



Formulation And Development Of Transdermal Patches Containing Saponin Phytoconstituents From Gokhru.

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ABSTRACT:

Transdermal patches provide a non-invasive and efficient method for delivering bioactive compounds, ensuring controlled and sustained release into the systemic circulation. *Tribulus terrestris*, commonly known as Gokharu, is a medicinal plant recognized for its diverse therapeutic properties, including aphrodisiac, anti-inflammatory, and wound-healing effects. This study investigates the formulation of a transdermal patch incorporating Gokharu extract to harness its pharmacological benefits. The process involves selecting suitable polymer matrices, permeation enhancers, and adhesives to optimize skin permeability and patch adherence. Preliminary evaluations suggest that the Gokharu transdermal patch exhibits promising characteristics, such as satisfactory mechanical properties and effective release profiles. In vitro studies demonstrate significant anti-inflammatory and wound-healing activities, aligning with the therapeutic potential of Gokharu. These findings indicate that a Gokharu based transdermal patch could serve as an effective alternative delivery system, offering enhanced bioavailability and patient compliance for managing various health conditions.

Keywords-Anti-inflammatory, Transdermal Patch, *Tribulus terrestris*,

Introduction

Transdermal Drug Delivery Systems (TDDS) are methods of delivering medications through the skin and into the bloodstream in a controlled and sustained manner. Instead of taking a drug orally or via injection, transdermal systems use patches or gels that are applied directly to the skin¹.

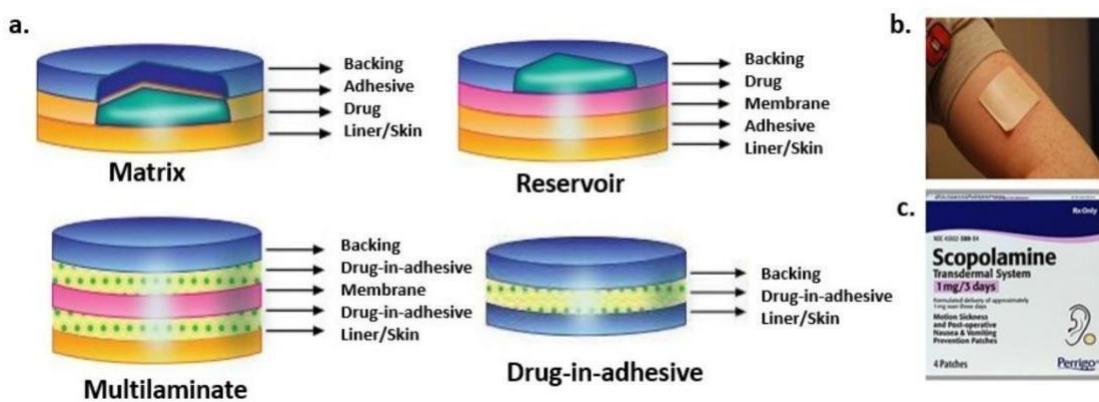


Figure 1. Transdermal Drug Delivery Systems (TDDS)

A transdermal patch is a type of medication delivery system that is applied directly to the skin, allowing the medication to be absorbed into the bloodstream². These patches are designed to release medication slowly and consistently over a prolonged period, providing sustained therapeutic effects³.

DRUG: GOKHARU(ANTI-INFLAMMATORY ACTIVITY)

Gokharu (*Tribulus terrestris*), a traditional herb with a range of pharmacological actions, including aphrodisiac, anti-inflammatory, hepatoprotective, and cardiotonic effects, is a prime candidate for transdermal delivery⁴. However, its phytoconstituents, such as saponins (protodioscin), face significant challenges due to poor oral bioavailability resulting from enzymatic degradation in the digestive tract⁵.

Formulating a transdermal patch of Gokharu offers a potential solution to this issue. By enabling controlled drug release, reducing dosing frequency, and improving bioavailability and patient adherence, a transdermal patch can provide a more effective and convenient treatment option for chronic therapy involving herbal medicines⁶. This approach has the potential to unlock the full therapeutic potential of Gokharu and improve patient outcomes⁷.

Gokharu, a traditional Indian herb, has been used for centuries to treat pain and inflammation⁸. It contains natural compounds that have pain-relieving and antiinflammatory effects. A transdermal patch is a special kind of band-aid that releases medicine slowly into the body⁹. By putting Gokharu extract into a transdermal patch, we can create a new way to manage pain that is safe, effective, and easy to use¹⁰. This study aims to develop and test this new pain management patch¹¹.

Medicinal plants and their isolated phytochemicals have been vital in healthcare for centuries, serving as essential resources for new drug development. Approximately 25% of the drugs prescribed globally are derived from plant sources. India, known for its rich biodiversity, is home to around 25,000 plant species, with 150 of them being commercially used in medicinal formulations. Additionally, more than 80% of the world's population relies primarily on plants for their healthcare needs¹².



Figure 2 *Tribulus terrestris*

Modern lifestyle changes, including increased stress, pollution, and dietary shifts, have contributed to a rising number of impotency cases in men, which is considered a major factor in the increasing rate of divorces¹³. Due to concerns about the side effects of synthetic medicines, there has been a growing preference for Ayurvedic treatments and medicinal plants¹⁴. One such beneficial plant is Gokharu, widely used as a food supplement in many countries¹⁵. Gokharu exists in two forms Chhota Gokharu (*Tribulus terrestris*) and Bada

Gokharu (*Pedalium murex* L.) both of which are valued for their medicinal properties¹⁶.

Drug Profile: Gokharu (*Tribulus terrestris*)

Parameter	Details
Common Name	Gokharu
Botanical Name	<i>Tribulus terrestris</i>
Family	Zygophyllaceae
Part Used	Fruits, Roots, Whole plant
Active Constituents	Saponins (especially protodioscin), flavonoids, alkaloids, glycosides
Traditional Uses	Aphrodisiac, diuretic, tonic, rejuvenator, urinary disorders, kidney stones

Pharmacological Actions	Diuretic, aphrodisiac, antiurolithic, hypotensive, anti-inflammatory
Therapeutic Uses	Erectile dysfunction, urinary tract infections, kidney stones, low libido
Dosage (Powder)	3–6 g/day (consult with a physician for specific dosage)
Dosage (Extract)	250–750 mg/day (standardized to saponins)
Side Effects	Generally well-tolerated; high doses may cause stomach upset or sleep issues
Contraindications	Pregnancy, lactation, hormone-sensitive conditions
Drug Interactions	May interact with diuretics, antihypertensives, or hormone therapy

Table 1. Drug Profile of *Tribulus Terrestris*

Advantages of Transdermal Patch:

- Avoidance of First-Pass Metabolism: Transdermal patches circumvent liver metabolism, preserving the activity of sensitive phytoconstituents like saponins¹⁷.
- Sustained and Controlled Drug Release: Continuous drug release over 12–24 hours leads to stable plasma concentrations and prolonged therapeutic effect¹⁸.
- Better Patient Compliance: Patches are non-invasive and reduce the frequency of administration, which improves adherence, especially in chronic therapy¹⁹.
- Minimized Gastrointestinal Side Effects: Since the digestive system is bypassed, the risk of nausea or irritation is reduced²⁰.

Disadvantages of Transdermal Drug Delivery System:

➤ Skin Reactions:

Some individuals may experience irritation, itching, or allergic responses at the application site²¹.

➤ Physicochemical Limitations:

TDDS is limited to drugs with low molecular weight, adequate lipophilicity, and sufficient potency²².

➤ Barrier Properties of Skin:

The stratum corneum presents a challenge for hydrophilic or large molecules, requiring chemical or physical permeation aids²³.

DRUG: GOKHARU(ANTI-INFLAMMATORYACTIVITY)

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Scientific Classification:

Botanical Name: *Tribulus terrestris*

Family: Zygophyllaceae **Chemical**

Constituent:

1. **Saponins:** Steroidal saponins, including protodioscin, dioscin, and tribuloside, which may help with:- Hormone regulation- Libido enhancement- Erectile function improvement²⁶.
2. **Flavonoids:** Quercetin, kaempferol, and isorhapontigenin, which may contribute to:- Antioxidant activity- Anti-inflammatory effects- Cardiovascular health support²⁷.
3. **Alkaloids:** Harmane, harmine, and harmaline, which may have - Anti-anxiety and anti-stress properties.
- Neuroprotective effects²⁸.
4. **Glycosides:** Tribuloside.
which may help with:- Immune system support, Anti-inflammatory effects²⁹.

LITERATUREREVIEW

- 1) Priyanka Devarshi, Megha Tone Transdermal patches offer a direct delivery system, bypassing liver processing and providing a steady dose of medication absorbed through the skin into the bloodstream over an extended period. This can be beneficial for patients experiencing severe side effects. Curcuma longa Linn, commonly known as turmeric, is a medicinal plant with various uses. Its rhizomes and roots are rich in curcuminoids, including curcumin, which is responsible for most of turmeric's biological effects. These compounds have natural antioxidant properties. Soxhlet extraction is a method used to extract curcumin from plants, highlighting the potential for harnessing turmeric's therapeutic benefits³⁰.
- 2) Siddhi S. Gavali, Hrishikesh M. Lawate, Siddhi A. Hadke A Centella asiatica transdermal patch shows promise in promoting wound healing, according to recent research. The study found that the patch enhanced wound healing properties, suggesting its potential as a novel therapeutic intervention. Further research is needed to understand the underlying mechanisms and optimize the patch's formulation for clinical use. This study adds to the growing evidence supporting the use of herbal remedies in wound management, highlighting Centella asiatica's potential as a valuable adjunctive therapy³¹.
- 3) Manish Singh Chouhan Matrix transdermal patches were prepared using the solvent casting technique, where polymers and plasticizers were dissolved in solvents. The mixture was cast onto a glass bangle wrapped in aluminum foil and left undisturbed at room temperature for 24 hours. The patches, consisting of drug, polymers, and plasticizer, were then retrieved intact and stored in a desiccator for further evaluation. This method allows for the optimization of formulation development, enabling the creation of effective transdermal patches³².
- 4) Mrunal Krishnarao Shirsat, Mahesh M. Thakare Tribulus terrestris, a member of the Zygophyllaceae family, is a small evergreen tree with heart-shaped leaves and yellow hibiscuslike flowers. The plant contains a diverse range of bioactive compounds, including antioxidants, tannins, flavonoids, and essential oils. These compounds contribute to its various pharmacological properties, such as anti-inflammatory, antioxidant, antimicrobial, and wound healing activities. Different parts of the plant, including roots, bark, leaves, flowers, and fruits, exhibit distinct medicinal characteristics, making it a valuable resource for drug development research³³.
- 5) V. Arunachalam, S. Arun Kumar, E. Aswini, R. Aarthy Rheumatoid arthritis, a chronic autoimmune disease, is typically treated with conventional allopathic methods that often have side effects. As an alternative, Ayurvedic herbal formulations offer a safer and effective option. A study developed transdermal patches using herbal extracts from Cardiospermum helicacabum and Aloe barbadensis to treat rheumatoid arthritis. The patches were prepared using the solvent casting method and evaluated for

physicochemical properties, including thickness, drug content, and in-vitro release, demonstrating a promising approach for managing this condition³⁴.

PLAN OF WORK

1. Literature review
2. Collection and Authentication of Plant Material
3. Extraction of Drug(Gokharu)
4. Phytochemical Screening
5. Formulation of Transdermal Patch
6. Evaluation Test

A) Organoleptic Evaluation

Appearance ,Clarity, Smoothness

B) Thickness of Patch

C) pH of Patch

D) Percentage Moisture Content E) Thumb Tack Test

MATERIALS AND METHODS

Sr.No.	Materials
1	Polyvinyl alcohol
2	Glycerin
3	Polyethylene Glycol
4	Propylene Glycol
5	Polyvinyl Pyrrolidone
6	Gokharu

Table No.2. List of Chemicals

Methods

➤Solvent Casting Method³⁵

Experimental Work

1. Collection of Plant- The Fully Natural fresh fruit of *Tribulus terrestris*(chota gokharu).The plants are common in hot, sandy and dry parts of the country such as Deccan, Gujarat, Andhra Pradesh, South Haryana and Rajasthan.The Fruits are grind by mortar and pestle.Fruit powder passing through the seive no.60. to obtain the fine and coarse powder.

2. Authentication of plant-The plant material was taxonomically identified

An authenticated by a noted botanist Mrs.Manjushree Bhagwat,Radhabai Kale Mahila Mahavidyalaya, Ahilyanagar

3. Solubility Analysis-After testing solubility of fruit powder in various solvents such as acetone, chloroform, water, alcohol and petroleum ether, it came to know that *Tribulus terrestris* leaf powder was more soluble in alcohol.

4. Preparation of herbal extract



Fig.No.3.Extraction Process

50gm of coarse fruit powder was weighed and filled in thimble packet for soxhlet extraction in ethanol 95% as solvent. Extraction process was continued for 6hrs. Another method used for extraction was cold maceration. The leaf powder was macerated in ethanol by shaking for one time initially and keeping for 24hrs without disturbing it³⁶.

5. Phytochemical Screening

Sr.No.	PHYTOCONSTITUENT	METHOD	INFERENCE
1	Saponin	Few ml of extract +5ml distilled water,shaken vigorously for 3min.	Formation of foam indicates presence of saponins.
		Lead Acetate Test -Add a few drops of lead acetate solution to the extract.	Formation of a white precipitate indicates presence of saponins.
		Liebermann-Burchard Test -Add acetic anhydride and concentrated sulfuric acid to the extract.	Formation of a bluishgreen color suggests the presence of steroid nucleus which may indicate steroid saponins.
2	Flavonoids	Alkaline Reagent Test Add NaOH to extract.	Intense yellow color that disappears with acid.
3	Alkaloids	Dragendorff's Reagent Add reagent to acidic extract.	Red precipitate.

Table no.3. Identification Test of Chota Gokharu³⁷

6. Formulation of herbal transdermal patch

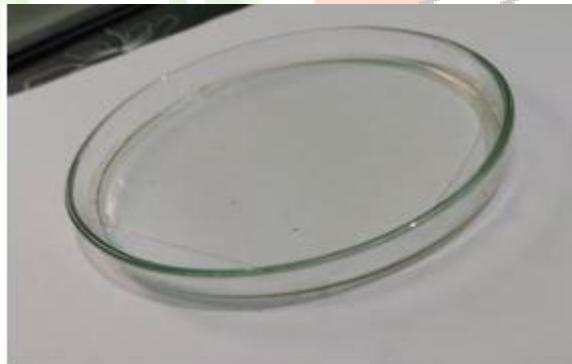


Fig.4. Formulation of herbal transdermal patch

Method used for patch formulation is solvent casting method.

A. Firstly 1gm of PVA & PVP (both are polymers) were weighed individually, then it was collected in beaker along with 10ml of Distilled Water.

B. dissolve it completely on hot water bath and avoid bubble formation with the help of glass rod. After complete dissolution of polymer, remove it from water bath and allow it to reach 25oC or to attain room temperature.

C. Then add extract of leaf powder (drug). Continuous stirring is important in patch formulation to obtain homogenous mixture.

D. Now we have to add propylene glycol(0.3ml) as plasticizer, glycerol(1ml). Next step for this to pour.

E. above solution into petri- plate with is covered with small quantity of glycerine as lubricant. Keep the petri-plate in hot air oven for 2-4hrs to remove air bubble and the keep it for 20hrs.at room temperature by covering in with funnel to avoid rapid evaporation³⁵.

Formulation Table of Transdermal Patch-

Ingredients	F1	F2	F3
Polyvinyl alcohol	0.3 gm	0.9 gm	1.5 g
Glycerin	0.2 ml	0.2 ml	0.2 ml
Propylene Glycol	0.5 ml	0.5 ml	0.5 ml
Polyvinyl Pyriolidine	1gm	1gm	1gm
Drug Extract	0.3gm	0.9gm	1.5gm
Polyvinyl alcohol	0.5 gm	0.5 gm	0.5 gm

Table no.4.Formulation Table

Evaluation of transdermal patch-

A) Organoleptic Evaluation-

The physical appearance of developed patch was evaluated by using a naked-eye examination as follows:

Appearance- formulated in circular shape and cutted into desire shape and size Colour green and whitish green Clarity- transparent Flexibility- yes(flexible) Smoothness- yes (smooth in texture)

B) Thickness of Patch- A vernier calliper was used to measure the transdermal patches' thickness three times at different site of patch, and the mean value was calculated. It was found to be 0.8 mm.

C) pH of Patch- Before using, the patch is swollen in 1ml of distilled water and allowed to sit at room temperature for 2 hrs. By using pH paper, it was come to know that pH of patch ranges from 5-6.5 (similar to that of skin). It can also analysed by digital electrode.

D) Percentage Moisture Content- After the patches were dried for 24 hours in a desiccator, their percent moisture content was calculated by weighing them. The formula for this calculation is as follows:

% moisture content= (initial weight– final weight)/initial weight* 100% moisture content of our patch was 8.12%.

E) Thumb Tack Test- This test is used to determine an adhesive's tack properties. The relative tack property is simply detected by pressing the thumb on the adhesive. It took around 2-2.5 sec to release from thumb.

F) Folding Endurance- This was determined by repeatedly folding one patch at the same place till it brock. The number of times the patch could be folded at the same place without breaking gave the value of folding endurance.

RESULT-

Pre formulation Studies

Melting Point:- The melting point of saponin was found to be 221-222°C

Surface Texture:- The surface texture of transdermal patch from gokharu were smooth.

Thickness :- The thickness of patch is measured using Vernier callipers. Thickness at the different points measure which average thickness of patch is determined is found to be thickness ranged between 0.21 mm and 0.28 mm

Surface pH of patch:- Surface pH of all patches found to be in the range 5- 6.5. All patches found to be in the range of skin pH .

Weight variation test:- All patches have uniform amount of ingredient in it,hence their weight and thickness varied with each other. Weight uniformity of the patch was found to be 72 to 80. The result shown in the table no.5

Formulation code	Physical Appearance	Surface Texture	Weight Uniformity	Surface pH	Thickness
F1	Transparent	Smooth	70.1	6.2	0.21
F2	Transparent	Very Smooth	74.5	6.5	0.28
F3	Transparent	Slightly Smooth	78.1	6.8	0.30

Table.no.5.Evaluation test of Transdermal Patch

CONCLUSION

The present study was successfully conducted to formulate and evaluate an herbal transdermal patch incorporating Gokharu (*Tribulus terrestris*) extract, aimed at providing asustained and patient-friendly mode of herbal drug delivery. The phytochemical screening of the extract confirmed the presence of biologically active constituents such as saponins, flavonoids, alkaloids, and glycosides, which are responsible for its therapeutic effects. Transdermal patches were formulated using suitable polymers such as PVP, and by the solvent casting technique. This study concludes that herbal transdermal patches containing Gokharu extract are apromising alternative to conventional dosage forms, offering sustained release, enhanced patient compliance, and reduced dosing frequency. Further in-vivo studies and clinical evaluations are recommended to validate its therapeutic efficacy and commercial potential.

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