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A SYSTEMATIC REVIEW ON EMULGEL

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ABSTRACT: A topical drug delivery system involves applying medication to the skin for therapeutic effects or to treat skin disorders. Traditional gels often struggle to deliver hydrophobic drugs effectively, a challenge that can be overcome with emulgels. Emulgels, which combine emulsions and gels, create a dual-release control system that enhances medication efficacy. This innovation is essential in topical delivery systems, significantly improving bioavailability and patient compliance. Emulgel are widely utilized in numerous cosmetic products and for medical applications such as analgesic, antifungals, anti- inflammatory and anti-acne therapies. These topical administration systems have the major benefit of being able to avoid first-pass metabolism, which increases the active compounds' bioavailability. Emulgels are non-greasy, thixotropic, and easily spreadable, having beneficial qualities for dermatological uses. They also have a longer shelf life because they are water-soluble, emollient and simple to remove. Emulgels are a noteworthy advancement in the field of topical drug administration because of their translucent and visually pleasant look, which also improve user experience. It is a very productive area of research and its prologue in human thereby has provided triumph outcomes in modifying the clinical and therapeutic effectiveness of drugs having less bioavailability.

INTRODUCTION: Topical systems for delivering drugs, which include creams, lotions, gels, foams, etc, are utilized to apply drugs directly to the skin or the inner lining of some organs and body cavities called the mucosal lining. With the ability to treat patients locally, this strategy considers confined treatment, upgrading the viability of formulation while limiting fundamental incidental effects, increasing patient compliance and maximizing the therapeutic value of the treatment. The fundamental objective of this system is to facilitate the systemic circulation of hydrophobic drugs by enabling their absorption through the skin [1].

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By employing novel drug delivery system because the effective delivery of hydrophobic chemicals is frequently a challenge for conventional techniques [2]. Formulations are meticulously prepared by combining active pharmaceutical ingredients with various excipients to optimize drug delivery. Skin disorders are prevalent worldwide, affecting people in all regions, not just tropical areas. These conditions encompass a wide range of issues that can alter the skin's appearance, behavior and functions.

Skin diseases vary in severity from mild to severe and can affect individuals of any age. Common skin disorders include acne, eczema, psoriasis, dermatitis and fungal infections [3]. Topical medications are frequently used to treat various skin conditions. Topical corticosteroids i.e. antibiotics, antifungals and antipruritics are common topical medications for various skin conditions. These administration techniques are crucial for enhancing drug absorption through the

skin, resulting in either localized effects at the application site or systemic therapeutic benefit throughout the body. With a focus on optimizing drug delivery efficiency and efficacy, research in this field explores innovative formulations, advanced techniques and novel drug carriers to enhance therapeutic outcomes and overcome clinical challenges, thus contributing significantly improving the bioavailability of existing drugs [4]. There are various advantages and limitations of topical drug delivery system some are given below:

Advantages of Topical Drug Delivery System:

- Avoids the pre-systemic metabolism that occurs when a medication is taken orally.
- User-friendly, efficient and designed with the end-user's comfort and ease in mind.
- Termination of medications is easy when needed.
- Drug is delivered selectively to a specific site.
- Avoids drug fluctuation in the plasma [5].

Limitations of Topical Drug Delivery System:

- High molecular weight and non-lipid-soluble drugs having trouble in penetrating the skin and mucous membranes, which reduces their potency when applied topically and impedes therapeutic absorption.
- Application site may experience localized skin irritation.
- Contact dermatitis may arise as a result due to some medications or excipients.
- This approach is limited to usage with medications that need low plasma concentrations [6].

Topical formulations need to ensure optimal drug penetration into the skin, which has a pH of 5.5. This can result in a change in the formulation's pH upon application [7]. This method produces pharmacological effects either on the skin's surface or within deeper layers, allowing for targeted treatment and enhanced therapeutic outcomes [8]. An overview of skin physiology and drug delivery through the skin is provided below:

Skin: Skin is the major structural component in the human body, comprising nearly 15% of an adult's total body weight [9]. This highlights its extensive surface area and vital role in protecting internal organs, regulating temperature and sensing the environment. This extensive coverage plays crucial role in protection, regulation and sensation [10].

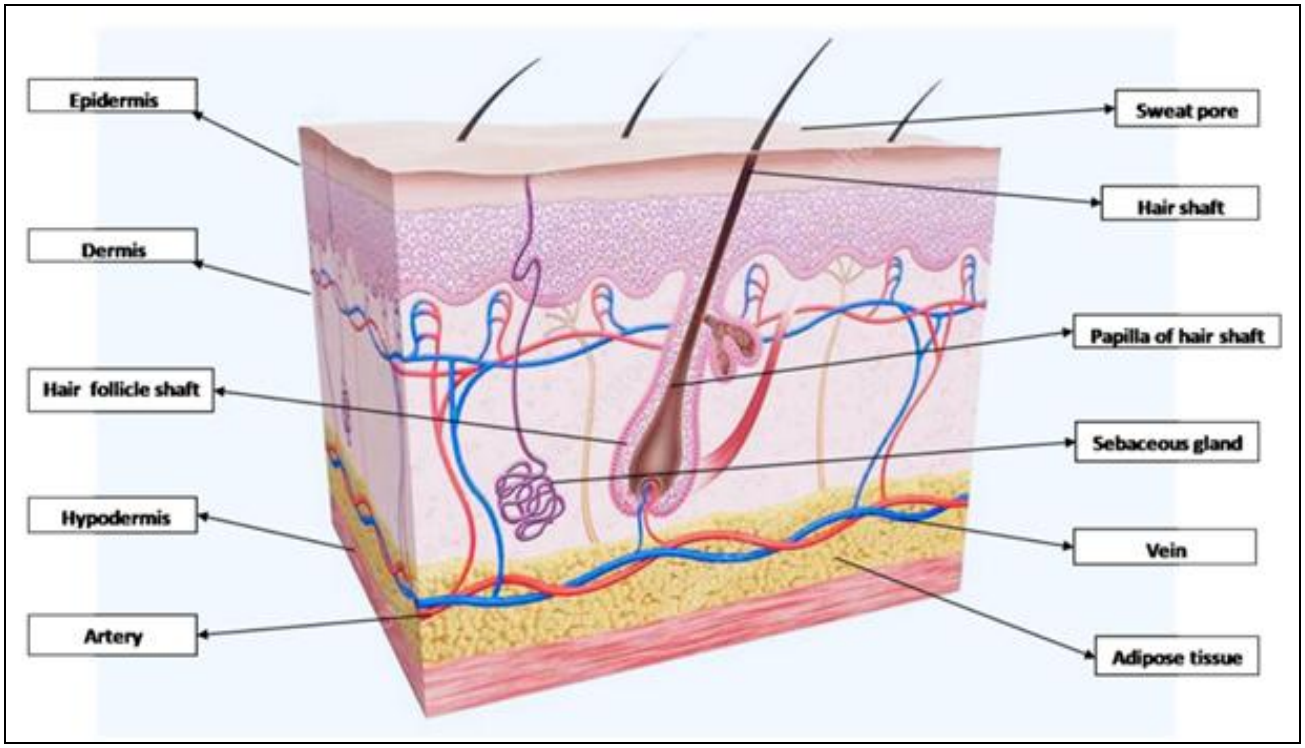

FIG. 1: STRUCTURE OF SKIN

Skin keeps the body hydrated by preventing excessive water loss, controlling body temperature to maintain ideal levels and acting as a protective layer against various chemicals, biological agents and potential physical risks. These functions are essential for maintaining general health and well-being since they guarantee that the body stays balanced and shielded from outside threats [11].

An adult's skin covers approximately $2m^2$ of area, providing a substantial protective barrier [12]. Its pH is typically low, influenced by acids released from sebum and body perspiration, which help to maintain skin's overall health [13].

Structure of Skin: Several layers make up the skin **Fig. 1.** Keratinocytes are the outermost primary cells found in the epidermis, forming a protective barrier. The thin, stratified tissue that connects the outer skin layer to the inner skin layer is known as basement membrane or dermo-epidermal junction, which provides essential support and stability. Primarily composed of fats, the hypodermis is the layer situated beneath the dermis [14].

The various layer of skin is briefly described below:

Epidermis: Skin's outermost layer, known as the epidermis, consists of multiple layers of flat, scale-like cells called stratified squamous epithelium, primarily made up of keratinocytes at various developmental stages. Its main function is to act as a biological and physical barrier, preventing allergens and irritants from entering the body while maintaining homeostasis. In addition to keratinocytes, the epidermis contains several other cell types that contribute to its functions. Around 95% of epidermal cells are keratinocytes. These include melanocytes, responsible for pigment production; Langerhans cells, which aid in immune defense; and Merkel's cells, which are involved in sensing touch. These specialized cells contribute to the skin's protective, sensor and immune functions [15].

Five Distinct Layers of Epidermis:

Stratum Corneum: Stratum corneum comprises 15 to 30 layers of dead keratinocytes called squamous or corneocytes. These cells are filled with keratin, forming a strong, impermeable barrier for the skin, hair and nails. This outermost layer is continuously shed and replenished by new cells migrating from the stratum basale. The length of this procedure varies depending on age and certain medical issues, but it usually takes upto 30 days [16].

Stratum Lucidum: Stratum lucidum is a thin, transparent layer of dead skin cells in the epidermis that's located between the stratum granulosum and stratum corneum. It's only found in the thick skin of the palms, soles, and digits.

Stratum Granulosum: Most of free nerve terminals extending from the dermis is found in this layer. Unencapsulated dendrites that emerge from a sensory neuron are known as free nerve ends. They are less susceptible, nevertheless, to sudden variations in stimulus.[17]

Stratum Spinosum: Stratum spinosum, a layer of the epidermis found between the stratum granulosum and stratum basale. This layer is composed of polyhedral keratinocytes.[18]

Stratum Basale: The only layer that continuously divides into new cells during mitosis. Keratinocytes, the primary cell type in the skin, are continuously generated in the basal stratum. They gradually migrate upward through the skin's layers, ultimately reaching the outermost layer, where they play a vital role in forming a protective barrier. Because, they are structural cells and carry out vital immunological tasks, they are essential to wound healing [19].

Dermis: The dermis, located between the basement membrane and the deeper layer of fats and tissue, constitutes inner skin layer and is significantly thicker than the epidermis, measuring 1 to 5 mm. Its primary role is to support and nourish the epidermis. The dermis comprises two layers papillary and reticular of connective tissue, which seamlessly blend together, providing structural integrity and elasticity to the skin. This layered structure also houses blood vessels, nerves, and other essential components that contribute to skin's health and functionality [20]. The topmost layer, known as the papillary layer, is thinner than the epidermis and is made up of free connective tissues. The thicker, denser and less cellular reticular layer is the deeper layer and is made up of collagen fiber bundle in dense connective tissue [21].

Hypodermis: Adipose tissue and connective tissue make up the majority of the hypodermis, which is situated beneath the dermis. This layer connects the skin to underlying components like muscles as well as bones and offers insulation, cushioning and support to the skin. It is also referred as the subcutaneous fascia and serves as a cushion, energy-storage and insulation layer. Furthermore, the hypodermis is essential for maintaining skin integrity, controlling body temperature and adding to the general structure and functionality of the skin [22]. It constitutes the skin's innermost layer and contains blood arteries, sensory neurons and hair follicles, among other skin appendages [23].

Important Functions of Skin and Regulation through Skin:

- Skin serves as a physical barrier against pathogens, UV rays and environmental pollutants.
- Skin stops the body from losing too much of water.
- Crucial for thermo-regulation to maintain internal homeostasis.
- Helps in the absorption of certain medications and cosmetics.
- Enzyme which is in the epidermis region can denature the drugs [24].

Drug Delivery Mechanism through Skin: Medication primarily enters the blood stream through passive diffusion through the stratum corneum, but limited active transport operates in three steps:

- First, the drug dissolves in its vehicle;
- It diffuses from the vehicle to the skin's surface,
- Lastly, the drug penetrates the skin's layers.

Topical medication's hydrophilic part enters the dermis and lipophilic part dermal-epidermal junction through the outer layer of skin (lipophilic), where they passively enter the epidermis before being transported by blood vessels in to the systemic circulation [25] **Fig. 2.** These drugs are usually applied for three main purposes:

- The main objective is to act on the skin's surface, like in the case of cosmetics, insect repellents, and disinfectants, also referred to as epidermal formulations.
- Secondly, some compositions, called endodermal or via dermal, are made especially for absorption into the dermis and viable epidermis. Skin-related disorders can be treated more effectively owing to this targeted penetration.
- Third, topical therapy may use transdermal application to accomplish systemic drug action.

There are two ways that the medication can enter the stratum corneum: via trans epidermal route and pores route [26].

A. Trans Epidermal Route: It is subdivided into the intercellular and transcellular pathways. The most direct route is transcellular, in which medicine enters the body through the cells in the outer skin layer. It moves through the dead cells and the fatty parts of the skin's surface or the stratum corneum but because the medication needs to pass through both hydrophilic and lipophilic components, there is a lot of resistance to this route of penetration [27].

B. Route through Pores: Intercellular drug transfer is the most common route between corneocytes. It was initially believed that the skin's constituents, hair follicles and glands, which account for only 0.1% of the skin's surface area, had no discernible impact on the dispersion pathway. However, these extremities may play a crucial role in the retention of lipophilic and large particles, along with other dispersion courses. When a lipophilic medication penetrates the hydrophilic epidermis, it exhibits slow diffusion and generates temporary deposition, often known as the reservoir effect [28].

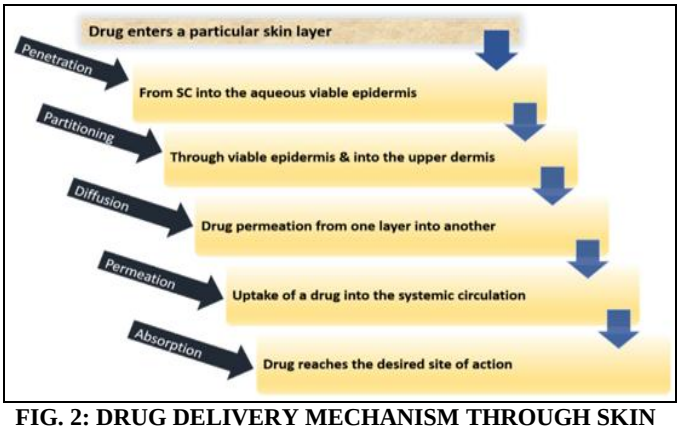

FIG. 2: DRUG DELIVERY MECHANISM THROUGH SKIN

Physiological and Physicochemical Factors affecting Drug Permeation: It is important to consider the physiological factors of the skin and physicochemical factors of drugs before formulating a topical drug delivery system to optimize its effectiveness, safety and compatibility with the skin **Fig. 3**. Formulations that closely match the skin's physiological conditions are more likely to be well-tolerated and effective in delivering drugs through the skin barrier, enhancing its efficacy, safety and patient compliance [29].

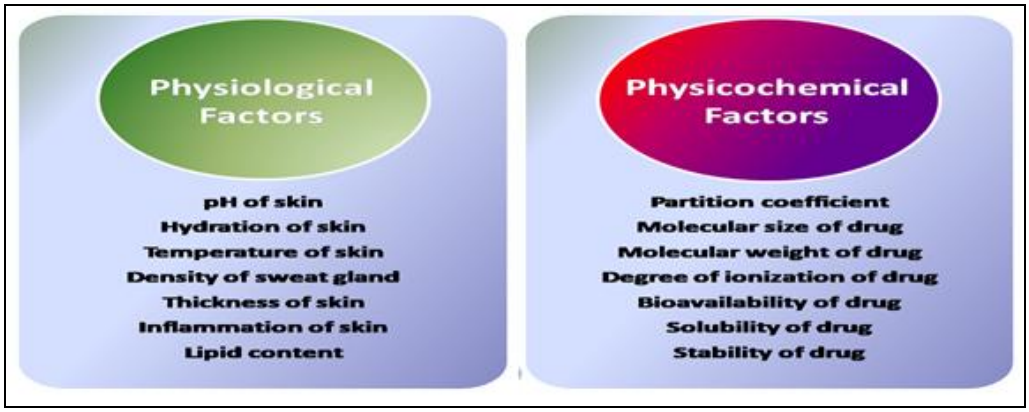

FIG. 3: VARIOUS FACTORS OF SKIN AND DRUG AFFECTING DRUG DELIVERY

Physiological Factors of Skin: Skin has many physiological functions that are essential for maintaining homeostasis, protection and social interaction. There are various factors which affect the physiology of skin these are:

Skin Thickness: From the outermost layer to the inner layers, the thickness of the skin varies. The skin is thicker as it descends towards the subsurface layers, with the surface epidermis typically measuring between 100 and 150 μm. This variance affects skin health overall, barrier function and absorption. The rate of diffusion via the skin is also high.

Lipid Content: Skin hydration and protection are improved when the stratum corneum's lipid content is minimal because percutaneous absorption improves and the stratum corneum becomes a stronger defense against loss of water and outside substances.

Capacity of Hair Follicles: The fundibulum of the hair follicle can store significantly more substances than the stratum corneum, with its capacity being approximately ten times greater, allowing for enhanced retention and delivery.

Density of Sweat Glands: Sweat glands can serve as effective pathways for drug delivery into the blood stream and deeper layers of the skin. The density of these glands influences the amount and rate of absorption of medications via skin. Consequently, a higher concentration of sweat glands may enhance the absorption of topical medications, improving their therapeutic efficacy.

Skin pH: The skin pH is affected by a great number of endogenous factors, e.g. skin moisture, sweat, sebum, anatomic site, genetic predisposition and age. In addition, exogenous factors like detergents, application of cosmetic products, occlusive dressings as well as topical antibiotics may influence the skin pH.

Circulation of Blood: Higher circulation of blood makes it easier for medications to enter the blood stream. While decreased blood flow can restrict the absorption of drugs, increased blood flow speeds up the process.

Hydration of Skin: It helps to improve the penetration.

Inflammation of Skin: This causes the stratum corneum to break and becomes more permeable.

Skin Temperature: The rate at which skin permeation occurs likewise rises with warmth [30].

Physicochemical Factors of Drug: Physicochemical factors of drugs are the physical and chemical properties of a drug that affect how it interacts with biomolecules and environments.

Partition Coefficient: A higher log P value implies better penetration across cell membranes and hence, increased drug absorption because of improved lipid solubility.

Molecular Weight (<400 Dalton): Smaller molecules with lower molecular weights are able to penetrate and move through the stratum corneum's intercellular gaps.

Degree of Ionization: Efficient absorption is only seen with unionized drugs.

Effect of Vehicles: Gel that is hydroalcoholic is effectively absorbed via layers of dermal tissues [31].

Classification of Topical Drug Delivery System: Its classification depends on formulation type, mechanism of action and application site. Common types include creams, gels, ointments, patches and aerosols **Fig. 4.**

Understanding these classifications are crucial for selecting the most suitable system to optimize drug delivery and therapeutic outcomes [32]. Since topical medicines are applied topically to the skin, it is crucial to take into account the physiological processes of the skin when formulating them. Understanding these processes is critical for creating effective and safe topical dosage forms that maximize therapeutic benefits.

The diagram **Fig. 4** illustrates topical formulations based on their existing phase.

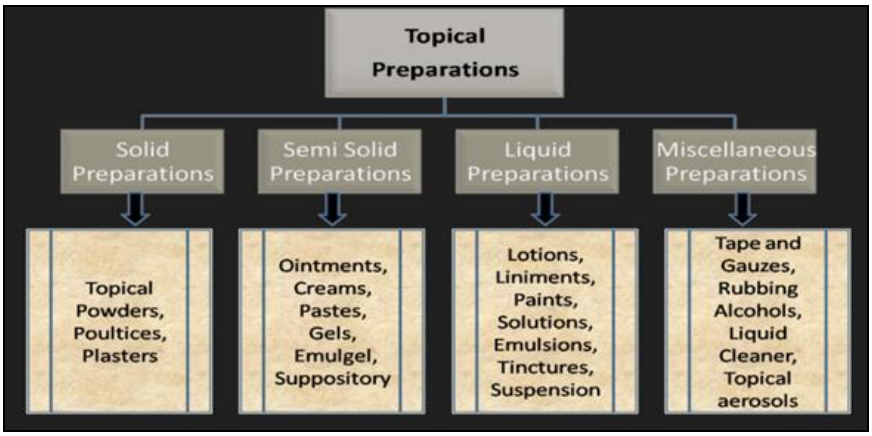

FIG. 4: CLASSIFICATION OF TOPICAL PREPARATIONS

A variety of medications can be topically administered to the skin or mucous membranes. Such treatments are designed to improve skin quality, restore essential functions and effectively address specific conditions, providing targeted and localized therapeutic benefits. Topical products including creams, lotions or ointments, often pose challenges such as stickiness, low spreading coefficient and stability issues. To nullify these limitations gels, employing emulsion-based techniques, are increasingly favored for integrating hydrophobic medicines in medicinal and cosmetic preparations, overcoming previous restrictions associated with semisolid formulations.[33] Emulgel is a combination of gel and emulsion which may enhance penetration as well as solubility of drugs.

Emulgel: An emulgel is a specialized topical formulation created by blending an emulsion with a gel base. With regard to topical drug delivery, its twin release mechanism which includes both gel and emulsion systems makes it extremely important [34]. This delivery system's main goal is to make it easier for hydrophobic medications to get through the skin barrier and enter the blood stream.

These emulgels possess several desirable properties for dermatological applications, including non-greasy texture, ease of removal, effortless spreadability, emollient properties, non-staining characteristics, extended shelf-life, transparency, appealing appearance and reduced risk of severe side effects [35].

An emulsion-based strategy effectively tackles the challenges associated with delivering hydrophobic medications. This approach enables these compounds to leverage the unique benefits of gels, enhancing their stability, absorption and overall therapeutic effectiveness in various formulations.

Emulgel formulated as either oil dispersed in water (o/w) or water dispersed in oil (w/o), can be stabilized with a gelling agent. It offers a stable and effective platform for incorporating poorly water-soluble drugs [36]. Emulgel's dual aqueous and non-aqueous phases allow it to handle both lipophilic and hydrophilic medicines. It additionally functions as a controlled-release formulation by utilizing a biphasic method to improve drug loading capacity and stability [37]. It operates as a dual-controlled release system, combining the beneficial properties of both gels and emulsions for enhanced delivery and efficacy [38, 39]. Due to several advantages, many pharmaceutical manufacturers have stepped in to commercial production of emulgel, some examples of products are Voltaren® Emulgel® (Diclofenac sodium), Pernox (Benzoyl Peroxide), Miconaz-H (Miconazole nitrate) and CLINAGEL (Clindamycin phosphate).[40]

Drug Delivery through Emulgel: Emulsions act as controlled-release drug administration devices by trapping drug particles within their internal phase, ensuring gradual and sustained release. This setup enables the drug to slowly diffuse through the external phase of the emulsion and gradually penetrate the skin, providing a sustained release and enhancing the drug's effectiveness, facilitating slow and sustained absorption. The controlled release of the drug is supported by a cross-linked gel network that effectively traps small particles, ensuring a steady supply of the active ingredient over time. Additionally, the mucoadhesive properties of these formulations enhance the duration of the drug's skin contact, further improving therapeutic outcomes. Water dispersed in oil emulsions are particularly valued for their emollient effects, making the deal for treating dry skin conditions. On the other hand, oil-in-water emulsions are widely utilized in cosmetics due to their ease of removal with water, making them convenient for everyday use [41].

Various types of emulgels are listed below:

Microemulsion Gel: Microemulsions gel represents a blend of biphasic oil-in-water formulations stabilized by a surfactant, ensuring thermodynamic stability and optical clarity. The droplets have a size range of 10 to 100 µm and include exact amount of water, surfactant, co-surfactant and oil. Microemulsions possess distinct properties, including a high surface area, low interfacial tension, and the ability to dissolve both water- and oil-soluble compounds. These characteristics are advantageous for drug delivery, as they enhance the permeation of drugs through the skin by minimizing the resistance to absorption of the stratum corneum. To overcome this challenge, Gelling Agents such as Carbopol 940, HPMC K100M, and Guar gum are incorporated into microemulsions, resulting in microemulsion-based gels. These gels offer improved consistency and stability for direct application on skin, allowing for better control of drug release and enhanced penetration into the skin. By modifying the formulation, these gels address the issues of poor absorption and optimize the therapeutic efficacy of pharmaceutical products [42, 43].

Nanoemulsions Gels: Nanoemulsion gels are clear oil-water dispersions, stabilized by surfactant and co-surfactant molecules that offer thermodynamic stability and feature globule diameters between 1 and 100 nm. When combined with a gel, they form nanoemulgel structures. Nanoemulsions, often incorporated in to the emulgels, enhance both *in-vitro* and *in-vivo* transdermal and dermal delivery capabilities. Compared to traditional products like emulsions and gels, nanoemulsions significantly improve transdermal drug permeability. Their small globule size and high loading capacity assists increased absorption of medication into skin, accelerating therapeutic impact.

Macroemulsion Gel: Emulgel classified as macro emulsion gel has emulsion droplet particles larger than 400 nm. Each of the droplets may be plainly seen under a microscope, even though they are physically undetectable. Considering their thermodynamic instability, macroemulsions gel can be stable with the use of surface-active agents [44-46].

Composition of Emulgel: The emulgel formulation consists of following materials.

Drug: The intrinsic qualities of a medicine play a major role in how well it absorbs through the skin. Numerous physicochemical and biological properties of the medication are crucial when producing an emulgel for topical or transdermal use. A high pKa value would be ideal for the

medication as it indicates its stability to stay in a non-ionized form that is favorable for skin penetration. Additionally, for better dispersion across the layers of the skin, it should have a molecular mass of 500 Daltons or less and a tiny molecular size. The drug is released and digested efficiently; its half-life ($t_{1/2}$) should be shorter than 10 hours.

The medicine's capacity to pass epidermal barriers is enhanced when it has a suitable partition coefficient (log) between 0.8 to 5. This indicates that the drug gets distribute in water and lipids well. The drug's low polarity facilitates absorption, it should be non-irritating and have a skin permeability coefficient 0.5×10^{-3}cm/h [47].

Vehicle: To prepare an emulgel, both aqueous and oily vehicles are used to handle both hydrophobic and hydrophilic drugs. Aqueous phase vehicles, such as alcohol, water and other water-based substances, help to dissolve and incorporate hydrophilic drugs, while oily vehicles assist with hydrophobic drugs, ensuring a well-balanced formulation [48].

Oils: In the oily phase of emulsion preparation, a variety of ingredients are combined to make the formulation. Mineral oils can be used by themselves or in conjunction with either hard or soft paraffin as a medication delivery system for exterior applications. These oils add sensory qualities to the emulsion's and have occlusive qualities that aids in moisture retention. Conversely, oils utilized in oral preparations like castor and mineral oils are not recyclable and frequently have a laxative action that is localized. Because of their nutritional advantages and unique health characteristics, fish liver oils and a variety of vegetable oils, including those from archies, cotton seed and maize are frequently utilized in dietary supplements [49].

Emulsifiers: Emulsifying agents are essential in the manufacturing process to ensure that emulsification occur smoothly. They also help to maintain the stability of emulsions over time. Formulated emulsions may last for days, while commercial preparations can remain stable for months or even years. Examples include polyethylene glycol (PEG) 4031 stearate, stearic acid, sodium stearate, sorbitan monooleate (Span 80) and polyoxyethylene sorbitan monooleate (Tween 80) [50].

Gelling agent: These substances are used to boost the viscosity of various dosage forms and act as thickening agents, enhancing the consistency and stability of the formulations. They play a significant role in preparing emulgels by providing viscosity, stability and rheological properties to the formulation. They help to transform the emulsion into a semi-solid gel matrix, enhancing its spreadability, adhesion and retention on the skin, there by optimizing drug delivery and therapeutic efficacy [51].

Types of Gelling Agents: The gelling chemicals used in emulgel come in many varieties. These consist of both synthetic and natural polymers. Based on the sources gelling agents are categorized as follows:

Natural Polymers: These are originating from organic materials such as proteins (gelatin, collagen, egg whites, casein) and Polysaccharides (guargum, acacia gum, tragacanth gum, pectin, starch, xanthan gum, dextran, succinogluconate etc.) [52].

Semi Synthetic Polymers: These are the polymer which contains both synthetic polymers along with natural polymers like carboxymethylcellulose, hydroxylpropylcellulose, ethylcellulose, hydroxyethylcellulose, silicate (Veegum®), methylcellulose, sodium alginate and Carbopol-940 etc.

Synthetic Polymers: These are purely synthetic in nature and synthesized in laboratory in larger scale for example: carbopols® (now known as carbomers), poloxamers (Pluronics®) and polyvinylalcohol [53-55].

TABLE 1: DIFFERENT GELLING AGENTS UTILIZED IN EMULGEL FORMULATIONS

Gelling Agent	Concentration % (w/w)	Advantages
Carbopol-940	1%	Produce extremely thick gels and regulated medication release
Combination of HPMC	1.2%	When it is combined, it improves

and Carbopol		Stability
HPMC (hydroxyl propyl methylcellulose)-2910	2.5%, 5%	Produce natural gel of very good Viscosity
HPMC(Hydrgoxy propyl methyl cellulose)	3.5%	It shows better drug release rate
Carbopol-934	1%	It provides control release of API which are incorporated, because of the highly viscous gel

Penetration Enhancers: Penetration enhancers improve drug delivery systems by facilitating the penetration of drugs across biological barriers, such as the skin or mucous membranes. These enhancers increase drug bioavailability and efficacy, enhancing the therapeutic outcomes of topical and transdermal [56].

Attributes of Penetration Enhancers:

- They need to be safe, gentle on the skin and non-allergenic.
- They should not adhere to receptor sites or possess any therapeutic effect in body.
- Penetration enhancers should facilitate pharmacological agents to enter the body and impede the loss of endogenous materials [57-59].

These enhancers are essential for formulating various topical preparations and must therefore be congenial with therapeutic agent as well as excipients. Various penetration enhancers have been described in **Table 2.**

TABLE 2: LIST OF PENETRATION ENHANCERS

Penetration Enhancer	Concentration% (w/w)	Dosage form
Oleic acid	1	Emulgel
Lecithine	5	Gel
Urea	10	Gel
Isopropyl myristate	5	Gel
Linoleic acid	5	Gel
Clove oil	8	Emulgel

Co-surfactants: Surfactants with single chains alone cannot sufficiently reduce the oil-to-water interfacial tension. Therefore, to enable an emulsification various co-surfactants are used such as propylene glycol (PG) and cetostearyl alcohol [60, 61].

Preservatives: Preservatives are essential to prevent the growth of microbes. For this, parabens including methyl, propyl, benzyl, butyl and p-hydroxy benzoate are frequently utilized.[62]

Methods for Preparation of Emulgel: An emulgel is a combination of an emulsion and a gel that is commonly used in topical formulations, such as for delivering active ingredients in skin care or pharmaceutical products.

Cold Process Method: This method involves preparing the gel and emulsion phases independently at room temperature while continuously combining them. Oil, water and an emulsifier are used to create the emulsion phase, while gelling agents such as carbomers or cellulose derivatives are employed to make the gel phase. To make a homogenized emulgel, gradually introduce the emulsion in to the gel phase while stirring.

Hot Process Method: This method involves separately preparing the gel and emulsion phases, which are heated until both become liquid. With steady mixing, the hot emulsion is slowly introduced to the hot gel phase till an emulgel is formed. This method can be useful for heat-sensitive substances, but it requires careful temperature management to prevent degradation.

***In-situ* Gelatin Method:** In this method, gelling agents are added directly to the emulsion phase.

This method involves the formation of a gelatin matrix in its natural environment (in situ), without the need for external molds or preformed structures. For instance, pH-sensitive polymers convert in to the gel upon contact with physiological fluids, while thermo responsive polymers, gel upon cooling.

Polymerization Method: This technique involves dispersing monomers within the emulsion phase

and causes the emulsion convert in to gel by starting the polymerization process to create a 3d network. This method often creates across-linked polymer network with desirable characteristics such as mechanical strength and controlled drug release kinetics.

Hydrophobic Modification Method: By incorporating hydrophobic or lipophilic substances, such as liposomes or lipid-based gelling agents, into the gel phase, emulgels with enhanced stability and extended-release properties can be produced. This technique is particularly effective for administering hydrophobic drugs.

Solvent Evaporation Method: In this method, drug-loaded liposomes or nanoparticles are dispersed with in a hydrogen matrix, followed by solvent evaporation to form the emulgel. The presence of nanoparticles magnifies the durability of hydrophobic drugs as well as ensures its bioavailability [63-65].

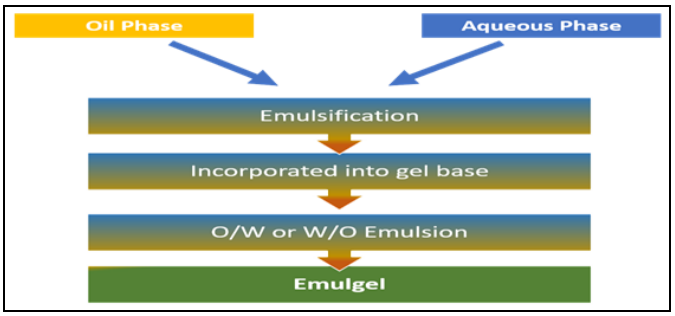

FIG. 5: STEPS INVOLVED IN THE PREPARATION OF THE EMULGEL

Evaluation of Emulgel:

Visual Examination: When visually inspecting, evaluate the color, phase separation and uniformity of the emulgel, as well as its appearance, color and odor [66].

Homogeneity: It can be assessed by visually inspecting the appearance of the gel and observing any aggregates in the formulation [67].

pH: To determine the pH of the emulgel, first prepare 1% solution by dissolving the emulgel in water. Then, measure the pH of this solution using a digital pH meter to obtain an accurate pH reading [68].

Spreadability: Spreadability was determined by excess of sample was applied within the two glass slides then compressed to uniform thickness by placing 1kg weight for 5 min. Weight accurate amount (50 gm) was added to the lower plate. The time required to spread the two slides, i.e. the time in which the upper glass slide moves over the lower plate was taken as measure of spreadability (S) [69].

$$\text{Spreadability (S)} = M \times L / T$$

Where M = weight tide to upper slide, L = length moved on the glass slide, T= time taken

Drug Content Determination: To determine the amount of drug in the emulgel, dissolve 1 gram in 100 ml of solvent. Clarity can be achieved by filtering the solution and then diluting it properly for spectrophotometric measurement [70].

Centrifugation Analysis: Centrifugation technique is employed to assess the stability of emulgel formulations by simulating high-speed conditions. Typically conducted a week after the emulgel's preparation, this technique helps to evaluate whether the formulation remains stable or if any phase separation or changes occur over time. The stability assessment entails centrifuging the emulgel for 30 minutes at 3000 rpm. Any phase separation, sedimentation or instability inside the emulgel can be detected by using centrifugation [71].

Determination of Viscosity: The viscosity of different emulgel formulation was determined at room temperature using the digital viscometer (Brookfield), which features a cone and plate setup. This instrument accurately measures how thick and resistant to flow the emulsion, providing essential data on its consistency [72]. The viscosity reading is taken while the spindle was free to rotate in the emulgel [73]. Using spindle 6 at 100 rpm the viscosity of emulgel is measured.

Skin irritation test: Skin irritation test is necessary for topical dosage form. To determine irritancy after single application of topical emulgel. The optimized formulation is applied on skin ($3cm^2$) and resulting reactions such as erythema and edema are scored after 24 h. The emulgel is removed after 24 h and treatment sites are cleaned [74].

Extrudability Study: The force required to drive emulgel out of a tube is used to determine extrudability. According to the approach, plug flow

occurs when the shear rate surpasses the yield value and the applied shear is determined in that region. The aluminum collapsible tube that is used to extrude the emulgel in this investigation. To measure extrudability, the weight in grams required to extrude an emulgel ribbon within 10 seconds is recorded. A higher weight indicates better extrudability. This process is repeated thrice, and the average value is calculated to ensure accuracy in the measurement. Using the following formula, extrudability is calculated.

Extrudability is determined is area (cm^2) / Weight (g) applied to extrude emulgel from the tube [75].

Size and Dispersion of Globules in Emulgel: Zetasizer device is utilized to determine the globule size and distribution within the sample. To achieve a uniform dispersion, one-gram sample is dissolved in filtered water and then thoroughly mixed by spinning. This process ensures accurate measurement of the globule characteristics using the zetasizer. Photocell of the zetasizer is then filled with this sample, and the distribution and mean globule diameter are measured [76].

Percentage *In-vitro* Cumulative Drug Release Studies: The outer shell membrane of the egg is prepared by immersing the egg in mixture of 50% aqueous solution of HCl to dissolve the calcified layer. The membrane is cut cautiously to expel the contents of the egg and wash with normal saline solution. The inner membrane is repeatedly washed with water and stored in distilled water. The required length of egg membrane is cut and tied with a thread to the bottom (grounded) layer of the diffusion cell and placed in a beaker containing 100 ml of 5.5 pH phosphate buffer. A magnetic bead is added to the outer compartment to stir the contents during the studies. The entire assembly is placed in a magnetic stirrer and temperature is maintained at 37 ±1 ºC. At different time intervals (up to 12 hr.), samples are withdrawn and absorbance is measured spectrophotometrically [77].

Swelling Index: Formulation that exhibits the highest swelling index shows that it can absorb wound exudates. A petridish with 10 ml of 0.1 N NaOH is filled with 1g of emulgel, cover with permeable foil made up of aluminum to calculate swelling index. The samples are drawn at various time intervals, allowed to dry for a short while, and then weighed. Next, a formula is used to calculate the swelling index.[78]

$$Swelling \text{ index } (SW)\ \% = [(W_t - W_o)/W_o] \times 100$$

Where, (SW) % = Equilibrium percent swelling, W_o = Original weight of emulgel at zero time, W_t = Weight of swollen emulgel after fixed time.

Stability Analysis: Stability refers to a medication formulation's ability to preserve its distinct chemical, physical, toxicological and therapeutic properties within a specific container [79]. ICH criteria are followed in the conduct of all stability investigations (Q1R2) [80]. There are different time intervals and storage conditions described below:

TABLE 3: STABILITY TESTING CONDITIONS

Analytical study	Conditions at storage	Time duration (in months)
Long term	25°C ± 2°C/60 %, RH ±5% or 30°C ± 2°C/65 %, RH ± 5%	12
Intermediate	30°C ± 2°C/65 % RH, ±5 %	6
Accelerated	40°C ± 2°C/75 % RH, ± 5 %	6

Advantages of Emulgel Over Conventional Topical Dosage forms are as Follows:

Increased Stability: Compared to other topical preparations, such as powders that break down easily, emulgel is more stable than creams that break and show phase inversion as well as ointments that go rancid because of an oily phase.

Greater Loading Capacity: While alternate novel approaches, such as nanosized liposomes and niosomes morphosed in to vesicles, emulgels offer a higher loading capacity because of their extensive structure. Thus, niosomes and liposomes have lower trapping efficiencies and produce leakage [81].

Hydrophobic Medication Incorporation is Simple: Since most hydrophobic drugs have solubility problems that prevent drug release, they cannot be directly added to gels. Emulgel mixes oily droplets into a water base, helping oil-soluble medicines blend better with the oil. This creates an oil-in-water emulsion, making the medicine more effective. This o/w emulsion can be used with a gel base.

Viability of Production: The emulgel preparation method is made up of short, easy phases that makes production more feasible [82].

Low Preparation Costs: For preparing the emulgel, no special equipment is required. Also, the materials utilized are less expensive and more widely available.

Lack of Vigorous Sonication: Producing vesicular preparation requires powerful sonication such as liposomes and niosomes formulation, which could cause medication leakage and degradation. However, problems with degeneration of the drug can be avoided because emulgels don't need strong sonication. Controlled medication release drugs with a shorter half-life can have their effects extended with the use of emulgels [83].

Patient Compliance: The product is easier to apply and less greasy [84].

Packaging of Emulgel: Emulgel comes in two kinds of packaging. One type is an aluminum tube with a molded seal and a screw-on cap. The other type is a lacquered aluminum tube with a special coating inside and a seal that needs to be broken. Both packaging types are designed to keep the emulgel fresh and effective [85]. These laminated tubes not only resemble plastic in appearance but also retain the advantageous properties of aluminum. By utilizing advanced technology, the new laminate tube design offers an optimal combination of aesthetics and functionality. The innovation in laminate technology maximizes the available graphic space, allowing for more vibrant and detailed designs, which enhances the overall product presentation and branding opportunities [86]. Laminate material is impermeable to light, air and moisture making it an excellent choice for packaging. It consists of two layers: an outer plastic layer that offers an attractive appearance on the shelf, and an inner aluminum layer that ensures structural integrity. This combination provides several key benefits. The high-gloss protective lacquer enhances visual appeal, while the aluminum layer acts as barrier, ensuring compatibility with a variety of contents. It also protects flavors and scents by minimizing absorption, preserving the quality of the packaged items. These features make laminate material ideal for products that demand maximum protection [87]. There are a number of commercially available emulgel formulations; a few of them are mentioned below [88].

TABLE 4: MARKETED PREPARATIONS OF EMULGEL

S. no.	Brand name	Active pharmaceutical ingredient	Manufacturer
1.	Voltaren Emulgel	Diclofenac Diethyl amine	Novartis
2.	Diclomax Emulgel	Diclofenac Sodium	Torrent Pharma
3.	Miconaz–H- Emulgel	Miconazol Nitrate Hydrocortisone	Medical Union Pharmaceuticals
4.	Dermafeet Emulgel	Urea	Herbitas
5.	Isofen Emulgel	Ibuprofen	Beit Jala Pharmaceutical
6.	Diclona Emulgel	Diclofenac Diethyl amine	Kuwait Saudi Pharmaceutical
7.	Avindo Gel	Azithromycin	Adcock Ingram Healthcare
8.	Volini Gel	Diclofenac Diethylamine	Ranbaxy Laboratories
9.	Dosanac Emulsion Gel	Diclofenac Diethyl ammonium	Saim Bheasach
10.	Denacine Emulgel	Clindamycin Phosphate	Beit Jala Pharmaceutical
11.	Cataflam Emulgel	Diclofenac Potassium	Novartis
12.	DiclonEmulgel	Diclofenac Diethylamine	Med Pharma
13.	Pernox Gel	Benzoyl Peroxide	Adcock Ingram Healthcare Pvt. Ltd.
14.	ClinagelAllantoin	Clindamycin Phosphate	Stiefel Pharma
15.	Lupigyl Gel	Metronidazole	Lupin Pharma
16.	Cloben Gel	Neomycin, Clotrimazole, Beclomethasone Dipropionate	Indoco Remedies
17.	Topinate Gel	Clobetasol propionate	SystopicPharma
18.	Levorag Emulgel	Hibiscus, Natural extracts	THD Ltd.
19.	Diclobar Emulgel	Diclofenac diethyl amine	Barakat Pharma
20.	Pennsaid Gel	Diclofenacumnatricum	Nuvo Pharma
21.	Acent Gel	Aceclofenac	Intra Labs India Pvt. Ltd.

Patented Formulations of Emulgel: Government legally protects innovators by granting patents, which give inventors exclusive rights to use their innovations for a specified period. These rights

typically include the ability to prevent others from making, using, selling or distributing the patented innovation without the inventor's consent. Patents encourage innovation by providing inventors with a financial incentive for investing time, money and effort in to research and development [89]. A patent on an emulgel, a type of topical medicinal preparation, would typically cover a specific formulation or manufacturing process. Pharmaceutical companies, academic institutions and individual inventors may file patents related to emulgels to protect their intellectual property rights and ensure their inventions are commercially viable. These patents are crucial for the pharmaceutical and cosmetic industries, as they encourage investment in research and development, foster innovation and secure exclusive rights to unique formulations and technology [90-91]. List of patented formulation is mentioned below:

TABLE 5: PATENTS OF EMULGEL

S. no.	Patent no.	Date & Year	Title of patent	Inventor	Reference
1	US20210161875A1	08.02. 2021	Topicalretinoid compositions	Sateesh Kandavilll Franklin Okumu Manish M. Bankar Sujit Kumar Dolai	[92]
2	AU2021205008AI	12.08.2021	Strategiesfor managing chronic acne	Sengupta, Shiladial; Chawrai Suresh Rameshlal; Gosh Shamik; Gosh, Sumana jain, Nilu; Sadhasivam, Suresh Buchta, Richard; Bhattacharyya Anamika	[93]
3	US2020/0140460AI	07.05.2020	Antibacterial Treatments and preventative measures	Shiladitya Sengupta, Shamik Ghosh, Sumana Ghosh, Mau Sinha Suresh Sadhasivam, Anamika Bhattacharya, Siva Ganesh Mavuduru, Nupar Tadon, Deepak Kumar.	[94]
4	US20220288086A1,	25.06.2021	Treatment for bacterial infection	Shiladitya Sengupta Suresh Rameshlal Chawrai Shamik Ghosh, Sumana Ghosh, Nilu Jain, Suresh Sadhasivam, Richard Buchta, Anamika Bhattacharyya	[95]
5	US2021/00 77509AI	18.03.2021	Formulations for the more effective management of acne and associated conditions	Dov Tamarki, Maccabim, Elana Gazal, Rehovot, Rita Keynan, Rehovot, MeirEini, Ness Ziona m, David Schuz, Gimzu	[96]
6	US20200197541A1	02.11.2023	Gel formulations for guiding radiotherapy in the composition	Thomas Lars Andresen, Rasmus Irming Jolck Morten, Albrechtsen Rottman, Jerusalem, Orit Gans, Efrailm, Alon Seri-Levy, Rehovot	[97]
7	US10,618,266B2	02.11.2023	Electrophoresisgel cassette and comb	Timothy Updyke, Jennifer D. Miller Thomas Diller, Robert Bennett, Siddharth Kannan	[98]
8	US20200188552A1	25.02.2020	Removable film forming gel compositions and methods for their application.	Delony L. Langer-Anderson George W. Griesgraber Semra Colak Atan Junia M. Pereira Katie F. Wlaschin Alexi J. Young Robert A. Asmus David S. Hays Jerald K. Rasmussen Michael J. Solberg	[99]
9	EP3040361B1	19.6.2020	Gel grinding device, and method for producing a polyacrylic acid (polyacrylate) superabsorbent polymer powder	Kazushi Torii, Kohei Omori Nobuya Tanaka, Shigeru Sakamoto, Kenji Tada Hironori Sato	[100]
10.	US10,973,898B2	13.04.2021	Gel for treating	Eng-Hong Lee	[101]

11.	US11737975B2	29.08.2023	Infectious bronchitis. DicloCompounded compositions and methods for treating pain.	Jay Richard Ray	[102]

CONCLUSION: Emulgels, the innovative medicinal compositions intended to apply on skin surface, integrates characteristics of emulsions and gels, offer significant potential for both the pharmaceutical and cosmetic industries. Their versatile nature makes them appropriate for a variety of uses, including cosmetic goods and medical therapies, thereby opening new avenues for product development and offering improved therapeutic and cosmetic outcomes. These formulations enable the controlled release of both hydrophilic and lipophilic drugs, ensuring stability and ease of application. The unique combination of emulsion and gel in emulgel enhances drug penetration through the skin, facilitating more effective delivery of active ingredients. This makes them particularly advantageous for treating dermatological disorders, where precise and sustained release of medication is crucial. Future research may focus on developing specialized formulations tailored to specific therapeutic needs. For instance, emulgels can be designed for targeted drug delivery, offering precise treatment for various skin conditions with minimal side effects. Additionally, advancements in emulgel technology could lead to the creation of advanced transdermal systems, enabling the systemic delivery of medicine by transdermal application, potentially revolutionizing the route of certain medications. Furthermore, the cosmetic industry can leverage emulgels to develop products that provide long-lasting effects and improved skin absorption. In continuation to explore and innovate within this field, researchers and developers can unlock new possibilities, ultimately enhancing the efficacy and convenience of topical treatment and cosmetic applications.

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