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ORIGINAL ARTICLE

Transdermal Therapeutic System of Glimepiride

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Abstract

Introduction: This study investigates the formulation and assessment of matrix-based transdermal patches for glimepiride, a therapeutic drug regularly prescribed for Type 2 diabetes management. These patches are intended to enhance the drug's bioavailability and ease of use, offering a promising alternative to oral administration, which often faces issues like gastrointestinal side effects and reduced effectiveness due to hepatic metabolism during the initial pass. The transdermal route supports controlled drug delivery, making it a valuable approach for glimepiride. **Materials and Methods:** In developing these patches, seven formulations (F1–F7) were created, each with different proportions of film formers of hydroxypropyl methylcellulose (HPMC) and polyvinylpyrrolidone (PVP K30). Polyethylene glycol (PEG 400) and dibutyl phthalate were added as plasticizers to improve flexibility. The patches were crafted using the solvent casting method and evaluated for their physical and mechanical properties, including thickness, tensile strength, folding endurance, percentage elongation, drug content uniformity, and moisture loss. *In vitro* and *ex vivo* studies were conducted to understand the drug permeation and release kinetics. **Results and Discussion:** Among the tested formulations, F4 stood out due to its balanced HPMC to PVP K30 ratio and optimized PEG 400 concentration. *In vitro* release studies demonstrated that F4 provided consistent drug release over a 24 h period, following zero-order kinetics and a non-fickian diffusion model, indicating it is particularly suited for prolonged therapeutic delivery. *Ex vivo* permeation studies using porcine ear skin further supported the F4 formulation's potential, showing effective permeation and a steady, controlled release of glimepiride. Spectroscopic analyses, including Fourier-transform infrared spectroscopy, confirmed that there were no significant interactions between the drug and polymers, attesting to the stability of the formulation. **Conclusion:** This research underlines the effectiveness of matrix-based transdermal patches as a practical delivery system for glimepiride, which could be particularly beneficial for patients seeking alternatives to traditional oral medications. The findings suggest that formulation F4 could serve as a reliable and stable transdermal patch for extended glimepiride delivery, offering advantages in dosing convenience, patient adherence, and overall drug bioavailability.

Key words: Controlled release, diabetes management, glimepiride, matrix system, transdermal patch

INTRODUCTION

Drug delivery systems are methodologies used to introduce therapeutic agents into the body. Effective drug delivery enhances the therapeutic effects of medications while minimizing side effects and improving patient compliance. The goal is to achieve optimal therapeutic outcomes by ensuring that drugs are delivered in the appropriate dosage, at the right time, and at the suitable site. Oral Administration has been the most common route for delivering medications due to its convenience and non-invasiveness. However, oral drugs often face numerous challenges, including variable absorption rates, degradation in the gastrointestinal tract, and Initial hepatic metabolism, which can significantly reduce their bioavailability.[1] Drugs that cannot be administered by the oral route may be delivered using alternative methods. Among these methods, the Transdermal Drug Delivery System (TDDS) is a notable approach. This method operates by delivering the drug through the skin using a patch.[2]

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TDDS refers to any topical medication formulation designed to release active ingredients through the skin and into the bloodstream. These systems are engineered to provide controlled, continuous delivery of drugs into the systemic circulation via the skin, allowing for steady therapeutic effects over time without frequent dosing.[3] Additionally, they allow for controlled dosage adjustments and can improve overall treatment outcomes by providing a stable release profile over time.[4] The skin, being the body's largest organ, covers a surface area of about 1.5–2.0 m^2 in adults and receives roughly one-third of the body's blood supply. The skin's broad surface area and accessibility make it suitable for transdermal drug delivery, though its outermost layer, the stratum corneum, presents a selective barrier, permitting only small, lipid-soluble molecules to penetrate effectively.[5,6] Glimepiride, a third-generation sulfonylurea, is used to manage type 2 diabetes mellitus by stimulating insulin release from pancreatic beta cells.[7] It has a long duration of action, up to 24 h, and is approved for use alone or with metformin or insulin.[8] By closing adenosine triphosphate -sensitive potassium channels, glimepiride causes calcium influx, leading to insulin secretion and blood glucose reduction.[9] Type 2 diabetes, making up 90% of cases, often develops from insulin resistance and progresses over time, with increasing prevalence due to obesity and lifestyle factors.[10]

MATERIALS AND METHODS

Materials

Glimepiride, serving as the active pharmaceutical ingredient, obtained from Lifecare Formulations Pvt. Ltd. Remaining all chemicals were used from PSG College of Pharmacy.

Pre-formulation studies

These studies provide critical insights into factors like solubility and drug-excipient interactions, which guide the development of a stable and effective formulation.

Formulation of transdermal patches

Glimepiride was dissolved in a small amount of dimethylformamide, stirred continuously to ensure it dissolved completely. This drug solution was slowly incorporated into the polymer mixture (Polymers in 1:1 water-to-ethanol ratio solution), with additional stirring for about 30 min to achieve full integration. To improve the flexibility of the resulting patch, polyethylene glycol 400 (PEG 400) was included as a plasticizer. Additionally, dimethyl sulfoxide was incorporated as a permeation enhancer to improve the drug's absorption through the skin. The final blend was stirred for another hour to ensure complete homogeneity and poured into a petri dish, pre-treated with a thin layer of glycerine to prevent sticking. An inverted funnel was placed over the dish, allowing for uniform solvent evaporation for 24 h. Once dry, the patch was carefully peeled off and stored in a desiccator to preserve its stability and integrity until further testing or application.[11]

Characterization of transdermal patches of glimepiride

Visual characteristics

The transdermal patches were examined visually assessed to ensure uniformity in color, texture, and flexibility.[12]

Weight uniformity

To evaluate weight uniformity, ten patches were randomly selected and weighed individually. The average weight was calculated, and each patch's weight was checked to ensure minimal deviation from this average, confirming consistency across the batch.[13]

Film thickness

The depth of each drug-loaded patch was determined by measuring it at several points using a screw gauge. An average value was then calculated to ensure uniformity in patch depth.[14]

Folding endurance

The number of folds each patch could withstand at this location before any sign of damage was recorded as its folding endurance value.[15]

Percentage moisture loss

Each patch was initially weighed and then placed in a desiccator with calcium chloride at ambient temperature. The patches were reweighed at set intervals until their weights stabilized. The percentage of moisture lost was calculated by comparing the initial and final weights of the patches relative to their final weight.[16]

Percentage moisture uptake

To measure this, Glimepiride transdermal patches were initially weighed and then stored in a desiccator containing a saturated potassium chloride solution to maintain 84% relative humidity at room temperature. The moisture absorption percentage was determined by comparing the patches initial weight to their final weight after exposure.[17]

Tensile strength

Tensile strength of the transdermal patch was measured using a texture analyzer. The patch was held between grips, and a continuous force was applied until it broke. This test assesses the patch's mechanical integrity, ensuring it is durable enough to endure stress during application without tearing.[18]

Percentage of elongation

Elongation of the patches was measured with a texture analyzer. Rectangular strips, each measuring 40 mm by 30 mm, were secured so that the length of the patch section positioned between the grips could be accurately tested.[19]

The elongation percentage was determined by recording the length immediately prior to the rupture point and substituting it in the subsequent equation.

Drug content

To determine drug content, a 1 × 1 cm^2 film sample was dissolved in 10 mL of DMSO to ensure the drug was fully solubilized. The solution was then filtered using Whatman filter paper, and the filtrate was brought up to 10 mL with a phosphate buffer (pH 5.5). After appropriate dilution, the drug concentration was measured spectrophotometrically at 229 nm.[20]

In vitro release studies

The *in vitro* release study was conducted using a two-compartment setup, with an open-ended cylinder (donor compartment) positioned inside a glass beaker (receptor compartment) on a magnetic stirrer. A 1 cm^2 patch was positioned within a dialysis membrane, made of transparent regenerated cellulose, which allows the passage of low molecular weight substances. The membrane was fully immersed in the receptor compartment containing 300 mL of phosphate buffer (pH 5.5) maintained at 37 ± 1°C. The solution was stirred continuously, and 1 mL samples were periodically withdrawn from the receiving compartment and replaced with fresh buffer, then analyzed spectrophotometrically at 229 nm using a reagent blank.[21]

Ex vivo drug permeation study

Fresh pig ear skin was carefully prepared by cleaning it and then mounting it onto the receptor chamber of a diffusion cell, ensuring that the epidermal side faced upward.[22] The formulated patches were applied by placing each patch on the stratum corneum (outer skin layer), with the dermal side facing the receptor compartment.[23] To initiate the test, a Glimepiride transdermal patch was applied to the skin, and a phosphate buffer solution with a pH of 5.5 was added to the receiving chamber. The system was kept at a steady temperature of 37 ± 0.5°C with continuous stirring to closely simulate the conditions of human skin. Over the course of the study, samples of 5 mL were collected from receptor chamber at set intervals (1, 2, 3, 4, 5, 6, 7, 8, 9, and 24 h). Each sample withdrawn was promptly replaced with fresh buffer to sustain optimal saturation conditions throughout the experiment. Afterward, the samples were filtered and analyzed using a UV-Visible spectrophotometer at 229 nm to measure drug concentration.

Stability studies

Stability studies of the best formulation were performed as per the International Council for Harmonization (ICH) guidelines.

RESULTS

Drug excipient compatibility

In this study, the compatibility of Glimepiride with other formulation components, such as hydroxypropyl methylcellulose (HPMC) and PVP K30, was examined using spectral analysis and confirmed that free from interactions.

Characterization of transdermal patches

Visual characteristics

Formulations incorporating higher proportions of PVP K30 resulted in smooth and uniform films, while those with increased HPMC content tended to produce denser, more opaque structures. The addition of PEG 400 enhanced flexibility across several formulations, improving patch resilience, whereas the absence of PEG 400 led to a more brittle texture. These variations suggest a diverse potential for patient use and drug release effectiveness [Table 1].

Weight uniformity

The transdermal patches in this study demonstrated consistent weight uniformity across all formulations, ranging from approximately 498.81 ± 1.36 mg in the lighter patches to 1064.94 ± 1.70 mg in the heavier formulations. This range confirms that each formulation maintains a reliable mass, which is essential for ensuring consistent dosing and therapeutic effectiveness, as shown in Table 2.[24]

Film thickness

The thickness of the transdermal patches was measured across formulations and demonstrated variation, ranging from 0.12 ± 0.004 mm in the thinnest patches (e.g., F2 and F7) to 0.603 ± 0.012 mm in the thickest (F4), as shown in Table 2. This range indicates a degree of structural diversity that can influence the patches' durability and drug release characteristics.[25]

Folding endurance

The folding endurance values of the transdermal patches varied across formulations, demonstrating a range of

Table 1: Visual characteristics of the obtained transdermal patches

Formulation	Visual characteristics
F1	Uniform and flexible
F2	Thin film, brittle, and transparent film
F3	Transparent, uniform, and flexible
F4	Smooth, transparent, uniform, and flexible film
F5	White film, non-flexible, tough
F6	Thick, flexible, transparent
F7	Thin film, transparent, uniform

Table 2: Characterization of glimepiride-loaded transdermal patches

Formulation	Weight uniformity (mg)	Thickness (mm)	Folding endurance (No.)	Moisture loss (%)	Moisture uptake (%)	Elongation (%)	Drug content (%)
F1	498.81±1.36	0.27±0.02	273.33±8.02	4.37±0.01	3.83±0.10	53	95.2±0.4
F2	505.34±1.05	0.12±0.008	220.67±8.02	7.22±0.04	5.15±0.15	45	92.52±0.34
F3	650.85±0.54	0.35±0.02	294.33±2.08	2.05±0.02	4.46±0.07	67	96.36±0.32
F4	1059.37±1.92	0.603±0.012	313.67±4.72	4.02±0.04	7.47±0.08	92	98.09±0.07
F5	1052.96±1.12	0.14±0.004	239.67±8.38	1.42±0.03	2.90±0.65	71	94.14±0.05
F6	1064.94±1.70	0.563±0.02	301±2.00	1.98±0.01	8.19±0.09	84	91.29±0.19
F7	952.61±0.97	0.12±0.004	225±8.71	2.54±0.03	6.27±0.26	75	96.25±0.26

flexibility and durability. Values ranged from 220.67 ± 8.02 for the more brittle patches, such as F2, up to 313.67 ± 4.72 for the most resilient formulation, F4. Higher folding endurance, as seen in formulations like F4 and F6, indicates improved flexibility, likely due to adequate plasticizer content, which enhances the patches' resistance to cracking or breaking during handling and application, as shown in Table 2.[26]

Percentage moisture loss

The percentage moisture loss across the transdermal patches varied among formulations, indicating different levels of moisture retention and stability. The values ranged from a low of 1.42 ± 0.03% in formulation F5 to a high of 7.22 ± 0.04% in formulation F2, as shown in Table 2. These variations highlight how different compositions influence the moisture content, which can affect patch flexibility and long-term stability.[27]

Percentage moisture uptake

The percentage moisture uptake of the transdermal patches showed a range across different formulations, reflecting their capacity to absorb environmental moisture. Values varied from 2.90 ± 0.65% in formulation F5, which had the lowest moisture uptake, to 8.19 ± 0.09% in formulation F6, which absorbed the most. This variation in moisture uptake impacts the patches' stability and flexibility, as higher uptake may improve flexibility but can also reduce stability in humid conditions, as shown in Table 2.[28]

Tensile strength

The tensile strength of the transdermal patches showed significant variability across different formulations. Values ranged from 341.50 kg/cm² for the least durable formulation (F2) to 596.68 kg/cm² for the strongest (F4), which demonstrated the highest tensile strength as shown in Figure 1. This variation indicates that formulations like F4, with a balanced polymer ratio and optimal plasticizer content, have enhanced mechanical strength, essential for maintaining patch integrity during application.[29]

Percentage of elongation

F4 exhibiting the highest elongation at 92%, indicating superior flexibility and stretching capacity. Formulations F1 and F2 had the lowest elongation values at 53% and 45%, respectively. Moderate elongation values were observed for F3, F5, F6, and F7, with percentages of 67%, 71%, 84%, and 75%, respectively [Table 2].[30]

Drug content

The drug content was between 91.29 ± 0.19% in F6 to 98.09 ± 0.07% in F4, as shown in Table 2. Variations in drug content across formulations highlight the influence of polymer composition and mixing homogeneity in the patch's preparation.[31]

In vitro release studies

Initial release rates were moderate for formulations F1, F2, and F3, with 18.5%, 14.4%, and 10.81% drug release within the 1st h, respectively, culminating in near-complete releases of 99.8%, 98.8%, and 99.5% by the 24-h mark. Formulations F5 and F6 demonstrated rapid release profiles, with F6 reaching 79.4% release by the 4th h and achieving 98.3% by the 6th h, indicating a faster dissolution due to the higher concentration of PVP K30. Formulation F4 was identified as the optimized controlled-release formulation, exhibiting a steady release that achieved 96.8% by 24 h, reflecting an extended-release suitable for controlled therapeutic effects.[32]

Ex vivo drug permeation study

The *ex vivo* drug permeation study of the optimized transdermal patch formulation (F4) was conducted using pig ear skin to simulate human conditions. The study revealed a controlled and gradual drug permeation over a 24 h period, starting with a slow release of 2.9% in the 1st h and reaching 91.4% cumulative permeation by the 24th h. This pattern suggests the patch's capability for controlled drug release, supporting extended therapeutic action suitable for prolonged application.[33]

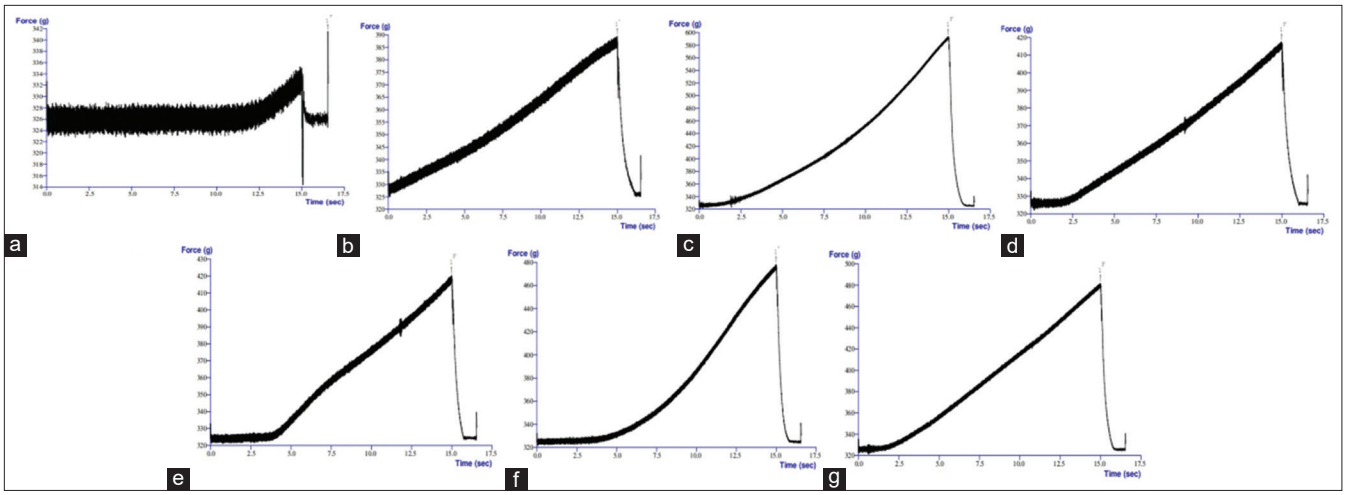


Figure 1: (a-g) Results of tensile strength

Stability studies

The stability of the formulation was confirmed by drug content uniformity.

DISCUSSION

The study's findings provide a comprehensive evaluation of the transdermal patches, focusing on key structural and functional properties crucial for patch performance. Fourier-transform infrared analysis confirmed the compatibility of glimepiride with HPMC and PVP K30, as no significant peak shifts or new peaks were detected. The physical appearance of the patches [Table 1] was consistent, showing smooth and uniform surfaces with minor variations in transparency and thickness due to polymer composition. Consistent weight uniformity and minimal thickness variation across formulations reflect precise control in the solvent casting process, which is essential for maintaining predictable drug release profiles and mechanical strength. The patches demonstrated adequate folding endurance, particularly in formulations with higher plasticizer content, suggesting they possess the flexibility needed to withstand daily handling without tearing or breaking. Moisture loss and uptake studies revealed the patches' resilience under different environmental conditions; lower moisture uptake improves storage stability, while moderate uptake contributes to flexibility, enhancing patient comfort. High tensile strength, as shown in Figure 1, especially in formulations with balanced plasticizer ratios, further supports the patches' durability, while the percentage elongation values indicate they are flexible enough to withstand stress without damage. Uniformity in drug content across formulations assures reliable dosing, with even drug dispersion achieved in the polymer matrix. *In vitro* drug release studies demonstrated controlled release profiles, ideal for maintaining therapeutic levels over 24 h; faster-release formulations like F6 provide a rapid effect, while slower-release formulations, such as F4, offer extended delivery, which is beneficial for prolonged therapy. *Ex vivo* permeation studies using pig ear skin confirmed effective drug diffusion, with formulation F4 showing a steady and controlled release, achieving significant permeation across 24 h.[34] This controlled profile suggests that the patch could provide consistent therapeutic drug levels for chronic conditions. Overall, these optimized transdermal patches exhibit a well-balanced combination of mechanical strength, consistent drug release, and stable permeation characteristics, indicating their potential for effective, patient-friendly drug delivery systems. As per ICH guidelines best formulation F4 shown stability by its drug content.

CONCLUSION

The development and evaluation of glimepiride transdermal patches in this study demonstrated their potential as an effective and stable drug delivery system. Through the use of compatible polymers and optimal formulation methods, the patches exhibited uniformity in physical characteristics, mechanical resilience, and consistent drug content, all essential for reliable dosing and patient compliance. The *in vitro* and *ex vivo* studies confirmed the patches capacity for controlled drug release, achieving steady permeation rates suitable for prolonged therapeutic effects. The findings demonstrate the potential of transdermal patches to serve as a substitute for oral administration, offering improved bioavailability, bypassing first-pass metabolism, and reducing dosing frequency. Overall, this formulation approach presents a promising strategy for managing chronic conditions like diabetes, enhancing therapeutic efficacy while maintaining patient convenience and adherence. Further research on long-term stability and clinical performance could solidify their role in advanced drug delivery applications.

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