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FORMULATION AND EVALUATION OF TRANSDERMAL PATCH OF AQUEOUS EXTRACT OF SYZYGIUM AROMATICUM (CLOVE)

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INTRODUCTION

1.1 Transdermal Patch: A transdermal patch is a medicated adhesive patch that is placed on the skin to deliver a specific dose of medication through the skin and into the blood stream.

Today about 70% of drugs are taken orally and are found not to be as effective as desired. To improve such character's transdermal drug delivery system was emerged. Transdermal drug delivery system (TDDS) provides a means to sustain drug release as well as reduce the intensity of action and thus reduce the side effects associated with its oral therapy and differs from traditional topical drug delivery. Transdermal drug delivery system (TDDS) provides a means to sustain drug release as well as reduce the intensity of action and thus reduce the side effects associated with its oral therapy. Transdermal drugs are self-contained, discrete dosage form.[1]

Transdermal drug delivery system, the delivery of drugs through the skin has been always a challenging area for researchers, due to barrier properties exhibit by the outermost layer of skin stratum corneum. Specially in last twenty years, the transdermal drug delivery system has become a more focusing technology that offers significant clinical benefits over other dosage forms, because transdermal drug delivery offers controlled as well as state blood concentration.[2]

1.1.1 Pathway of transdermal permeation

Drug molecules permeate through skin surface by the different potential pathways including through the sweat ducts, through the hair follicles and sebaceous glands or directly across the stratum corneum. Since the last few years there is a point of debate among scientists for the relative importance of the shunt or appendageal route of transport across the stratum corneum and is further complicated by the lack of a suitable experimental model to permit separation of these pathways.[3]

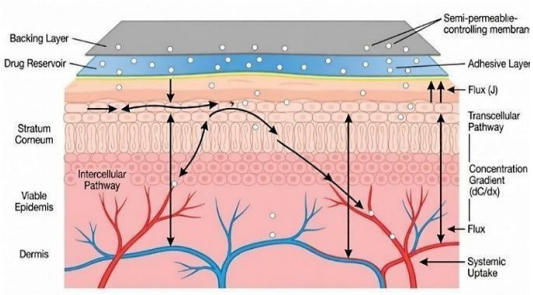

Figure 1: Pathway of transdermal patch.

Diffusion of pharmaceuticals via the intact epidermis and through skin appendages, such as hair follicles and sweat glands, which establish shunt channels through the intact epidermis, are examples of drug penetration through the skin. However, these skin appendages make up only 0.1 percent of the total human skin surface area, therefore their contribution is frequently overlooked (with only a few exceptions having been noted). The Stratum corneum, as previously indicated, usually limits medication absorption through the skin. The intercellular lipid route between the corneocytes and the transcellular route crossing through the corneocytes and intervening lipids are the two pathways through the intact barrier that can be identified. In both cases, the permeant must diffuse at some point through the intercellular lipid matrix, which is now recognised as the major determinant of percutaneous transport rate.[4]

1.1.2 Advantages

- Hepatic first pass metabolism, salivary metabolism and intestinal metabolism are avoided.
- The ease of usage makes it possible for patients to self-administer these systems.
- In case of an emergency, removing the patch at any point of time during therapy can instantly stop drug input.
- Since the composition of skin structurally and biologically is the same in almost all the humans, there is minimal inter and intra patient variation.
- Drugs showing gastrointestinal irritation and absorption can be suitably administered through the skin.

1.1.3 Disadvantages

- There is possibility of skin irritation due to the one or many of the formulation components.
- Binding of drug to skin may result in dose dumping.
- It can be used only for chronic conditions where drug therapy is desired for a long period of time including hypertension, angina and diabetes.
- Lag time is variable and can vary from several hours to days for different drug candidates.
- Cutaneous metabolism will affect therapeutic performance of the system.[3]

1.1.4 Limitations of TDDS

- A lot of medications, especially those with hydrophilic components that penetrate the skin too slowly, might not work as intended.
- Local erythema, itching, and oedema can be brought on by the medication, the adhesive, or any excipients in the patch formulation.
- Ionic medicines cannot be delivered using TDDS.
- TDDS is unable to achieve high drug concentrations in plasma or blood.
- Drugs with large molecular sizes cannot be created using TDDS.[5]

1.2 Clove

The clove is usually known as "lavang."Due to the increase in nutrition and medicinal properties, Plants' importance in human life has increased every day. Clove is the topical evergreen Myrtaceae family tree native to the islands of Maluka in east Indonesia. It is commonly used for tooth care. Clove is used extensively in dental care for relieving toothache, sore gums and oral ulcers. Gargling with clove oil can also aid in sore throat conditions and bad breath. This is commonly used as an expectorant for the treatment of dental discomfort, the digestive problem, oral ulceration, mosquito repellent. Clove is a pharmacologically active medicinal plant that includes Anti-oxidant, antipyretic, anti-viral, anti-microbial, anti-diabetic, anti-inflammatory, analgesic, anti-platelet, anti-stress, anti-disease, and anti-carcinogenic in cervical cancer.[6]

3.2 MATERIAL AND METHOD

3.2.1 Pre-formulation study: Pre-formulation study of a transdermal patch of Clove extract involves the investigation of physicochemical and biopharmaceutical properties of the drug before formulation development. These studies help in selecting suitable polymers, plasticizers, and permeation enhancers for effective patch preparation. Parameters such as solubility, melting point, partition coefficient, pH, and moisture content are evaluated to determine drug suitability for transdermal delivery. Drug–excipient compatibility studies using FTIR and DSC are also performed to ensure stability and absence of interactions. Preliminary phytochemical screening identifies active constituents such as eugenol, flavonoids, and tannins responsible for therapeutic activity. Pre-formulation studies are essential for improving drug stability, skin permeation, and controlled drug release from the patch system.[7]

3.2.2 METHODS

3.2.2.1 Organoleptic evaluation

Organoleptic evaluation of clove oil was performed by visual observation viz. parameters like colour, odour and taste.



Figure 3.1: Organoleptic Evaluation of Clove oil.

Table 3.1: Organoleptic Evaluation of Clove oil.

S. No.	Parameters	Method of Evaluation	Obseravtion	Result
1	Colour	Few drops of clove oil were placed on white paper and observed in natural light	Pale yellow to yello wish brown	Complies
2	Odour	A drop of clove oil was smell directly	Strong, Aromatic, characteristics of Clove	Complies
3	Taste	A small amount of clove oil was tasted (using a clean glass rod)	Pungent, spicy, Characteristic taste	Complies

3.2.2.2 Solubility study

Solubility of clove oil was performed by solvent addition method. 250mg of clove oil was taken in a beaker to which solvents were added per ml of clove oil and the solubility was determined accordingly. The solvents used for studying the solubility of clove oil are Purified water, propylene glycol, methanol, polyethylene glycol 400 (PEG 400), Isopropyl alcohol, ethanol and Dimethyl sulphide (DMSO).

3.2.2.3 Density of oil

Density of oil was determined using the specific gravity apparatus (Borosil) India. The weight of empty specific gravity bottle was noted and was filled to fixed volume of clove oil and reweighed to obtain the actual weight of clove oil, and then density was calculated as weight per ml. The results were noted in triplicate.

$$\text{Density of oil} = \frac{Wt.\ of\ sample}{vol.\ of\ sample}$$

3.2.2.4 Viscosity

Viscosity of clove oil was measured using a Brookfield cone and plate rheometer (R/S rheometer, Brookfield, USA) where the drop of oil to be tested was placed on the plate and the cone is placed on the drop of oil and rotated to 100rpm of torque and the viscosity of the sample was measured in m.pas/sec.

3.2.2.5 Boiling point

The boiling point of the sample was measured using the boiling point assembly. The flash tube was attached to a thermometer and the sample was loaded in the silicon oil and the temperature at which the oil starts to vaporise was noticed till the sample is completely evaporated. The results were noted in triplicate.[8]

3.2.2.6 Solubility studies

The solubility of paracetamol in phosphate buffer (pH 5.5) was determined by equilibrium solubility method by adding excess amounts of paracetamol in the medium and keeping flask on a water bath shaker (REMI Equipment, Mumbai, India) for 24 h at 25°C. After 24 h, dispersions were filtered, suitably diluted and analysed spectrophotometrically in UV-V is spectrophotometer (UV 1900I – SHIMADZU) at 257 nm and concentration of drug dissolved was obtained from the standard curve of the drug in the medium.

3.2.3 Physico-mechanical characterization of transdermal patches

3.2.3.1 Percentage moisture loss

The films were weighed accurately and kept in a desiccator containing anhydrous calcium chloride as desiccant. Films were reweighed after exposing the films for 24 hrs. The percentage moisture loss was calculated using Equation 1.

$$\text{Percentage moisture loss} = \frac{Initial\ weight - Final\ weight}{\text{initial weight}} \times 100$$

3.2.3.2 Percentage moisture absorption

The films were weighed accurately and placed in a vacuum desiccator containing saturated solution of potassium chloride. After 24 hours, the films were taken out and weighed. The percentage moisture absorption was calculated using Equation 2.

$$\text{Percentage moisture absorption} = \frac{Final\ weight - Initial\ weight}{Intial\ weight} \times 100$$

3.2.3.3 Weight variation test

Weight variation test was carried out by weighing three different films of the individual batch and the average weight was calculated.[9]

3.2.3.4 Thickness of film

To verify the thickness of the produced patch, the thickness of the drug-loaded patch was measured at multiple locations using a digital micrometre. The average thickness and standard deviation was then computed.

3.2.3.5 Folding endurance

A precisely measured strip of material was cut, then folded back and forth at the same spot until it broke. The value of folding endurance was determined by counting how many times the film could be folded in the same direction without breaking.[10]

3.2.4 Preliminary Phytochemical analysis

These extracts were tested in order to find out the presence of active compounds by use of following standard methods.

3.2.4.1 Test for Carbohydrates

Molisch's test

- 1 ml of plant extract was added to 0.4 ml of Molisch's reagent. Afterwards, 1 ml of conc. Sulphuric acid was added along the side of the test tube. A purple colour indicates the presence of carbohydrates (starch).

Benedict's test

- 1 millilitre of plant extract and 1 millilitre of Benedict's reagent were heated for 5 minutes. The presence of carbohydrates (disaccharides) was shown by the formation of an orange precipitate.

Fehling's Test

- Boiling and filtering 1 ml of plant extract with 2 ml of purified water. Then, 2 ml of Fehling's reagent were added to 2 ml of filtrate, which was then heated. Reddish brown precipitate indicates the presence of carbohydrate (glucose).[11]

3.2.4.2 Flavonoids Test

2 ml of the plant extract was mixed with 5 drops of dilute NaOH, and then diluted HCl was added.

3.2.4.3 Tannins Test

0.5 g of the plant extract was simmered in 20 ml of water in a beaker and subsequently filtered it. A few drops of ferric chloride at a concentration of 0.1% were subsequently added.

3.2.4.4 Terpenoids

In a test tube, about 0.5 ml of extract was mixed with 3 mL of chloroform. Then, 2 mL of concentrated H_2SO_4 was gently added along the tube's sides to form a separate layer. The emergence of a reddish-brown interface signified the presence of terpenoids.

3.2.4.5 Salkowski test

A mixture was created by dissolving 0.5 g of plant extract in 2 mL of chloroform. Then, 3 mL of concentrated sulfuric acid (H_2SO_4) was gently added along the side of the test tube. The formation of a reddish-brown layer at the interface signified the presence of sterols and terpenoids, as indicated by the Salkowski test.[12]

3.2.4.6 Cardiac glycoside test (keller-killiani test)

Approximately 5 ml of each plant extract was evaporated at 40 °C, and the remaining residue was collected. A few milligrams of residue were suspended in 5 ml of water. 2 ml of glacial acetic acid containing 1 drop of ferric chloride solution were added, followed by an underlayer of 1 ml of concentrated sulfuric acid. The formation of a brown ring at the interface indicated the presence of deoxy sugars, characteristic of cardiac glycosides.

3.2.4.7 Protein tests Xanthoproteic Test

- To 1 ml of plant extract, 0.25 ml of nitric acid was added. The appearance of a yellow precipitate signified the presence of proteins.

Biuret Test

- A mixture of 1 ml of plant extract, 4% NaOH, and 1% CuSO4 was prepared. The formation of a violet-pink color confirmed the presence of proteins.[13]

3.2.5 Taxonomy Classification

Kingdom-Plantae
Sub Kingdom-Tracheobionta Super Division-Spermatophyta Division-Magnoliphyta
Class-Magnoliopsida
Subclass-Rosidae Order-Myrtales Family-Myrtaceae
Genus-Syzygium
Species-aromaticum [14]

3.2.6 Pharmacological activities of Syzygium aromaticum

- Antiviral
- Antimicrobial
- Antifungal
- Anticancer
- Antioxidant
- anti-inflammatory [15]

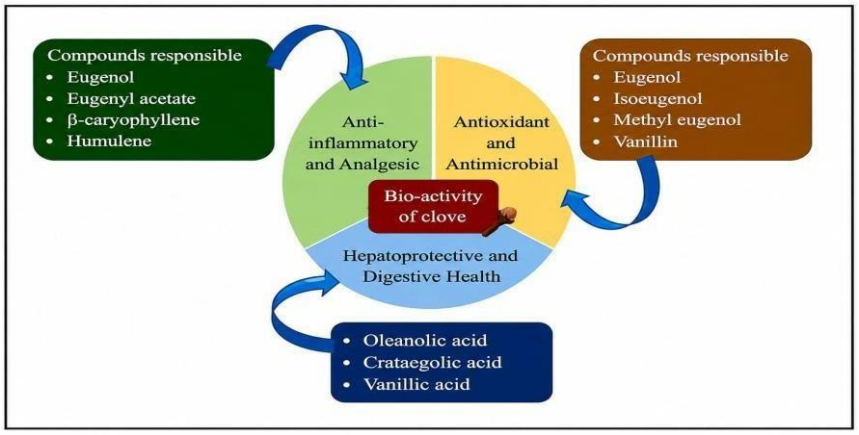

Figure 3.2: Bio-activity of the compounds present in Syzygium.

3.2.7 Excipient Profile

3.2.7.1 Glycerine

Glycerol or commercially known as glycerine is a colourless, odourless and viscous liquid. used as demulcent and anti-inflammatory agent. In pharmaceutical formulation, high purity glycerol is added as lubricant and humectant.

3.2.7.2 Properties: colourless, odourless and viscous liquid, hygroscopic character and soluble in water.

3.2.7.3 Uses: Antimicrobial preservative, emollient, humectant, plasticizer, solvent.

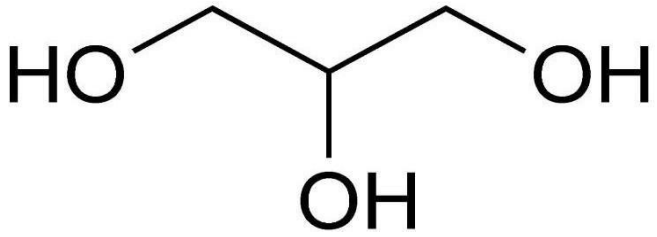

Figure 3.3: glycerine.

Glycerol is generally produced as a major by-product from the chemical reaction between vegetable oil or animal fat with the addition of short chain alcohol (normally methanol or ethanol) in the presence of catalyst (normally sodium hydroxide). This process is called the transesterification process and is the principal process for biodiesel production.

3.2.7.4 Molecular Weight of Glycerine - 92.09 g/mol.

3.2.7.5 Pharmaceutical Uses of Glycerine

- Used as a humectant to retain moisture in formulations.
- Acts as a lubricant and provides smooth texture in medicines.
- Acts as a plasticizer in soft gelatine/medicine capsules.
- Used as a carrier/solvent for antibiotics and antiseptics
- Helps control water activity and improves shelf life of pharmaceutical products.[16]

3.2.8 HPMC

Hydroxypropyl methylcellulose (HPMC) is a semi-synthetic, inert, viscoelastic polymer derived from cellulose that is widely used in pharmaceutical formulations as a binder, film-forming agent, thickener, controlled-release polymer, and stabilizer. In transdermal patches, HPMC is commonly used as a matrix-forming polymer because of its excellent film-forming ability, biocompatibility, non-toxicity, and capability to control drug release.[17]

3.2.8.1 Properties

- HPMC is a semi-synthetic polymer derived from cellulose.
- It is odourless, tasteless, and non-toxic in nature.
- HPMC is soluble in cold water and forms a clear colloidal solution.
- It possesses excellent film-forming properties.
- It acts as a good thickening and suspending agent.
- HPMC shows high swelling ability in aqueous media.[18]

3.2.8.2 Uses

Binder, film-coating material, biological adhesive, gelling agent, as well as an encapsulation, suspending, and thickening agent.

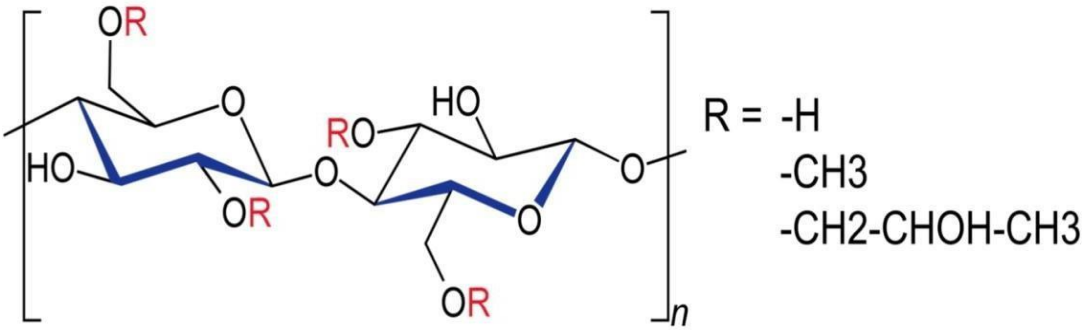

Figure 3.4: Hydroxypropyl methylcellulose.

3.2.8.3 Source

Hydroxypropyl methylcellulose is derived from natural cellulose through etherification, where hydroxyl groups in the cellulose structure are replaced with hydroxypropyl and methyl groups. This alteration can improve cellulose solubility, viscosity, film-forming properties, and soothing effects.

3.2.8.4 Molecular weight: 1261.4g/mol

3.2.8.5 Pharmaceutical Uses

Film-Coating Material

- Forms transparent, flexible, and stable films.
- Protects tablets from moisture, light, oxygen, and abrasion.
- Masks unpleasant taste/Odor.
- Improves tablet appearance and swallowing.
- Used at 2–20% w/w concentration.

Mucoadhesive / Bio adhesive Agent

- Used in controlled-release and mucosal drug delivery systems.
- Swells in water and adheres to mucous membranes.
- Helps prolonged drug release.
- Useful in oral, buccal, GI, and transdermal systems.

Gelling Agent

- Produces clear, stable, non-toxic gels.
- Stable at pH 3–11.
- Used in topical gels, cosmetics, and medicines.
- Common concentration: 1–4%.[19]

3.2.9 Ethanol

Ethanol, also known as ethyl alcohol, a straight-chain alcohol, is a volatile and colourless liquid. It has a number of different uses, including its use as a solvent or as a preservative in the production of pharmaceutical products, especially, even if not exclusively, in orally administered drugs. Ethanol may not be considered an inactive substance; on the contrary, its presence in drugs is associated with some safety issues, especially when ethanol-containing medicines are intended for prescription in particular populations, for example for infants and children.[20]

3.2.9.1 Property

Ethanol has bacteriostatic, bactericidal, fungicidal and virucidal activity. In addition, ethanol also has anhidrotic, rubefacient, and astringent and haemostatic properties.

3.2.9.2 Uses

it is used as a solvent to keep active ingredients in solution and also functions as a preservative, Antalgic effects, Antiseptic, Alcohol withdrawal, as an antidote.

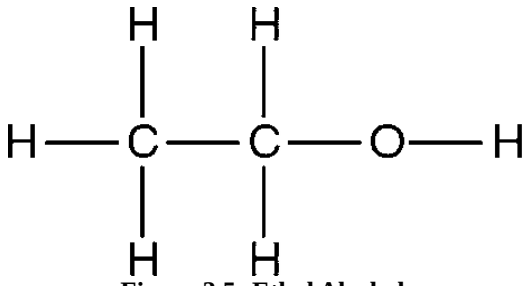

Figure 3.5: Ethyl Alcohol.

3.2.9.3 Source

Fermentation source

- sugars/molasses from sugarcane, corn, grains followed by distillation and purification.

Synthetic source

- hydration of ethylene, then purification to pharmacopeial grade.
- Yeast converts the sugars (e.g., glucose, galactose, and fructose) to ethanol, carbon dioxide, and other by-products in metabolic processes that can occur under both aerobic and anaerobic conditions.

3.2.9.4 Molecular weight: 46.07g/mol.[21]

3.2.9.5 Therapeutic Uses of Ethanol

Antiseptic / Disinfectant

- Used externally as skin antiseptic and surface disinfectant.
- Effective against bacteria, viruses, and fungi.
- Best antimicrobial action at 60–90% concentration.

Alcohol Withdrawal Syndrome

- Used internally in some cases to manage alcohol withdrawal.
- Benzodiazepines are still preferred first-line treatment.

Antidote
- Used in methanol and ethylene glycol poisoning.
- Prevents formation of toxic metabolites.

Neurolysis
- Used for pain relief in cancer pain, chronic pain, shingles, and spasticity.
- Injected locally to destroy nerve tissue.

Embolization
- Used to block abnormal blood vessels or tumours.
- Applied in AV malformations and some cancers.

Sclerosing Agent
- Used for treatment of hepatic, renal, thyroid cysts.
- Causes shrinkage and fibrosis of cyst wall.

Cardiology
- Used in alcohol ablation for certain cardiac arrhythmias when other methods fail.[22]

Table 3.2: Preliminary Phytochemical Screening of Plant Extract.

Phytochemical	Test	Observation	Inference
Alkaloids	Dragendroff ‘s Test	Orange /red	Alkaloids Present
Alkaloids	Mayer ‘s Test	Cream precipitate	Alkaloids present
Flavonoids	Shinoda Test	Pink/ red color	Flavonoids present
Tannnis	Ferric chloride Test	Blue-black/green color	Tannins Present
Saponins	Foam Test	Stable foam formation	Saponins Present
Glycosides	Keller-Killani Test	Brown ring at interface	Cardiac glycosides present
Phenols	Ferric Chloride Test	Deep blue/black color	Phenolic compounds present
Terpenoids	Salkowski Test	Reddish-brown color	Terpenoids Present
Steroids	Liebermann-Burchard Test	Green/blue color	Steroids Present
Carbohydrates	Molisch’s Test	Violet ring	Carbohydrate Present
Proteins	Biuret Test	Violet color	Proteins Present

3.3 MATERIALS

Table 3.3: Materials.

Ingredient	Quantity (g)	Pharmacological/ Functional Property
HPMC (Hydroxypropyl Methylcellulose)	5g	Film-forming polymer, controls drug
Glycerine	10g	Plasticizer, provides flexibility to patch
Ethanol	10g	Solvent & Permeation enhancer
Clove Extract	5g	Active ingredient (analgesic, anti-inflammatory due to eugenol)
Distilled water	20g	Vehicle/solvent for polymer swelling

3.4 Method of Formulation (Solvent Casting method)

Step 1: Preparation of polymer solution
- Take required amount of HPMC (5g)
- Add it slowly into distilled water (20g)
- Stir continuously to avoid lump formation
- Allow it to swell for 30-60 minutes until a clear viscous solution form

Step 2: Addition of plasticizer
- Add glycerine (10g) into the swollen HPMC solution
- Mix thoroughly using magnetic stirrer or manual stirring
- This improves flexibility of the patch

Step 3: Preparation of drug Solution
- Take clove extract (5g)
- Dissolve it in Ethanol (10g)
- Stir properly to get a uniform solution

Step 4: Mixing
- Slowly add the drug solution (Ethanol + Clove Extract) into the polymer mixture
- Stir continuously to ensure uniform distribution
- Avoid air bubble formation

Step 5: Degassing
- Keep the solution undisturbed for some time or sonicate lightly
- This removes entrapped air bubbles air bubbles

Step 6: Casting
- Pour the prepared solution into a clean, levelled petri dish or glass mold
- Spread evenly to maintain uniform thickness

Step 7: Drying
- Dry the cast film at 40-50 degree C in a hot air oven or at room temperature (24 hours)
- Ensure complete evaporation of solvent

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Step 8: Cutting and storage

- Carefully peel of the dried patch
- Cut into required size (e.g., 2×2 cm)
- Store in Desiccator or air light container



Figure 3.6: Transdermal Patch.

RESULT AND DISCUSSION

4.1 Result

The formulated transdermal patches containing clove extract were successfully prepared using the solvent casting method. All prepared formulations showed satisfactory film-forming properties. The patches obtained were smooth, transparent to slightly brownish in appearance, flexible, and easy to handle.

The use of HPMC as a polymer provided good film-forming characteristics. Patches prepared with appropriate concentrations of HPMC exhibited uniform thickness and acceptable mechanical strength. The addition of glycerine significantly improved flexibility and reduced brittleness of the films.

The thickness of the prepared patches was found to be uniform, indicating proper distribution of formulation solution during casting. Weight variation among different patches was minimal, which confirmed uniformity of the prepared films.

Folding endurance values were found to be satisfactory, demonstrating that the patches possessed adequate flexibility and mechanical resistance. The prepared patches could withstand repeated folding without breaking, which is an important parameter for patient handling and application.

Surface pH values of all formulations were found near neutral, indicating compatibility with skin and reduced possibility of skin irritation.

Moisture content studies showed moderate moisture uptake, which helped maintain flexibility without making the patches excessively sticky.

Drug content uniformity studies revealed uniform distribution of clove extract throughout the patch matrix. This confirmed proper mixing of ingredients during formulation.

In-vitro drug release studies demonstrated gradual and sustained release of clove extract over an extended period. The release pattern indicated that the polymeric matrix effectively controlled diffusion of the active constituents.

The optimized formulation showed the best balance between flexibility, stability, and drug release characteristics.

4.2 DISCUSSION

The present study demonstrated the successful formulation of a herbal transdermal patch using clove extract and HPMC polymer. The solvent casting method proved to be simple, economical, and effective for preparation of uniform transdermal films.

Clove extract was selected due to its well-known analgesic and anti-inflammatory activities mainly attributed to eugenol. The incorporation of clove extract into a transdermal system provided a novel approach for prolonged pain management.

HPMC was chosen as the polymer because of its excellent film-forming ability, biocompatibility, non-toxicity, and controlled release properties. The polymer formed smooth and uniform films that were suitable for transdermal application.

The concentration of HPMC played a major role in determining film thickness and drug release rate. Higher polymer concentration increased film thickness and slowed drug release due to formation of a denser matrix. Lower polymer concentration produced thinner films but reduced mechanical strength.

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Glycerine acted as an effective plasticizer by improving elasticity and flexibility of the patch. Formulations without sufficient glycerine were brittle and difficult to peel from petri plates. Adequate glycerine concentration improved patient handling characteristics.

Ethanol performed dual functions in the formulation. It acted as a solvent for clove extract and also enhanced permeation of active constituents through the skin barrier. Ethanol increased drug diffusion and contributed to improved release characteristics.

The prepared patches exhibited acceptable physicochemical properties including uniform thickness, satisfactory folding endurance, and proper surface pH. These parameters indicate suitability of the patches for topical application.

The sustained drug release pattern observed during in-vitro studies suggests that the transdermal patch can provide prolonged therapeutic action. Sustained release is beneficial in pain management because it reduces the need for frequent administration and maintains consistent drug levels.

The herbal nature of clove extract provides an additional advantage due to reduced chances of severe side effects commonly associated with synthetic analgesics. Moreover, transdermal delivery minimizes gastrointestinal irritation and first-pass metabolism.

The study also indicated that environmental conditions during drying significantly affect patch quality. Controlled drying conditions are essential to obtain smooth and defect-free films.

Overall, the optimized transdermal patch formulation demonstrated promising characteristics for pain management. The formulation showed satisfactory physical properties, controlled drug release, and good flexibility. The results suggest that clove extract-loaded transdermal patches may serve as an effective herbal alternative for pain relief.

CONCLUSION & FUTURE ASPECTS

CONCLUSION

The present study successfully demonstrated the formulation and evaluation of a herbal transdermal patch containing clove extract for pain management using the solvent casting method. The transdermal drug delivery system was developed using HPMC as the film-forming polymer, glycerine as the plasticizer, ethanol as the solvent and penetration enhancer, and distilled water as the solvent medium. The prepared formulation showed satisfactory physicochemical and mechanical properties suitable for transdermal application. The use of clove extract in the formulation proved beneficial because of its well-known analgesic and anti-inflammatory properties mainly attributed to the presence of eugenol. Incorporation of the herbal extract into a transdermal system provided a prolonged and controlled release of the active constituents, which may help in effective pain management. The prepared patches were found to be smooth, flexible, uniform in thickness, and easy to handle. The addition of glycerine improved flexibility and prevented brittleness of the films, while HPMC formed a stable polymeric matrix capable of sustaining drug release. Evaluation studies confirmed that the formulated patches possessed acceptable weight uniformity, folding endurance, surface pH, moisture content, and drug content uniformity. The surface pH of the patches was found near neutral, indicating reduced chances of skin irritation during application. Folding endurance studies showed that the patches had good mechanical strength and could withstand repeated folding without breaking. Drug content uniformity studies indicated proper distribution of clove extract throughout the patch matrix. The in-vitro drug release study demonstrated a sustained and controlled release pattern of clove extract over an extended period. Such sustained release characteristics are highly advantageous in pain management because they maintain therapeutic drug concentration for a longer duration and reduce the need for frequent administration. The transdermal route also offers several advantages such as avoidance of first-pass metabolism, improved patient compliance, reduction in gastrointestinal side effects, and ease of administration. The study further highlighted that the concentration of polymer and plasticizer plays an important role in determining the quality and performance of the transdermal patch. Proper optimization of formulation ingredients is necessary to achieve desirable flexibility, stability, and drug release characteristics. Overall, the developed clove extracts transdermal patch showed promising potential as a safe, effective, and patient-friendly herbal drug delivery system for pain management. The formulation may serve as an alternative to conventional oral analgesic therapy with reduced side effects and improved therapeutic effectiveness. Further studies such as stability studies, skin permeation studies, irritation testing, and clinical evaluation can be carried out to confirm the long-term safety and efficacy of the formulation for commercial pharmaceutical applications.

FUTURE ASPECTS

The formulation and evaluation of transdermal patches containing aqueous extract of Syzygium aromaticum (Clove) possess significant future potential in the field of novel drug delivery systems. Herbal transdermal patches are gaining increasing importance because they provide controlled drug release, improved patient compliance, reduced dosing frequency, and avoidance of first-pass metabolism. Clove extract, which contains active constituents such as eugenol, has well-known analgesic, anti-inflammatory, antimicrobial, and antioxidant properties that make it a promising candidate for transdermal therapeutic applications.

In the future, clove-based transdermal patches may be

developed as an alternative to conventional oral pain management therapies. Since oral administration of drugs may cause gastrointestinal irritation, poor bioavailability, and frequent dosing requirements, transdermal delivery offers a safer and more effective route for long-term treatment. The herbal origin of clove extract may also reduce the risk of severe adverse effects commonly associated with synthetic analgesic drugs.

Further research can be carried out to improve the formulation by using advanced polymers, permeation enhancers, and nanotechnology-based carriers. The incorporation of nanoparticles, liposomes, or nano-emulsions may enhance skin penetration and increase the therapeutic efficiency of clove extract. Future studies may also focus on optimizing the stability, drug release profile, bio-adhesion, and mechanical strength of the patch for commercial pharmaceutical applications.

The developed transdermal patch can also be evaluated for various therapeutic activities such as arthritis management, muscular pain relief, localized inflammation, wound healing, and antimicrobial treatment. Clinical trials and in-vivo studies may help establish the safety, efficacy, and pharmacokinetic profile of the formulation in humans. In addition, large-scale production techniques and industrial manufacturing methods can be explored for commercialization.

Future investigations may also include combination therapy by incorporating clove extract with other herbal drugs to achieve synergistic therapeutic effects. Personalized herbal transdermal systems based on patient-specific requirements may become an emerging area of pharmaceutical research. Due to the growing demand for herbal and non-invasive drug delivery systems, clove extract transdermal patches hold considerable promise in modern healthcare and pharmaceutical industries.

Overall, the future scope of this research is broad and valuable, as it may contribute to the development of safe, effective, economical, and patient-friendly herbal transdermal drug delivery systems for pain and inflammation management.

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