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Formulation & Characterization of Transdermal Patch of Ginger Extract

[1]Sonali R. Devne, [2]Vidya M. Yelam, [3]Swati T. Sukale, [4]Rutuja R. Awate, [5] Neelam S. Bhagdewani, [6] Smita S. Waghmare

[1,3,4,5,6]SGMSP's Dnyanvilas College of Pharmacy, Dudulgaon, Pune, [2] Jayoti Vidyapeeth women's University Jaipur Rajasthan

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KEYWORDS

GINGER, MENTHA OIL, HERBAL EXTRAC, IN – VITRO DRUG RELEASE, SOLVENT CASTING

ABSTRACT: This study focuses on the formulation and characterization of a transdermal patch containing ginger extract. Ginger (Zingiber officinale) is renowned for its bioactive compounds, particularly gingerols and shogaols, which exhibit significant medicinal benefits. The transdermal patch formulation involves the incorporation of ginger extract into a suitable polymer matrix to ensure controlled and sustained release of the active ingredients through the cellulose membrane. A combination of polymers, plasticizers, and permeation enhancers was evaluated to optimize the patch's mechanical properties, adhesiveness, and drug release profile. In vitro drug release studies were performed using Franz diffusion cells, and the results indicated that the transdermal patch effectively released ginger extract.

OBJECTIVES: To create a new dose form of the ginger extract containing transdermal patch.

METHODS: The ginger extract were collected by maceration method. The Mentha leaves were hydro-distilled to obtained the Mentha oil. The transdermal patch containing the ginger extract were prepared by the solvent casting method.

RESULTS: The optimized formulation demonstrated satisfactory tensile strength, uniform drug distribution, and prolonged drug release, making it a promising candidate for transdermal drug delivery systems.

1. Introduction

Developing novel drug delivery systems for plant extracts is essential to harness their full therapeutic potential, given the inherent challenges associated with their use. Plant extracts often exhibit poor solubility, limited bioavailability, rapid metabolism, and insufficient targeting to specific sites of action, which significantly impede their clinical efficacy. Innovative approaches, such as nano-formulations, liposomes, and polymer-based carriers, are being explored to address these limitations and enhance the delivery of phytoconstituents. For instance, nanotechnology-based delivery systems can improve the solubility and stability of plant extracts, facilitate controlled release, and target specific tissues or cells, thereby maximizing their therapeutic benefits and minimizing side effects (1). Such advancements in drug delivery not only improve the bioavailability and efficacy of plant-derived compounds but also open new avenues for their application in modern medicine (2).

Ginger extract has been increasingly studied for its antispasmodic properties and its potential application in transdermal patches for targeted therapeutic delivery. Transdermal delivery offers a non-invasive and efficient route to administer bioactive compounds directly through the skin, ensuring sustained release and improved bioavailability. Ginger *(Zingiber officinale)* contains active compounds such as gingerols and shogaols, which have demonstrated significant antispasmodic effects by modulating smooth muscle contractions and reducing spasms. Incorporating ginger extract into transdermal patches could provide a continuous and controlled release of these bioactives, potentially enhancing their therapeutic efficacy and minimizing gastrointestinal side effects commonly associated with oral administration (3). Studies have

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shown that such transdermal systems can maintain consistent plasma levels of the active compounds, offering a promising alternative for managing spasmodic conditions effectively (4). In this research work we have focused on preparation and evaluation of transdermal patch which containing the ginger extract.

2. Material & Methods

Material

The ginger and the fresh Mentha leaves are collected from the local market. The solvent ethanol is of HPLC grade.

Method:

Extraction of Ginger

Ginger was cut into small or moderately coarse pieces. Place the ginger pieces in a closed vessel and let it stand for 7 days, shaking it occasionally. Afterward, add the whole menstruum, strain off the liquid, and press the solid residue (Marc) to recover as much as possible. Mix the strained and expressed liquids, then clarify the mixture by subsidence and filtration. Finally, evaporate and concentrate the mixture (Figure 1).

Extraction of Mentha (Peppermint) Oil

Fresh peppermint leaves were collected. The leaves and water were placed in a distillation flask connected to a Clevenger apparatus. The water was heated to produce steam. The steam passed through the peppermint leaves, releasing the essential oil. The steam carrying the oil travelled through a condenser, where it cooled and turned back into liquid. The Clevenger apparatus separated the oil from the water. The peppermint oil floated on top of the water and was collected in a separate chamber, this process efficiently extracted and collected pure peppermint oil using hydro-distillation by Clevenger apparatus.

Figure 1: Extraction of Ginger

Formulation of Transdermal Patch Containing Ginger Extract

HPMC K 400 and PVP were added 1:1 ethanol-water mixture. Let the HPMC and PVP swells properly with stirring. Then add ginger extract and mentha oil in the polymer mixture. After running the entire mixture through the homogenizer, set it aside for 24 hours. Using a syringe, transferred the preserved liquid into a greased petri-dish and allowed the solvent to evaporate slowly. Different transdermal patches (F1 to F5) were prepared as per table no 1.

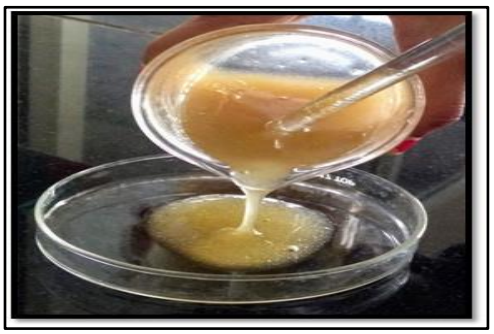

Figure 2: Formulation of transdermal patches Using Solvent Casting Method

Table no.1 Formulation Design

Ingredients	**F1**	**F2**	**F3**	**F4**	**F5**
HPMC (mg)	0.5	0.4	0.5	**0.5**	10
PVP (mg)	0.5	0.15	0.3	**0.2**	0.7
Dry Ginger extract(mg)	0.5	0.5	0.5	**0.5**	0.5
Peppermint Oil (ml)	1	1	1	**1**	1
Ethanol (ml)	5	8	5	**5**	6
Water (ml)	5	2	5	5	4

3. characterization

A) Folding Endurance

The folding endurance value was determined by repeatedly folding a 2 cm×2 cm strip of film at the same place until it broke.

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B) Uniformity of weight

This was done by weighing five different patches of individual batch taking the uniform size at the random also calculating the average weight of three patches. The tests were performed on the patch which was dried at 60°C for 4 h prior to testing.

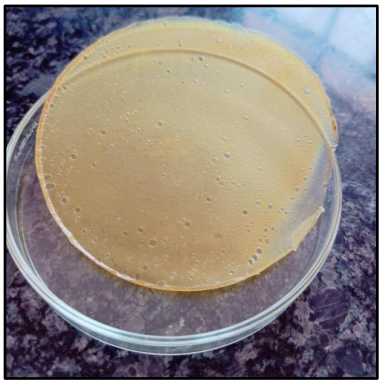

Figure 3: Transdermal Patch

C)Thickness

The thickness of the patch was determined by taking measurements at three different locations using a digital vernier calliper gauge, and then calculating the average value.

D) Percentage Moisture Content

After each manufactured film was weighed, it was stored for 24 hours at room temperature in a desiccator filled with fused calcium chloride. The films were reweighed after a 24-hour period, and the percentage moisture content was calculated using the procedure below:

$$\% \text{ Moisture Content} = \frac{Initial\,weight - Final\,weight}{Final\,weight} \times 100$$

E) Moisture Uptake

percentage of moisture absorption After being stored in a desiccator at room temperature for a full day, the weighted films were subjected to 84% relative humidity using a potassium chloride 6 saturated solution. After the films were weighed, the following formula was used to determine the percentage of moisture uptake.

$$\% \text{ moisture uptake} = \frac{Final\,weight - Initial\,weight}{Initial\,weight} \times 100$$

F) Determination of Surface pH

The patches were allowed to swell by being in contact with 1 milliliter of distilled water for two hours at room temperature. The electrode was then brought in touch with the patch's surface and allowed to equilibrate for one minute to record the pH.

G) Calibration of ginger extract

The calibration of ginger extract was carried out in phosphate buffer pH 7.4. For calibration a series of dilution in phosphate buffer were made and the absorbance was determined for each dilution.

H) Drug content

The transdermal system measuring 2.9865 cm^2 was divided into small pieces and placed in a 50 ml volumetric flask. 25 ml of phosphate buffer pH 7.4 was then added, and the mixture was gradually heated to 45ºC for 15 minutes. The system was then left for 24 hours, stirring it occasionally. Filter the solution. The absorbance of the resultant solution was measured with proper dilution with PBS 7.4 at 282 nm.

I) In Vitro Drug Release Studies:

A Franz diffusion cell featuring a receptor compartment capacity of 60 ml was utilized for conducting in vitro drug release.

The diffusion cell's donor and receptor compartments were separated by a cellulose acetate membrane with a pore size of 0.45µ. The cellulose acetate membrane was coated with aluminum foil after the transdermal film placed on it. Phosphate buffer, pH 7.4, was put into the diffusion cell's receptor compartment. The entire system was mounted on a hot plate magnetic stirrer at 32+/- 0.5°C (typical skin temperature). The receptor compartment was continuously swirled using magnetic beads. The samples were taken out at various time intervals and subjected to spectrophotometric analysis at λ max 282 nm to determine the drug release. After every sample withdrawal, the receptor phase was refilled with a fresh phosphate buffer.

J) Screening of Antimicrobial Activity

Antimicrobial activity was carried out by using the transdermal patch. against test microorganism Escherichia coli by the agar well diffusion method.

3. Results and Discussion

A. Folding endurance

A specific area of strip is cut and repeatedly folded at the same place till it broke. As shown in the figure 4.

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Figure 4: Folding endurance

The folding endurance of different patches is recorded in table 2.

Table no. 2 Folding endurance:

Sr. No.	Patch Code	Folding endurance
1.	F1	12 ± 0.76
2.	F2	9 ± 0.81
3.	F3	10 ± 0.75
4.	F4	35 ± 0.12
5.	F5	12 ± 0.65

B. Weight uniformity-

The prepared patches are to be dried at 60°C for 4 h before testing. The patch is to be cut in different parts of the patch and weighed in digital balance. The average weight and standard deviation values are to be calculated from the individual weights**.** The weight uniformity of the different patches is recorded in table no 3.

Table no. 3 Weight Variation

Sr. No.	Patch Code	Weight uniformity
1.	F1	1.13 ± 0.19
2.	F2	1.20 ± 0.64
3.	F3	1.01 ± 0.67
4.	F4	1.05± 0.17
5.	F5	1.25 ± 0.71

C. Thickness of the patch

The thickness of the prepared patch is measured by using a vernier calliper at different point of patch and this determines the average thickness and standard deviation for the same to ensure the thickness of the prepared patch. Thickness of the different patches is recorded in table no 4.

Table no. 4 Thickness Test

Sr. No.	Patch Code	Thickness of the patch
1.	F1	0.14 ± 0.63
2.	F2	0.13± 0.72
3.	F3	0.18 ± 0.91
4.	F4	0.13 ± 0.34
5.	F5	0.15 ± 0.28

D. Percentage Moisture content

The percentage moisture content and percentage moisture uptake content were calculated using the desiccators.

The prepared patches are to be weighed individually and to be kept in a desiccator containing fused calcium chloride at room temperature. After 24 h, the films are to be reweighed and the percentage moisture content determined. Percentage moisture content of the different patches is recorded in table no. 5.

Percentage moisture content (%)

$$= \frac{Initial\ weight - Final\ weight}{Final\ weight} \times 100$$

Table no.5 Percent Moisture Content

Sr No.	Patch code	Initial wt.	Final wt.	% moisture content
1.	F1	1.13	1.08	4.6 ± 0.45
2.	F2	1.20	1.17	2.5± 0.38
3.	F3	1.01	0.95	6.31 ± 0.78

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4.	F4	1.05	1.00	5 ± 0.30
5.	F5	1.25	1.19	4.16 ± 0.23

E. Percentage Moisture Uptake

The prepared patches are to be weighed individually and to be kept in a desiccator reweighed containing saturated solution of 1 potassium chloride. After 24 h, the films are to be. Percentage moisture uptake of different patches is recorded in table no 6.

Percentage moisture uptake (%)

$$= \frac{Final\ weight - Initial\ weight}{Initial\ weight} \times 100$$

Table no. 6 Percentage moisture uptake

Sr No	Patch code	Initial wt.	Final wt.	Percentage moisture uptake (%)
1.	F1	1.12	1.15	2.67 ± 0.12
2.	F2	1.20	1.26	5.00 ± 0.81
3.	F3	1.01	1.07	5.940 ± 0.71
4.	F4	1.05	1.115	6.190 ± 0.21
5.	F5	1.25	1.31	3.10 ± 0.90

F. Determination of surface pH

pH of the different patches is recorded in the table no 7.

Table no. 7 determination of surface pH

Sr. No.	Patch Code	pH
1.	F1	5.9 ± 0.18
2.	F2	7.4 ± 0.68
3.	F3	6.7 ± 0.35
4.	F4	6.2± 0.21
5.	F5	7. ± 0.41

G) Calibration curve of Ginger extract

For the preparation of Calibration curve, a different dilutions of ginger extract were prepared in phosphate buffer 7.4. The absorbance of sample was determined at 282 nm by using Shimadzu 1900 UV spectrophotometer. The absorbance vs concentration shows a linear relationship with regression coefficient of 0.991.

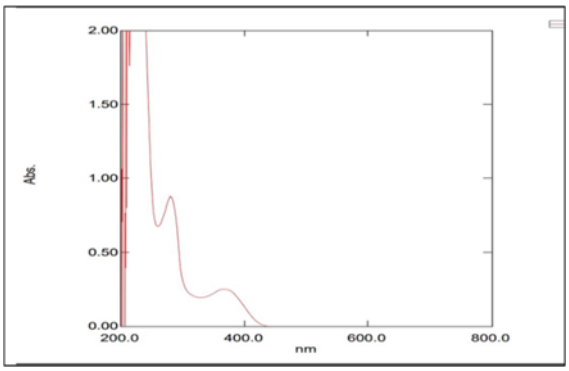

Figure 5: UV peak of ginger extract

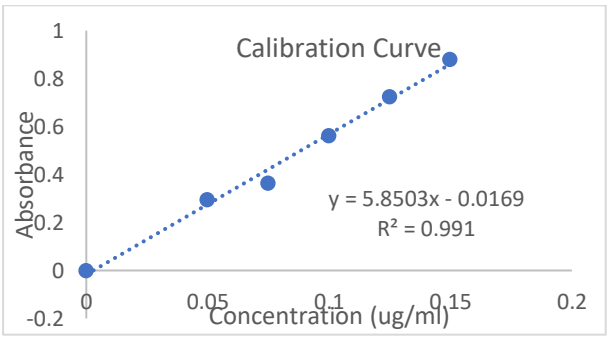

Figure 6: Calibration Curve of Ginger Extract

H) Drug content

The drug content present in $2cm^2$ area of patch (P4) was recorded by U.V spectroscopic method at 282 nm. The drug content was found to be 0.4276 µg/ml in $2cm^2$

I) In vitro drug release study-

The in vitro drug release study was performed using Franz diffusion cell apparatus. The absorbance was recorded with respect to time. From this the % drug release from Transdermal patch were calculated, & the graph is plotted between the % Drug Release vs Time.

From this graph it is concluded that, drug release from the patch shows sustained release action.

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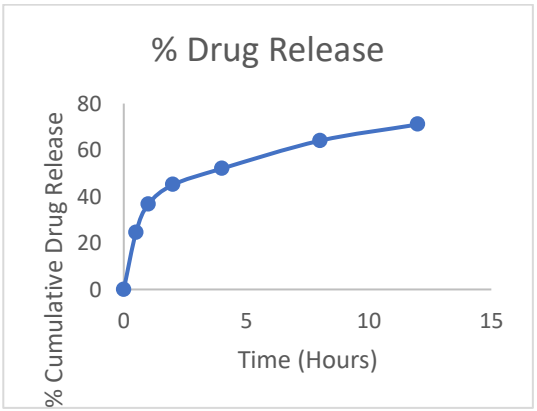

Figure 7: % Cumulative drug release from patch

J) Screening of Antimicrobial Activity

Antimicrobial activity was carried out by using the transdermal patch. against test microorganism Escherichia coli by the agar well diffusion method the results are shown in Figure no 7. The prepared patch containing ginger extract shows a good antimicrobial activity against a control.

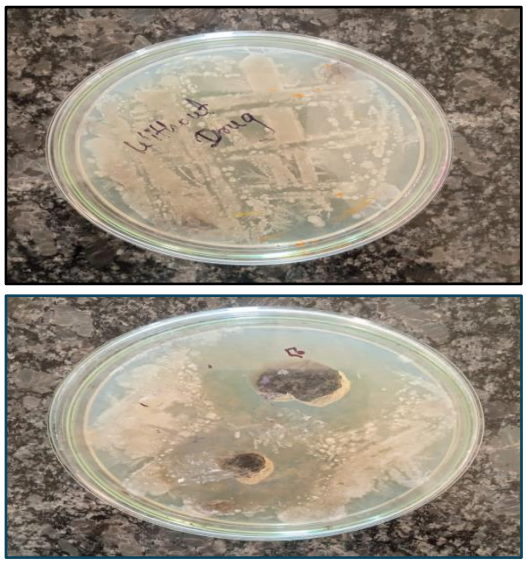

Figure 8: Antimicrobial Activity

Conciusion

The research successfully developed and characterized a transdermal patch incorporating ginger extract. The formulated patches demonstrated excellent mechanical properties.

Transdermal patch (P4) shows a good characteristic such as moisture uptake, folding endurance, pH. Hence This formulation was chosen for determination of drug content, in vitro drug release and antimicrobial activity. In vitro drug release studies using Franz diffusion cells revealed that the transdermal patches effectively released ginger extract, achieving a controlled and sustained release profile. The optimized formulation ensured consistent drug distribution and prolonged release, which are critical for maintaining therapeutic efficacy.

Overall, the study demonstrates that the ginger extract transdermal patch is a promising alternative to traditional oral and topical formulations, offering improved patient compliance and enhanced therapeutic outcomes. The results lay a solid foundation for further in vivo studies and clinical trials to validate the safety and effectiveness of the transdermal patch in real-world applications.

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