IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 20, April 2026
Impact Factor: 8.2

Formulation and Evaluation of Herbal Transdermal Patches for Irregular Menstrual Cycle

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Abstract: *The present research was aimed at the development and evaluation of a transdermal patch formulated with herbal actives Asparagus racemosus (Shatavari), Saraca asoca (Ashoka), and Symplocos racemosa (Lodhra) for the management of irregular menstrual cycles. Extracts of the selected herbs were obtained through appropriate extraction techniques and incorporated into a polymeric matrix system to fabricate the transdermal patches. Selection of polymers and plasticizers was carried out to optimize the film-forming characteristics and to facilitate sustained and controlled release of the phytoconstituents.The formulated transdermal patches were assessed for different physicochemical characteristics including organoleptic evaluation, surface pH, weight uniformity, thickness, folding endurance, and moisture content. Results demonstrated satisfactory physical attributes, adequate flexibility, and homogeneous distribution of the herbal constituents within the matrix.[1] The surface pH values were comparable to that of human skin, suggesting that the patches are likely to be non-irritant upon application.In vitro drug release analysis revealed a sustained and controlled release profile of the phytoconstituents over a prolonged duration. Kinetic modeling of the release data indicated that drug release from the polymeric matrix was predominantly governed by a diffusion mechanism. Furthermore, stability assessments showed that the developed transdermal patches retained their physicochemical characteristics under varying storage conditions.[2]*

Keywords: Irregular menstrual cycle, TDDS, Herbal patch, Ashoka, Shatavari, Lodhra, Controlled drug release, Hormonal imbalance.

I. INTRODUCTION

In women of reproductive age, menstruation is a normal physiological process. However, many women experience irregular menstrual cycles, which can be caused by hormonal imbalances, stress, inadequate diets, changes in lifestyle, and underlying endocrine issues.[3]

Irregular Menstrual Cycle

Menstrual irregularities that are commonly observed in young women and teenagers include oligomenorrhea, polymenorrhea, amenorrhea, and dysmenorrhea. Among the main causes include endocrine disorders, food deficiencies, stress, hormonal imbalance, and lifestyle changes. Interest in herbal and alternative therapies has increased as a result of the drawbacks

The main treatment for irregular menstrual periods is oral hormonal medication, which often has side effects such nausea, weight gain, gastrointestinal issues, and low patient compliance. Furthermore, oral administration results in first-pass metabolism, which reduces the drug's bioavailability.[4]

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Types of Transdermal Patches (TDDS)

1. Single-layer Drug-in-Adhesive System

The medication is directly integrated into the adhesive layer of this kind of transdermal patch. The adhesive layer regulates the drug's release in addition to aiding in the patch's adherence to the skin.

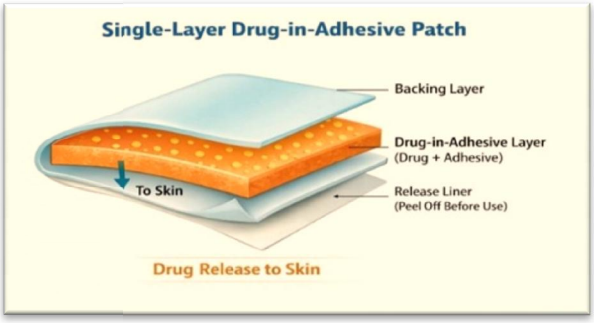

Fig No 1. Single-layer Drug-in-Adhesive System

2. Multi-layer Drug-in-Adhesive System

A more sophisticated version of the single-layer patch, the multi-layer drug-in-adhesive system is intended to offer enhanced therapeutic efficacy and better control over drug release.

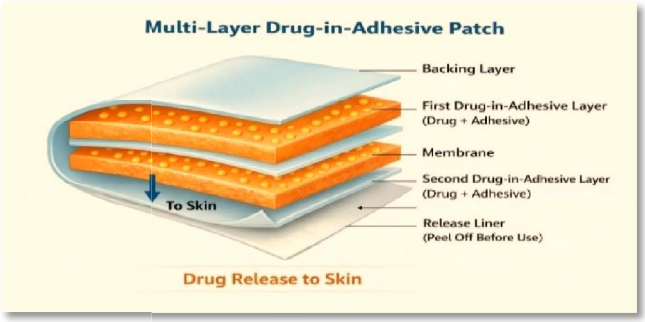

Fig No 2.Multi-layer Drug-in-Adhesive System

3. Reservoir System

In this system, the drug is present in a separate reservoir compartment in the form of a solution or suspension.[5]

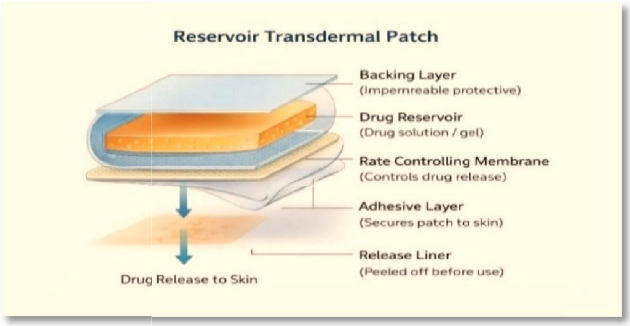

Fig No3. Reservoir System

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4. Matrix System

The matrix system is a widely used transdermal drug delivery approach. It works by homogeneously distributing the drug throughout a polymeric matrix. This matrix regulates the rate at which the drug is released into the skin.

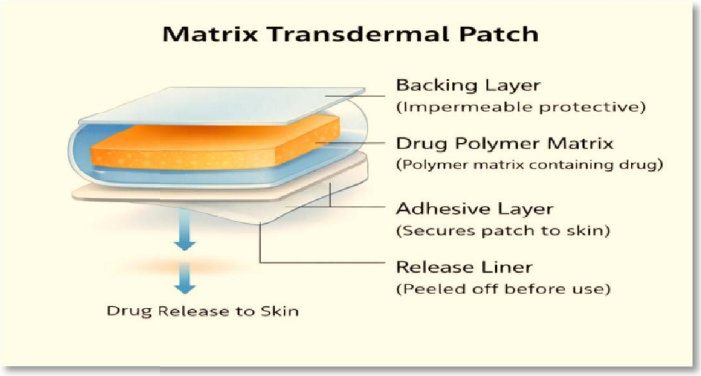

Fig No 4. Matrix System

Components Of Transdermal Patch :

Release Liner
Adhesive Layer
Membrane Polymer matrix
Drug
Backing Laminates

1. Release Liner

A release liner is a protective layer used in transdermal patches to cover the adhesive surface until the patch is ready for use.

2. Adhesive Layer

The adhesive layer ensures skin attachment of the transdermal patch. Made from pressure-sensitive adhesives, it maintains proper skin contact for effective drug delivery.[6]

3. Membrane Polymer matrix

The membrane or polymer matrix in a transdermal patch serves as a drug reservoir and regulates the release rate of the active constituents.

4. Drug

The drug is the active ingredient in a transdermal patch that produces the desired therapeutic effect.

5. Backing Laminates

The backing laminate forms the outermost layer of a transdermal patch. It prevents drug loss, shields the patch from moisture and air, and provides structural support and flexibility.

II. MATERIAL AND METHODOLOGY

The herbal transdermal patch was formulated using active extracts of Saraca asoca (Ashoka), Asparagus racemosus (Shatavari), and Symplocos racemosa (Lodhra), which are traditionally employed in the management of menstrual disorders. Hydroxypropyl methylcellulose (HPMC) and ethyl cellulose were used as film-forming polymers to impart mechanical strength and regulate drug release from the matrix. Polyethylene glycol 400 (PEG 400) and glycerin were incorporated as plasticizers to enhance flexibility and elasticity of the films. Tween 80 was included as a permeation enhancer to improve transdermal absorption of the phytoconstituents. Ethanol and distilled water served as solvents for solubilizing the drug and extracting the active constituents. For stability and protection, the prepared patches were packaged in aluminum foil pouches to prevent exposure to moisture and environmental factors. Release liners made of

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butter paper were applied to facilitate easy removal of the patches prior to use. The primary packed patches were further placed in carton boxes for additional protection during storage.[7]

Methodology

1. Collection Of Herbal Material

The herbal materials used in the present study were the bark of Symplocos racemosa (Lodhra), the bark of Saraca asoca (Ashoka), and the roots of Asparagus racemosus (Shatavari). All crude drugs were obtained from an authenticated local supplier. The plant materials were washed thoroughly with distilled water to remove adherent dirt and foreign matter. They were then shade dried at room temperature until completely dry. The dried materials were reduced to a coarse powder using a mortar and pestle, and the resulting powder was passed through sieve no. 60 to achieve uniform particle size.[8]

2. Preparation Of Herbal Extract

For the preparation of herbal extract, 0.5 g of powdered crude drug comprising Symplocos racemosa (Lodhra), Asparagus racemosus (Shatavari), and Saraca asoca (Ashoka) was accurately weighed and transferred to a beaker. To this, 15 mL of distilled water was added. The mixture was heated gently with continuous stirring until the volume was reduced to approximately one-fourth of the initial volume. After boiling, the mixture was allowed to cool to room temperature. It was then filtered through Whatman filter paper to separate insoluble residues. The clear filtrate obtained was used for the formulation of transdermal patches.[9]

Fig No 5. Decoction Process

Fig No 6.Filtration Process

4. Phytochemical Screening

Sr .No.	Test	Procedure	Observation	Inference
1	Terpenoid	1ml extract +1ml chloroform + 1ml acetic anhydride	Reddish-brown colour	Presenceof terpenoids
2	Phenol	2 ml extract + 2 ml ferric chloride solution	Bluish-green colour	Presence of phenol
3	Tannin	5ml extract + few drops of lead acetate	Yellow Precipitation	Presence of tannin
4	Alkaloid	5ml extract + potassium bismuth iodide	Reddish Precipitate	Presence of alkaloid
5	Saponins	2ml extract + 5ml distilled water, shaken	Foam formation	Presence of saponin

Table No 1. Phytochemical Screening

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5. Preparation Of Polymer Solution

Take appropriate amount of Solvent anddissolvethe polymer (HPMC) into it under continuouslystirring

6. Incorporation Of Herbal Extract

The herbal extract wasadded slowly to the polymer solution. With continuously stirring

7. Addition Of Excipients

Add Plasticizier (PEG 400)and penetration enhancer (Tween-80) were added and mixed troroughly .

8. Casting of Patch

The prepared solution was poured into a clean glassmould/petri dish.

9. Drying

The casted solution was dried in hot air oven for 8 -10 hr at 40^0c to 50^0c

10. Cutting

Dried films were removed and cut into uniform sized patches .

11. Packaging

Use of aluminium foil or laminated backing layer .Protects from moisture, light, and contamination .Individual packaging of patches .[11]

Formulation Table

Sr .No.	Ingredients	F1	F2	F3	Category
1	Ashoka powder	0.5 gm	0.4 gm	0.3 gm	Active Ingredient
2	Lodhra powder	0.5 gm	0.4 gm	0.3 gm	Active Ingredient
3	Shatavari power	0.5 gm	0.4 gm	0.3 gm	Active Ingredient
4	Hytroxypropyl methyl cellulose (HPMC)	1.2 gm	0.1 gm	0.8 gm	Film Forming polymer
5	Polyethylene glycol (PEG 400)	0.5 ml	0.4 ml	0.3 gm	plasticizer
6	Tween 80	0.25 ml	0.2 ml	0.18 ml	Penetration enhancer
7	Distilled water	12 ml	12 ml	12 ml	solvent

Table No 2. Formulation Table

B. EVALUATION TEST

1. Organoleptic Properties :

Colour : Light cream / pale yellow

Odour : Mild characteristic herbal odor

Appearance : Smooth and uniform surface

Texture : Soft and flexible , Slightly smooth to touch

Clarity : Semi- transparent.

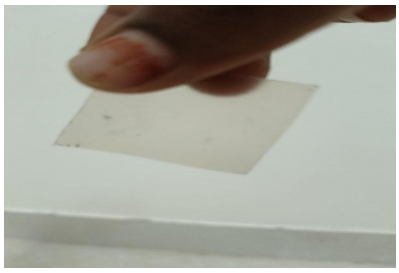

Fig No 7. Transdermal Patch

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2. PH determination

The pH of the patch was determined by allowing it to swell in 1 mL of distilled water for 2 h at room temperature. The surface pH, measured using a calibrated digital pH meter, was observed between 5.0 and 6.5, indicating compatibility with the physiological pH of skin.[12]

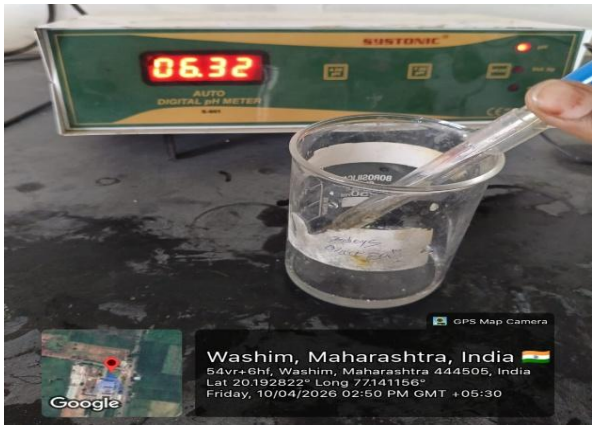

Fig No 8.PH determination

3. Weight Variation

The weight of each formulated transdermal patch was determined using a calibrated digital balance. The mean weight was found to be 0.4 g.[13]

Fig No 9. Weight Variation

4. Folding Endurance

Folding endurance was assessed by repeatedly folding a patch strip at the same position until rupture occurred. The folding endurance value, defined as the number of folds the patch withstood without breaking, was recorded as 15**.**

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Fig No 10. Folding Endurance

5. Percentage Moisture Content

For moisture content analysis, the transdermal patch was accurately weighed and recorded as initial weight (W_1). It was then dried in a hot air oven at 50°C ± 2°C for 24 h. After drying, the patch was cooled to room temperature in a desiccator and reweighed to obtain the final weight (W_2). The percent moisture content was calculated using the following formula:Moisture Content (%)=W1W1−W2×100The moisture content of the prepared patch was found to be 10%.[14]

6. Skin irritability test

The skin irritation test is an important parameter in the evaluation of transdermal patches. It is performed to determine whether the patch produces any irritation, redness, swelling, or allergic reaction on the skin. The transdermal patch is applied to different sites such as the upper arm, lower abdomen, and thigh, and secured using surgical tape. The patch is kept in continuous contact with the skin for 24 hours and is replaced daily for a period of 7 to 10 days. After evaluation, the formulation showed no signs of skin irritation or adverse reactions.[15]

III. RESULT AND DISCUSSION

In order to manage irregular menstrual cycles, a herbal transdermal patch including Shatavari (Asparagus racemosus), Ashoka (Saraca asoca), and Lodhra (Symplocos racemosa) was developed and tested.The following is a summary of the various physicochemical analyses that were performed on the prepared patches:
Organoleptic Characteristics: The created patches had a subtle, distinctive herbal scent and looked light cream to pale yellow in colour. They demonstrated acceptable elasticity and a uniform, smooth surface, both of which point to appropriate film formation.
pH of the surface: The measured pH was in the range of 5.0 to 6.5, which is comparable to the skin's natural pH. This suggests that the patches are appropriate for cutaneous usage and unlikely to cause irritation.
Variation in Weight: The patches' average weight of about 0.4 g indicates that the chemicals were evenly distributed and the formulation was consistent.
Folding Endurance: The patches withstood 15 folds without breaking, demonstrating adequate strength and flexibility.
Moisture Content: The moisture content was found to be 10%, which is appropriate to maintain the integrity of the patch and prevent it from becoming too dry or brittle.
Skin Irritation Test: No visible irritation, redness, or allergic response was observed during the application period, indicating that the formulation is safe for topical application**.**

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Phytochemical Screening: The extract showed the presence of important phytoconstituents such as terpenoids, phenolic compounds, tannins, alkaloids, and saponins, supporting its potential therapeutic effectiveness.

IV. CONCLUSION

For the treatment of irregular menstrual cycles, the current study effectively developed and assessed a herbal transdermal drug delivery system containing Ashoka (Saraca asoca), Lodhra (Symplocos racemosa), and Shatavari (Asparagus racemosus).The produced transdermal patches showed acceptable physicochemical properties, such as optimal moisture content, uniform weight, suitable thickness, acceptable surface pH, and good folding endurance. These characteristics show that the patches have the stability, flexibility, and mechanical strength needed for successful application. It was discovered that theformulation's surface pH was nearly identical to that of normal skin, which reduces the possibility of irritation and increases patient acceptability.

The skin irritation test, which revealed no evidence of redness, inflammation, or allergic reaction, further supported this.Important bioactive components like alkaloids, tannins, phenols, terpenoids, and saponins—which are recognized for their medicinal significance in controlling menstrual diseases and enhancing hormonal balance—were found by phytochemical screening. The uniform distribution and efficient delivery of active ingredients were guaranteed by the integration of these herbal extracts into a polymeric matrix technology.

The development of a stable and regulated medication delivery system was aided by the use of appropriate polymers and excipients. Compared to traditional oral medication, the transdermal method has a number of benefits, including as avoiding first-pass metabolism, sustained and regulated drug release, increased bioavailability, fewer doses, and better patient compliance.The produced patches maintained their functional and physical characteristics under various storage circumstances, according to stability studies, indicating good shelf stability. The study's overall findings demonstrate the herbal transdermal patch's safety, stability, and efficacy as well as its great promise as a substitute method for treating irregular menstrual periods.

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