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Research Paper

Design and Evaluation of Herbal Topical patch Containing Polianthes tuberosa Extract for Controlled Drug Delivery

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ABSTRACT

The aim of the current Research to design and test herbal Topical Drug Delivery with Polianthes tuberosa L. extract as a controlled and sustained drug delivery system. The polyphenols, alkaloids, saponins and flavonoids are the bioactive constituents that are validated by the preparation and screening of Polianthes tuberosa ethanolic extract. The Topical patches of different concentrations of hydroxypropyl methylcellulose (HPMC) and polyvinyl alcohol (PVA) and polyethylene glycol (PEG 400), a plasticizer were made using the solvent casting method. The prepared formulations (F1- F3) were tested on the basis of physicochemical properties such as the thickness, individuality of weight, folding endurance, tensile strength, percentage of moisture and percentage of extract content. All the formulations showed acceptable physical and mechanical properties showing that they can be used in transdermal use. The agar well diffusion method of antimicrobial activity was used to assess the antimicrobial activity of the formulations against Cutibacterium acnes and Staphylococcus epidermidis. These findings demonstrated that the antibacterial activities were high with formulation F2 which was explained by the presence of bioactive phytoconstituents. The stability experiments had the effect of making sure that the optimized formulation was stable at different storage conditions. On the whole, the research indicates that Polianthes tuberosa extract-impregnated Topical patches have the potential to become a promising and effective herbal drug delivery system with controlled extract release, and antimicrobial use.

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INTRODUCTION

The topical drug delivery systems have elicited a lot of interest over the last few years owing to their capacity to offer localized medicinal effect, high compliance by the patient and less systemic side effects. These systems have the bioactive compounds directly delivered to the compromised part of the skin and find extensive application in the therapy of skin infections, inflammation, wound healing and acne. Topical patches have a number of advantages over traditional forms of oral dosage such as controlled release of the active constituents, simplicity of use, gastrointestinal irritation is avoided and an increase in therapeutic efficacies. The development of herbal bioactivity compounds contained in polymeric dermal patches developed by utilizing biodegradable and biocompatible polymers has become a promising treatment method to deliver these compounds locally and in a sustained manner. [1-3]

The extensive use of herbal medicines in conventional healthcare systems is due to their natural source, potential curing effects as well as less adverse effects compared to synthetic drugs. Medicinal plants are rich in many types of phytoconstituents that include flavonoids, alkaloids, phenolic compounds, tannins, and saponins that have antimicrobial, antioxidant, anti-inflammatory and wound healing effects. The use of herbal extracts however is usually constrained by low stability, inadequate skin retention and uncontrolled release of active constituents which restrict their use of herb extracts as a therapeutic agent. Herbal extracts incorporated into more

sophisticated topical drug delivery systems can be used to increase their stability, promote controlled drug release and elevate their therapeutic efficacy. [4,5]

Tuberose *Polianthes tuberosa*, also called tuberose, is a perennial flower which is a member of the Asparagaceae family. Besides its ornamental and fragrance value, the plant has been reported to contain various biologically active phytoconstituents such as flavonoids, phenolics, alkaloids, glycosides and essential oils. The components play a role in a number of pharmacological mechanisms, including antimicrobial, antioxidant, anti-inflammatory, and anti-acne. Other earlier researchers have indicated that *Polianthes tuberosa* extracts possess anti-acnes effect on microbes such as *Cutibacterium acnes* and *Staphylococcus epidermidis*, which suggests that it can find dermatological uses. [6-8] In current research an effort was made to prepare and determine a herbal topical patch with a newly prepared ethanolic extract of *Polianthes tuberosa*, which will release bioactive constituents controlled and sustained release. The solvent-casting method was used to prepare the patches with the help of hydroxypropyl methylcellulose (HPMC) and polyvinyl alcohol (PVA). The formulations were prepared and analyzed regarding physicochemical characteristics, mechanical stability, extract analysis, moisture kinetics, antimicrobial activity, in-vitro release of extracts and stability. This research seeks to investigate the possibility of *Polianthes tuberosa* as a highly effective natural and profitable skin delivery system based on topical herb use.



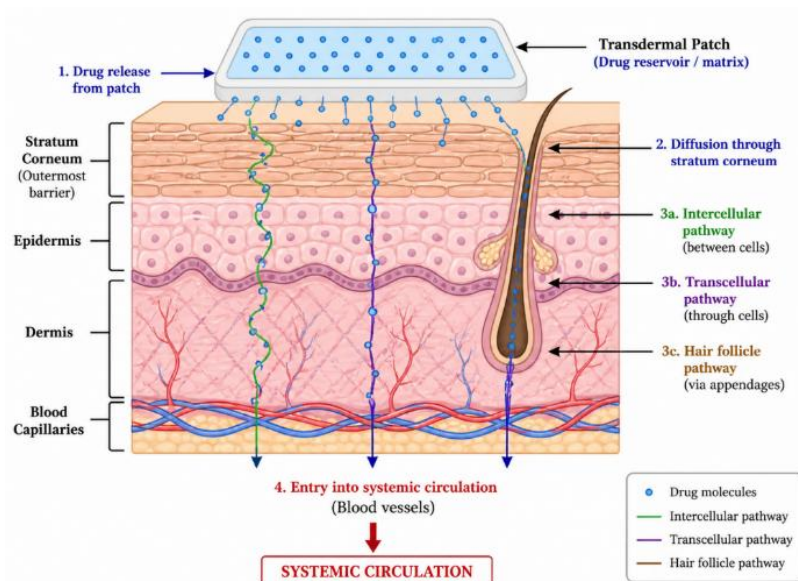


Figure 1: Mechanism of Drug Permeation through Skin in Topical Drug Delivery [8]

MATERIALS AND METHODS



Figure 2: Fresh flowers of Polianthes tuberosa

1. Plant Material Collection

Fresh flower of Polianthes Tuberosa L. They were collected at Kolhapur, Maharashtra, India. Based on standard taxonomical parameters, according to the rules of the World Health Organization (WHO), and identified the identity and purity of the specimen.[9]

The gathered flowers were sprayed down with the running tap water to rinse the remaining contaminant and then with the double distilled water to wash out the remaining contaminant. The shade-dried at room temperature until constant weight was obtained to ensure that all moisture

was removed, and thermolabile constituents were not destroyed.

The dried flowers were then ground in mechanical grinder to fine powder. The powdered material was put into the clean, dry and airtight glass containers and stored in a cool place until used. [10]

2. Extraction of Plant Material

Ethanol was used as the solvent in which the bioactive constituents were to be extracted using the dried powdered flower material of Polianthes tuberosa L.[11]

The cold maceration method was used in extracting it. The powdered sample (e.g. 50 g) was incubated in 1000 mL ethanol and left to incubate in 72 hours (3 days) of room temperature and stirred with some frequency, to help the phytoconstituents be diffused into the solvent.[12,13]

The mixture was filtered with muslin cloth and whatman filter paper that removes the insoluble plant residue, was used at the end of the process of maceration. The resulting filtrate then evaporated in the steam bath at 50 degree Celsius in order to remove the solvent, and to obtain the crude extract.

Cooling temperature helped in preserving thermolabile bioactive compounds.[14]

The concentrated extract was left to cool after which the extract was transferred to clean airtight container and stored in 4 degree Celsius until further use .

3. Phytochemical Screening

Preliminary phytochemical screening of the ethanolic extract of *Polianthes tuberosa* L. was carried out to identify the presence of various secondary metabolites using standard qualitative methods[15,16]

Test for Alkaloids (Dragendorff's Test)

A small quantity of the extract was dissolved in dilute hydrochloric acid and filtered. To the filtrate, a few drops of Dragendorff's reagent were added.

Observation: Formation of an orange or reddish-brown precipitate indicates the presence of alkaloids.

Test for Flavonoids (Shinoda Test)

To the extract, a small amount of magnesium turnings was added followed by the addition of concentrated hydrochloric acid.

Observation: Development of a pink or red coloration confirms the presence of flavonoids.

Test for Saponins (Foam Test)

The extract was diluted with distilled water and shaken vigorously in a test tube.

Observation: Formation of stable persistent foam indicates the presence of saponins.

Test for Phenolic Compounds (Ferric Chloride Test)

A few drops of 5% ferric chloride solution were added to the extract.

Observation: Formation of a dark green or blue-black coloration indicates the presence of phenolic compounds.

Table 1. Preliminary Phytochemical Screening of *Polianthes tuberosa* Ethanolic Extract

Phytoconstituent	Test Performed	Observation	Result
Alkaloids	Dragendorff's test	Reddish-brown ppt	Present (+)
Flavonoids	Shinoda test	Pinkish red color	Present (+)
Saponins	Foam test	Foam produced	Present (+)
Phenols	Ferric chloride test	Green-black color	Present (+)

FORMULATION OF TOPICAL PATCH

Herbal topical patches containing the ethanolic extract of *Polianthes tuberosa* were prepared using the solvent casting method for sustained and localized delivery of bioactive constituents. [17-20]

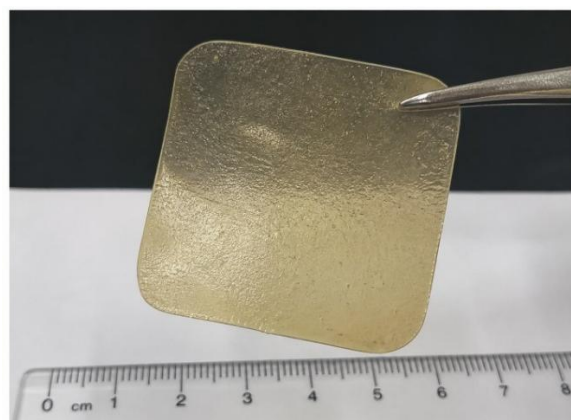


Figure 3: Photograph of Prepared Topical patch showing a smooth, uniform, and flexible film with slight translucency.

1. Composition of Formulations

Different formulations (F1–F3) were prepared by varying the concentration of hydroxypropyl methylcellulose (HPMC) while keeping other components constant.[18,19]

Table 2. Composition of Formulations

Ingredients	Function	F1 (% w/v)	F2 (% w/v)	F3 (% w/v)
HPMC	Film-forming polymer	2	3	4
PVA	Supporting polymer	1	1	1
Polianthes tuberosa extract	Active herbal constituent	1	1	1
PEG 400	Plasticizer	0.5	0.5	0.5
Distilled Water	Solvent	q.s.	q.s.	q.s.

2. Method of Preparation (Solvent Casting Method)

a) Preparation of Polymer Solution

Required quantities of HPMC and PVA were accurately weighed.

- HPMC was dissolved in a small quantity of warm distilled water with continuous stirring to avoid lump formation.
- PVA was dissolved separately in distilled water by heating at approximately 60–70°C until a clear solution was obtained.

b) Mixing of Polymers

The continuous mixtures were combined with the ready polymer solutions to make sure that it had a homogenous polymeric solution.

c) Incorporation of Extract

Slowly the quantity of Polianthes tuberosa ethanolic extract calculated was slowly added to the polymeric solution in a slow steady stream to stir the mixture and ensure that it was thoroughly mixed.

d) Addition of Plasticizer

PEG 400 was introduced as a plasticizer to enhance the patch flexibility and decrease a brittle character to the patch.

e) Degassing

A given number of minutes was given to the solution to allow the solution to overcome trapping any air bubbles trapped in the solution.

f) Casting of Film

The solution prepared was carefully poured into a clean and leveled glass Petri dish and mixed thoroughly.

g) Drying

The films were left at room temperature (or left in a hot air oven at 40 °C) over a time of 24 hours so that there was complete evaporation of the solvent.

h) Film Removal and Storage

The dry coatings were delicately stripped off, and cut into standard sizes. The resulting patches were put in a desiccator which would be analysed later.

3. Polymer Ratio Optimization

The Topical patches preparation was maximised by exposing the concentration of HPMC to a range of concentrations, and maintaining the other components of Topical patches constant, relative to their previous values. Three preparations and testings are done on the three formulations (F1, F2 and F3) using physicochemical properties, extract release, and mechanical strength.

It was observed that the higher the concentration of HPMC, the higher the concentration of polymeric matrix, thus resulting in lowering the rate of extract release, and increasing the mechanical strength.

Formulation F2 was chosen due to the good extract release profile, the good mechanical property, as well as being the optimized formulation which

demonstrated good results to pursue further studies.[20]

EVALUATION OF TOPICAL PATCHES

The Topical patches prepared were put under test in relation to the physicochemical, mechanical, chemical and moisture factors with the use of the standard methods.[21-24]

Physical Evaluation

a) Thickness

A digital vernier caliper was used to measure the thickness of the patches at 3 different points (in the middle of the patches and on the edges) of the patches. An average was calculated and in millimeters (mm).

b) Weight Uniformity

The same size patches (i.e., 2 x 2 cm²) were excised and weighed individually using a digital balance. The means and the standard deviation of the weight were calculated.

c) Folding Endurance

A patch was folded in a lot of folds till it was torn at a certain point. The value of the folding endurance of the patch was provided as the frequency of the patch entering a state of folded and not breaking.

Mechanical Properties

d) Tensile Strength

Tensile strength of the patch was determined using a tensile strength apparatus.

$$\text{Tensile Strength} = \frac{\text{Force at Break (N)}}{\text{Cross-sectional Area (cm}^2\text{)}}$$

The force required to break the patch was recorded, and tensile strength was calculated accordingly.

e) Percentage Elongation

The percentage elongation was calculated to determine the elasticity of the patch.

$$\text{Percentage Elongation} = \frac{\text{Increase in Length}}{\text{Original Length}} \times 100$$

Higher elongation indicates better flexibility of the patch..

Moisture Studies

f) Moisture Uptake

Pre-weighed patches were placed in a desiccator containing saturated salt solution (high humidity condition) for 24 hours. After exposure, patches were reweighed.

$$\text{Moisture Uptake (\%)} = \frac{\text{Final Weight} - \text{Initial Weight}}{\text{Initial Weight}} \times 100$$

a) Moisture Loss

Pre-weighed patches were placed in a desiccator containing anhydrous calcium chloride (low humidity condition) for 24 hours. The patches were then reweighed.

$$\text{Moisture Loss (\%)} = \frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$$

Table 3. Evaluation Parameters of Topical patch Formulations

Parameter	F1	F2 (Optimized)	F3
Thickness (mm)	0.21 ± 0.02	0.25 ± 0.01	0.29 ± 0.02
Weight Variation (mg)	112 ± 3.2	118 ± 2.5	121 ± 3.0
Folding Endurance	250 ± 5	285 ± 4	270 ± 6
Tensile Strength (kg/cm ²)	2.1 ± 0.2	2.6 ± 0.1	2.3 ± 0.2



Parameter	F1	F2 (Optimized)	F3
Percent Elongation (%)	18.5 ± 1.2	24.2 ± 1.0	21.3 ± 1.5
Moisture Content (%)	4.2 ± 0.3	3.8 ± 0.2	4.5 ± 0.4
Moisture Uptake (%)	6.5 ± 0.4	5.9 ± 0.3	6.8 ± 0.5
Extract content (%)	92.4 ± 1.1	95.4 ± 0.9	93.1 ± 1.2
Surface pH	6.2 ± 0.1	6.1 ± 0.1	6.0 ± 0.1

ANTIMICROBIAL STUDY

a) Method (Agar Well Diffusion Method)

Sampling of the *Polianthes tuberosa* extract-embedded Topical patches was done using agar well diffusion method against bacteria that caused acne symptoms.[25,26]

Test microorganisms:

- *Cutibacterium acnes*
- *Staphylococcus epidermidis*

Agar plates were made with Nutrient agar that were sterilized. All the bacterial cultures were swab inoculated putting a sterile cotton swab on all the agar plates evenly covering the agar plate. Cork borer that was used in making wells was the sterile

cork borer, which was approximately 6 mm in diameter.

The wells received samples of formulations (F1, F2 and F3) that were in turn placed in the wells. It was also used with a positive control (e.g., clindamycin gel), and a negative control (or blank formulation which is the absence of extract) was developed as well.

The 24-hour incubation at 37 °C temperature was used to incubate the plates. The zone of inhibition (ZOI) was measured in millimeter (mm) at the end of an incubation period which denoted the antimicrobial activity. [27]

Table 4.

Antimicrobial Activity of Topical patch Formulations

Sample	Zone of Inhibition (mm) – <i>Cutibacterium acnes</i>	Zone of Inhibition (mm) – <i>S. epidermidis</i>
F1	14.2 ± 0.6	13.5 ± 0.5
F2	18.6 ± 0.8	17.9 ± 0.7
F3	16.4 ± 0.7	15.8 ± 0.6
Standard (Clindamycin)	22.5 ± 0.9	21.8 ± 0.8
Blank Patch	No inhibition	No inhibition

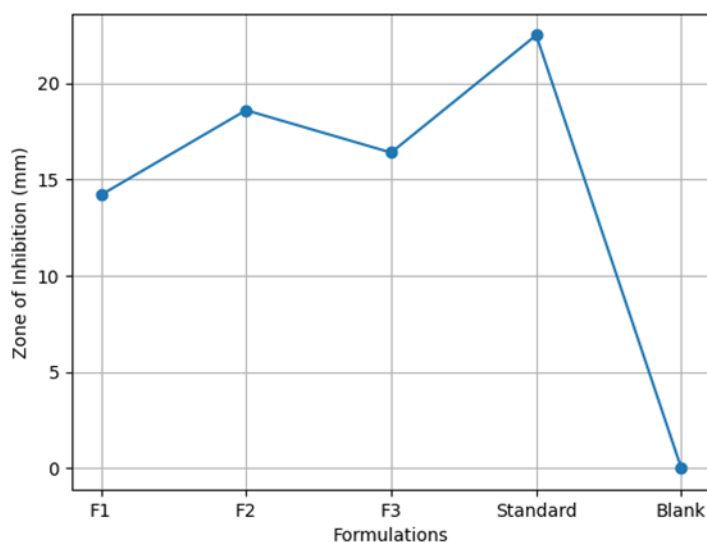


Figure 4: Zone of Inhibition Showing Antimicrobial Activity of Formulations (F1, F2, F3)

The antimicrobial study demonstrated that all formulations exhibited noticeable antibacterial activity against both *Cutibacterium acnes* and *S. epidermidis*.

F2 showed the greatest zone of inhibition that shows improved antimicrobial action.

The presence of biocentric phytoconstituents e.g. flavonoid, phenolic compounds and essential oils in *Polianthes tuberosa* are the reason why it has the observed antibacterial activity. Reports on such substances have been reported to cause disruption with cell membrane and retardation in development of the microbes.

The blank formulation was not found to exhibit any inhibition and that corroborates the idea that the antimicrobial activity is purely as a consequence of the plant extract and not as a consequence of the polymeric components.

Although the activity was slightly less than the standard drug, the formulation had a tremendous potential in the context of using it as a natural alternative in treatment of acnes and any other skin infection.[28]

STABILITY STUDY

The optimized formulation (F2) was subjected to stability studies as per ICH guidelines. [29] Conditions:

- $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (room temperature)
- $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (accelerated condition)
- Duration: 3 months
- Parameters evaluated:
 - Appearance
 - pH
 - Extract content
 - Folding endurance

Table 5. Stability Study Data

Time Period	Appearance	pH	Extract content (%)	Folding Endurance
Initial	Smooth	6.2	95.4	285
1 Month	Smooth	6.1	94.1	280
2 Months	Smooth	6.0	93.5	276
3 Months	Smooth	5.9	92.3	270

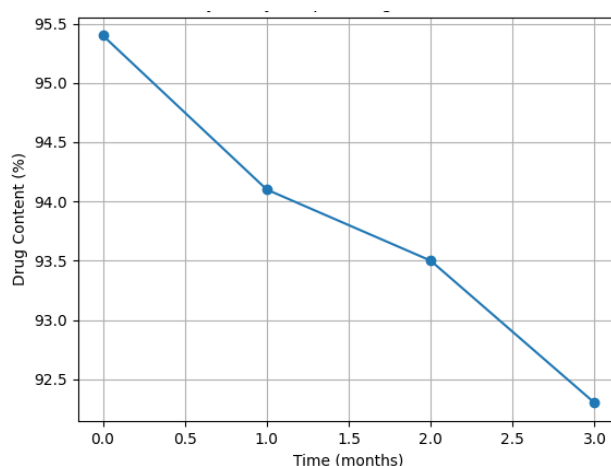


Figure 5: Stability Study Graph (Extract content vs Time)

No significant changes were observed in physicochemical properties, indicating that the formulation is stable under both storage conditions.

IN-VITRO DRUG RELEASE STUDY

The in-vitro drug release study of the prepared transdermal patches was carried out using a Franz diffusion cell. The patch was placed on a dialysis membrane previously soaked in phosphate buffer pH 7.4. The receptor compartment was filled with

phosphate buffer (pH 7.4) maintained at $37 \pm 0.5^\circ\text{C}$ and continuously stirred using a magnetic stirrer.

At predetermined time intervals, 5 mL samples were withdrawn and replaced with an equal volume of fresh buffer solution to maintain sink conditions. The withdrawn samples were analyzed using a UV-Visible spectrophotometer at the predetermined λ_{max} . The cumulative percentage drug release was calculated and plotted against time.

Table:

Cumulative Drug Release

Time (hr)	F1 (%)	F2 (%)	F3 (%)
1	22.4	18.6	14.2
2	39.8	32.5	25.4
4	61.5	52.8	43.1
6	78.2	69.4	58.6
8	91.6	82.3	71.8
12	98.4	94.6	86.5

- **F1** → releases too quickly
- **F3** → releases too slowly
- **F2** → optimum sustained and controlled release

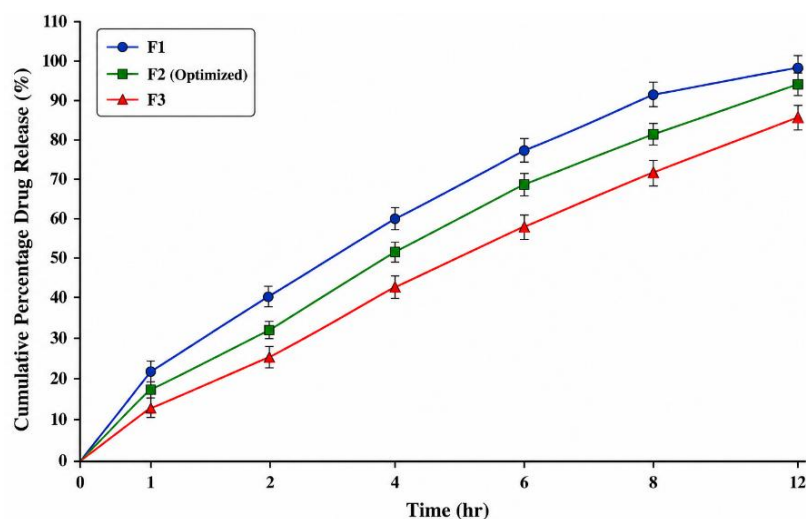


Figure 6: Cumulative Percentage Extract release Profile of Formulations F1–F3

11. STATISTICAL ANALYSIS

All experimental data is represented as an average $\pm$ standard deviation (SD), and have been done in triplicate ($n = 3$). Statistical significance of the differences in formulations (F1, F2 and F3) was tested by one-way Analysis of Variance (ANOVA). A p -value < 0.05 was considered statistically significant.[32]

RESULT AND DISCUSSION

The ethanolic extract of *Polianthes tuberosa* was subjected to preliminary phytochemical screening, which confirmed the presence of important bioactive phytoconstituents including flavonoids, phenolic compounds, alkaloids, and saponins. These phytoconstituents are known to possess antimicrobial, antioxidant, and anti-inflammatory activities, which may contribute to the therapeutic potential of the formulated topical patch. The presence of flavonoids and phenolic compounds particularly supports the antimicrobial activity observed against acne-causing microorganisms. Herbal topical patches containing *Polianthes tuberosa* extract were successfully prepared using the solvent casting method with varying concentrations of HPMC while maintaining constant concentrations of PVA and PEG 400. All the formulations (F1-F3) that had been prepared

appeared smooth on the surface, their texture was even, and flexible with no noticeable cracks or air bubbles. The ready patches were peelable and acceptable physically with respect to integrity, which suggests good compatibility of the polymers with the plant extract.

The physicochemical analysis showed that the thickness and weight difference of all formulations was acceptable, that the polymeric matrix and extract were equally distributed throughout the films. Investigations on both folding endurance and tensile revealed that formulation F2 had superior mechanical properties than F1 and F3. The optimum concentration of HPMC and plasticizing influence of PEG 400 could explain the reason why F2 has a better flexibility and mechanical strength. The moisture uptake and moisture content tests suggested satisfactory stability of the patches to varying environmental conditions. The surface pH was estimated as close to neutral indicating that the formulations are potential to be used over the skin without skin irritation.

The content analysis of the extract showed an equal integration of the herbal extract in the polymeric matrix. F2 contained the most amount of extract and it displayed higher uniformity when compared to any other formulations, showing that

the extract is dispersing well in the patch formulation. A satisfactory stability of the optimized formulation was also achieved, as there were no significant changes in appearance, pH, folding endurance, or extract content, during the storage studies. The results suggest excellent resistance to shearing forces and integrity of the made topical patch. The study on in-vitro extract release revealed a sustained and controlled release of the herbal extract of the prepared formulations within a 12-hour time span. Formulation F1 had a comparatively more rapid release since it had lower polymer concentration and F3 had slower release because of the denser polymeric matrix formed by a high concentration of HPMC. Formulation F2 showed that it had an optimum release profile and release of extract was controlled and sustained during the study. Controlled release can be explained by the fact that this ratio of HPMC and PVA was balanced and thus, was able to control the diffusion of extract through the polymer matrix.

The antimicrobial activity test carried out the agar well diffusion test showed that all the formulations were antibacterial against *Cutibacterium acnes* and *Staphylococcus epidermidis*. Only F2 showed maximum inhibition against the two microorganisms (or higher zone of inhibition) implying that F2 had excellent antimicrobial properties. The antimicrobial effect can be explained by the existence of bioactive phytoconstituents flavonoids, phenolic compounds and essential oils that are found in *Polianthes tuberosa* extract. No antimicrobial activity was observed with the blank formulation, and this proved the herbal extract, but not the polymeric components that was causing the antibacterial effect.

One-way ANOVA statistically revealed significant differences among the formulations concerning physicochemical parameters, antimicrobial activity and the extract release

profile ($p < 0.05$). In general, formulation F2 was selected as the optimized formulation with its good level of mechanical behavior, balanced release rate of extracts, high level of antimicrobial effect, and adequate stability properties. The findings of the current study imply that the produced herbal topical patch can be a promising alternative to local therapy of acne and microbial skin infections.

CONCLUSION

The current study was able to design and test a herbal topical patch of an *Polianthes tuberosa* ethanolic extract using the solvent casting method. The crude formulations demonstrated good physicochemical and mechanical character such as acceptable thickness, uniform weight change, excellent folding capacity, tensile strength, surface pH, moistness maintenance, and even extract content signifying their appropriateness in the topical dermal use.

Initial phytochemical screening was carried out to identify the presence of bioactive phytoconstituents that are known to have antimicrobial and therapeutic effects, including flavonoids, phenolic, alkaloids and saponins. F2 was found to have the best performance of balanced mechanical strength, controlled and sustained release of extracts, good antimicrobial activity and good stability at various storage conditions among the formulations prepared.

The antimicrobial research indicated that the developed patches worked with the *Cutibacterium acnes* and *Staphylococcus epidermidis* implying that the formulation could be useful in the topical management of acne as well as other microbial skin infections. The observed property of the optimized formulation which allows a controlled release behavior can enhance therapeutic efficacy in that the bioactive constituents are in sustained contact with the site of application.

All in all, the results of the current paper demonstrate that *Polianthes tuberosa* extract can



be successfully integrated into a herbal topical patch to deliver bioactive constituents in the long term and to localize them. The formulation that was developed showed great potential as a natural and probably an effective substitute of traditional topical formulations. Nevertheless, additional research such as ex-vivo skin penetration analyses, toxicity testing and clinical trials are necessary in order to determine the safety and therapy efficacy of the formulation in the long run.

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CONFLICT OF INTEREST

According to the authors, there is no conflict of interest when publishing this paper.

ETHICAL APPROVAL

No human research subjects, animal research subjects or biological tissues were involved in the current research but all research was conducted using in-vitro only research methods. Hence, it was not necessary to obtain an ethical approval of an Institutional Ethics Committee or Animal Ethics Committee.

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