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Formulation and Evaluation of Herbal Transdermal Patches using Abutilon indicum linn for Rheumatoid Arthritis

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ABSTRACT:
Transdermal drug delivery systems (TDDS) offer a promising alternative for the controlled and non-invasive delivery of drugs. This study explores the development and evaluation of herbal transdermal patches using Abutilon indicum linn leaves, a plant known for its anti-inflammatory properties, as a potential treatment for rheumatoid arthritis (RA). The leaves were collected, authenticated, and subjected to phytochemical screening, which confirmed the presence of bioactive compounds such as alkaloids, glycosides, flavonoids, and tannins. Ethanolic extracts of Abutilon indicum linn were incorporated into transdermal patches formulated with hydroxypropyl methylcellulose (HPMC) as the polymer base. Various formulations (F1, F2, F3) were prepared and evaluated for their physicochemical properties, including thickness, moisture content, drug content, and in-vitro drug release. The patches exhibited favorable characteristics such as flexibility, smoothness, and consistent drug release. The FTIR analysis confirmed the presence of key functional groups, supporting the plant's therapeutic potential. In-vitro release studies demonstrated controlled drug release, suggesting that Abutilon indicum linn based transdermal patches could serve as an effective, non-invasive treatment option for RA. These findings support the traditional medicinal use of Abutilon indicum linn and highlight its potential for transdermal drug delivery.

Keywords: Herbal transdermal patch, Anti-arthritic patch, Anti inflammatory patch, Painless drug delivery, Rheumatoid arthritis patch.

I. INTRODUCTION:

Transdermal drug delivery is one of the most popular and widely utilized drug delivery modalities. When compared to other methods of administration, the transdermal route has gained more attention in medicine delivery due to its flexibility in palatability and convenience [1]. The transdermal route is one of the most appropriate, older, easy, safe, and cost-effective pharmaceutical delivery techniques. Targeting a particular region of action and controlling the rate of distribution are the primary goals of a transdermal drug delivery system. When applied to healthy skin, transdermal drug delivery devices—separate, self-contained dosage forms—release drugs into the bloodstream at a regulated pace [2]. Transdermal patches, sometimes referred to as skin patches, are medicated adhesive patches that are put to the skin to administer a specific dosage of medication via the skin and into the bloodstream. When applied to undamaged skin, transdermal drug delivery systems (TDDS patches), which are self-contained discrete dose forms, administer the medication via the skin at a regulated rate of systemic circulation. Dosage design for transdermal drugs aims to minimize drug metabolism and retention in the skin while increasing drug flux through the skin into the systemic circulation. One promising technique for both local and systemic drug delivery is the transdermal route of administration. The TDDS offers several benefits, including a non-invasive, painless way to deliver medications straight into the body; a more efficient way to administer medications that are broken down by stomach acids; a controlled, consistent distribution of medications over an extended period; fewer side effects than oral medications or supplements; ease of use and memory; a substitute for those who cannot or do not want to take medications or vitamins orally; and cost-effectiveness [3]. The cause of rheumatoid arthritis (RA), a chronic, progressive autoimmune disease, is uncertain. Chronic inflammation that mostly affects the peripheral joints is what sets it apart. There are two common treatments for rheumatoid arthritis in the allopathic medical system, and both have clear drawbacks. Therefore, it would be wiser to use a safe, efficient, and tried-and-true Ayurvedic herbal treatment formulation. Newer and safer

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pharmaceuticals are always being sought after, in addition to the conventional therapy methods of glucocorticoids, disease-modifying anti-rheumatic medications, and non-steroidal anti-inflammatory drugs, as long-term use of these drugs has led to negative side effects. Another treatment option for RA is alternative medicine, and several medicinal plants are currently being researched to provide a new medication [4,5]. Abutilon indicum linn leaves' anti-inflammatory properties through the stability of HRBC membranes. The leaves aqueous, chloroform, and ethanolic extracts were tested for anti-inflammatory properties. A biphasic impact was observed in all three portions on the stabilization of the membrane [6]. The study examined the anti-inflammatory properties of Abutilon indicum linn leaves using the HRBC membrane stabilization technique.

The anti-inflammatory properties of the leaves ethanolic, chloroform and aqueous extracts were examined[7].

II. MATERIALS AND METHODS:

Materials:

Collection of plant material:

The leaves of Abutilon indicum linnwere collected from Kolivakkam, Kanchipuram district in Tamil Nadu in the month of November 2024.

Identification and authentication of plant material:

The collected specimens were botanically identified and authenticated by Dr. N. K. Sunil Kumar, Research officer, Department of Pharmacognosy, Siddha Central Research institute, Chennai - 600106. The Sample was identified as Abutilon indicum linnbelongs to the family Malvaceae.

Chemicals:

All of the following chemicals were purchased from Spectrum Reagents and Chemicals Pvt. Ltd. in Chennai, Tamil Nadu.

- Chloroform
- Ethanol
- TWEEN 80
- HPMC
- Glycerol

METHODS:

1. Extraction of plant material:

The leaves of plants were washed three times with tap water to remove dirt and leaves were dried in the shade at room temperature.A coarse powder of the dried leaves is obtained by blending the leaves.Then, coarse powder is used for solvent extraction.Abutilon indicum linn coarse leaf powder (100g) was macerated for 3 days in 500ml of ethanol by using the cold maceration extraction method.Concentrated the extracts using an evaporation technique, and stored in an airtight container at a cool temperature for future use.

Fig 1: Abutilon indicum linn

Fig.2: Liquid extract of Abutilon indicum linn Leaves powder

2. Phytochemicalscreening:

The various extracts obtained from successive solvent extraction were then subjected to qualitative chemical tests to determine the presence of phytoconstituents like alkaloids, glycosides, carbohydrates, phenolics&tannins, proteins, amino acids, saponins, phytosterols using reported methods.

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SI.NO	Identification test	Observation	Inference
1	**Alkaloids :** **Mayer's test** To 1 ml of extract, 1 ml of Mayer's reagent (potassium iodide solution) was added	Formation of whitish yellow or cream coloured precipitate	Presence of alkaloids
2	**Phenols :** **Lead acetate test** To 1ml of extract,1ml of lead acetate was added	Formulation of precipitate	Presence of phenols
3	**Flavanoids :** **Alkaline reagent test** To 1ml of extract, few drops of dilute ammonium solution and few drops of concentrated hydrochloric acid was added	A yellow colouration	Presence of Flavanoids
4	**Aminoacids :** **A)Ninhydrin test** To the 1ml of sample,3 to 4 drops of ninhydrin solution was added and boiled in water bath for 10 minutes **B)Millon's test** To the 1ml of extract add Millon's reagent	Formulation of puprple or blue colour White precipitate	Presence of amino acids Presence of amino acids
5	**Reducing sugar :** **Fehling's test** To the 1ml of extract,equal quantities of Fehling solution A and B were added and heated	Formulation of brick red precipitate	Presence of reducing sugar
6	**Saponins :** **Froth test** To 1ml of extract,1ml of distilled water was added and shaked vigorously	Formulation of froth	Presence of saponins
7	**Terpenoids :** **A)Salkowski test** To 1ml of extract,2ml of chloroform and few drops of sulphuric acid were added **B)Sulphur test** To 1ml of extract add sulphur powder	Formulation of reddish brown ring Sinks at the bottom	Presence of terpenoids Presence of terpenoids
8	**Tannins :** **Gelatin test** To 1ml of extract add Gelatin solution containing 10% NaCl	Precipitate is formed	Presence of tannins
9	**Carbohydrates :** **Molisch's test** To 1ml of extract add Molisch's reagent, shake and add concentrated H_2SO_4 from sides of test tube	Formation of violet colour ring at junction of 2 liquids	Presence of carbohydrates

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10	**Gums and mucilage :** To 1ml of extract add Ruthenium red solution	Pink colour	Presence of gums and mucilage.
11	**Glycoside :** To 1ml of extract add 5ml diluted H2SO4, heat on water bath, neutralize with 5% NaOH solution, 0.1ml Fehling's A and B until it becomes alkaline, heat on water bath for 2 minutes	Red precipitate	Presence of Glycosides
12	**Steroids :** **Libermann Burchard test** To 1ml of extract add 2ml of acetic anhydride and 2ml of concentrated sulphuric acid were added	Formation of violet to blue or green colour	Presence of steroids

Table1: Phytochemical Screening of Plant Extracts

3. Formulation development:

Transdermal patches were developed by using ethanolic extract of Abutilon indicum linnleaves in various values (4ml,5ml,6ml) and polymer. A weighed amount of polymer was mixed in a calculated quantity of chloroform and ethanol and then heated on hot plate .The calculated amount of extract was added to the polymer solution and thoroughly mixed until the mixture became homogeneous. After the permeation enhancer and glycerin were then added in the calculated amounts. The resulting solution was put into a petri dish and air dried for 24 hours at room temperature. The patches from the petri dish were then removed with a knife and then stored in a desiccator.

Ingredients	**FormulationCode**		
	Fl	F2	F3
Abutilon indicum linn EXTRACT	4ml	5ml	6ml
HPMC	0.5g	0.5g	0.5g
CHLOROFORM	6.25ml	6.25ml	6.25ml
ETHANOL	2.25ml	1.25ml	0.25ml
TWEEN80	1.5ml	1.5ml	1.5ml
GLYCERINE	0.3ml	0.3ml	0.3ml

Table2:Formulation development

Fig: 3 Poured plates are kept undisturbed for 24hr

EVALUATION OF HERBAL TRANSDERMAL PATCHES:

Formulated patches were subjected to preliminary assessment procedures. Patches exhibiting flaws, entrapped air, or varying in thickness, weight (or) content homogeneity were rejected from further

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research.

I. Organoleptic Characteristics:

The physical appearance of developed patch was evaluated by using a naked-eye examination for its appearance, colour, clarity, flexibility, and smoothness.

II. Physio-Chemical Evaluation:

A. Thickness of Patch:

A Vernier caliper was used to measure patch thickness uniformity at six different places. The mean thickness of all six places was then determined.

B. Determination of Surface pH:

The pH of the patch is evaluated by swelling it with 1 ml of distilled water for two hours at room temperaturebeforeuse. Then place the pH electrode on the patch's surface to record the pH value and make them to adjust itself for 1 minute.

C. Percent moisture content

The percent moisture content of the patches was determined by weighing the patches after placing them inside a desiccators for 24 hours. The percent moisture content can be calculated using the following formula:

$$\text{Percentage Moisture content} = \frac{\text{Initial weight - Final weight}}{\text{Initial weight}} \times 100$$

D. Percentage drug content:

Small fragments of patches were cutted and then immersed in a phosphate buffer (PH 7.4) solutionfor 24 hours. The entire solution was then ultra sonicated for 15 minutes. Following filtering, the drug content was measured spectro photometrically.

$$\text{Percentage drug content} = \frac{\text{Absorbance of test}}{\text{Absorbance of standard}} \times 100$$

E. Folding endurance:

Folding endurance was evaluated by folding the patches repeatedly in the same area even after it broke. Folding endurance is the number of times the patches can be folded in the same area without breaking.

F. Uniformity of weight:

Each of the three patches were weighted for each batch, and the mean weight were determined.

G. Moisture Uptake:

At room temperature the previously Weighed patches were placed in desiccators for 24 hours ina saturated potassium chloride solution in order to keep 84% RH. After 24 hours, the patches were reweighed and the % moisture uptake was calculated using the following formula.

$$\text{Percentage Moisture uptake} = \frac{\text{Initial weight - Final weight}}{\text{Initial weight}} \times 100$$

H. Percent Elongation test:

When external Stress is applied to patches, it stretches to produce strain and elongation increases as plasticizer concentration increases.

$$\text{Percentage elongation} = \frac{\text{Increase in length of patch}}{\text{Initial length of patch}} \times 100$$

I.Water vapour permeability test:

Normal air circulation oven can be used to measure water vapour permeability. The WVP can be calculated using the formula below,

$$WVP = \frac{\text{Amount of vapour permeated through the patch}}{\text{Surface area}} \times 100$$

J. Flatness test:

Patches were cut into three longitudinal strips, with the length of each strip was measured and the difference due to non-uniformity in flatness calculated using

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percentage constriction, with 0% constriction.

$$\text{Percentage Constriction} = \frac{\text{Final length of each strip}}{\text{Initial length of each strip}} \times 100$$

III.INVITRO DRUG RELEASE:

Principle:

Passive diffusion is the biological process of movements of the biochemical across the cell membranes and tissues. It is the most straightforward method by which molecules can flow through the plasma membrane. A molecule merely dissolves in the phospholipid bilayer, diffuses across it, and then dissolves in the aqueous solution on the opposite side of the membrane during passive diffusion.

Cellophane Membrane Treatment:

Cellophane membrane was boiled in the Distilled water for 1 hr and washed with fresh distilled water for three times and kept in ethanol for 24 hrs. It was washed with D.Wand treated with0.3% sodium sulphite and soaked in distilled water for 2min at60°C followed by acidified with 0.2% sulphuric acid. Finally the membrane is dipped in boric buffer (pH 9) till it is used for permeation study.

Drug Permeation Studies:

The in vitro diffusion rate of developed Transdermal patches were evaluated by Open ended tube through using distilled water as diffusion medium up to 8 hrs. The cellophane membrane was tide in one end of the tube and then immersed in there captor compartment containing 200ml of 7.4 buffer solution. It was stirred at medium speed and maintained at 37°C±2°C. Samples were withdrawn at regular time intervals and the same volume was replaced by fresh diffusion medium. The samples were analyzed using UV -visible spectrophotometer (Shimadzu UVl700) set at 260- 280nm.

IV. FTIR Analysis:

IR spectrum was recorded in spectrophotometer (PerkinElmer Spectrum Two FT-IR Spectrometer). The active principle was mixed with KBr and pellet technique was adopted to record the spectra.

III. RESULTS AND DISCUSSION:

2.Phytochemical analysis:

S.No.	Test	Ethanolicextractof Abutilon indicum linn
1.	Alkaloids	+
2.	Glycosides	+
3.	Tannins	+
4.	Carbohydrates	+
5.	Flavonoids	+
6.	Aminoacids	+
7.	Proteins	+
8.	PhytosterolsandTriterpenoids	-
9.	Terpenoids	-
10.	Fatsandoils	-
11.	Gums&Mucilage	-

Table 3: Phytochemical analysis

I. Organoleptic Characteristics:

S.No.	Physical Appearance	Fl	F2	F3
1	**Appearance**	Jellified Preparation	Jellified Preparation	Jellified Preparation
2	**Colour**	Lightgreen	Lightgreen	Lightgreen

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3	**Clarity**	Opaque	Opaque	Opaque
4	**Flexibility**	Yes	Yes	Yes
5	**Smoothness**	Good	Good	Good

Table4: Organoleptic Characteristics of Herbal Transdermal patches

II. Physio-chemicalEvaluation:

S.No	**Physio- Chemical Evaluation**	**Fl**	**F2**	**F3**
1	**Thicknessof Patch**	0 3± 0.141	0 33±0.163g	02±0 089g
2	**Determination ofSurfacepH**	4.62±0.124	4.68±0.095	4.84±0168
3	**Percent moisture content**	2.23±0.632%	2.47±0.760%	3.94±2.385%
4	**%drugcontent**	78±1.405%	81±2.092%	83±1.796%
5	**Folding endurance**	29.6±4.725	33.6±3.214	34±3.214
6	**Uniformityof weight**	1.67±0.289g	1.64±0.367g	1..66±0295 g
7	**Percent Moisture Uptake**	6.00±3.567%	9.47±6.301%	4.24±2.197%
8	**Percent Elongation**	108±1.435%	107±4.3606%	110±1.538%
9	**Watervapour permeability test**	0.12±0.006 g/m2	0.13±0.063 g/m2	0.14±0.032 g/m2
10	**Flatnesstest**	96.12±1.631%	97.04±1.632%	95.84±1.768%

Values are expressed as the Means ± SD, where(N=3).

Table5:Physio-chemicalevaluation

III. INVITRO DRUG RELEASE:

Time (mins)	**Absorbance at 260nm**		
	F1	**F2**	**F3**
0	0	0	0
30	0.036	0.045	0.032
60	0.115	0.132	0.143
120	0.278	0.235	0.289
180	0.327	0.287	0.456
240	0.401	0.387	0.546
300	0.556	0.543	0.654
360	0.767	0.679	0.756

Table6: In-vitro analysis

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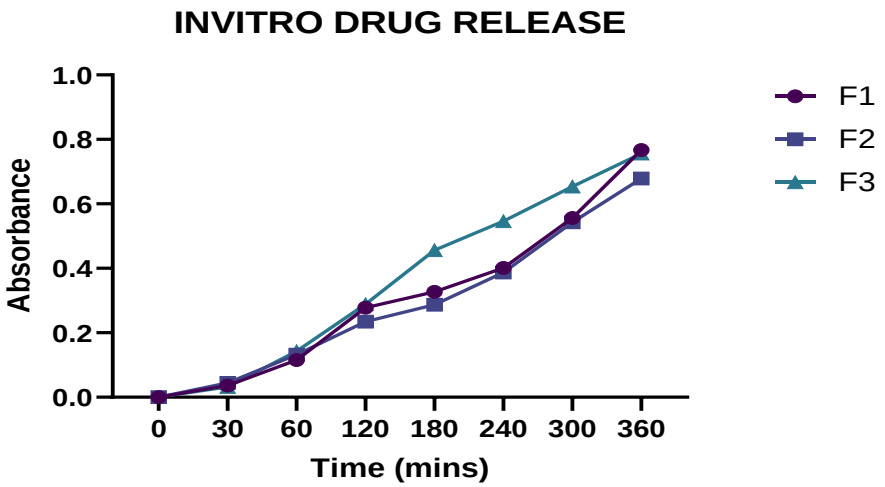
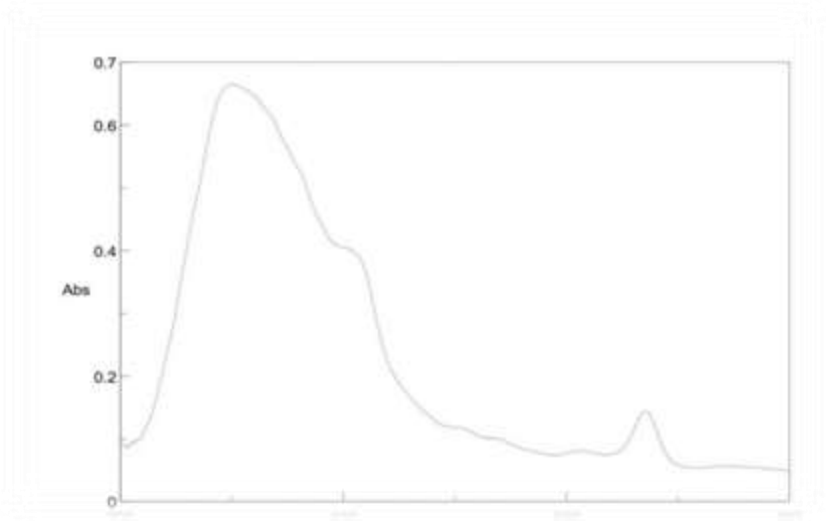


IV. FTIR : Abutilon indicum linn Extract



Wavenumber (cm^{-1})	Functional Group	Type of Vibration
3600-3200	O-H (Alcohol, Phenol)	Stretching (Broad)
3500-3300	N-H (Amine, Amide)	Stretching
3300-3000	≡C-H (Alkyne)	Stretching
3100-3000	=C-H (Aromatic, Alkene)	Stretching
3000-2850	C-H (Alkane)	Stretching
2260-2100	C≡C, C≡N (Alkyne, Nitrile)	Stretching
1750-1700	C=O (Carbonyl: Ketone, Aldehyde, Ester, Carboxylic Acid)	Stretching
1680-1600	C=C (Alkene, Aromatic)	Stretching
1600-1500	N-H (Amine, Amide)	Bending
1500-1300	C-H (Alkane)	Bending
1300-1000	C-O (Ester, Ether, Carboxylic Acid)	Stretching
900-650	C-H (Aromatic, Alkene)	Bending (Out of Plane)

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The FTIR analysis of Abutilon indicum linn extract successfully identifies the presence of key functional groups associated with bioactive compounds. The spectrum reveals characteristic peaks corresponding to hydroxyl (O-H), carbonyl (C=O), aromatic (C=C), and ether (C-O) groups, indicating the presence of flavonoids, tannins, alkaloids, polysaccharides, and essential oils.These findings align with the traditional medicinal uses of Abutilon indicum linn, supporting its antioxidant, antimicrobial, and anti-inflammatory properties. The presence of phenolic compounds and flavonoids suggests that the plant has potential pharmaceutical applications.

IV. SUMMARY AND CONCLUSION:

The development of herbal transdermal patches using Abutilon indicum linn leaves offers a promising alternative for the treatment of rheumatoid arthritis (RA). The phytochemical analysis of the plant confirmed the presence of bioactive compounds such as alkaloids, flavonoids, and tannins, which are known for their anti-inflammatory and therapeutic properties. In the formulated transdermal patches,F1 demonstrated favorable physical and chemical properties, including uniformity in thickness, moisture content, and drug release. The FTIR analysis further validated the presence of key functional groups, supporting the plant's medicinal value. The in-vitro drug release studies showed a controlled and sustained release of the bioactive compounds, indicating that these patches could be a viable non-invasive option for systemic drug delivery. The study highlights the potential of Abutilon indicum linn as a natural and effective remedy for RA, offering an innovative approach to transdermal drug delivery systems for enhanced patient compliance and minimized side effects. Future studies should focus on optimizing the formulations for clinical applications and exploring the long-term efficacy of these herbal patches in treating RA.

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