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DESIGN, FORMULATION AND EVALUATION OF TRANSDERMAL PATCH OF ASPIRIN

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ABSTRACT

The present study focuses on the design, formulation, and evaluation of a transdermal patch containing aspirin, The aimed of this work to enhancing patient compliance, reducing gastrointestinal side effects, and providing sustained drug release. Aspirin, widely used for its analgesic, anti-inflammatory, and antiplatelet properties, typically suffers from low oral bioavailability and gastrointestinal irritation when administered orally. To address these issues, transdermal patches were formulated using the solvent evaporation technique, employing polymers such as HPMC and Guar gum, with methanol as the solvent and glycerine and Tween 80 as plasticizer and permeation enhancer, respectively. The prepared patches were evaluated for physical characteristics, drug content, pH, and uniformity. After this formulation and Evaluations, we are look that the patches were uniform, stable, and released the drug effectively over a 24-hour period. The study concludes that transdermal delivery of aspirin offers a promising alternative to oral administration, ensuring improved bioavailability and patient tolerance.

KEYWORDS: TDDS, NDDS, Patch, Aspirin, Analgesic and Anti-Inflammatory.

1. INTRODUCTION

Transdermal patch is a medicated adhesive patch that placed on the skin to deliver a specific dose of medication through the skin and into the bloodstream. 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.

The transdermal drug delivery system (TDDS) is a widely accepted mode of drug delivery, and transdermal patches are devised to treat various diseases. Transdermal delivery leads to over-injectable and oral routes by increasing patient compliance and avoiding the first pass metabolism, respectively. They can even prevent drug-related gastrointestinal problems and low absorption. The goal of the transdermal drug delivery system is to maximize the skin flux into systemic circulation while reducing the retention and metabolism of the drug in the skin at the same time. These therapeutic benefits reflect the higher marketing potential of TDDS.[1]

In the recent few years, a research interest has been evolved to design a wide variety of novel drug delivery systems (NDDS) using the existing drug molecules.. There are several advantages of TDDS like controlled release of the drug, steady blood-level profile, minimized systemic side effects, bypassing first-pass hepatic metabolism, self-administration, enhanced patient compliance, improved efficacy over any other conventional dosage forms. Transdermal system has been designed for delivering an effective amount of drug across the intact skin to accomplish both the local and systemic effects. Pain, hypertension, motion sickness, angina, nicotine addiction are the diseases which can be treated by the aid of transdermal delivery of drugs.[2]

Transdermal polymeric patches are low-cost systems used to treat numerous non communicable diseases (e.g., non-infectious and non-transmissible pathologies). For example, nicotine and anticholinergic transdermal patches are now on the World Health Organization's (WHO) model list as necessary medicines for a basic care health system.[3]

The drug is carried through the skin into the bloodstream and circulates systemically in the body before reaching the target site. The transdermal drug delivery method has several advantages over other routes of administration.[4]

Fig. 1: Transdermal patch.

The first Transdermal system, Transderm-SCOP was approved by FDA in 1979 for the prevention of nausea and vomiting associated with travel, particularly by sea. The evidence of percutaneous drug absorption may be found through measurable blood levels of the drug, detectable excretion of the drug and its metabolites in the urine and through the clinical response of the patient to the administered drug therapy.[5]

1.1 TYPES OF TRANSDERMAL PATCHES

- **Single layer drug in adhesive:** In this type the adhesive layer contains the drug. The adhesive layer not only serves to adhere the various layers together and also responsible for the releasing the drug to the skin. The adhesive layer is surrounded by a temporary liner and a backing.

- **Multi -layer drug in adhesive:** This type is also similar to the single layer but it contains a immediate drug release layer and other layer will be a controlled release along with the adhesive layer. The adhesive layer is responsible for the releasing of the drug. This patch also has a temporary liner-layer and a permanent backing.

- **Reservoir system:** In this system the drug reservoir is embedded between an impervious backing layer and a rate controlling membrane. The drug releases only through the rate controlling membrane, which can be micro porous or non porous. In the drug reservoir compartment, the drug can be in the form of a solution, suspension, gel or dispersed in a solid polymer matrix. Hypoallergenic adhesive polymer can be applied as outer surface polymeric membrane which is compatible with drug.

- **Matrix system**

- ✓ **Drug-in-adhesive system:** In this type the drug reservoir is formed by dispersing the drug in an adhesive polymer and then spreading the medicated adhesive polymer by solvent casting or melting (in the case of hot-melt adhesives) on an impervious backing layer. On top of the reservoir, unmediated adhesive polymer layers are applied for protection purpose.

- ✓ **Matrix-dispersion system:** In this type the drug is dispersed homogenously in a hydrophilic or lipophilic polymer matrix. This drug containing polymer disk is fixed on to an occlusive base plate in a compartment fabricated from a drug impermeable backing

layer. Instead of applying the adhesive on the face of the drug reservoir, it is spread along with the circumference to form a strip of adhesive rim.[6]

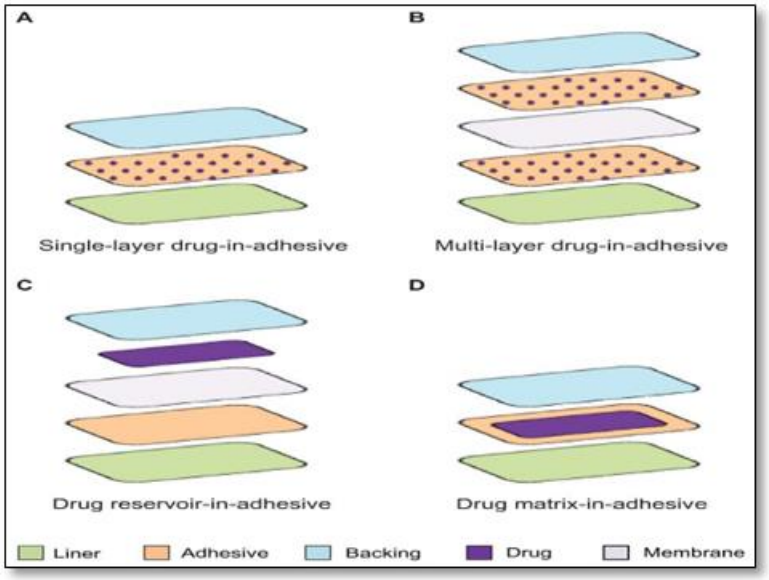

Fig. 2: Types of transdermal patch.

1.2 ASPIRIN

Aspirin is one of the most frequently used and cheapest drugs in medicine. It belongs to the non-steroidal anti-inflammatory drugs with a wide range of pharmacological activities, including analgesic, antipyretic, and antiplatelet properties. Aspirin in low doses is the single most cost-effective medicine for the prevention of secondary events of thrombosis.

Aspirin is known to act by inhibiting platelet aggregation in acute arterial thrombosis, an underlying pathologic process in myocardial infarction and stroke.

Aspirin is polar at physiological pH and it is rapidly hydrolyzed to salicylic acid in the skin, which is rich in enzymes, like esterases. A 1993 study showed that aspirin in monohydroxy alcohols applied directly to the skin surface, selectively inhibited the activity of cyclooxygenase in platelets. However, a large dose (750mg) of aspirin was required, which necessitated a large volume applied over a wide area. Aspirin in a transdermal patch (surface area of 50 cm2) at a lower dose (84 mg and 120 mg) without and with 12% limonene as penetration enhancer respectively, was also found to induce marked suppression of platelet cyclo-oxygenase, though the bioavailability of aspirin applied to the skin was only 20%.[7,8,9,10]

These formulations were recognized for their antipyretic, analgesic and anti-inflammatory properties, but were also found to have gastrointestinal side effects. The modern form, aspirin or acetylsalicylic acid, is the acetylated version of the natural product and was developed with the aim of improving the tolerability of the drug. Aspirin was suggested as a first-line antiplatelet medication in all acute diseases that might result from platelet dependent thrombotic blockade. The primary antithrombotic effect of aspirin is achieved by the persistent acetylation of a specific serine amino acid residue, which inhibits Prostaglandin H synthase (cyclooxygenase); the enzyme that trigger platelet aggregation.[11,12,13]

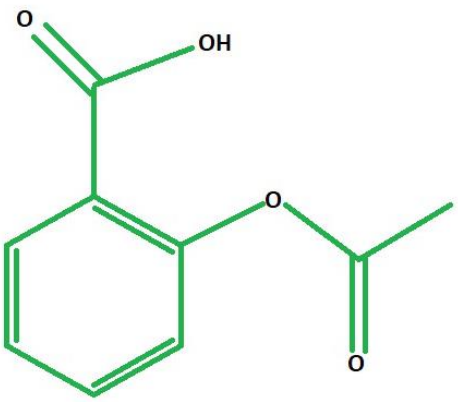

Fig. 3: Structure of Aspirin.

Aspirin is acetyl derivative of salicylic acid these are Colourless to white crystalline solid.[12]

Table No. 1: Physical properties of Atorvastatin Calcium.

Synonyms	✓ 2-Acetoxybenzenecarboxylic acid. ✓ 2-Acetoxybenzoic acid. ✓ 2-Carboxyphenyl acetate. ✓ A.S.A. ✓ ASA. ✓ Acetilsalicilico. ✓ Acetilum acidulatum. ✓ Acetosalic acid. ✓ Acetosalicylic Acid
IUPAC Name	2-Acetoxybenzoic acid
Appearance	White colourless crystalline powder
Molecular Formula	$C_9H_8O_4$
Molecular Weight	180.16g/mol
Melting Point	136 °C
Boiling Point	140°C
Solubility	Freely Soluble: Ethanol Slightly Soluble: Water

1. 3 THE SKIN

The skin is largest organ in the body. It protects against the influx of toxins and the efflux of water and it is largely impermeable to the penetration of foreign molecules. Skin serves as the point of administration for systemically active drugs. The topically applied drug will first be absorbed into the systemic circulation and then transported to target tissues. There are three layers that make up skin. Epidermis, dermis and subcutaneous tissue. The epidermis, in particular the stratum corneum is the major barrier to drug absorption. With respect to drug delivery, molecules must penetrate the stratum corneum, the viable epidermis, the papillary dermis and the capillary walls into the blood stream or lymph channels, whereupon they are removed from the skin by flow of blood or lymph.

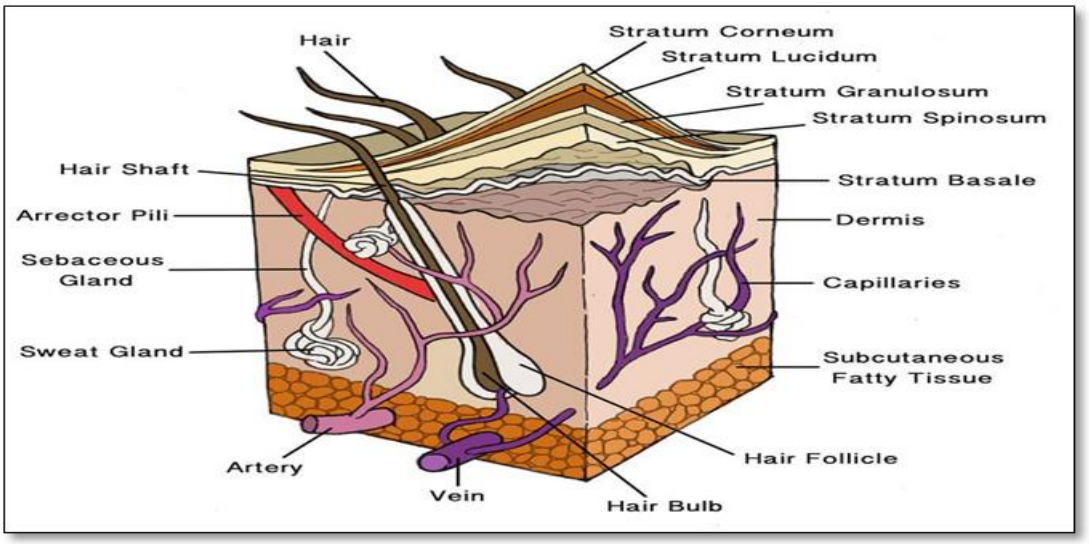

Fig. 4: Structure of skin.

- **Routes of penetration**

The following routes are observed in transportation of the drug through the skin barrier:

- Across the intact horny layer.
- Through the hair follicles with the associated sebaceous glands, or
- Via the sweat glands.[13, 14]

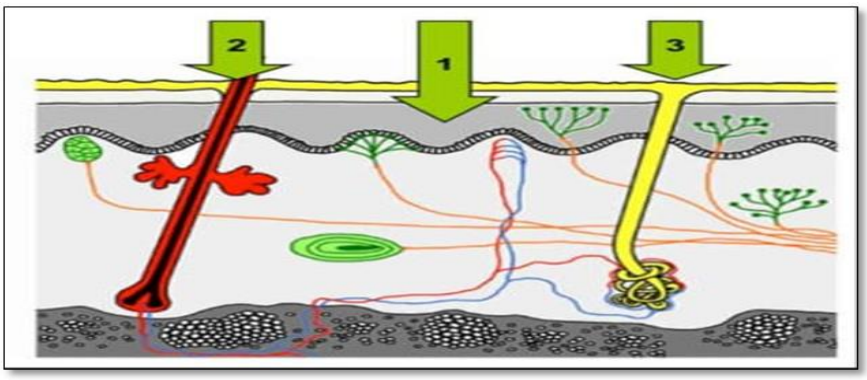

Fig. 5: Possible routes of penetration.

1. METHOD AND MATERIAL

In this Research work, all the reagents and excipients were used have analytical grade. Aspirin purchased from Yarrow chem pvt. Ltd. Excipients such as HPMC, Guar Gum, Methanol, Methanol and Glycerine from Loba Chemie Mumbai.

➢ Method

The active ingredient and other excipients were accurately weighed according to the formulations (Table 1). The patches were developed by solvent casting evaporation technique. HPMC and Gaur gum were used. Polymers were added in 30ml volume of solvent Methanol. Stir the solution for about 10 min until it forms clear solution. Weight amount of Glycerine and Tween 80 was added to above solution.13mg of drug (Aspirin) was mixed thoroughly by the use of magnetic stirrer for few minutes. The uniform solution was formed which was poured into petri plate and placed inverted funnel which will help to control the evaporation of solvent and will avoid the cracking of patches. This was kept aside for overnight. Dried patches were separated from the plate, cut and stored in desiccator.

Table no. 2: Composition of Transdermal Patch of Aspirin.

S. No	Name of ingredient	Category	Quantity
1.	Aspirin	API	13 mg
2.	HPMC	Polymer	150 mg
3.	Gaur gum	Polymer	200 mg
4.	Methanol	Solvent	2.5 ml
5.	Tween 80	Enhance Permeation	0.1 ml
6.	Glycerine	Plasticizer	0.8 ml

Fig. 06: Prepared Transdermal Patch of Aspirin.

2. EVALUATION PARAMETER

- **Physical appearance:** Physical parameters like colour and odour were checked visually.

- **Thickness:** The thickness of the drug loaded patch is measured in different points by using a digital micrometre and determines the average thickness and standard deviation for the same to ensure the thickness of the prepared patch.

- **Weight uniformity:** The prepared patches are to be 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.

- **pH:** Use a pH meter, placing the electrode on the swollen surface of the patch after it has been allowed to soak in a buffer solution.

- **Drug content uniformity:** A specified area of patch is to be dissolved in a suitable solvent in specific volume. Then the solution is to be filtered through a filter medium and analyse the drug contain with the suitable method (UV technique). Each value represents average of three different samples.

3. RESULT AND DISCUSSION

Table no. 3: Evaluation result of Transdermal Patch of Aspirin.

S.No.	Formulation Parameter	Results
1	Physical state	Solid
2	Colour	Off white
3	Odour	Odourless
4	Thickness	0.22± 0.01mm
5	Weight uniformity	±5%
6	Drug content uniformity	98.5%±1.2%
7	pH	6.2± 0.1

4. SUMMARY AND CONCLUSION

Aspirin-loaded transdermal patches were successfully formulated by solvent evaporation technique and this are providing sustained drug release and improved patient compliance. The patches showed good physical properties, effective drug release over 24 hours, enhanced skin permeation, and no skin irritation. Overall, they offer a promising alternative to oral aspirin therapy.

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