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Review Article

A Review on Transdermal patches in NDDS

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ABSTRACT

Transdermal patches are now widely used as cosmetic, topical and transdermal delivery systems. These patches represent a key outcome from the growth in skin science, technology and expertise developed through trial and error, clinical observation and evidence-based studies that date back to the first existing human records. This review begins with the earliest topical therapies and traces topical delivery to the present-day transdermal patches, describing along the way the initial trials, devices and drug delivery systems that underpin current transdermal patches and their actives. This is followed by consideration of the evolution in the various patch designs and their limitations as well as requirements for actives to be used for transdermal delivery. The properties of and issues associated with the use of currently marketed products, such as variability, safety and regulatory aspects, are then described. The review concludes by examining future prospects for transdermal patches and drug delivery systems, such as the combination of active delivery systems with patches, minimally invasive microneedle patches and cutaneous solutions, including metered-dose systems.

INTRODUCTION

Transdermal patches also called transdermal drug delivery system are topically dosage form. Which deliver the drug through a skin. The drugs are in the form of patches (medicated adhesive patch) which applied on the skin to deliver a specific dose of drug into the systemic circulation through the skin. [1]

□ Advantages of TDDS:

1) It increases patient compliances avoid first pass metabolism.
2) It is non-invasive and avoids the inconvenices of parenteral therapy.
3) Easy to use
4) Self-medication is possible.
5) Drug therapy can be terminated rapidly by removal of the application from the skin surface.

□ Disadvantages of TDDS:

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1) It may cause dermatitis at the site of application in same patients.

2) Don't provide long term adherence.

3) Only provide long term adherence.

4) Only potent drug can be formulated in patches.

5) In some cases, it placed behind the ear, making it uncomfortable for the patient.

□ Skin Structure and Anatomy:

The skin is the largest organ of the human body which covers a surface area of approximately 2 sq. and receives about one third of the blood circulation through the body.it serves as a permeability barrier against the transdermal absorption of various chemical and biological agents. It is one of the most readily available organs of the body with a thickness of few millimetres (2.97-0.28) which, [2]

1) Separates the underlying blood circulation network from the outside environment.

2) Serves as a barrier against physical, chemical and microbiological attacks.

3) Acta as a thermostat in maintaining body temperature.

4) Play role in the regulation of blood pressure.

5) Protects against the penetration of UV rays.

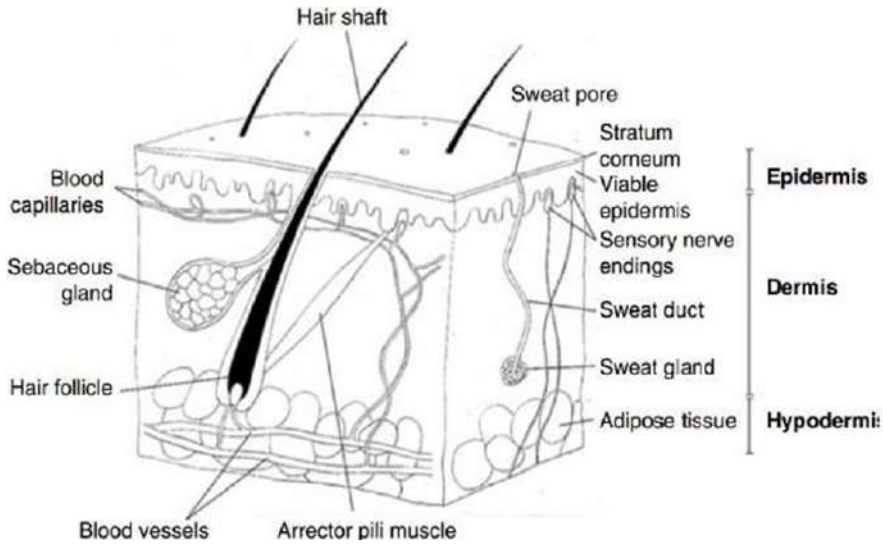


Fig no :1 skin structure

□ Anatomy of skin:

The structure of human skin (fig.1) can be categorized into 3 main layers:

1)The epidermis

2)The dermis

3)The Hypodermis (subcutaneous tissue)

4) Percutaneous Absorption

1) The Epidermis:

The epidermis is a continually self- renewing, stratified squamous epithelium covering the entire outer surface of the body and primarily composed of two parts: the living or viable cells of the Malpighian layer (viable epidermis) and the dead cells of the stratum corneum commonly referred to

as the horny layer viable epidermis is further classified into five distinct layer.

1) Stratum corneum
2) Stratum lucidium
3) Stratum granulosum
4) Stratum spinosum
5) Stratum Basale

1.STRATUM CORNEUM: - It is 15-20 um in size. (Lizelle T. Fox, Dec 2011) It is the outermost layer of epidermis is stratum corneum which has several layers of keratinized flat dead cell which continuously sheds off the skin and they have direct contact with the environment. This layer is anucleate and also lack cytoplasmic organs. [2] The stratum corneum layer prevents both penetration of substance from environment and insensible loss of body water from surface to the environment. As it is outermost it contains blocks of cytoplasmic protein embedded in lipid.

2.STRATUM LUCIDIUM: - It is present in specific area of body where skin is thick and lack hairs. This contains the layer of keratinized compact dense cells.

3.STRATUM GRANULOSUM: - This layer is a layer below stratum lucidium. This contains or has 3-5 layers of flat cells and also contain irregular shaped, nonmembrane bound, keratohyalin granules. This granule has structured protein profilaggrin which are involved in keratinization and barrier function of skin.

4.STRATUM SPINOSUM: - This has several layers of irregular polyhedral shaped cells and in uppermost layer contain small granules or membrane coating granules.

5. STRATUM BASALE: - It is also called as Stratum Germinativum which is made of a single layer consisting of columnar or cuboidal in shape

2. Dermis:

Dermis is composed of network of collagen and elastin fibres embedded in mucopolysaccharides matrix which contains blood vessels, lymphatic nerve endings, etc. Dermis is a mesodermal in origin which support to epidermis. It contains the network of dense irregular connective tissue and extend from basement membrane to hypodermis or subcutaneous tissue. Matrix of connective tissue has collagen, elastic and reticular fibres embedded in substance of mucopolysaccharides. Dermis is approx. 3-5 mm thick layer.

2. Hypodermis:

The hypodermis or subcutaneous fat tissue supports the dermis and epidermis. It serves as a fat storage area. This layer helps to regulate temperature, provides nutritional support and mechanically protection. It is the deepest layer of skin and it connect the skin to the underlying tissue of the body.

3. Percutaneous absorption:

Before a topically applied drug can act locally or systemically, it must penetrate through stratum corneum. Percutaneous absorption is defined as penetration of substance into various layers of skin and permeation across the skin into systemic circulation. Percutaneous absorption of drug molecules is of particular importance in transdermal drug delivery system because The drug has to be absorbed to an adequate extent and rate to achieve and maintain uniform, systemic, therapeutic levels throughout the duration of use.in general, once drug molecule crosses the stratum corneal barrier, passage into deeper dermal layers

and systemic uptake occurs relatively quickly and easily. [2]

 Drug Permeation Through Skin:

The drug is absorbed through follicular epithelium and sebaceous Gland. Then when the steady state is achieved then diffusion through intact Stratum corneum occurs.

Drug penetrates in skin via two routes and that are [3]

1.Trans epidermal route: -

If drug penetrates through this route, then drug penetrate through 2 route like Trans cellular and Intercellular.

2.Trans follicular: -

Here drug is transported via sweat gland and hair follicles. This route has high permeability but it is of minor importance

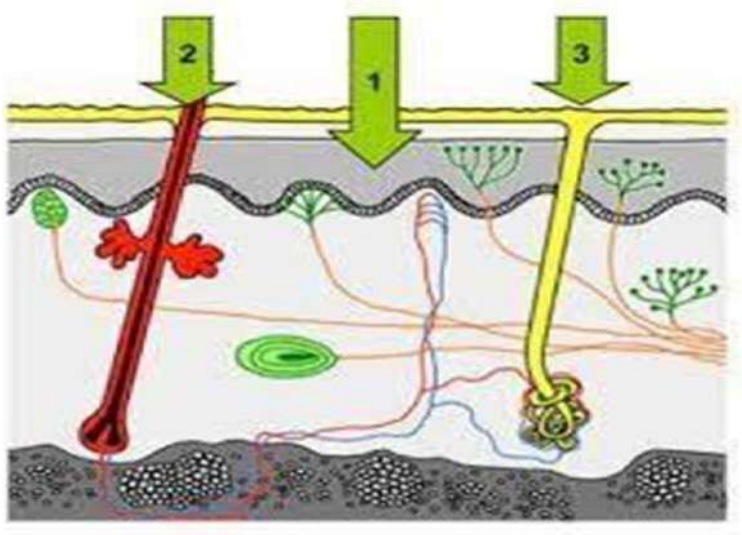


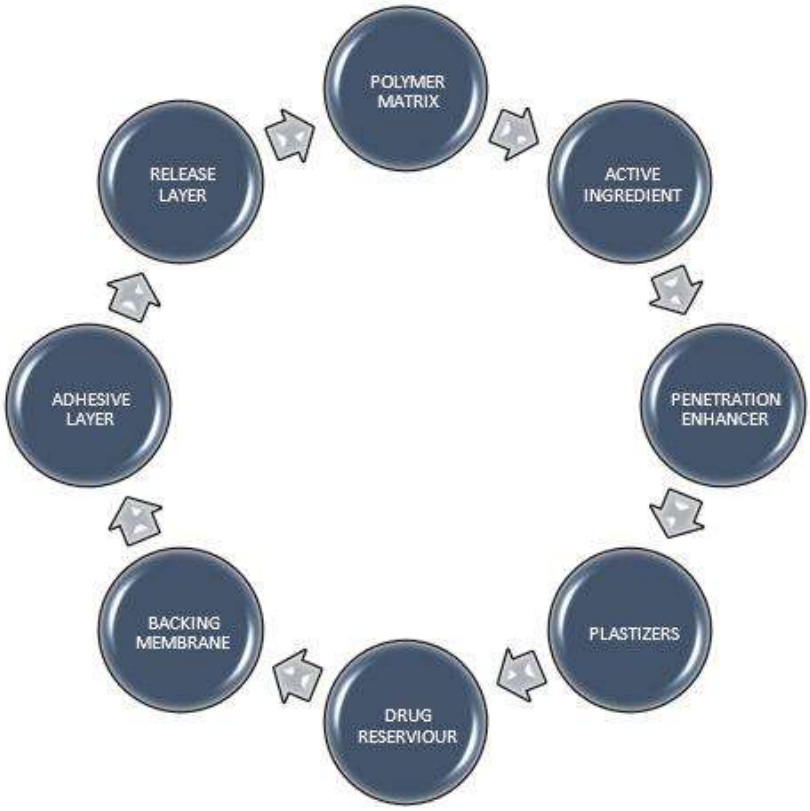
Fig no 2. drug permeation through skin

- Across the intact horny layer,
- Through the hair follicles with the associated sebaceous glands,
- Via the sweat glands

 Transdermal Patches:

Transdermal patches are a mediated adhesive patch which have coating of drug and is then placed on skin to deliver the drug in the blood stream through the skin. The delivery technology like TDDS helps to enhance the convenience for patients and also increases their effectiveness and protection of drug. Transdermal patches are formulated mainly to deliver drug through skin which diffuse through various skin layer and reach systemic circulation i.e., blood. TDDS patches are defined as self-contained dosage form which when applied to the skin and deliver the drug through the skin and drug reach the systemic circulation at the controlled rate for prolonged period. [3] Transdermal patches can avoid or bypass the first pass metabolism which can't be bypassed by oral route. It is easy to stop the drug uptake in blood can be stopped easily by removing patches from the skin. Several synthetic drugs are prepared by transdermal patches for example Nicotine patches, Lidocaine patches, Ketoprofen patches, Diclofenac patches and many more. In the mechanism of transdermal patches skin act as a partition membrane to create barrier that control release and absorption of drug.

Fig No 3. Transdermal Patches



Various Components of Transdermal Patches:

1.Polymer Matrix:

This mainly helps to release the drug from transdermal patches depend on or controlled by the polymer. As we increase the concentration of polymer then it forms a very dense matrix which results in slow-release rate of drug. Polymer forms the backbone of transdermal drug delivery system. The drug diffusion across the polymer matrix and release rate of drug depends on the concentration and various physiochemical properties of drug as well as polymer. [4]

Ideal Properties of Polymer Matrix Are -

1.It should be inert and should not react with drug.

2.It must not get decomposed in presence of drug and excipients.

3.It should not interfere in stability of drug.

4.It should be easily available.

5.It should be inexpensive.

6.It must not lead to any type of Antagonistic effect.

7.It should not result in any type of Hypersensitivity reaction.

Examples Of Polymer Matrix: -

Gelatine, Hydroxy propyl methyl cellulose, PVA (polyvinyl Alcohol), PVC (polyvinyl chloride), Starch, PVP, Polyethylene etc.

1.Active Ingridient: -

Drug reservoir is most important component of transdermal patches. It should be selected with very much intense care. [4] Drug that ionizes rapidly are not the suitable agents for formulating transdermal patches because ionized drug molecule has poor skin permeation and penetration.

Ideal Properties Oe Active Ingriedient Are: -

1.It should be non-irritant to human skin.

2.It should have short biological half-life.

3.It should be potent to impart the required pharmacological action.

4.It should not show any type of hypersensitivity reaction when administered.

5.It should be non-toxic in nature.

6.Drug should have the affinity towards lipophilic and hydrophilic phases

3. Penetration Enhancers: -

This are the substances which enhance the skin permeability by enhancing properties of skin to drug. Polar, non-polar and polar/nonpolar are 3 pathways for drug penetration through skin. Penetration is enhanced by altering one of these pathways. Polar pathway can be altered by causing protein conformational changes. Non-polar pathway can be altered by altering the rigidity of the lipids [4]

□ **Ideal Properties Of Penetration Enhancers Are**

1. It should not damage the layer of skin permanently.
2. It should be pharmacologically inert.
3. It should be non-toxic.
4. It should be non-allergic.
5. It should be action specific.
6. It should be non-irritant

Surfactants: -

These are added when drug used shows hydrophilic character. They enhance polar pathway transport of the drug. Cationic surfactant is not used. They are considered to be most irritating to skin. Example of Non-ionic surfactant is Pluroni. An example of Anionic surfactant is SLS (sodium lauryl sulphate)

Solvents: -

The example of solvents used are Ethanol, Methanol, Glycerol, Propylene glycol

4. Plastisizers: -

They are used to reduce or minimize the brittleness of polymer film. They provide or give Flexibility

and elasticity to the polymeric film. If Plasticizer are used in high concentration, then they make the film sticky and damp.

Ideal Properties Of Plasticizers Are: -

1. It should be easy to handle.
2. It should be non-reactive and non-irritant.
3. It should be pharmacologically inert.
4. It should not affect the stability of drug.
5. It should be cost effective. 6. It should be easily and readily available.

Examples Of Plasticizers Are- Glycerol, Propylene glycol, Dibutyl Phthalate, Polyethylene glycol

5. Drug Reserviour Component:

This is a component that contains one polymer or the combination of polymers in various different concentrations and ratios.

6. Backing Laminates: -

This helps to give and provide support. They should prevent the release of drug surface which is not in contact with skin. It should be compatible with drug and excipients. While selection the flexibility, strength, elasticity should be considered. This imparts appearance, flexibility, occlusions to transdermal drug delivery system. While selecting backing laminates the excipients compatibility should be considered. The most suitable backing laminates is the one with high flexibility. [4]

 Example Of Backing Laminates Are: - Metallic Plastic Laminates, Polyurethane, Aluminium foil.

7. Adhesive Layer: -

This layer adheres the transdermal device on surface of skin at proper site and position.

Ideal Properties Of Adhesive Layers Are: -

1.It should have ability to stick with minimum pressure.

2.It should not interfere with release rate of drug.

3.It should not affect solubility of drug.

4.It should be non-irritant to the skin.

8. Release Liners: -

These are the protective layer which are removed before the application of transdermal patches on skin. They are helpful to prevent drug loss during storage and transportation condition.

Examples Of Release Liners Are: - Teflon, Silicon, Polyester etc.

Various Types Of Transdermal Patches: - Following are various types of transdermal patches-

1. Single Layer Patches
2. Multi Layer Patches
3. Reservoir
4. Matrix
5. Vapour Patch

1. Single Layer Patches: -

Here the adhesive layer not only serves to adhere the various layers together along entire system to skin but also helps and is responsible for drug release from the patch. This adhesive is also

surrounded by the backing laminate and release liner. This type of patches is characterized by inclusion of drug directly in the skin contacting adhesive placed onto the epidermis [4].

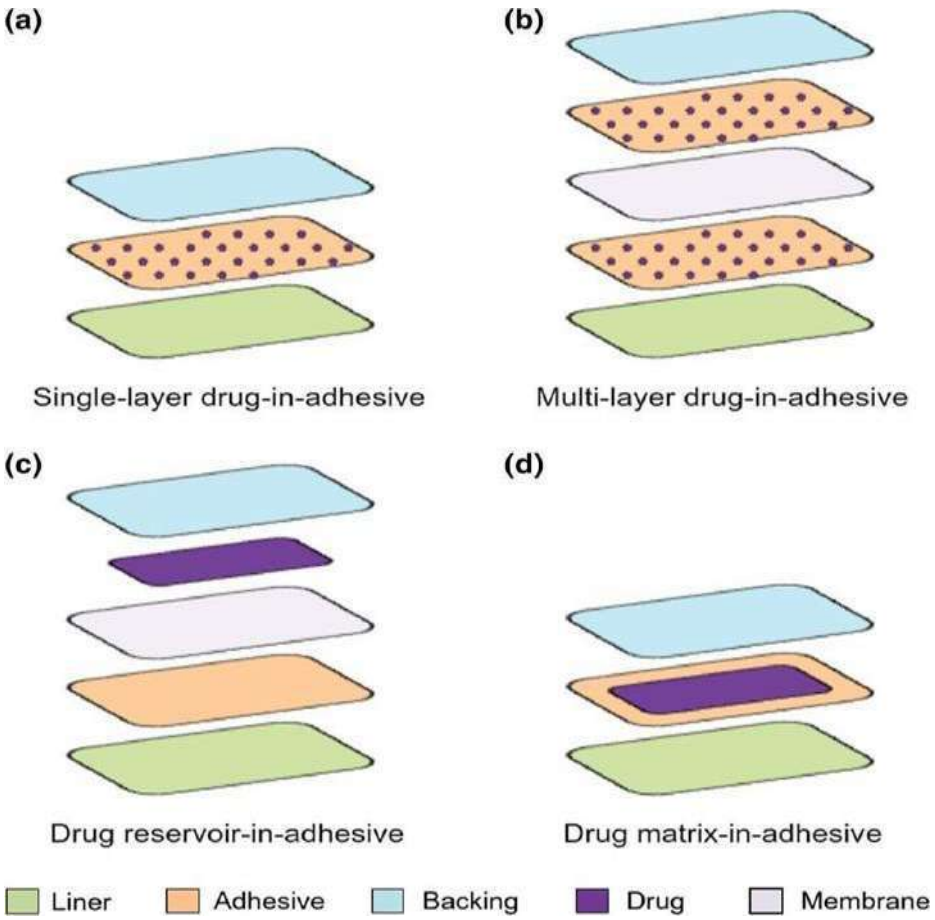


Fig no 4. Types of transdermal patches

2.Multi Layer Patches: -

These patches are similar to single layer patches. It consists more than one layer. One of the layers is for immediate release of the drug and other one is for control release of the drug from temporary liner layer and a permanent backing layer. In this patch the drug release depends on the membrane permeability and diffusion capacity of drug molecule.

3.Resrevoir Type Patch: -

In this patch there is a separated drug layer. The drug layer is a liquid compartment containing a drug solution or suspensions. Here the drug compartment is totally encapsulated in shallow compartment moulded with metallic plastic laminates which have rate controlling membrane made with polymer. This patches also has backing membrane present

4.Matrix Type Patch: -

The Matrix system has a drug layer of semisolid matrix which contains drug in solution or suspension form. This is also called as monolithic device.

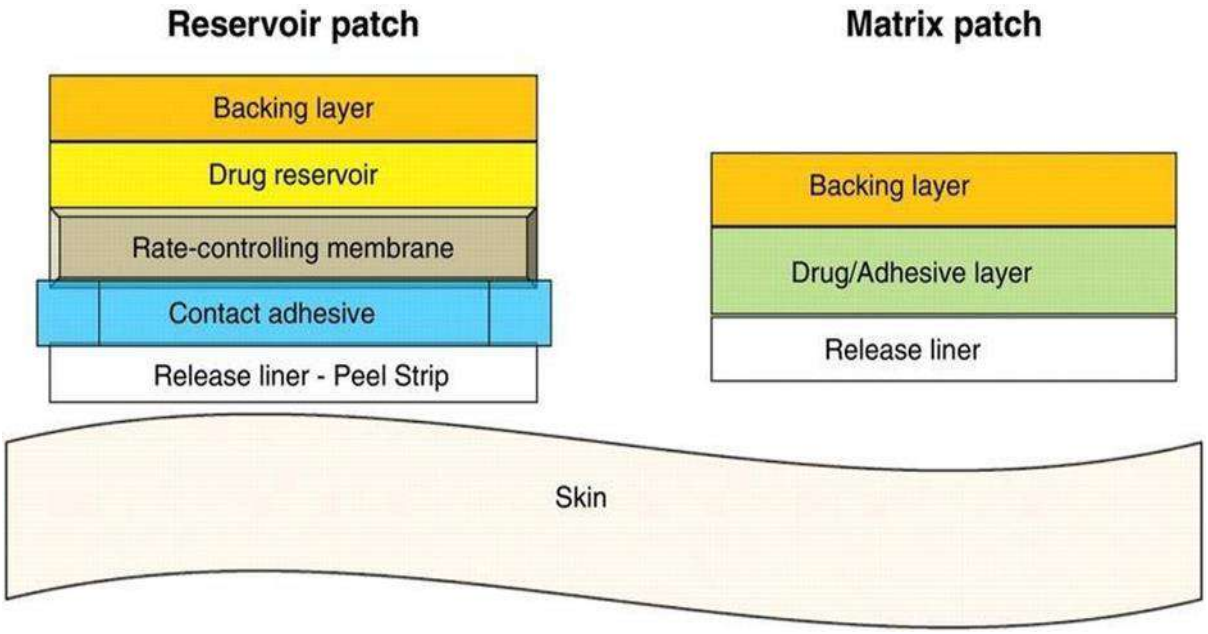


Fig no 5. reservoir and matrix patches

5.Vapour Patches: -

In this patch the adhesive layer carries out two roles one to adhere the various layers and other one to release the vapours. This vapour patches release the essential oils for up to time period of 6 hours. This vapour patches are mainly and widely used for decongestion. Other vapour patches are formulated to enhance the quality of sleep and as an aid for smoking cessation.

□ Factors Affecting The Permeation Of Transdermal Patches: -

There are 3 types of main types of factors which affects transdermal permeation and they are as follows;

A] Physiochemical properties of penetrant

B] Physiochemical properties of delivery system

C] Physiological and pathological Skin conditions

A] Physiochemical Properties Of Penetrant: -

1. Partition Coefficient: -

The partition coefficient value of 1 or more is ideal for the transdermal drug delivery.

2. Ph Condition: -

The rate of absorption of acidic or basic drug are affected by PH whereas unchanged form of drug exhibits better penetrating capacity. Moderate PH is a suitable for transdermal patches. High or low PH can cause destruction of skin or can cause damage to the skin. [5]

3. Composition Of Drug Delivery System: -

This includes concentration of various component such as drug, polymer, plasticizer, thickness of membrane etc. The transdermal permeability across mammalian skin in passive diffusion process that depends on concentration of penetrant molecule on skin surface[5].

B] Physiochemical Properties of Drug Delivery System:

1. Affinity Of Vehicle For Drug Molecule: -

Solubility in carrier determine the release rate of drug. Mechanism of drug release depends on whether the drug is dissolved or suspended in delivery system.

2. Composition Of Drug Delivery System: -

This affects the rate of drug release and also permeability of subcutaneous layer by hydration.

3. Enhancement Of Transdermal Permeation: -

The subcutaneous layer is dead in nature. Permeation enhancer can cause physiological changes in subcutaneous layer and increases drug penetration through the skin.

C] Physiological And Pathological Skin Condition: -

1. SKIN AGE: - The permeability of foetal and infant skin is more than that of mature adult skin. Therefore, percutaneous absorption of topical steroid is rapid in children's as compare to adults. [5]

2. LIPID FLIM: - Formation of thin lipid film of skin occurs by excretion of sebaceous gland like sebum

3.SKIN HYDRATION: - Transdermal permeation can be increased by hydration of subcutaneous layer.

4.SKIN TEMPERATURE: - Increased skin temperature enhance the skin permeation rate. It tends to increase the vasodilation of blood vessels in contact with skin. This increases the percutaneous absorption.

5.SPECIES DIFFERENCE: - Skin of different mammalian species shows various anatomical differences like thickness of subcutaneous, hair follicles etc.

□ Factors Affecting The Rate Of Drug Release: -

Following are the various factors the rate of drug release from the transdermal patches and they are as follows

1. Pore size of rate controlling membrane
2. Molecular weight of drug
3. Molecular size of drug
4. Solubility of the drug.
5. Thickness of the membrane

New Approches In Transdermal Drug Delivery System:

Following are the various new approaches related to transdermal drug delivery system. These new approaches are emerging and are having a great scope of innovation and development.

1. IONTOPHORESIS: - Iontophoresis is defined as facilitation of drug permeation across skin by applying electrode. Here the charged electrodes are connected to drug reservoir and current is applied. So, in the Presence of electric current the permeability of stratum corneum is increased which help to enhance the drug release. [5].

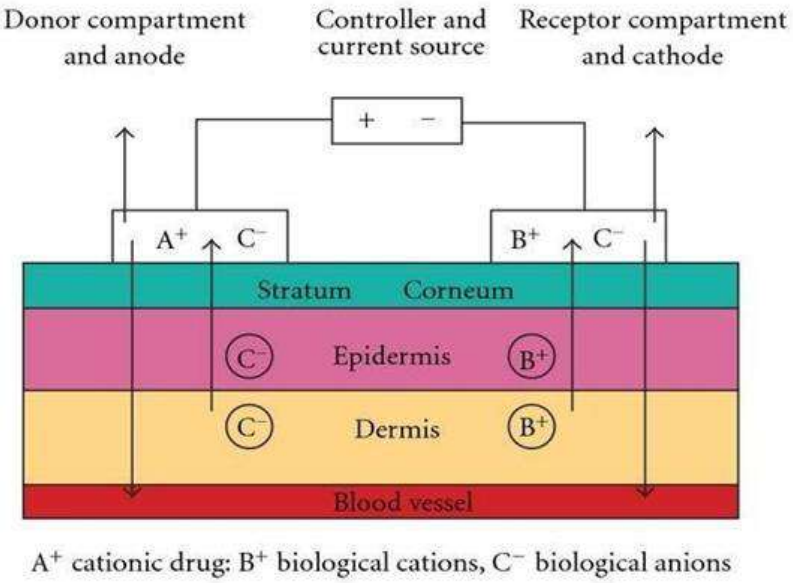


Fig no 6. iontophoresis

2. ELECTROPORATION: - There is formation of small pores with the help of electric pulses in stratum corneum through which drug is transported.

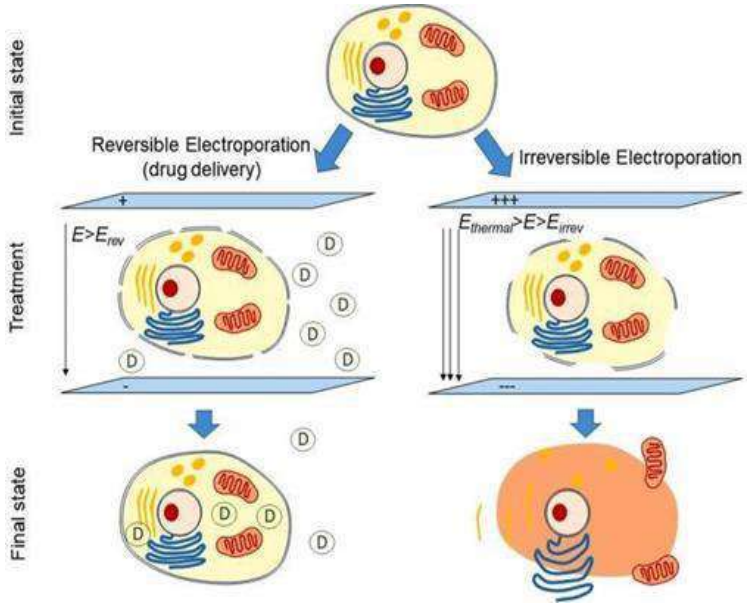


Fig No 7. Electroporation

3. PHOTOMECHANICAL WAVE: - This wave makes stratum corneum permeable to drug by developing transient channel.

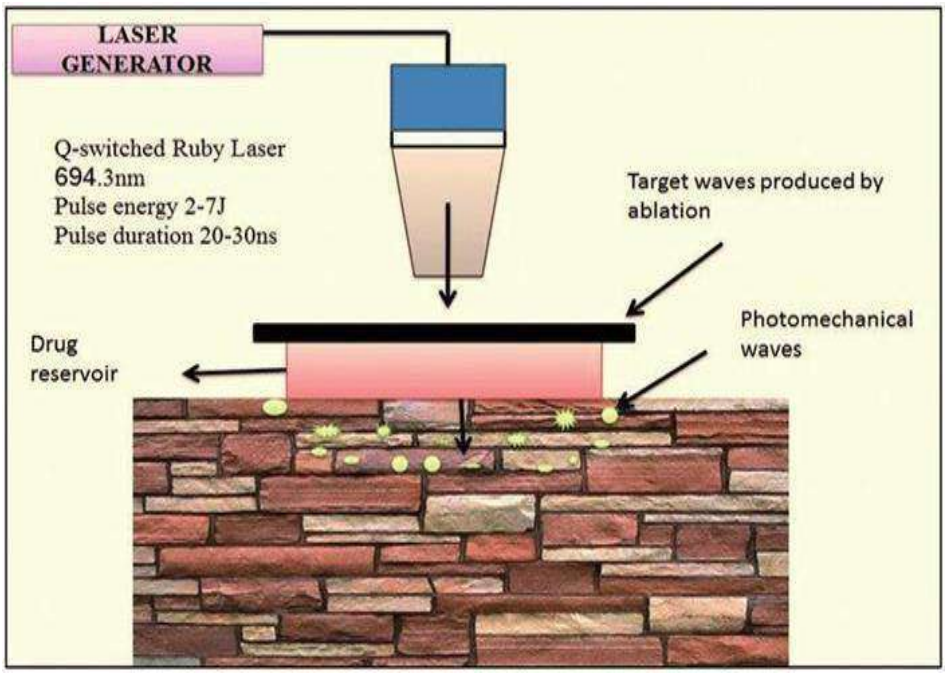


Fig no8. Photomechanical wave

4. MEDICATED TATTOOS: - This are also called as Med-Tats. Med-Tats contains active drug substance. This is beneficial and used for drug administration in children's which do not take or believe in traditional dosage form. Here there is no predetermined duration of therapy. So, manufacturer gives colour chart which is then compared with patients tattoo to analyse when tattoo is to be removed.

5.MICRONEEDLE: - This was seen or observed first in 1976. Micro needle which are 50100mm long are used. They are penetrated from reservoir to stratum corneum for the drug delivery.

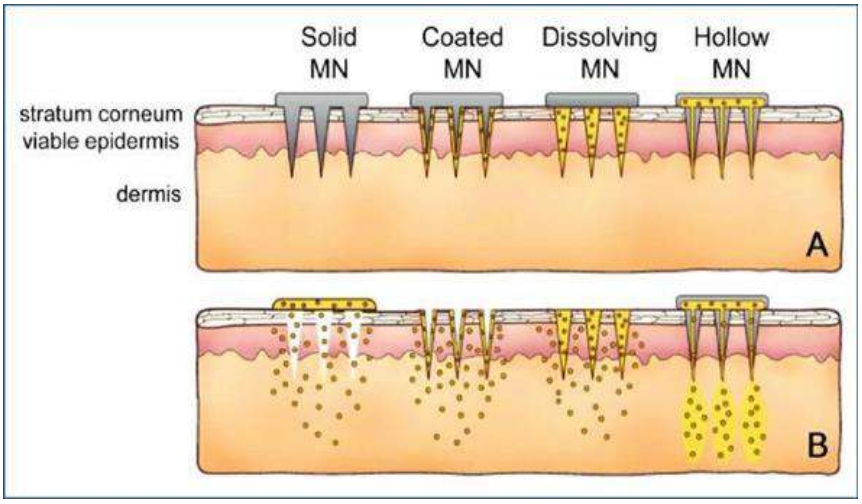


Fig no 9. Microneedle

6.SKIN ABRASSION: - Here there is removal and destruction of upper layer of skin to enhance the permeation of medicament. Such technique is used in treatment of acne, scars, skin blemishes etc. [5].

7. LASER RADIATION: - In this there is a direct use and exposure of laser to skin which results in ablation of stratum corneum without any damage caused to epidermis this is beneficial for lipophilic or hydrophilic drugs delivery.

8. ULTRASOUND: - Here there is use of low frequency ultrasound for average 15 seconds to enhance the permeation of skin.

 General Methods For Formulation Of Transdermal Patches**:** - [6]

1. Circular Teflon mould method.
2. Mercury substrate method
3. By using EVAC membrane method 4. Aluminium Backed Adhesive film method.
4. By using free film method.

 General Procedure for Applying Any Type of Transdermal Patches: -

Following are the steps which should be followed for applying the transdermal patches and they are as follows [6].

1. Initially wash your hands and area where patch will be applied.
2. Make the area clean and sterile.
3. Hold the patch so that the plastic backing is facing to side applicator.
4. Peel off one side of the patches backing.
5. Apply exposed half of patch to the skin in the spot you have chosen.
6. Now then press sticky side of patch against the skin and smooth it down. [6]

What Are the General Differences Between Topical and Transdermal Formulation?

	Topical Formulation		Transdermal Formulation
1.	Topical medication works on surface of skin and do not reach the blood stream [6]	1.	Transdermal medication penetrates the skin and enters the blood and also distribute through whole bloodstream
2.	For Example: - Hydrocortisone ointment for skin rashes	2.	For Example: - Nitro-glycerine patches to treat chest pain
3.	Topical formulations are cream, ointments, lotion, sprays, foam, powder etc.	3.	Transdermal formulations are Patches, Nano gels, and Pastes
4.	These formulations can't avoid first pass metabolism	4.	Transdermal formulation bypass and avoids first pass metabolism.
5.	There are some chances for occurrence of local skin irritation and rashes	5.	Can Help to minimize adverse drug reactions due to low drug concentration
6.	Drug when given through topical route Just show superficial action	6.	Here drug penetrates deep inside the layers of tissues

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