IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Formulation And Evaluation Of Transdermal Patches

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Abstract: Conventional drug delivery system has many issues so bulk of studies has now shifted from synthetic drugs to herbal drugs. The proposed observe turned into achieved and completed to assess the wound healing potential of the herbs like azadiracta indica (neem) and aloe Vera while formulated in shape of transdermal patches. The present study includes the drug delivery via transdermal patches for treating, curing, stopping diverse pores and skin allergy, contamination or wound healing. The fundamental purpose of this observe turned into to formulate the natural transdermal patches where in neem plant extract is loaded in aloe vera patches which assist to deal with the pores and skin contamination like rashes, redness, and in wound healing. Herbal method includes the extract of herbs, vegetation and its element like root system and shoot system that are wealthy in diverse phytochemicals which allows to deal with diverse injuries, disorder or contamination. In diverse observe it's been visible and located that the vegetation like neem and aloe have the wound healing activities. Formulations were evaluated for the various organoleptic properties, pH, thickness, moisture content etc.

Keywords: Azadirachta indica, Aloe barbedensis miller, rashes, redness

1. INTRODUCTION

A transdermal drug delivery tool, which can be of an energetic or a passive design, is a device which provides an opportunity for administrating medication. This device allowed for pharmaceuticals to be brought throughout the pores and skin barrier. Simple theory in the back of transdermal permeation is that a drug is carried out in a relatively high dosageat the surrounded through a patch or other system,that is worn on the skin for an extended periodof time. Throughout a diffusion course, the drug inters in the blood circulation directly through theskin and pores. Since there is increased concentration at the patch and small concentration in the blood, the drug will hold diffusion in to the blood for a long episode of time; maintain the unchanging concentration of drug withinside blood flow.[5]

A transdermal patch is defined as medicated adhesive patch that is located above the skin to deliver a specific dose of medication through the skin with a predetermined rate of release to reach into the bloodstream.[5]

1.1. TRANSDERMAL DRUG DELIVERY SYSTEM

The (TDDS) are described as self-contained, discrete dosage forms which, when applied to the intact pores and skin, deliver the drug(s), through the skin, at a controlled rate to the systemic circulation. Transdermal drug delivery is a possible administration route for potent, low-molecular weight therapeutic agents which cannot withstand to opposed environment of gastrointestinal tract and/or subject to considerable first-pass metabolism by liver.[5]

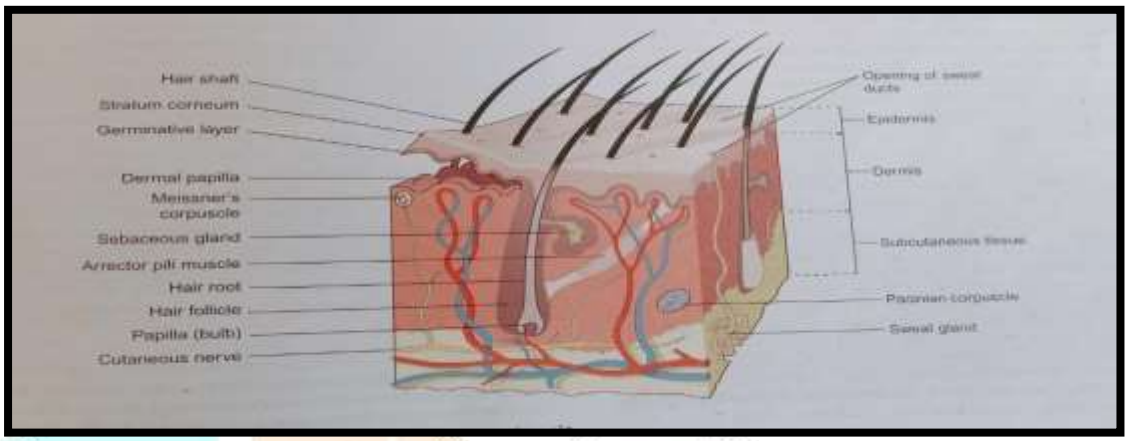

Fig Transdermal drug delivery system[12]

Transdermal drug delivery systems are topically administered medicaments in the form of patches that deliver drugs for systemic effects at a predetermined and managed rate. A transdermal drug delivery device, which can be of an energetic or a passive design, is a device which provides an alternative route for administering medication. These devices allow for pharmaceuticals to be delivered throughout the pores and skin barrier.[5]

In theory, transdermal patches work very simply. A drug is carried out in a relatively high dosage to the inside of a patch, that is worn at the pores and skin for an prolonged period of time. Through a diffusion process, the drug enters the bloodstream at once via the skin. Since, there is high concentration on the patch and low concentration in the blood, the drug will keep diffusing into the blood for a prolonged period of time, maintaining the steadyconcentration of drug in the blood flow.[5]

1.1.1. ADVANTAGES OF TDDS[5]

This approach to drug delivery offers many advantages over traditional methods:

- As alternative choice for the oral route.
- Transdermal drug delivery permits the avoidance of gastrointestinal absorption, with itsrelated pitfalls of enzymatic and pH associated deactivation.
- This method also allows for reduced pharmacological dosing because of the shortened metabolization pathway of the transdermal route versus the gastrointestinal pathway
- The patch also permits steady dosing rather than the peaks and valleys in medication level related with orally administered medications. Multi-day therapy with a single application. Rapid notification of medication in the event of emergency, as well as the potential to terminate drug effects rapidly via patches removal.

1.1.2. DISADVANTAGES OF TDDS [5]

- The drug that requires excessive blood levels cannot be administered and might evencause irritation or sensitization of the pores and skin.
- The adhesives may not adhere properly to all types of pores and skin and can beuncomfortable to wear
- High cost of the product is also a major drawback for the wide acceptance of this product.
- Properties that have an impact on transdermal delivery diffusion of the medicament fromvehicle.
- Penetration via the pores and skin barrier activation of the pharmacological response.

1.2. PATHWAY OF TRANSDERMAL PERMEATION[1]

The permeation of drugs via the pores and skin consists of the diffusion via the intact epidermis and through the pores and skin appendages i.e., hair follicles and sweat glands, which form shuntpathways via the intact epidermis. However these pores and skin appendages occupy most effective 0.1% of the total human pores and skin surface and contribution of this pathway is usually considered to be small (with only some exceptions having been noted). As stated above, drug permeation via the pores and skin is generally restricted by the Stratum Corneum. Two pathways via the intact barrier may be identified the intercellular lipid route between the corneocytes and the transcellular route crossing via the corneocytes and the intervening lipids thatis in both cases the permeant should diffuse at some point through the intercellular lipid matrix, that is now recognized as the major determinate of percutaneous transport rate.

1.3. BASIC COMPONENTS OF TRANSDERMAL DRUG DELIVERY SYSTEMS[1]

1. Polymer matrix or matrices
2. The drug
3. Permeation enhancers
4. Other excipients

1.3.1. POLYMER MATRIX [1]

The polymer controls the diffusion of the drug from the device. Possible beneficial polymers for the diffusion of the drug from the device. Possible useful polymers for transdermal devices are:

a. Natural Polymers: e.g. cellulose derivative, Zein, Gelatin, shellac, waxes, proteins, gums, and their derivatives, Natural rubber, Starch etc.
b. Synthetic Elastomers: e.g., polybutadiene, Hydrin rubber, Polysiloxane, Silicone rubber, nitrile, Acrylonitrile, Butyl rubber, Stryenebutadieine rubber, Neoprene etc.
c. Synthetic Polymers: e.g., polyvinyl alcohol, polyvinyl chloride, polyethylene, polypropylene, polyacrylate, polyamide, polyurea, polyvinyl pyrrolidone, polymethyl methacrylate, Epoxy etc.

1.3.2.DRUG[1]

For successfully developing a transdermal drug delivery system, the drug must be selected with great care. The following are some of the desirable properties of a drug for transdermal delivery.
Physicochemical properties

- The drug must have a molecular weight much less than approximately 1000 Daltons.
- The drug must have affinity for both lipophilic and hydrophilic phases. Extreme partitioning characteristics

are not conducive to successful drug delivery via the pores and skin.

- The drug must have low melting point
- Along with these properties the drug must be potent, having short half life and be non irritating.

1.3.3. PERMEATION ENHANCERS [1]

These are compounds which promote skin permeability by altering the skin as a barrier to the flux of a desired penetrant. These may conveniently be classified under main headings.

1.3.3.1. Solvents

These compounds increase penetration possibly through swallowing the polar pathway and/or by fluidizing lipids. Examples include water alcohols – methanol and ethanol; alkyl methyl sulfoxides – dimethyl sulfoxide, alkyl homologs of methyl sulfoxide dimethyl acetamide and dimethyl formamide; pyrrolid- ones- 2 pyrrolidone, N-methyl, 2-purrolidone; laurocapram (Azone), miscellaneous solvents- propylene glycol, glycerol, silicone fluids,isopropylpalmitate.

1.3.3.2. Surfactants[1]

These compounds are proposed to enhance polar pathway transport, specifically of hydrophilic drugs. The ability of a surfactant to alter penetration is a feature of the polar head group and the hydrocarbon chain length.

- Anionic Surfactant: e.g. Diocytylsulpho-succinate, Sodium lauryl sulphate, Decodecyl-methyl sulphoxide etc. Nonionic Surfactants: e.g. Pluronic F127, Pluronic F68, etc
- Bile salts: e.g. Sodium mstaurocholate, Sodium deoxycholate,Sodium tauroglycocholate
- Binary systems: These systems apparently open up the heterogenous multilaminate pathway as well as the continuous pathways.

1.3.3.3. MISCELLANEOUS CHEMICALS[1]

These include urea, a hydrating and keratolytic agent, N, N-dimethylm- toluamide, calcium thioglycolate, anticholin- ergic agents.Some potential permeation enhancers have recently been defined however the to be had records on their effectiveness sparse. These include eucalyptol, di- o- methyl- ßcyclodextrin and soyabean casein.

. 1.3.3.4. OTHER EXCIPIENTS[1]

A. Adhesives:

The fastening of all transdermal devices to the pores and skin has so far been done through usage of a pressure sensitive adhesive which may be located on the face of the device and in the back of the device and increasing peripherally.

Both adhesive systems must fulfil the subsequent standards

- Should adhere to the pores and skin aggressively, should be easily removed
- Should not leave an un washable residue on the skin
- Should not irritate or sensitize the skin

The face adhesive system should also fulfil the subsequent standards

- Physical and chemical compatibility with the drug, excipients and enhancers of the deviceof which it is a part
- Permeation of drug should not be affected
- The delivery of simple or blended permeation enhancers must not be affected.

A. Backing membrane: [1]

Backing membrane are flexible and that they provide a good bond to the drug reservoir ,prevent drug form leaving the dosage form leaving the dosage form through the top and accept printing.

It is impermeable substance that protects the product during use on the skin e.g. metallicplastic laminate, plastic backing with absorbent pad and occlusive base plate

Desirable characteristic of transdermal patches*:*

- Composition relatively invariant in use
- System size affordable
- Defined site for application
- Application technique highly reproducible
- Delivery is (typically) zero order
- Delivery is efficient

2. MATERIALS AND METHODS

All the required raw materials were procured from local market, Sonai.Procedure for preparation of Transdermal Patches[5]

1. Weigh given quantity of gelatine dissolve in water and heated on water bath.
2. Addition of extract through continuous stirring to form homogenous mixture.
3. Addition of DMSO and glycerine then pour mixture into petri dish.
4. Air dry for 24 hrs at room temperature.
5. Patches peel off from petri dish with knife and keep in desiccators.

Figure.2. Formulation of Transdermal Patche

Table 1: Plants used for preparation of transdermal patches[5, 7, 8, and 9]

Plant	Pharmacognosy of Plant		
	Common name, biological source, and family	***Parts used***	***Uses***
	**Neem** A.indica, Meliaceae	Leaves	Antibacterial, antifungal
	**Aloe** A. barbadensis , Liliaceae	Leaf pulp	Moisturizer, cooling agent

A. barbadensis: Aloe barbadensis **,** *A. indica: Azadirachta indica*

Table 2: Formula for Transdermal patches[5]

Plant			
	Ingredients	**Quantity**	**Pharmacological activity**
	Neem Aq.Extract A.indica	40mg	Antibceria l, Antifungal
	Aloevera Extract A.barbedensis	40mg	Cooling agent
	Gelatine	240 mg	Gelling, Thickening
	DMSO	0.3ml	Penetration Enhancer
	Glycerine	0.3ml	Antimicrobial
	Water	q.s	Solvent

A. barbadensis: Aloe barbadensis , A. indica: Azadirachta indica

3. EVALUATION PARAMETERS

The formulated Transdermal patches were evaluated by Biological and Physical evaluation method.

3.1. Surface ph determination: [1]

In this evaluation test the Ph of the surface of transdermal patches was evaluated using the phMeter.

Figure.3.Evaluation of PH by PH meter

3.2. Phytochemical Screening

3.2.1. Phytochemical screening of aloevera[5]: - In Phytochemical screening of Aloevera Extract the Chemical tests like

1. Ferric Chloride test- Take 5 mg of extract and add 1 ml of water 0.5ml ammonia solution and also add conc.H2SO4.

2. Mayer's test- Take 5 mg of extract and add 1 ml of water 0.5ml ammonia solution and also add conc. H2SO4.

3. Steroid test- Take 5 mg of extract and 1 ml Chloroform and then add 1 drop of H2SO4.

4. Lieberman's test- Take 5 mg of extract and then add 2ml of chloroform and 2 ml acetic acid.Then cool the test tube in ice and then add 1 ml H2SO4.

5. Ninhydrin test- Take the extract and add 2ml 0.2% ofNinhydrin solution and boil test tube for 2 min

6. Killer killani test- Take 5mg of extract and add 1ml glacial acetic acid. Then add 2% Fecl2+1mlH2SO4.

7. NaOH test-Take 5 mg of extracts and adds 1 ml of 10% NaOH and when yellow colour occurs then add 1 ml Hcl.

8. Benedicts's test-Take 5 mg of extract and add benedicts reagent and boil them

3.2.2. Phytochemical screening of neem[1]-

3.3.2. 1. Test for Alkaloids-

1. Dragandroffs test: The extract was treated with Dragendroff's reagent(potassium bismuthiodide solution) then Orange brown Precipitate was formed

2. Mayer's test: The extract was treated with Mayer's (potassium mercuric iodide solution)reagentthen precipitate formed

3. Wagner's reagent: The extract was treated with Wagner's reagent(iodide and potassiumtriiodide solution) then Reddish brown precipitate was formed

3.3.2. 2. Test for Glycosides*:*

1.Borntrager's test: To the extract add dilute H2SO4 and filtered.Filtrate Was extract with little chloroform layer was separated out and add equal volume of dilute NH3 then red colour observedin ammonical layer.

2. Foam test: Shake the extract with water then foam was produce

3.3.2.3. Test for Tannins and Phenolic compounds

1. Ferric chloride test: To the aqueous extract few drops of ferric chloride solution were addedthen Dark brown colour formed

2. Bromine water test: To the aqueous extract is treated with bromine water discolouration ofbromine water

3. KMnO4 test: To the aqueous extract is treated with kMnO4 then discolouration of solution

3.3.2.4. Test for reducing sugar

Benedict test: 0.5 *ml of extract solution 1 ml of water 5 to 8 drops of Fehlins's solution was addedthen brick red precipitate was formed*

3.3.2. 4. Test for Amino acids

Ninhydrin Test:

1. The aqueous extract is heated with 5% ninhydrin solution on boiling water bath for 10 min. thenpurple colour formed

2. The aqueous extract is treated with solution sodium hydroxide and lead acetate solution andboiled then black precipitate is formed

3.3.2.6. Test for Flavonoids:

1. Shinoda test

a) To the methanol extract add potassium hydroxide solution and then 10% ammonia. Yellowcoloured precipitate was formed.

b) To the ethanol extract, add few drop of Lead acetate solution .Yellow colour precipitate formed

2.Salkowski Test: To the extract add chloroform solution few drops of conc.H2SO4 was added shaken and allowed to stand. Greenish fluorescence was formed.

3.3. Measurement of thickness of patches[1]: -

The Thickness of Formulated Transdermal Patches was Evaluated Vernier Calliper

Figure.4.Vernier Calliper

3.4. Percentage moisture content[1]: -

The % Moisture content was studied using Dessicator. Initially the individual patches were weighed and then kept in the dessicator containingactivated silica at the room temperature for period of 24 hours. Then afterward the Patches were reweighed.

%Moisture content [Initial Wt-Final Wt]/Initial Wt*100

Figure: Dessicator

Table.3.Evaluation of Transdermal patches[1]

Evaluation Parameter	Inference
Texture	Smooth
Thickness	0.22mm
pH	8.5
Color	Whitish cream
Odour	Aromatic

Table 4: Phytochemical evaluation of aloevera[1]

Sr. No	Name of chemical	Result of Aloevera
1	Ferric chloride	++
2	Mayer	++
3	Steroid	++
4	Liebermann	++
5	Ninhydrin	_
6	Killer Killani	++
7	NaOH	-----
8	Benedict's	-----

Table. 5. Phytochemical evaluation of neem[5]

Sr.No	Chemical onstituent	Result of Neem
1	Alkaloid	++
2	Saponin	++
3	Tannin	++
4	Phenolic compounds	++
5	Reducing sugar	—
6	Amino Acid	—
7	Flavonoid	++
8	Steroids	++

4. RESULT AND DISCUSSION

Color and Odour of the transdermal sample were typical of their constituents.
The pH of transdermal patches was found to be 8.5 which were relevant with human skin.

5. CONCLUSION

The extract of Azadirachta indica was used for the preparation of transdermal patch. To achieve thin, clear, smooth, stable, and excessive permeable transdermal patches, various formulation parameters. Drug Polymer ratios and permeation enhancers had been evaluated. To make a flexible patch 0.3 ml of glycerin was added as a plasticizer without changing its diffusion properties.If the amount is exceeded the film becomes rigid and loses its flexibility. The plastizer softens the polymer particles as it diffuses through the patch. Latex coalescence and patch formation are accelerated through this softening. Percentage moisture content, thickness, pH, phytochemical tests were all assessed on the patches. There was no noticeable change in medication content between the patch formulation. This implies that the medicine was dispersed

in a uniform way during the patch production.Using various polymers , the current work has achieved the goal of producing a transdermal patch containing Azadirachta indica aqueous extract.

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