPMC+PVA)	F3 (Chitosan)
Thickness (mm)	0.24 ± 0.02	0.29 ± 0.01	0.21 ± 0.02
Weight variation (mg)	112 ± 3	118 ± 2	109 ± 4
Folding endurance	265	310	280
Surface pH	6.5	6.8	6.2
Moisture content (%)	4.2	3.8	5.1

Table 4 summarizes the physicochemical properties of the prepared transdermal patches. Formulations were prepared consistently with all formulations showing good uniformity in thickness and weight. Folding endurance values assure that the patches are mechanically stable and can be handled. Surface pH near skin pH is compatible and has less likelihood of irritation. The moisture content analysis indicates that chitosan-based patches can retain more moisture, which could have a positive impact on drug permeation and skin hydration.

4.2. Drug Content Uniformity

The analysis of drug content revealed that there was a homogenous distribution of Aloe vera extract in all patches with an analysis ranging between 96.2 and 98.7. This shows that the solvent casting technique was a good way of ensuring uniform mixing of the herbal extract in the polymer matrix. F2 was the formulation with the highest drug content (98.7%), which probably is so because of improved polymer compatibility and dispersion properties.

Table 5 Drug Content Uniformity

Formulation	Drug Content (%)
F1	96.2 ± 1.1
F2	98.7 ± 0.8
F3	97.5 ± 0.9

The results of the transdermal patches content uniformity of drugs are shown in table 5. The values show that the incorporation of Aloe vera extract was close to complete in all of the formulations but with very little variation. Consistent content uniformity of the drug is critical in obtaining consistent therapeutic effects. This small positive change in F2 is indicative of a better polymer-drug compatibility and F2 would be a good formulation to optimize and continue to be used in the future.

5. In Vitro Drug Release Study

The in vitro drug release experiment demonstrated a prolonged release pattern of all the formulations during 12 hours. F1 had a cumulative drug release of 78.4, F2 and F3 a release of 92.3% and 85.6% respectively. Enhanced release in F2 could be due to the interaction of HPMC and PVA which promoted optimum swelling and diffusion.

Various mathematical models were used to analyse the release kinetics and the data was most appropriate to the Higuchi model, which is diffusion-controlled drug release. This indicates that the drug spread slowly through the polymer matrix, thus, prolonging its therapeutic effects.

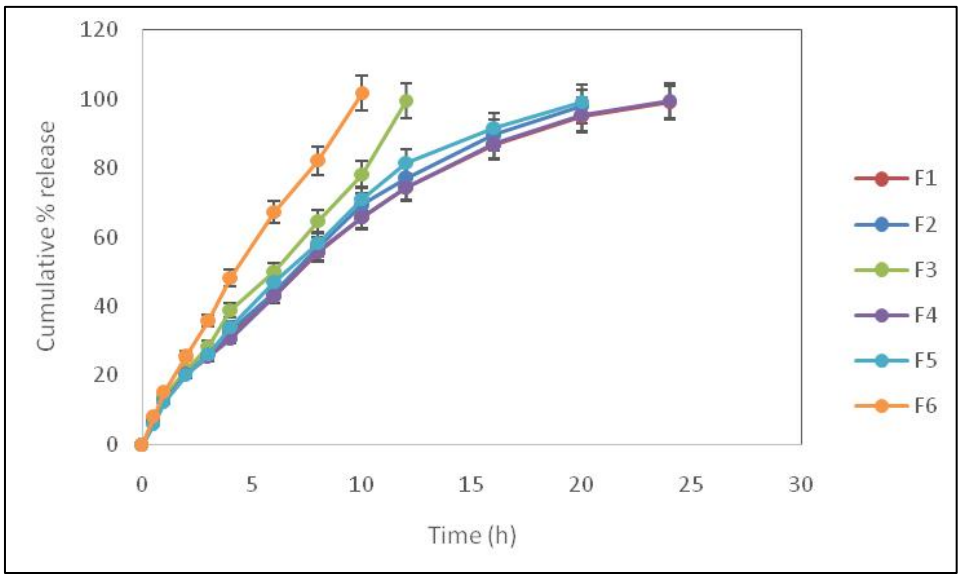

Figure 5 Comparative Drug Release Profile

This figure 5 illustrates the cumulative profile of drug release of the formulations F1, F2, and F3 at the same time. F2 exhibits the best and the most stable drug release, which implies a better formulation performance. F1 and F3 release at slower rates because of the increased polymer density and moderate release, respectively of chitosan and its hydrophilic nature. The graph shows clearly that there is sustained drug release behavior, which is critical to transdermal therapeutic systems.

6. Conclusion

This current research was able to show how Aloe vera herbal transdermal patches could be developed and evaluated using various polymeric mixtures. The results support the idea that transdermal delivery could also be used to improve the therapeutic effects of Aloe vera, through the control and sustained release of the drug. The physicochemical characteristics of all the formulated patches such as uniform thickness, acceptable weight variation, suitable surface pH and good folding endurance were acceptable. These properties imply that the ready films are mechanically stable, flexible and can be used as a transdermal film. The content of moisture and uptake studies also confirmed stability of the formulations in different environmental conditions. The uniformity in drug content exhibited proved to be an effective incorporation and distribution of the Aloe vera extract in the polymer matrix. F2 (HPMC + PVA) was the most successful of all the formulations based on mechanical strength, drug content and release behavior. In vitro drug release study showed a sustained drug release profile of up to 12 hours with F2 recording the greatest cumulative drug release. The diffusion process was consistent with the Higuchi diffusion, and the release kinetics were verified.

The paper has indicated the impact of the choice of polymer used in patches. The swelling, drug diffusion and overall therapeutic efficacy were improved by the combination of hydrophilic polymers. Moreover, natural properties of Aloe vera, such as its moisturizing and skin penetration enhancing properties, were beneficial in drug delivery by the skin.

To sum up, transdermal patches made of Aloe vera are a promising and effective alternative to a traditional topical preparation. The optimized formulation (F2) is a potentially promising candidate to undergo further clinical testing and even commercialization. Future studies can be aimed at including nanocarriers, enhancing stability, and in vivo research to confirm therapeutic effects.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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