WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Detail Overview on Herbal Transdermal Patches for Wound Healing Property

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ABSTRACT:

Background

Wound is an anatomical and functional disruption of the skin. Wound healing is the response to injury is the complex process of repairing of the cell or tissue which include the tissue like the collagen fiber .the wound is the type of the cell damage or the damage to the tissue caused by the various stimuli which include the physical, chemical and the mechanical stimuli . it may be the internal and external damaging factor.

Main text

The aim of our study was to formulate transdermal herbal patches for the wound healing natural herbs of the plant aloe vera, marigold, tea and turmeric. The most optimal formulation was further combined with penetration enhancers to improve bioavailability of the active ingredient. In the current times, different types of biopolymers are introduced for developing economical, sustainable, stable, and effective delivery system for the treatment of wounds.

Keywords: Transdermal patch , matrix, NDDS, reservoir, herbal transdermal patch, controlled release rate delivery system, wound , polymer.

INTRODUCTION:

There are increasing the demand of the development of the new pharmaceutical dosage form that means the novel drug delivery system for the purpose of the increasing the bioavailability of the drug and also reduce the drug dose as well as the target specific binding of the drug. for overcome these challenges the transdermal drug delivery system [TDDS] is being introduced in the market. it also gives the therapeutic effect at the target specific site.

The transdermal drug delivery system mostly the transdermal patches are used as the modern or novel drug delivery system. The transdermal patches are the device which is in the form of the medicated adhesive patches of various shapes and size [5- 20cm^2] which deliver a specific dose at the constant rate of release at the target specific site through the skin into the systemic circulation via the stratum corneum.

HISTORY:

The world first transdermal system patch was the scopolamine drug patch for the 3 days to treat the motion sickness approved in US in 1979. just few years later the nicotine patch introduced in the market, at present time there are various transdermal delivery system of drugs like oestradiol fentanyl & testosterone are introduced in the market and also the combination patches containing drug also introduced for contraception and hormone replacement.

Advantages:

- Avoid the first pass metabolisms
- Easy to apply

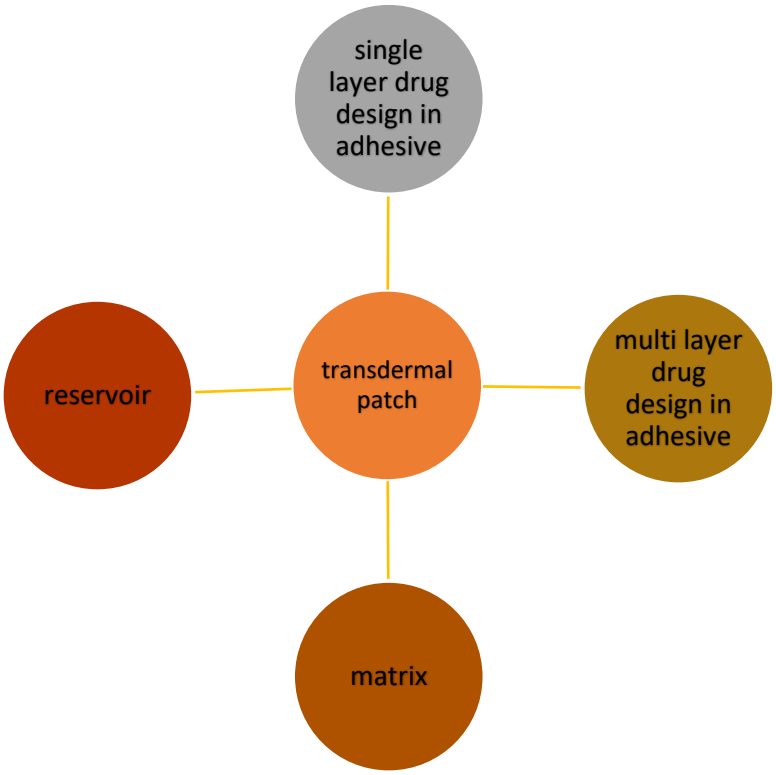
- Longer duration of action
- Controlled rate of drug release
- Easy to remove when produce toxicity

D**isadvantages:**

- Can not deliver ionic drug
- Drug molecule must be potent
- Only small lipophilic drug can be delivered
- It requires high blood concentration
- Drug having bulky dose cannot be suitable for patches.

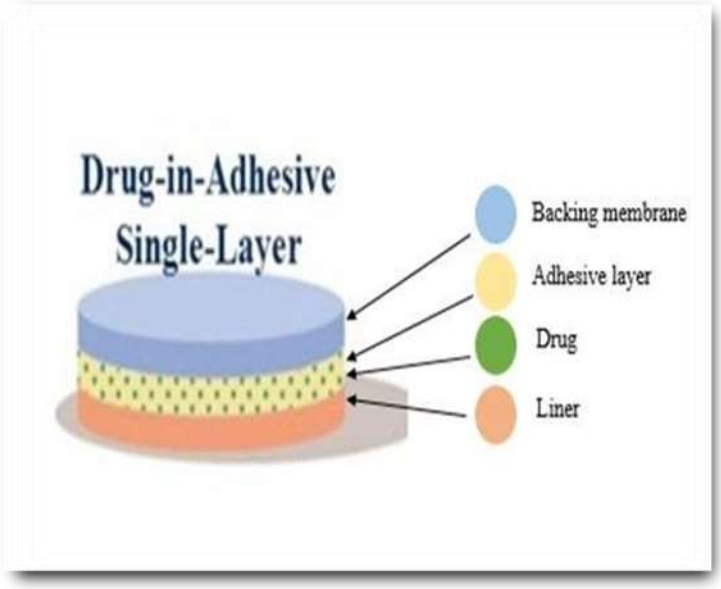
TYPES:

1. SINGLE LAYER DRUG IN ADHESIVE
2. MULTI LAYER DRUG IN ADHESIVE
3. RESERVOIR
4. MATRIX



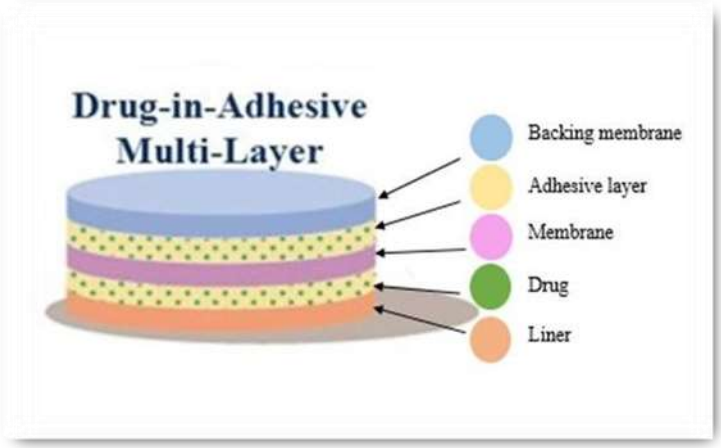
- **Single layer drug in adhesive.**

Single-layer transdermal patches are comprised of one layer: combined drug and adhesive. When single-layer patch is applied to the skin, adhesive layer adheres to the skin and then release the drug at controlled release in a specific time of the period.



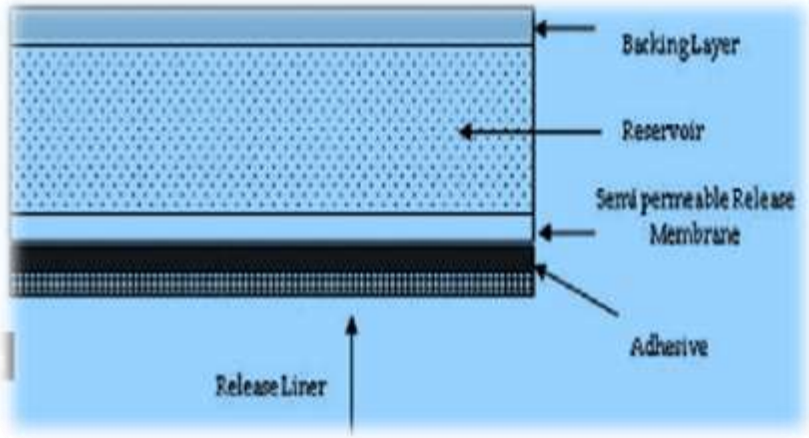
- **Multilayer drugs in the adhesive**

The multilayer transdermal patches are similar to the single layer drug in the adhesive but the additional layered of drug- in-adhesive usually separated by the membrane whose one layer is for immediate release and the other for the controlled release drug. when it is applied to the skin, adhesive layer adheres to the skin and then release the drug at controlled release in a specific time of the period. This patch has the temporary linear -layer and a permanent backing.



- **Reservoir:**

The transdermal drug reservoir type of the drug are liquid contain the drug solution or the suspension separated by the adhesive layer. The drug reservoir is encapsulated by the polymer like the vinyl acetate on the one surface and then it is also backed by the backing layer. the rate of release is the zero order kinetic. The transdermal patch should not be cut [with exception hyoscine bromide 1.2 mg patch according to the British national formulary for children. This reservoir type consists of a drug between a backing membrane and rate controlling membrane, with skin contacting adhesive layer.



- **Matrix**

It consists of the drug layer of a semisolid matrix which contain the drug solution or the suspension. the adhesive layer is surrounding the patch's drug layer which can partially overlaying it. The rate of release is determine by the physical property of the matrix.

- **Basics components of transdermal patch**

1. DRUG CONTAINING RESERNOIR OR MATRIX
2. ADHESIVE
3. LINEAR OR PROTECTIVE LAYER
4. BACKING
5. CONTROLLED RELEASE MEMBRANE

- **Drugs containing reservoir or matrix**

This component acts as the reservoir for the drug which may either be dissolved or dispersed within the matrix. it consists of the primary ingredient which is responsible for the transdermal delivery through the skin via stratum corneum, ensuring controlled release and absorption of the API into the body.

- **Adhesive**

The adhesive layer sticks the patch to the skin. It ensures that the patch remains in the place during wear and facilitates the transfer of a drug from the patch of the skin.

- **Liner or protective layer:**

A removable liner covers the adhesive layer before use to protect it. This layer is peeled off before applying the patch to the skin. Linear or protective layer can also maintain the integrity of the adhesive layer.

- **Backing**

The backing layer provide the structural support to the patch. And it also protects the drug containing layer as well as adhesive from the external factors like moisture and contamination. It also prevents the drug from leaking out of the patch.

- **Controlled release membrane**

In some patches, a controlled release membrane or the rate controlling membrane may be included. This membrane controls the rate at which drug is released from the transdermal patch into the skin.

- **Drug product and clinical use of transdermal patches in current market.**

Drug	**Product name**	**Clinical use**
Scopolamine	Transderm-Scop	Motion sickness
Nitroglycerin	Transderm-Nitro	Angina pectoris
Clonidine	Catapres-TTS	High blood pressure
Estradiol	Estraderm	Menopause
Fentanyl	Duragesic	Chronic pain
Nicotine	Nicoderm	Smoking cessation
Testosterone	Testoderm	Testosterone low level
Lidocaine/epinephrine	Iontocaine	Pain relief
Estradiol/norethidrone	Combipatch	Menopause
Lidocaine	Lidoderm	Pain relief
Norelgestromin	Ortho Evra	Contraception
Estradiol/levonorgestrel	Climara Pro	Menopause
Oxybutynin	Oxytrol	Overactive bladder
Lidocaine (ultrasound)	SonoPrep	Pain relief
Lidocaine/tetracaine	Synera	Pain relief
Fentanyl HCl	Ionsys	Postoperative pain
Methylphenidate	Daytrana	ADHD
Selegiline	Emsam	Depression
Rotigotine	Neupro	Parkinson’s disease
Rivastigmine	Exelon	Dementia

- **Polymers used for the transdermal patches**

There are the various polymer used for the formulation of the preparation of the transdermal patch. Polymer is the molecule which are the made up of the single repeating unit called monomer. when this monomer are form a chain then the forms the polymer play a role in the development of the transdermal patches, which are used to deliver the medication through the skin

- **Types:**

1. ***Acrylic Polymers***: Used for adhesive and matrix layers.

- Example: Polyacrylate, Polymethacrylate.

- Use: Enhance adhesion, control drug release.

2. ***Cellulose Derivatives***: Used for backing layers and matrix systems.

- Example: Cellulose acetate, Cellulose nitrate.

- Use: Provide mechanical strength, control moisture.

3. ***Polyurethanes***: Used for adhesive and matrix layers.

- Example: Polyurethane foam, Polyurethane film.

- Use: Enhance adhesion, improve drug permeability.

4. ***Polyesters***: Used for backing layers and matrix systems.

- Example: Polyethylene terephthalate (PET), Polybutylene terephthalate (PBT).

- Use: Provide mechanical strength, chemical resistance.

5. ***Silicone Elastomers***: Used for adhesive and matrix layers.

- Example: Polydimethylsiloxane (PDMS).

- Use: Enhance adhesion, improve drug permeability.

6. Ethylene-Vinyl Acetate (EVA): Used for matrix layers.

Some common polymers used in transdermal patches:

Matrix Polymers:

1. Ethylene-Vinyl Acetate (EVA)

2. Polyvinylpyrrolidone (PVP)

3. Polyethylene (PE)

4. Polypropylene (PP)

5. Polyurethane (PU)

Adhesive Polymers:

1. Acrylic Polymers (e.g., Polyacrylate, Polymethacrylate)

2. Silicone Elastomers (e.g., Polydimethylsiloxane)

3. Polyisobutylene (PIB)

4. Polyvinyl Alcohol (PVA)

5. Polyethylene-Vinyl Acetate (EVA) copolymers

Backing Layer Polymers:

1. Polyethylene Terephthalate (PET)

2. Polyethylene (PE)

3. Polypropylene (PP)

4. Polyvinyl Chloride (PVC)

5. Polycarbonate (PC)

Release Liner Polymers:

1. Polyethylene (PE)

2. Polypropylene (PP)

3. Polyethylene-Vinyl Acetate (EVA) copolymers

4. Polyvinyl Alcohol (PVA)

5. Silicone-coated paper

Other Polymers:

1. Poly(lactic-co-glycolic acid) (PLGA) for biodegradable patches

2. Poly(caprolactone) (PCL) for biodegradable patches

3. Polyvinylpyrrolidone-vinyl acetate (PVP-VA) copolymers

polymer selection criteria for transdermal patches.

Physical and Chemical Properties

1. Solubility and permeability
2. Molecular weight and distribution
3. Crystallinity and glass transition temperature
4. Mechanical strength and flexibility
5. Chemical stability and resistance

Biocompatibility and Safety

1. Cytotoxicity and irritation potential
2. Biodegradability and non-toxic degradation products
3. Hypersensitivity and allergic reactions
4. Sterilization and packaging compatibility

Pharmacological and Therapeutic Considerations

1. API properties (solubility, stability, potency)
2. Release profile and kinetic control
3. Skin permeability and absorption
4. Bioequivalence and interchangeability

Manufacturing and Scalability

1. Processability and extrudability
2. Adhesion and coating properties
3. Material costs and availability
4. Regulatory compliance and certifications

Patient-Centric Factors

1. Wear comfort and adherence
2. Skin sensitivity and irritation
3. Cosmetic acceptability and discreetness
4. User-friendly design and application

Regulatory Requirements

1. FDA and EMA guidelines
2. ISO and ASTM standards
3. Biocompatibility and toxicity testing
4. Labeling and packaging regulations

POLYMERS PARAMMMMMETERS THAT ARE USED TO FORMULATED HERBAL TRANSDERMAL PATCHES

1. Biocompatible
2. Biodegradable
3. Non-toxic

4. Non-irritating

5. Permeable for herbal extract

Some suitable polymers for herbal patches:

Natural Polymers:_

1. Cellulose derivatives (e.g., Cellulose acetate, Cellulose nitrate)

2. ***Starch-based polymers (e.g., Starch acetate)*** :- Chitosan, Alginate, Gelatin

Synthetic Biodegradable Polymers:

1. Polylactic acid (PLA)

2. Poly(lactic-co-glycolic acid) (PLGA)

3. Poly(caprolactone) (PCL)

4. Polyhydroxyalkanoates (PHA)

Herbal Patch-Specific Polymers:

1. EVA 40% (Ethylene-Vinyl Acetate) - suitable for herbal extracts

2. PVP K30 (Polyvinylpyrrolidone) - suitable for herbal extracts

3. Hydroxypropyl methylcellulose (HPMC) - suitable for herbal extracts

Matrix Polymers:

1. Ethylene-Vinyl Acetate (EVA)

2. Polyvinylpyrrolidone (PVP)

3. Hydroxypropyl methylcellulose (HPMC)

Adhesive Polymers:

1. Acrylic Polymers (e.g., Polyacrylate)

2. Silicone Elastomers (e.g., Polydimethylsiloxane)

Herbal Patch-Specific Polymers:

1. Chitosan 2. Alginate 3. Gelatin

Information about Aloe vera, Turmeric, Ginger, and Marigold according to the Indian Pharmacopoeia:

Aloe vera (***Aloe barbadensis)***

Family: Liliaceae

Part used: Gel from leaves

Description: Aloe vera gel is a clear, jelly-like substance obtained from the leaves of the ***Aloe barbadensis*** plant.

Constituents:

1. Aloin (anthraquinone glycoside)
2. Aloe-emodin (anthraquinone)
3. Vitamins A, C, E
4. Minerals (Ca, Mg, K)

Uses:

1. Skin conditions (wounds, burns, eczema)
2. Digestive issues (constipation, diarrhea)
3. Anti-inflammatory
4. Antimicrobial

Pharmacological Actions:

1. Anti-inflammatory
2. Antimicrobial
3. Antioxidant
4. Wound healing

Dosage: 500-1000 mg (gel), 250-500 mg (extract)

Precautions: Pregnancy, breastfeeding, kidney problems

Interactions: Diabetes medications, blood thinners

Side Effects: Gastrointestinal upset, allergic reactions

IP Dosage:

1. Gel: 500-1000 mg
2. Extract: 250-500 mg

IP Precautions:

1. Pregnancy
2. Breastfeeding
3. Kidney problems

IP Interactions:

1. Diabetes medications
2. Blood thinners

IP Standards (Indian Pharmacopoeia, 2018):

1. **Definition**: Dried gel of Aloe barbadensis leaves.
2. **Identification**: TLC, HPLC.
3. **Purity**:

a. ***Aloin content***: 2.5-3.5%.

b. ***Moisture***: Not more than 10%.

c. ***Total ash***: Not more than 5%.

d. ***Acid-insoluble ash***: Not more than 2%.

4. Assay:

a. Aloin content: HPLC.

b. Aloe-emodin content: HPLC.

Indian Pharmacopoeia Standards:

1. Aloin content: Not more than 3%

2***. Moisture content:*** Not more than 10%

3. ***Total ash***: Not more than 5%

Turmeric (***Curcuma longa***)

Family: Zingiberaceae

Part used: Rhizome

Description: Turmeric is a yellow-orange spice obtained from the rhizome of Curcuma longa.

Constituents:

1. Curcumin (polyphenol)

2. Demethoxycurcumin (polyphenol)

3. Volatile oils (turmerone, atlantone)

Uses:

1. Anti-inflammatory

2. Antioxidant

3. Digestive issues (dyspepsia, diarrhea)

4. Skin conditions (wounds, acne)

Pharmacological Actions:

1. Anti-inflammatory

2. Antioxidant

3. Anti-cancer

4. Anti-diabetic

Dosage: 1-2 tsp (powder), 500-1000 mg (extract)

Precautions: Pregnancy, breastfeeding, gallbladder problems

Interactions: Blood thinners, diabetes medications

Side Effects: Gastrointestinal upset, allergic reactions

IP Dosage:

1. Gel: 500-1000 mg

2. Extract: 250-500 mg

IP Precautions:

1. Pregnancy

2. Breastfeeding

3. Kidney problems

IP Interactions:

1. Diabetes medications

2. Blood thinners

IP Standards (Indian Pharmacopoeia, 2018):

1. Definition: Dried rhizome of Curcuma longa.

2***. Identification***: TLC, HPLC.

3. Purity:

a***. Curcumin content***: 2-4%.

b. Moisture: Not more than 10%.

c. **Total ash**: Not more than 5%.

d***. Acid-insoluble ash***: Not more than 2%.

4. Assay:

a. ***Curcumin content***: HPLC.

b. ***Demethoxycurcumin content***: HPLC.

Indian Pharmacopoeia Standards:

1. ***Curcumin content***: Not less than 2%

2. ***Moisture content***: Not more than 10%

3. ***Total ash***: Not more than 5%

Ginger (***Zingiber officinale***)

Family: Zingiberaceae

Part used: Rhizome

Description: Ginger is a spicy, aromatic root obtained from the rhizome of Zingiber officinale.

Constituents:

1. Gingerol (volatile oil)

2. Shogaol (volatile oil)

3. Zingiberene (sesquiterpene)

Uses:

1. Digestive issues (nausea, vomiting)

2. Anti-inflammatory

3. Antioxidant

4. Respiratory issues (cough, cold)

Pharmacological Actions:

1. Anti-inflammatory

2. Antioxidant

3. Anti-emetic

4. Anti-diabetic

Dosage: 250-500 mg (powder), 500-1000 mg (extract)

Precautions: Pregnancy, breastfeeding, bleeding disorders

Interactions: Blood thinners, diabetes medications

Side Effects: Heartburn, digestive upset

IP Dosage:

1. ***Rhizome***: 250-500 mg

2. Extract: 500-1000 mg

IP Precautions:

1. Pregnancy

2. Breastfeeding

3. Bleeding disorders

IP Interactions:

Blood thinners

IP Standards (Indian Pharmacopoeia, 2018):

1. **Definition**: Dried rhizome of Zingiber officinale.

2. **Identification**: TLC, HPLC.

3. **Purity*:***

a. Gingerol content: 1-3%.

b***. Moisture***: Not more than 10%.

c. Total ash: Not more than 5%.

d. Acid-insoluble ash: Not more than 2%.

4. Assay:

a. Gingerol content: HPLC.

b. Shogaol content: HPLC.

Indian Pharmacopoeia Standards:

1. ***Gingerol content***: Not less than 1%

2. ***Moisture content***: Not more than 10%

3. ***Total ash***: Not more than 5%

Marigold (***Calendula officinalis***)

Family: Asteraceae

Part used: Flowers

Description: Marigold flowers are bright yellow or orange in color.

Constituents:

1. Flavonoids (quercetin, kaempferol)

2. Carotenoids (lutein, zeaxanthin)

3. Saponins

Uses:

1. Skin conditions (wounds, eczema)

2. Anti-inflammatory

3. Antimicrobial

4. Digestive issues (diarrhea)

Pharmacological Actions:

1. Anti-inflammatory

2. Antimicrobial

3. Antioxidant

4. Wound healing

Dosage: 500-1000 mg (flower), 250-500 mg (extract)

Precautions: Pregnancy, breastfeeding, allergic reactions

Interactions: Blood thinners, diabetes medications

Side Effects: Gastrointestinal upset, allergic reactions

IP Standards (Indian Pharmacopoeia, 2018):

1. ***Definition***: Dried flowers of Calendula officinalis.

2**.** ***Identification***: TLC, HPLC.

3. ***Purity:***

a. ***Flavonoid content:*** 1-3%.

b. ***Moisture:*** Not more than 10%.

c. ***Total ash:*** Not more than 5%.

d. ***Acid-insoluble ash***: Not more than 2%.

4. Assay:

a. ***Flavonoid content***: HPLC.

b***. Saponin content***: HPLC.

Indian Pharmacopoeia Standards:

1. Flavonoid content: Not less than 1%

2. Moisture content: Not more than 10%

3. Total ash: Not more than 5%

Herbal Combinations

1. Aloe vera + Turmeric: Enhanced anti-inflammatory effects

2. Ginger + Turmeric: Improved digestive health

3. Marigold + Aloe vera: Enhanced wound healing

Toxicity Studies

1. Aloe vera: LD50 (oral) > 5000 mg/kg

2. Turmeric: LD50 (oral) > 2000 mg/kg

3. Ginger: LD50 (oral) > 5000 mg/kg

4. Marigold: LD50 (oral) > 2000 mg/kg

Regulatory Status

1. Aloe vera: FDA approved (oral, topical)

2. Turmeric: FDA approved (food, supplement)

3. Ginger: FDA approved (food, supplement)

4. Marigold: FDA approved (topical

Herbal Patch Development:

- ***Steps:***

1. *Selection of Herb*: Choose herbs with therapeutic properties.

2. *Extraction:* Extract active compounds from herbs.

3. F*ormulation*: Mix extracted compounds with polymers.

4. *Patch Design*: Design patch shape, size, and thickness.

5. *Evaluatio*n: Test patch physical characteristics, release profile, and bioequivalence.

Key Considerations:

1. Herb-Drug Interactions

2. Standardization of Extracts

3. Stability and Shelf-Life

4. Skin Permeability

5. Bioavailability

Challenges:

1. Standardization of extracts

2. Variability in herb quality

3. Skin irritation and allergic reactions

4. Bioequivalence and bioavailability

Future Directions:

1. Nanotechnology-based herbal patches

2. Controlled-release systems

3. Personalized herbal patches

4. Combination products (herbal and pharmaceutical)

Conclusion:

The transdermal patches are the device which is in the form of the medicated adhesive patches of various shapes and size [5- 20cm^2] which deliver a specific dose at the constant rate of release at the target specific site through the skin into the systemic circulation via the stratum corneum. By the using of different types of polymer the transdermal patches are formulated , it is the emerging technique of the drug formulation offers benefits over the conventional routes of drug administration it minimizes the dose of the drug and also convenient for the unconscious patients also . it saves the time as well as for the administered of the dose it does not require the skill person when toxicity produce it is easily remove.

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