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Research Article

Formulation and Evaluation of Herbal Anti-Acne Patches Containing ethanolic extract of Amla and Neem Showing Antioxidant and anti-inflammatory action on Acne

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ABSTRACT

Objective: The purpose of this research is to create and assess anti-acne patches that contain ethanolic extracts of neem and amla, which serve as anti-inflammatory and antioxidants. The purpose of herbal anti-acne patches is to reduce breakouts, absorb excess oil, promote healing, prevent infection, and alleviate discomfort in order to treat acne and blemishes. They are also beneficial for hydrating the skin due to their simplicity of use and convenience. Without making irritation or discomfort worse, these patches are designed to efficiently target and treat acne lesions, promote healing, prevent recurrences, and offer all-encompassing care for cleaner, healthier skin. **Methodology:** The composition includes fresh *E. officinalis* fruits and *A. indica* leaves that were weighed, washed, dried, and powdered before being kept in a sealed container. Hydropropyl cellulose (HPC), polyvinyl alcohol (PVA), glycerine, propylene glycol, polyethylene glycol, and 70% ethanol are excipients that are utilized in addition to extracts. **Results:** The findings reveal that the anti-acne patches' pH, thickness, absorption, folding resistance, moisture content, and swelling were all taken into consideration while assessing their quality. Several chemical assays were used to confirm the phytoconstituents in the ethanolic extract.

INTRODUCTION

1.1 Transdermal patches

Another method of delivering drugs through the skin layer is transdermal. Before the medication

reaches the site of action, it passes through the skin and enters the bloodstream, where it becomes systemic. When compared to alternative drug administration methods, transdermal drug delivery offers certain benefits. Examples include its

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capacity to bypass the liver's first-pass metabolism, to stay out of the digestive system, and to continuously deliver a dose of medication over time. Other drug delivery methods, such as intravenous injection, may result in discomfort and raise the possibility of infection. Oral delivery is less effective, though, and dose management is challenging when using the inhalation approach. Due to its benefit over the other pathways, Drugs for ailments like motion sickness, chronic pain, and quitting smoking are administered transdermally, as is hormone replacement treatment. (1) Transdermal patches are medicinal patches that, by gradually piercing the layers of the skin, can transport drugs directly into the bloodstream. Actually, the most practical method of administration is through patches (2). They don't involve any intrusive procedures, and the course of treatment can be stopped at any moment after a few days. They come in a variety of sizes and include multiple ingredients. Through diffusion processes, the patch's active components can enter the systemic circulation when applied topically to the skin. Concentrated dosages of active ingredients that stick to the skin for a long time may be found in transdermal patches. The nitroglycerin patch was one of the first transdermal patches created in 1985 (3). The patch, which employs a rate-controlling ethylene vinyl acetate membrane, was created by Gale and Berggren. Many medications, including nicotine, scopolamine (hyoscine), fentanyl, clonidine, estradiol, and estradiol with norethisterone acetate, are now available as transdermal patches (4). Depending on the drug's therapeutic class, the application site may vary. For example, you can apply estradiol to the buttocks or abdomen and nitroglycerin to the chest. Additionally, the duration of drug release varies with consumption, ranging from up to nine hours for the shortest to up to nine days for the longest. (5)

1.1.2 Transdermal patch's major elements

The following elements could be present in a transdermal patch:

- 1) **Liner:** The liner protects the patch during storage. The liner is removed prior to use.
- 2) **Material:** the material solution close to the launch line
- 3) **Adhesive:** This material helps the patch's component pieces stick to the skin.
- 4) **Membrane:** Controls the release of drugs from reservoirs and multilayer patches via the membrane.
- 5) **The backing shields the patch from the outside world (6).**

1.1.3 Types of transdermal patches

1.1.3.1 Medicated adhesive patches

Single layer

The medicine is released using a reservoir, which is a single polymer layer with sticky qualities. This single layer is placed beneath an impervious backing laminate. When the medication is inserted and bonded to the polymer layer, it is released from the backing laminate layer that supports the drug reservoir (7). For instance, Daytarana is a single-layer drug-in-adhesive transdermal patch that contains methylphenidate.

Multilayer

Over time, the drug reservoir layer and the sticky layer regulate drug release (8). In multi-layer systems, it has a backing laminate and a temporary covering layer. Multi-layer patches are used for hormone therapy, smoking cessation therapy, and the delivery of pain medications. They can last up to seven days.

1.1.3.2 Skin patches



These patches allow vapors to escape since they are composed of One layer of a sticky polymer that has the ability to emit vapor. Numerous vapor dermal patches are employed for different purposes (9). Nicoderm CQ, A patch that is applied on the skin that includes nicotine vapor and essential oils to aid in quitting smoking, is an example of this. It was first offered for sale in Europe in 2007 and releases these oils to help people stop smoking. Altacura vapor patches, which are used for decongestion and contain essential oils, are an additional kind of. Additionally, regions of vapors that are specifically designed as sedatives or antidepressants are available on the market.

1.1.3.3 Drug release membrane reservoir patches

One component of a transdermal patch is a drug reservoir, a metallic plastic laminate backing layer that is impermeable, and a porous polymeric membrane that controls the drug's release. (10) Polymeric components such as Hypoallergenic sticky polymer and Ethylene vinyl acetate copolymer comprise the membrane. During preparation, the drug's molecular dispersion in a polymer matrix controls the amount of drug in the transdermal patch.

1.1.3.4 Patches for micro reservoirs

A drug reservoir and matrix dispersion are combined in micro-reservoir transdermal patches. The medication is aqueously suspended in a hydrophilic polymer solution to create the reservoir, which is thereafter evenly distributed as a suspension of a medication on a lipophilic polymer. High mechanical force of shear is needed for the dispersion process, which produces a large number of microscopic, non-leachable spheres. (11) These patches release the drug at a zero-order kinetic rate, maintaining a steady drug

concentration in the plasma. The drug's dispersion usually contains crosslinking polymeric agents to ensure thermodynamic stability.

1.1.3.5 Matrix patches

Drug-in-adhesive system

The medicine and an adhesive polymer are blended to create the drug reservoir in this approach. After that, the medicated sticky polymer is applied by melting or solvent casting. In hot melt application, the medicated layer is covered with unmedicated sticky polymer layers. (12)

Dispersion matrix system

This regimen distributes the medication uniformly across a hydrophilic or lipophilic polymer matrix. The drug-containing polymer disk is attached to an occlusive base plate in a compartment created by a drug-impermeable backing layer. An adhesive rim is formed by spreading adhesive around the edge instead of directly covering the drug reservoir. (13)

1.1.3.6 Advantages

- 1) Transdermal delivery allows a substance to be continuously and consistently absorbed for a long time, avoiding first-pass metabolism.
- 2) Increase patient adherence.
- 3) It has no effect on the stomach and intestinal fluids.
- 4) Provides long-term control by maintaining steady and consistent blood levels. (14)
- 5) Lower medication plasma concentration levels.
- 6) Utilize drug candidates with a low therapeutic index and a brief half-life to lessen the fluctuations in plasma levels brought on by medications. (15)
- 7) Drug delivery is easily eliminated in the event of toxicity.



- 8) Reduce dosage frequency and enhance patient adherence.
- 9) The effectiveness of many pharmaceuticals is increased via transdermal administration, which removes some of the drug's problems, such as low absorption and stomach irritation.
- 10) The shortened prescription schedule results in less diversity in drug response across and within patients.

1.1.3.7 Disadvantages

- 1) For the medication to penetrate the stratum corneum, it must possess favorable physicochemical characteristics.
- 2) A once-daily dosage should not exceed 5 mg per day; transdermal medication distribution becomes challenging if the dosage exceeds 10–25 mg per day.
- 3) The medication, adhesive, and additional chemicals that make up the patch may irritate the area.
- 4) The transdermal delivery method must have a clear clinical necessity.
- 5) Unable to attain high drug concentrations in Blood/ plasma.
- 6) Cannot be prepared in large molecular size of drugs.
- 7) Risk of inflammation at application site. (16)
- 8) Uncomfortable to use.
- 9) It might be expensive.

1.1 Each person has a unique skin barrier, which may even change over time in the same individual. (17)

1.2 Acne

Around the world, acne is a widespread skin problem. Numerous skin imperfections, including pimples, blackheads, whiteheads, cysts, and nodules, may result from it. The face is the primary area affected by acne, which can be brought on by

dietary changes, stress, hormone fluctuations, and heredity. (18) The age group of 15 to 20 years old has the highest prevalence of acne. In youngsters before puberty, acne is very rare and diminishes after puberty. However, acne affects a sizable percentage of adults as well. Acne's complicated and multidimensional pathophysiology includes genetic predisposition, metabolism, hormone levels, environment, food, immunity, and other factors. (19) The most common clinical signs of acne include scars, nodules, cysts, papules, pustules, and pimples. Patients may suffer from anxiety, depression, or even suicidal thoughts as a result of these diseases, which can significantly impair their physical and emotional well-being. The main objectives of acne treatment are to effectively manage and treat existing acne lesions, avoid irreversible scarring, reduce the frequency of recurrences, and minimize the length of the condition (20). Traditional treatment options, which consider the type and severity of acne lesions, general health, and possible side effects, include topical and systemic application of antibiotics and retinoids, oral anti-androgens, phototherapy, and chemical peeling, depending on the individual circumstances of the patient. Topical medications such as topical antibiotics, benzoyl peroxide, and retinoic acid are usually used as the first line of treatment for patients with mild acne. Additionally, a combination of topical therapies, systemic medications, and phototherapy is usually recommended for moderate to severe acne in order to achieve better results. (21) Recent years have seen tremendous advancements in the creation of innovative acne therapies that target many pathologic mechanisms. These new therapies have generated a lot of interest and show promise. This article aims to provide an overview of the most current developments in acne therapy research, with a focus on novel approaches and patient-benefiting therapeutic outcomes. Four important elements contribute to the

pathophysiology of acne: inflammation, excessive growth of *Propionibacterium acnes* (*P. acnes*), hyperkeratinization of pilosebaceous follicles, and excessive sebum production. Acne vulgaris must be diagnosed and treated by recognizing acne lesions that are non-inflammatory (black heads, white heads) and inflammatory (papule, pustule, nodule, and cyst) (22).

1.2 Herbal Anti-Acne Patches

Natural, plant-based remedies called herbal anti-acne patches are intended to lessen acne outbreaks while being kind to the skin. These patches work by absorbing additional oil, reducing inflammation, and promoting speedier healing utilizing herbal extracts instead of synthetic chemicals. (23) Those who favor natural skincare products or have delicate skin would love them. Numerous conventional treatments for acne exist, including topical and systemic antibiotics, retinoids, hormonal, anti-androgen, or antiseborrheic drugs, and others, because they carry little to no risk. These days, everyone is becoming more interested in herbal goods because of their high quality, effectiveness, and safety. Herbal remedies with anti-acne properties include Aloe vera (*Aloe barbadensis*), Indian madder (*Rubia cordifolia*), tea plant (*Camellia sinensis*), pot marigold (*Calendula officinalis*), basil/sweet basil (*Ocimum basilicum*), American walnut (*Juglans nigra*), witch hazel (*Hamamelis virginiana*), and amla/Indian gooseberry (*Emblica officinalis*) (24). *Azadirachta indica* (neem) and *Emblica Officinalis* (amla) were selected for study because to their effectiveness and accessibility. The Indian gooseberry, sometimes called amla (*E. Officinalis*), has numerous biological actions, including anti-inflammatory, anti-oxidant, anti-microbial, anti-diabetic, and wound-healing qualities. (25). Neem leaves (*A. indica*) are also

known to have anti-inflammatory, anti-hyperglycemic, antiulcer, antimalarial, antifungal, antibacterial, antiviral, antioxidant, antimutagenic, and anticarcinogenic qualities. Amla contains a variety of bioactive phytochemicals, including tannins, flavonoids, polyphenols, alkaloids, amino acids, ellagitannins, hydrolyzable tannins, and phlorotannins, which have anti-inflammatory and anti-oxidant properties. Azadirachtin, nimbin, and nimbidin are phytochemicals that are present in neem leaves and have potent antibacterial properties.

Benefits of herbal Anti-Acne patches

- 1) Quick healing: Overnight reduction in pimple size and redness
- 2) Prevents scarring: Lowers the possibility of squeezing or picking pimples.
- 3) Protects skin: Prevents bacteria and debris from causing acne
- 4) Easy to Use: Perfect for everyday wear, it's inconspicuous and convenient.
- 5) Gentle on skin: They are appropriate for sensitive skin because they don't contain harsh ingredients.
- 6) Eco-Friendly: They are a sustainable skincare choice and are often made with biodegradable materials.

MATERIALS AND PREPARATION

MATERIALS

Sr.no.	Material used
1	Neem powder
2	Amla powder
3	Polyvinyl alcohol
4	Hydroxypropyl cellulose
5	Propylene glycol
6	Glycerin
7	Ethanol (70%)
8	Polyethylene glycol



Sr. No.	Instrument used
1.	Electronic weighing balance
2.	Seive Shaker
3.	Mortar pestle
4.	Magnetic stirrer
5.	Hot air oven



Fig 1:- Neem leaves



Fig 2:- Amla

2.2 Preparation

Neem leaves

Azardicum indica were collected from the local market of tathawade pune district.

Firstly clean the neem leaves by washing using water, then using a tray dryer, neem leaves were dried. Then all dried leaves of neem are further crushed in blender until become powdered then sieve neem powder using 40 mesh sieve ,weighted ,and then stored in airtight glass container.

Amla

Amla fruit *Phyllanthus emblica* was obtained from the local market Pimpri Pune district. Wash amla fruits with water then grind the amla fruit in blender and dried in tray dryer then completely dried amla powder seive using 60 mesh seive, weighted and then stored in airtight glass container

2.3 Extract preparation

For preparation of neem extract:

12 gram of neem powder was added to 24 ml of ethanol at room temperature

This mixture was dried in water bath then ethanolic extract of neem was collected.

For preparation of amla extract :

13 gram of amla powder was added in 26 ml of ethanol at room temperature for 24 hours

This mixture was dried in water bath then ethanolic extract of amla was collected.



Fig 3:- Ethanolic Extract Of Amla And Neem

2.4 Preparation

For the preparation of herbal patch containing neem and amla

Firstly, the backing membrane was prepared by adding 2-gram polyvinyl alcohol in 100ml of water and then heat and stir the solution until it become completely soluble.

Drying at 60°C for 6 hours

HPC and glycerin were mixed in mortar and mixed properly with help of pestle until homogeneous. Then neem and amla extract were added in mixture with 70% ethanol polyethylene glycol as humactant and propylene glycol as plasticizer were added.

Mixed until it become uniform then added remaining ethanol with continuous stirring

Pour this mixture in petriplate containing polyvinyl alcohol as backing membrane and dried at room temperature.

Ingredients	F0 (50 ml)	F1 (50ml)	F2 (50 ml)	Function
Neem powder	-	0.25g	0.5g	API
Amla powder	-	0.25g	0.5g	API
Polyvinyl alcohol	2.5g	2.5g	2.5g	Polymer
Hydroxypropyl cellulose	2.5g	2.5g	2.5g	Polymer
Polyethylene glycol	0.60g	0.60g	0.60g	Humactant
Propylene glycol	2.5g/ml	2.5g/ml	2.5g/ml	Plasticizer
Glycerin	2.5g	2.5g	2.5g	Humactant
Ethanol(70%)	50ml	50ml	50ml	Solvent



Fig 4:- Anti- Acne Patches

Evaluation

Physical Assessment of the extract

The ethanol extract of neem leaves (*A. indica*) and amla fruit (*E. officianalis*) was evaluated physically (color, odor, and consistency).(26)[Table 1].

Table 1: Physical Evaluation of Extract

Parameter	Observation
Color	Light brown/creamy (Amla fruit) Dark green (neem leaves)
Appearance	Powder form

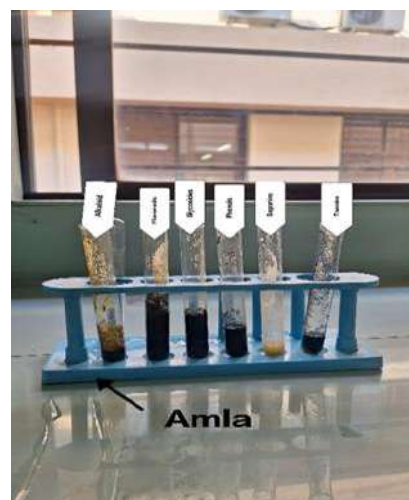


Fig 6:- Phytochemical Tests Of Amla Extract

1.3 Preliminary phytochemical tests

An ethanolic extract of Amla fruit (*E. officianalis*) and neem leaves (*A. indica*) was subjected to phytochemical screening for the existence of tannins, phenolic compounds, proteins, alkaloids, flavonoids, saponins, and glycosides(27) [Table 2].



Fig 7: - Phytochemical tests of Neem extract

Table 2: Evaluation of phytochemical constituents in ethanolic extract of amla and neem.

Tests	Amla ethanolic extract (<i>E. officianalis</i>)	Neem ethanolic extract (<i>A. indica</i>)

Alkaloids (Wagner test)	++	++
Flavanoids	-----	-----
Glycosides (Lieberman Birchurd test)	++	++
Phenol	++	++
Saponins (Froth test)	++	++
Tannins (Ferric Chloride test)	++	++

3.3 Evaluation of patch

3.3.1 Folding resistance

In the folding resistance test, the patch is folded repeatedly in the same way until it breaks. The number of folds is then calculated to determine a patch's resistance to folding.(28)

Thickness of patch

Patch thickness is used to verify the thickness of each of the four patch compositions by measuring

their thickness separately. Each formulation is measured at three different places.

Moisture absorption

After the patch was weighed, it was kept at room temperature for twenty-four hours. After being kept at 40°C for 24 hours, it was weighed again. To calculate the percentage absorption of moisture, the formula % Humidity = $\frac{\text{initial weight} - \text{final weight}}{\text{initial weight}} \times 100\%$ was used.(29)[Table 3].

Table 3: Evaluation of moisture absorption in anti-acne patch.

Formulation	Initial weight	Final weight	Moisture absorption (% Humidity)
F (0)	0.1025	0.0992	3.21
F (1)	0.1027	0.0995	3.11
F (2)	0.1029	0.0999	2.91

3.3.2 pH measurement

A pH meter was used to measure the prepared patches' pH. The electrode was placed in contact with the patch after it had been dipped in diluted water to determine the pH.

3.3.3 Test for percentage elongation break

The length before the breaking point was measured to obtain the percentage elongation break, and the formula was computed as follows: $\text{percentage elongation} = \frac{\text{final strip length} - \text{initial strip length}}{\text{initial strip length}} \times 100$.(30)[Table 4].

Table 4: Evaluation of % elongation break in anti-acne patch.

Formulation	Folding Resistance	Thickness (mm)	% elongation	pH
F(0)	6	0.01	20.27	5.0
F(1)	4	0.01	23.33	6.4

3.3.2 Swelling study

The weighed (W1) patches were separately kept at $37 \pm 0.5^\circ\text{C}$ in agar gel (2%) plates.. The patches



were taken out of the Petri dish every 15 min to an hour, and the excess water on the surface was removed by wiping it with filter paper. The swollen patches were again weighed (W2), and the swelling index formula was calculated by (30)

$$= W2 - \frac{W1}{W1} \times 100$$

3.3.7 Anti-microbial test

Firstly, prepare 5ml of sterile nutrient broth, and subsequently a sterile piece of cotton smeared with sterile water is used to swab skin surface and obtain skin sample with acne or pimple. Now insert the sterile cotton into the nutrient broth and sterilize it through autoclaving for 15-16 minutes and then place the culture under observation for 24 hr. Then prepare a medium of 20ml nutrient agar and autoclave it for 15-20 minutes. Once the medium becomes solidified, add 0.1-0.2 ml culture to it. Then with assistance of borer create bore for test, standard and control samples and maintain it for 24 hr. Observe zone of inhibition(mm) after 24 hr for samples.

Sample	Zone of Inhibition (mm)
Control Sample	9
Standard Sample	13.5
Test Sample 1	8.5
Test Sample 2	10



Fig 8: - Before Test

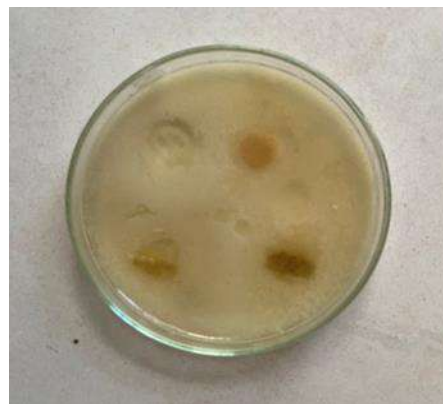


Fig 9:- After Test

4 RESULTS

4.3 Preliminary phytochemical screening

The phytochemicals present in Amla extract are alkaloids, glycosides, phenol, saponins, and tannins, while phytochemicals present in neem extract are alkaloids, tannins, phenol, saponins, glycosides.

4.4 Anti-acne patch preparation evaluation

The evaluation process includes determining whether the patch preparations meet predefined quality criteria by calculating the percentage moisture content, performing a pH test, analyzing thickness, performing moisture absorption, evaluating folding resistance, and performing a swelling test. The evaluations show that the patch preparations meet the set quality standards. Studies on swelling provide crucial information about patch effectiveness and application suitability. According to these results, the patches have the optimal swelling ratio, which guarantees high skin adherence and efficient drug release. The swelling characteristics of the patches are consistent with their intended use.

CONCLUSION

The creation and testing of herbal anti-acne patches with ethanolic extracts of neem (*Azadirachta indica*) and amla (*emblica officinalis*) showed encouraging anti-inflammatory and antioxidant qualities for the treatment of acne. The study found that the bioactive components, polyphenol, saponins, and tanins, helped these extracts' antibacterial and healing effects on acne lesions. The patches exhibit good adherence, extended release, and a noticeable decrease in redness and irritation, making them a potential natural alternative to conventional acne treatments. More clinical testing is necessary to guarantee their efficacy and safety for widespread use.

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