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Formulation and Evaluation of Diclofenac Sodium Patch.

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Abstract: *Present study was to develop Diclofenac Sodium Transdermal patches to bypass first pass metabolism and overcome all the problem of conventional dosage forms. A recent approach to drug delivery is to deliver the drug into systemic circulation at predetermined rate using skin as a site of application. The release rate from TDS can be tailored by varying polymer composition. Transdermal drug delivery has made an important contribution to medical practice. It is a medicated patch that delivers a specific amount of medication through the skin into the blood stream. An advantage of a transdermal drug delivery route over other types of medication delivery is that the patch provides a controlled release of the medication into the patient, usually through either a porous membrane covering a reservoir of medication or through body heat melting thin layers of medication embedded in the adhesive. Diclofenac is a NSAID agent used for the treatment of rheumatoid arthritis, osteoarthritis and relief the pain of varying origin treatment. Evaluation parameters like physical appearance, uniformity of weight, thickness, folding endurance, moisture content, drug content, dissolution study and diffusion study are all carried out. The results show that patches of diclofenac sodium obtained by the solvent evaporation method had acceptable physicochemical characteristics and satisfactory % drug release. The present investigation was aimed to formulate transdermal films of non steroidal anti-inflammatory drug, Diclofenac sodium using mercury substrate method and evaluated for physicochemical parameters like thickness, weight variation, moisture uptake, moisture content, folding endurance, and drug content values. Three transdermal patches were prepared using different concentrations of ethyl cellulose. It was concluded that as the concentration of polymer increases the thickness of patch, weight uniformity and folding endurance increases. Percentage moisture content and percentage moisture uptake decreases with increase in polymer concentration.*

Keywords: Transdermal; Inflammation; Skin; NSAID; HPMC polymer

I. INTRODUCTION

Transdermal Drug Delivery System (TDDS) is a method of delivering medications through the skin to achieve systemic effects. Unlike traditional oral or injectable routes, TDDS offers a non-invasive, controlled release of drugs into the bloodstream, bypassing the gastrointestinal tract and first-pass metabolism by the liver.The system typically involves the use of patches that adhere to the skin and contain a reservoir or matrix of the drug. These patches are designed to release the drug at a controlled rate over a prolonged period.

TDDS is particularly useful for drugs with short half-lives, poor oral bioavailability, or when sustained plasma levels are desired. It improves patient compliance, minimizes side effects, and allows easy termination of therapy if adverse effects occur.Common drugs administered through TDDS include nicotine (for smoking cessation), fentanyl (for pain management), and hormonal therapies (like estrogen or contraceptives). TDDS represents a promising approach in modern drug delivery, combining convenience, efficacy, and safety.

Objective of TDDS is to achieve systemic medication through topical application on intact skin; therefore, it is important to review the structural and biochemical features of the human skin and those characteristics that contribute to the barrier function and the rate of drug access into the body via the skin.anatomically, the skin can be divided into two layers: epidermis and dermis or corium penetrated by hair shafts and gland ducts. The skin is one of the most extensive organs of the human body, covering an area of about 2 m2 in an average human adult. The major skin layers,

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from inside to outside, comprise the fatty subcutaneous layer (hypodermis), the dermis of connective tissue and the stratified avascular cellular epidermis.

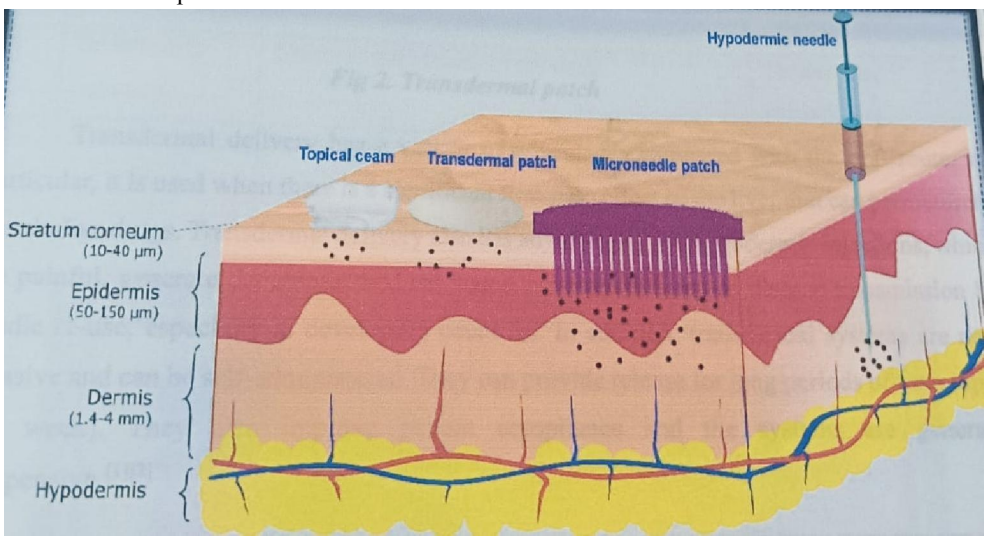

Fig.1 Transdermal drug delivery system

Nonsteroidal anti-inflammatory drugs (NSAIDs) are among the most frequently prescribed drugs, which are used in both acute and chronic symptoms of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and dysmenorrhea treatment because of their analgesic, antipyretic and anti-inflammatory roles. Diclofenac(2-[2-(2,6 dichlorophenyl amino) phenyl]acetic acid) is one of the most prospective and commercially successful drug in the family of NSAIDs.

Diclofenac sodium is non steroidal anti-inflammatory agent, widely used in musculoskeletal disorders, arthritis, toothache, etc., for symptomatic relief of pain and inflammation. Diclofenac sodium is reportedly used for topical applications. The drug undergoes substantial hepatic first-pass metabolism and only about 50% of administered dose reaches systemic circulation.

In Rheumatoid Arthritis patients are advised to take the NSAIDs effects such as systemic toxicity, GIT irritation, nausea, vomiting, gastric erosion, headache are the main drawbacks of Diclofenac sodium. Because of its short biological half-life and frequent administration, it is considered as a suitable candidate to formulate it into a sustained release matrix type transdermal patch system.

Main objective of study is to develop transdermal patch of Diclofenac sodium to achieve more patient compliance, to reduce the dosing frequency, to enhance the release rate of drug for quick onset of action, to avoid the oral administration of drug to omit the GIT related bioavailability problems and to improve local availability of drug to site of action in arthritis

Transdermal patch generally refers to topical application delivers agents to healthy intact skin either for localized treatment of tissues underlying the skin or for systemic therapy. Transdermal Patch offers many advantages over the conventional dosage forms or controlled release oral systems. Transdermal patch provides constant blood levels, avoids first pass metabolism, increased patient compliance, and avoids dose dumping . The application of transdermal delivery to a wider range of drugs is limited due to the significant barrier to penetration across the skin which is allied primarily with the outermost stratum corneum layer of the epidermis.

Formulation on skin can be classified into two categories according to the target site of the action. One has systemic action after drug uptake from the cutaneous micro vascular network and other exhibits local effects in the skin. Transdermal drug delivery can closely mimics the slow intravenous infusion without its potential hazards and also offer another most important advantage in allowing the patient to terminate the drug therapy by simply removing the patch at desired time if toxicity develops.

In animals and humans in vivo by reduced concentrations of various prostaglandins in urine, gastric mucosa and synovial fluid during treatment with diclofenac Also, in common with other NSAIDs, diclofenac is a potent reversible

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inhibitor of the secondary phase of induced platelet aggregation. However, diclofenac at usual therapeutic dosages has little effect on bleeding time in humans.

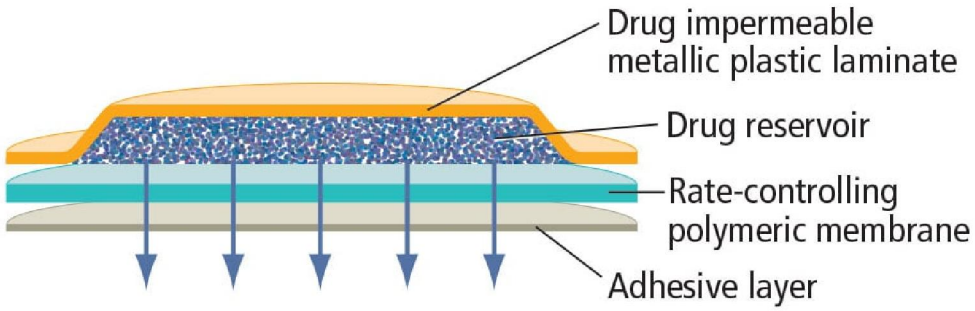

Fig.2 Transdermal drug delivery system show in patch

II. TYPES OF TRANSDERMAL DRUG DELIVERY SYSTEM

Transdermal patches come in the following types: Three fundamental design principles (a specialized design constitutes the fourth) can be used to characterize the developed patch-type TDDS :

1. Drug in reservoir (membrane type)
2. Drug in matrix (monolithic type)
3. Drug in adhesive (matrix)
4. Drug in micro reservoir (reservoir in adhesive matrix)

Drug in Reservoir (Membrane Patch) :

A delivery rate-controlling membrane sits between the skin and the drug reservoir in membrane patches. Dense polymeric membranes, through which the drug permeates by dissolution and diffusion, or microporous membranes, which regulate drug flux by the size and tortuosity of pores in the membrane, can also be employed . Materials that can be used as rate-controlling membranes include polyester elastomers, silicones, high-density polyethylene, ethylene vinyl acetate copolymers, and polyacrylonitrile. The optimal membrane should retain other formulation excipients while remaining permeable to the medication and enhancer, if any are present. A drug reservoir can be made of many different substances, from straightforward formulations like mineral oil to intricate formulations like polymeric materials and aqueous-alcoholic solutions and gels with or without co solvents. If the drug is formulated as a suspension, the reservoir material will become saturated with the drug during the product application period, allowing zero-order drug release throughout the delivery period

Drug in Matrix :

The medication permeates a polymeric matrix to reach the skin's surface after being evenly distributed throughout. The matrix, which can be thought of as the drug reservoir, is made up of silicone elastomers, polyurethanes, polyvinyl alcohol, and polyvinyl pyrrolidones. The drug molecules from this system dissociate from the crystal lattice, they solubilize and partition in the polymer matrix, and finally they diffuse through the matrix to the skin's surface . These are the steps in the drug delivery process. If a drug is kept at saturation level in the fluid phase of a polymeric matrix and its diffusion rate within the matrix is significantly higher than its diffusion rate outside of it, the drug can be released from the matrix under zero-order kinetics.

Drug-in-Adhesive Matrix :

These are the most basic systems, where an adhesive mixture containing the drug and enhancer is applied to a backing membrane (like a polyester film) to create an adhesive tape. These systems do have certain drawbacks, though :

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1. They could interact chemically, which could disrupt the functioning of the adhesive, lead to the disintegration of active species, or create new chemical entities.
2. Different release rates for hydrophilic and hydrophobic drugs may be provided by the physicochemical properties of the drug and adhesive system; for example, silicone adhesives' lipophilicity restricts the solubility of hydrophilic drugs in the adhesive matrix.
3. The adhesive properties and drug release rates of a drug-in-adhesive system may change when additional excipients (Such as skin permeation enhancers) are added.

Drug in Micro reservoir :

This TDDS combines matrix dispersion and reservoir systems. The drug is suspended in ~ 9 ~ International Journal of Pharmaceutical Research and Development an aqueous solution of a water-soluble polymer to prepare the drug reservoir in this system. The drug-soluble solution is then uniformly dispersed in a lipophilic polymer to form multiple imperceptible, microscopic spheres of drug reservoirs . By instantly cross-linking the polymer, the thermodynamically unstable dispersion is stabilized.

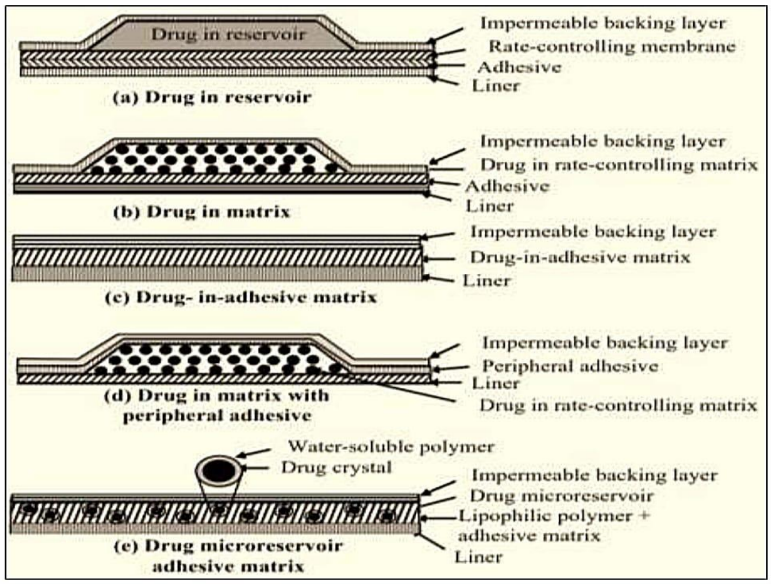

Fig 3: Types of Rate-Programmed Transdermal DDS

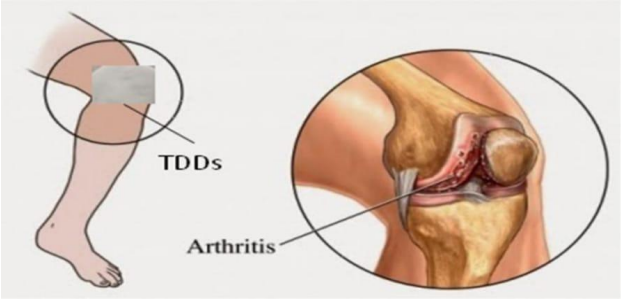

Fig. 4 : Diclofenac sodium transdermal patch is applicable at joints for the treatment for arthritis.

Diclofenac sodium is a nonsteroidal anti-inflammatory drug (NSAID) commonly used for its analgesic, anti-inflammatory, and antipyretic effects. main medicinal uses :

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1. Pain Relief:
Used to treat mild to moderate pain (e.g., dental pain, post-operative pain, musculoskeletal pain).

2. Inflammatory Conditions:
Osteoarthritis, Rheumatoid arthritis ,ankylosing spondylitis, gout attacks

3. Dysmenorrhea :
Effective in relieving menstrual pain.

4. Migraine :
Used in acute migraine attacks (e.g., diclofenac potassium in sachet form).

5. Post-operative Inflammation :
After surgeries, especially orthopedic or dental, to reduce swelling and pain.

6. Soft Tissue Injuries :
Sprains, strains, and sports injuries.
It can be administered orally, topically (gel/patch), intramuscularly, or as a suppository depending on the condition being treated.

III. ADVANTAGES OF DICLOFENAC SODIUM PATCH

1. Pain Management:
- Provides localized pain relief for musculoskeletal conditions such as sprains, strains, and sports injuries.
- Used for chronic pain conditions like osteoarthritis and rheumatoid arthritis.

2. Anti-Inflammatory Action:
- Reduces inflammation in conditions like tendonitis and bursitis.
- Helps in post-operative and post-traumatic inflammation control.

3. Alternative to Oral NSAIDs:
- Reduces gastrointestinal side effects associated with oral NSAIDs (e.g., ulcers, gastritis).
- Suitable for patients who have difficulty swallowing pills.

4. Improved Patient Compliance:
- Provides a non-invasive and convenient method of drug administration.
- Requires less frequent dosing compared to oral formulations.

IV. DISADVANTAGES OF DICLOFENAC SODIUM PATCH

1. Skin Reactions – May cause irritation, redness, itching, or rash at the application site.
2. Limited Absorption – Compared to oral forms, the absorption may be insufficient for severe pain.
3. Not Suitable for All Areas – Cannot be applied to broken skin, wounds, or certain body parts (e.g., mucous membranes).
4. Potential Systemic Effects – Though lower than oral forms, prolonged use can still cause gastrointestinal, cardiovascular, or renal side effects.
5. Adhesion Issues – Some users may find that the patch does not stick well, especially in humid or sweaty conditions.

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AIM :

The aim of this study is to formulate and evaluate a transdermal patch containing diclofenac sodium to provide sustained drug release, improve patient compliance, and enhance therapeutic efficacy for pain and inflammation management.

OBJECTIVES :

1. Formulation Development:

Design and develop a transdermal patch of diclofenac sodium using suitable polymers.

Optimize the formulation by selecting appropriate excipients to achieve desired drug release characteristics.

2. Physicochemical Characterization:

Evaluate the thickness, weight uniformity, folding endurance, and moisture content of the prepared patches.

Assess the drug content uniformity to ensure consistent dosing.

3. In Vitro Drug Release Studies:

Perform drug release studies using a suitable dissolution medium.

Analyze the release kinetics and mechanism of drug diffusion.

4. Ex Vivo Permeation Studies:

Evaluate skin permeability using animal or human cadaver skin models.

Determine the flux and permeability coefficient of diclofenac sodium.

5. Mechanical and Adhesive Properties:

Assess tensile strength, elongation, and bioadhesion properties for durability and adherence to the skin.

6. Stability Studies:

Conduct stability testing under different environmental conditions to evaluate the shelf life of the patc

V. MATERIAL AND FORMULATION TABLE :

Diclofenac sodium is the main active ingredient collects from pharmaceutics laboratory. all the reagent and materials were of analytical or pharmacopoeia grade. formulation of trandsdermal patch drug, blacking agent, solvent, plasticizer, polymer, penetration enhancer, stabilizer, and solvents are use.

Sr.no	Ingredients	F1	F2	F3
1	Diclofenac sodium (API)	10gm	10gm	10gm
2	HPMC polymer	25 mg	50 mg	100mg
3	Ethanol	10ml	10 ml	10ml
4	Glycerine	1ml	1ml	1ml

Table 1: Formulation Table of Diclofenac sodium TDDs in different ratio

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VI. METHOD OF PREPARATION

Buccal patches are novel drug delivery system they elegant and effective dosage form with improve bioavailability compare to other conventional dosage forms has it passes hepatic first pass metabolism is a most expetible and pelatible dosage form.

Diflofenac sodium which is used as a (API drug) active pharmaceutical drug and then HPMC (Hydroxypropyl methylcellulose) used as backing agent polymer , glycerine which used as plasticizer , ethanol which used as solvent in this solution.following steps will be follows for preparing the patch.

Now first we will take 10 ml of ethanol as solvent.

It transfer it into a beaker or it pour into a beaker then slowely API drug diclofenac sodium as 5gm quantity dissolved in ethanol at small quantity and still continuously until it dissolves.

Then drug it completely dissolved add 10 mg HPMC (Hydroxypropyl methylcellulose) polymer in same patch solution keep stiring until it dissolved in solution.

Then should add 1 ml of glycerine into same solution which used as plasticizer in this patch solution all procedure of patch solution is prepared or done then transfer this prepared patch solution into flate petri dish.

Spread it into uniformely have to allow the alcohol to evaporate at room temperature and keep it for drying envoting funnel over the petridish after 24 hour we can notice that patch is completely drying now it can take we see the buccal patch is formed and it is thin and which can be cut into diffetent shapes and dimentions and can be placed in the buccal mucosa for sustained drug delivery.

Diclofenac sodium patch are topical nonsteroidal anti inflammatory drug (NSAID) treatments used to relieve localized pain and inflammation.they are particulary effective for musculoskeletal conditions.

Mechanism of action of diclofenac sodium

Diclofenac inhibits cyclooxygenase (COX) enzymes (mainly COX-2),reducing the production of prostaglandins that cause pain inflammation.

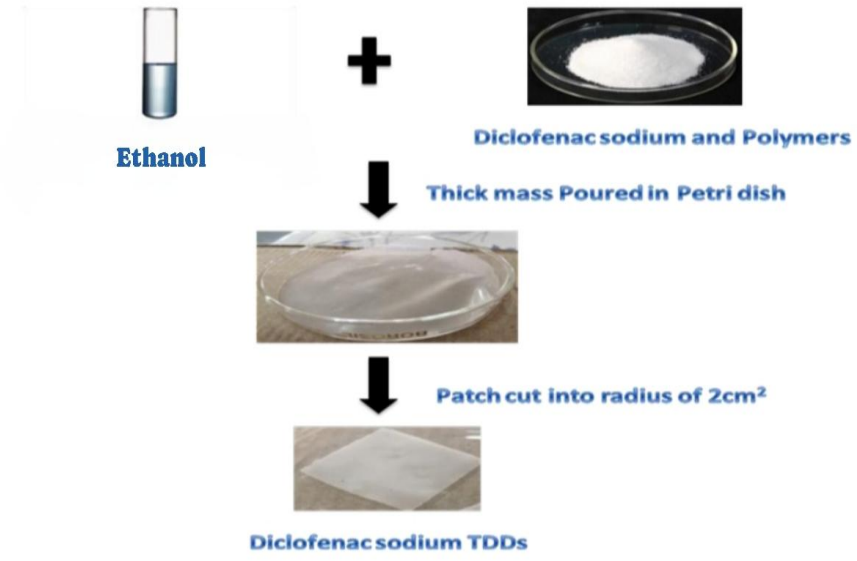

Fig.5 Method of preparation of diclofenac sodium TDDS

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VII. MARKETED PRODUCT OF TRANSDERMAL PATCH :

list of some well-known transdermal patch products that are marketed and approved in various regions (primarily the U.S. and EU). These patches deliver medications through the skin into the bloodstream:

Pain Relief

1. Duragesic® (fentanyl) – opioid pain reliever
2. Lidoderm® (lidocaine) – local anesthetic for postherpetic neuralgia
3. Salonpas® – over-the-counter (OTC) patches containing menthol, methyl salicylate, or lidocaine

Hormone Replacement Therapy (HRT)

1. Climara® / Vivelle-Dot® / Estraderm® – estradiol patches for menopause symptoms
2. CombiPatch® – combination of estradiol and norethindrone acetate
3. Androderm® – testosterone patch for male hypogonadism

Contraception

1. Xulane® / Twirla® – ethinyl estradiol and norelgestromin patch

Smoking Cessation

1. NicoDerm CQ® / Nicotinell® / Habitrol® – nicotine patches to help quit smoking

Neurological Disorders

1. Exelon® Patch – rivastigmine for Alzheimer's and Parkinson's dementia
2. Neupro® – rotigotine for Parkinson's disease and restless legs syndrome

Cardiovascular

1. Nitro-Dur® / Minitran® – nitroglycerin for angina
2. Catapres-TTS® – clonidine for hypertension

Brand Name	Drug	Manufacturer	Indications
Nicotine‖	Nicotine	Novartis	Pharmacological Smoking cessation
Matrifen	Fentanyl	Nycomed	Pain relief patch
Ortho EvraTM	Norelgostronin / Ethinyl Estradiol	ORTHO-McNEIL	Postmenstrual syndrome
NuPatch 100	Diclofenac diethylamine	Zydus Cadia	Anti Inflammation
Neupro	Rigotine	UCB and schwarrz pharma	Early stage idiopathic parkinsons diseases
Alora	Estradiol	TheraTech/protocol and Gamble	Postmenstrual syndrome
Nicoderm	Nicotine	Alza/GlaxoSmithKlie	Smoking cessation
Estraderm	Estradiol	Alza/Norvatis	Postmenstrual syndrome
Climara	Estradiol	3M pharmaceuticals/ Berlex labs	Postmenstrual syndrome
Androderm	Testosterone	TheraTech/GlaxoSmithkli ne	Hypogonadism in males
Nitrodisc	Nitroglycerine	Roberts pharmaceutics	Angina prctoris

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Transdermscop	Scopolamine	Alza/Norvatis	Motion sickness
Nuvelle TS	Estrogen/progesterone	Ethica Holdings/schering	Hormone replacement therapy

Table No 2 : Marketed product of Various Patch products

EVALUATION TEST AND CHARACTERIZATION OF MEDICATED PATCH :

The composition and concentration of the transdermal films has a considerable influence on the physical, mechanical properties as well as the permeability of the drugs. Physical and mechanical properties of blank and medicated transdermal films such as thickness uniformity, percent flatness, moisture uptake, drug content, shear adhesion test, peel adhesion test, water vapour transmission studies, stability studies tensile strength and percent elongation at break and modules of elasticity were studied. also medicated films were evaluated for area, drug content and in-vitro drug release.

Physical Appearance :

The general appearance of TDDs its visual identity and all over elegance - shape, colour, surface textures. These all parameters are essential for consumer acceptance.

Thickness Of The Patch :

The thickness of the drug loaded patch is measured in different points by using a digital micrometer and the average thickness and standard deviation is determined to ensure the thickness of the prepared patch. The thickness of transdermal film is determined by travelling microscope dial gauge, screw gauge or micrometer at different points of the film.

Weight Uniformity Test :

The prepared patches are dried at 60°c for 4hrs before testing. A specified area of patch is to be cut in different parts of the patch and weigh in digital balance. The average weight and standard deviation values are to be calculated from the individual weights.

Folding Endurance :

A strip of specific area is to be cut evenly and repeatedly folded at the same place till it breaks. The number of times the film could be folded at the same place without breaking gives the value of the folding endurance.

Percentage Moisture Content :

The prepared films are to be weighed individually and to be kept in a desiccators containing fused calcium chloride at room temperature for 24 hrs. After 24 hrs the films are to be reweighed and determine the percentage moisture content from the below mentioned formula.

$$\% \text{ Moisture Uptake} = \frac{\text{Final Weight} - \text{Initial Weight}}{\text{Final Weight}} \times 100$$

Drug content :

An accurately weighed portion of film (about 100 mg) is dissolved in 100 ml of suitable solvent in which drug is soluble and then the solution is shaken continuously for 24 hours shaken manually. Then the whole solution is sonicated. after sonication and subsequent filtration, drug in solution by appropriate dilution is estimated spectrophotometrically.

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Stability Studies

Stability studies are to be conducted according to the ICH guidelines by storing the TDDS samples at 40±0.5°c and 75±5% RH for 6 months. The samples are withdrawn at 0, 30, 60, 90 and 180 days and analyze suitably for the drug content.

In-vitro drug diffusion studies

These studies are performed using a modified Franz diffusion cell with a receptor compartment capacity of 50 ml. The synthetic cellophane membrane was mounted between the donor and receptor compartment of the diffusion cell. The formulated patches were cut into size of 1 cm2 and placed over an adhesive tap and fixed to the cellophane membrane and attached to glass tube by the aid of rubber bands. The drug releasing membrane and the receptor compartment of the diffusion cell were filled with phosphate buffer pH 7.4. The temperature was maintained at 32ºC.

In-vitro drug dissolution study

The paddle method (USP apparatus I) can be employed for the assessment of the release of drug from the prepared patches. Dry films of known thickness is to be cut into definite weighed and fixed over a glass plate with an adhesive. The glass plate was then placed in a 500 ml dissolution medium or phosphate buffer (pH7.4) and the apparatus was calibrated to 32.50c±20c. The paddle was then set at distance of 2.5cm from the glass plate and operated at a speed of 50 rpm. Samples (5ml aliquots) can be withdrawn at appropriate time intervals up to12 hours and analyzed by UV spectrophotometer. The experiment is to be performed in triplicate and mean value calculated.

IX. RESULT AND CONCLUSION

Standard graph of Diclofenac sodium :

The lambda max of the Diclofenac sodium was found to be 320nm. After the determination of lambda max the calibration curve and absorption are to be evaluated by the UV spectroscopy. The result of the absorption and concentration was given below in the are help to explain the standard graph of diclofenac sodium.

Sr.no	Concentration(µg/ml)	Absorption
1)	2	0.160
2)	4	0.310
3)	6	0.463
4)	8	0.623
5)	10	0.790
6)	12	0.925

Table 3 : Concentration and Absorption of Diclofenac sodium.

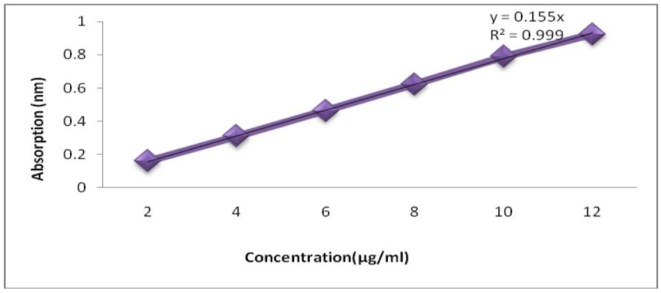

Fig. 6: Standard graph of Diclofenac sodium.

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Physical appearance

The physical appearance test of the transdermal patch is done by observing it through sensory organ and following observation is made.The patches were visually inspected for colour, clarity, flexibility, thickness and smoothness.

The physical appearance test of the transdermal patch is done by observing it through sensory organ and following observation is made. Table 2 help to explain the physical appearance and (Figure 4) show the transdermal patch and (Figure 5) Transdermal patch cut in 2cm2 radius.

SL.NO	PATCH CODE	COLOUR	CLARITY	FLEXIBILITY	SMOOTHNESS
1)	F1	Colourless	Clear	Flexible	Smooth
2)	F2	Colourless	Clear	Flexible	Smooth
3)	F3	colourless	Clear	Flexible	Smooth

Table 4: Physical Appearance of Patches.

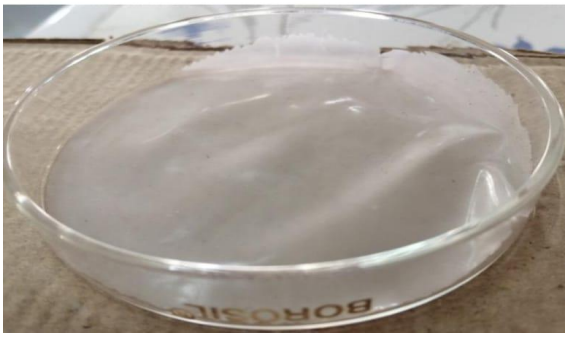

Fig. 7: Transdermal patch.

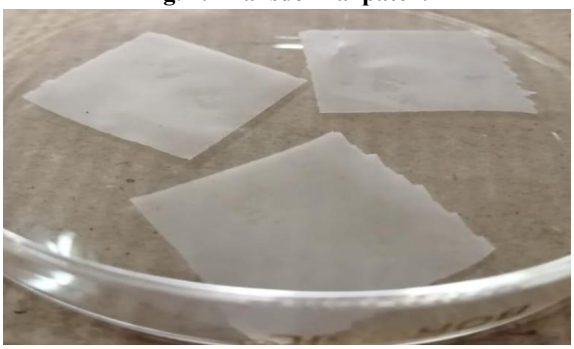

Fig. 8 : Transdermal patch cut in 2cm2 radiuses.

3) Thickness of the patch : The thickness of the prepared TDDs are measured by vernier caliper was given in the Table 6

The thickness of the prepared TDDs are measured by vernier caliper was given in the

Sr.No	Sample	Thickness (mm)
1)	F1	0.235
2)	F2	0.250
3)	F3	0.242

Table 5 : Thickness of Samples of Diclofenac sodium Patch

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Weight Uniformity Test : The weight variation of the samples is given below in the Table 7

Sr.No	Sample	Wt.Variation (mg)
1)	F1	550
2)	F2	562
3)	F3	560

Table 6 : Weight uniformity test of Diclofenac sodium Patch

Folding Endurance : The folding endurance of the samples are given below in the Table 8

Sr.No	Sample	Folding Endurance
1)	F1	26
2)	F2	30
3)	F3	27

Table 7 : Folding endurance of Diclofenac sodium Patch

Percentages Moisture Content : The Percentage moisture content of the samples are given below in the Table 9

Sr.No	sample	% of moisture content
1)	F1	4.2%
2)	F2	3.57%
3)	F3	4.11%

Table 8 : Percentage moisture content of Diclofenac sodium Patch

Content Uniformity Test : The Content uniformity of the samples are given below in the Table 10

Sr.No	Sample	Content Uniformity
1)	F1	99%
2)	F2	100%
3)	F3	97%

Table 9 : Content uniformity of Diclofenac sodium Patch

Moisture Uptake : The Moisture uptake of the samples is given below in the Table 8

Sr.No	Sample	Moisture uptake
1)	F1	7.94 %
2)	F2	12.5%
3)	F3	13.4%

Table 10 : Moisture uptake of Diclofenac sodium Patch

Drug Content Test : The Drug content of the samples are given below in the Table 12

Sr.No	Sample	Drug content
1)	F1	80%
2)	F2	95%
3)	F3	91%

Table 11 : Drug content of Diclofenac sodium Patch

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Stability Studies : The Stability of the samples are given below in the Table 13- 14 at different temperature.

Sr.No	Sample	Temperature		
		2-4 c	20-25 c	35-40 c
1)	F1	Stable	Stable	Stable
2)	F2	Stable	Stable	Stable
3)	F3	Stable	UnStable	UnStable

Table 12 : Stability data after 7 days

Sr.No	Sample	Temperature		
		2-4 c	20-25 c	35-40 c
1)	F1	Stable	Stable	UnStable
2)	F2	Stable	Stable	Stable
3)	F3	Stable	UnStable	UnStable

Table 13 : Stability data after 14 days

Sr.No	Sample	Temperature		
		2-4 c	20-25 c	35-40c
1)	F1	Stable	Stable	UnStable
2)	F2	Stable	Stable	Stable
3)	F3	Stable	Stable	Stable

Table 14 : Stability data after 21 days

Sr.No	Sample	Temperature		
		2-4c	20-25c	35-40c
1)	F1	Stable	Stable	Stable
2)	F2	Stable	Stable	UnStable
3)	F3	Stable	UnStable	UnStable

Table 15 : Stability data after 28 days

X. CONCLUSION

Transdermal application of Diclofenac sodium for rheumatoid arthritis use was successfully prepared with different polymers by solvent evaporation method. The present work was helped in understanding the effect of formulation process variables especially the concentration of different polymers on the drug release profile. This work is further aimed to perform in Vivo studies for rheumatoid arthritis the concentration of Diclofenac sodium reaching into the skin and to study its effect, which will help to avoid the first pass metabolism and to make novel transdermal dosage form for the treatment of Joint pain.

The important criterion for selection of components for TDDs formulation is their compatibility with other component. It has been demonstrated that only few excipients combinations lead to effective TDDs formulations. Diclofenac sodium was selected as absorbent for the development of the TDDs because it is known to treat the symptoms related with rheumatoid arthritis.

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REFERENCES

[1]. Yairi MB, inventor; Los Gatos Research Inc, assignee. Transdermal patch system. United States patent application US 12/100,250. 2009 Oct 15.

[2]. Jadhav RT, Kasture PV, Gattani SG, Surana SJ. Formulation and evaluation of transdermal films of diclofenac sodium. International Journal of Pharm Tech Research. 2009 Oct;1(4):1507-11.

[3]. Sahu P, Mishra S, Sahu GK, Sharma H, Kaur CD. Formulation and Characterization of Resorcinol Gel. Research Journal of Pharmaceutical Dosage Forms and Technology. 2019;11(3):159-63.

[4]. Sahu P, Mishra S, Sahu GK, Sharma H, Kaur CD. Formulation and Characterization of Resorcinol Gel. Research Journal of Pharmaceutical Dosage Forms and Technology. 2019;11(3):159-63.

[5]. Tripathi S, Meshram J, Kumari R, Tripathi DK, Alexander A, Sharma H, Sahu GK. Formulation and characterization of Virgin Coconut Oil Emulsion (VCOE) for treatment of Alzheimer's disease. Research Journal of Pharmaceutical Dosage Forms and Technology. 2018;10(2):49-54.

[6]. Vary Jr JC. Selected disorders of skin appendages--acne, alopecia, hyperhidrosis. The Medical Clinics of North America. 2016 Jan 19;99(6):1195-211.

[7]. Bhate K, Williams HC. Review article on the epidemiology of acne vulgaris: The British Journal of Dermatology. Published on March 2013: 168 (3): 474 85. doi:10.1111/bjd.12149. PMID 23210645.

[8]. Tilles G. Acne pathogenesis: history of concepts. Dermatology. 2014;229(1):1 46.

[9]. Gupta SS, Sahu G, Sharma M, Chandrakar S, Sahu VD, Sharma G, Dewangan K, Solanki H, Majumdar M, Tripathi DK, Alexander A. Preparation and Optimization of floating microbeads of ciprofloxacin HCl. Research Journal of Pharmacy and Technology. 2016;9(7):848-52.

[10]. Dapurkar KV, Sahu KG, Sharma H, Meshram S, Rai G. Anti-arthritic activity of roots extract of Boerhaavia Diffusa in adjuvant induced arthritis rats. Sch Acad J Pharm. 2013;2(2):107-9.

[11]. Tripathi J, Thapa P, Maharjan R, Jeong SH. Current state and future perspectives on gastroretentive drug delivery systems. Pharmaceutics. 2019 Apr;11(4):193.

[12]. Sahu P, Mishra S, Sahu GK, Sharma H, Kaur CD. Formulation and Characterization of Resorcinol Gel. Research Journal of Pharmaceutical Dosage Forms and Technology. 2019;11(3):159-63.

[13]. Powell JH. Beyond the Affordable Care Act: A Physicians' Proposal for Single Payer Health Care Reform.

[14]. Broven J. Rhythm and blues in New Orleans. Pelican Publishing Company, Inc.; 2016.

[15]. Wahane AR, Karankal S, Sharma P, Khutel D, Singh O, Shardul V, Sabha N, Dewangan J, Dewangan A, Jangde A, Rani C. Pharmaceutical Aspects on the Formulations of Hydrogel: An Update. Research Journal of Pharmaceutical Dosage Forms and Technology. 2018;10(2):79-84.

[16]. Sahu P, Mishra S, Sahu GK, Sharma H, Kaur CD. Formulation and Characterization of Resorcinol Gel. Research Journal of Pharmaceutical Dosage Forms and Technology. 2019;11(3):159-63.

[17]. Sharma H, Sahu U, Kumar G, Kaur CD. A Spectrum of Skin Cancer in Kashmir Valley of India: Kangri Cancer. Journal of Atoms and Molecules. 2019;9(1):1196 205.

[18]. Tripathi S, Meshram J, Kumari R, Tripathi DK, Alexander A, Sharma H, Sahu GK. Formulation and characterization of Virgin Coconut Oil Emulsion (VCOE) for treatment of Alzheimer's disease. Research Journal of Pharmaceutical Dosage Forms and Technology. 2018;10(2):49-54.

[19]. Vary Jr JC. Selected disorders of skin appendages--acne, alopecia, hyperhidrosis. The Medical Clinics of North America. 2016 Jan 19;99(6):1195-211.

[20]. Bhate K, Williams HC. Epidemiology of acne vulgaris. British Journal of Dermatology. 2013 Mar;168(3):474-85.

[21]. Tilles G. Acne pathogenesis: history of concepts. Dermatology. 2014;229(1):1-46.

[22]. Gupta SS, Sahu G, Sharma M, Chandrakar S, Sahu VD, Sharma G, Dewangan K, Solanki H, Majumdar M, Tripathi DK, Alexander A. Preparation and Optimization of floating microbeads of ciprofloxacin HCl. Research Journal of Pharmacy and Technology. 2016;9(7):848-52.

[23]. Sahu P, Mishra S, Sahu GK, Sharma H, Kaur CD. Formulation and Characterization of Resorcinol Peel. Research Journal of Pharmaceutical Dosage Forms and Technology. 2019;11(3):159-63.

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[24]. Dapurkar KV, Sahu KG, Sharma H, Meshram S, Rai G. Anti-arthritic activity of roots extract of Boerhaavia Diffusa in adjuvant induced arthritis rats. Sch Acad J Pharm. 2013;2(2):107-9

[25]. Banga A, Unal R, Tripathi P, Pokrovskaya I, Owens RJ, Kern PA, Ranganathan G. Adiponectin translation is increased by the PPARγ agonists pioglitazone and ω-3 fatty acids. American Journal of Physiology-Endocrinology and Metabolism. 2009 Mar;296(3):E480-9.

[26]. Duggirala HJ, Tonning JM, Smith E, Bright RA, Baker JD, Ball R, Bell C, Bright Ponte SJ, Botsis T, Bouri K, Boyer M. Use of data mining at the Food and Drug Administration. Journal of the American Medical Informatics Association. 2016 Mar 1;23(2):428-34.

[27]. Powell JH. Beyond the Affordable Care Act: A Physicians' Proposal for Single Payer Health Care Reform.

[28]. Sahu P, Mishra S, Sahu GK, Sharma H, Kaur CD. Formulation and Characterization of Resorcinol Gel. Research Journal of Pharmaceutical Dosage Forms and Technology. 2019;11(3):159-63.

[29]. Baichwal MR. Polymer films as drug delivery systems, Advances in drug delivery systems, MSR Foundation, 1985; 136-147.

[30]. Baichwal MR. polymer films as drug delivery system, advances in drug delivery systems. Bombay, MSR Foundation, 1985; 136-147.

[31]. Benson Heather AE Transdermal Drug Delivery: penetration Enhancement Techniques Current Drug Delivery, 2005; 2: 23-33.

[32]. British Pharmacopoeia Vol-II, Her majestry"s stationary office, London, 2001; A-169.

[33]. Chein YW Transdermal therapeutic system .In: Robinson, JR, Lee VHL., eds. Controlled Drug Delivery Fundamentals and applications 2nd ed. New York: Marcel Dekker, Inc, 1987; 524-552.

[34]. Chetana Modi, Effect of components (polymer, plasticizer, solvent) as a variable in fabrication of diclofenac transdermal patch, J Pharm Bioallied Sci, 2012 Mar; 4(Suppl 1): S57–S59.

[35]. Dorle AK, Satturwar PM, Fulzele SV, "Evaluation of Polymerized Rosin for the Formulation and Development of Transdermal Drug Delivery System" A Technical Note; Pharm Sci Tech, 2005; 6(4): 649-654.

[36]. Garala KC, Shinde AJ, Shah PH formulation and invitro characterization of monolithic matrix Transdermal systems using HPMC/eudragit s 100polymer blends, international Journal of pharmacy and Pharmaceutical science, 2009; 108-115.

[37]. Shankar M.S. et al., Design and Evaluation of matrix-type transdermal patches containing Aceclofenac, International Journal of Advances in Pharmaceutical sciences, 2010; 1: 201-211.

[38]. Heather AE Benson Transdermal Drug Delivery: Penetration Enhancement Techniques Current Drug Delivery, 2005; 2: 23-33.

[39]. Jain NK, 1st edition, 1997. Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, 89-90.12. K.D .Tripathy, Essentials of pharmacology. 4th edition, 462-466.

[40]. Kapoor D, Patel M, Singhal M, "Innovations in Transdermal Drug Delivery System I" Int pharm sci, Jan-March 2011; 1(1): 54-61. 14. Keith AD. Polymer matrix consideration for transdermal devices, Drug Dev. Ind. Pharm, 1983; 9: 605-621.

[41]. Zhonggui He et al., preparation and Evaluation of monolithic drug-in-adhesive type patches of diclofenac diethanolamine (DFD) containing penetration enhancers, International journal of Current Pharmaceutical Research, 2013; 3(2): 97-106.

[42]. Knutson K, Krill SL, Lambert WJ, Higuchi WI, Physicochemical aspects of transdermal permeation, J. Control. Release, 1987; 6: 59-74.

[43]. Kumar A, pullakandam N, prabu S, Gopal V, "Transdermal Drug Delivery System: An Overview" Int J. Pharm Sci Rev Res, July- August 2010; 3(2): 49-54.

[44]. Liu Y, Fang L, Zheng H, Zheo L, Ge X, He Z Development and in vitro evaluation of a topical use patch containing Diclofenac diethanolamine salt. Asian Journal of Pharmaceutical Sciences, 2007; 106-113.

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Impact Factor: 7.67

[45]. M S Ahmed, M G Mamdough, G S Shadeed, & A M Emam., Formulation and evaluation of different transdermal drug delivery systems of Ketoprfen, Int J Pharm Pharm Sci, 5, Suppl 2: 600-607.

[46]. Mallikarjuna Setty et al., Development and evaluvation of ethylcellulose transdermal patches for diclofenac diethylamine (DDA) using chemical penetration enhancers, Acta pharma, 2007; 57: 151-159.

[47]. Matrindale, "The complete Drug Reference" Pharmaceutical Press, London, 2006; 1: 1575-1579.

[48]. Murthy SN, Shobha R, Hiremath, Paranjothy KLK. „Evaluation of carboxymethyl guar films for the formulation of transdermal therapeutic systems" Int J. Pharm, 2004; (272): 11–18.

[49]. Nokhodchi A, Nazemiyeh H, Ghafourian T, Hassan-Zadeh D, Valizadeh H, Bahary LAS, The effect of glycyrrhizin on the release rate and skin penetration of diclofenac sodium from topical formulations, Farmaco, 2002; 57(11): 883-888.

[50]. P. Ravikumar Reddy, Rajashekar S. B, Karthik U. S. "Comparing the Effectiveness of Transdermal Diclofenac Patch and Inramuscular Diclofenac Injecton in Postoperative Pain Relief after Inguinal Hernia Mesh Repair: A Randomised Study in the Department of General Surgery". Journal of Evidence based Medicine and Healthcare; Volume 2, Issue 34, August 24, 2015; Page: 5286-5292, DOI: 10.18410/jebmh/2015/736

[51]. 25. Panchagnula R. Transdermal delivery of drugs. Indian journal of pharmacology, 1997; 29: 140-156. 26. Paola B, Eleonora A, Luisa V, Stefano A, Adriana M, Diclofenac sodium multisource prolonged release tablets- a comparative study on the dissolution profiles, J. Pharm. Biomed. Anal, 2005; 37: 679-685.