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A Review of Formulation Perspectives in Topical Antifungal Drug Therapy

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Abstract: *To cure skin or general disorders, topical medicine is applied to the skin to lessen its pharmacological or other effects. Topical therapies include semisolids, liquids, sprays, powders, gels, creams, and ointments. Liquid cross-linked polymers form gels. Many features depend on liquid-solid polymer interactions. Gel flows erratically. Polymers and liquid dispersions produce 3D networks. Low grease and easy removal make topical gels ideal for medication delivery. Gels are more stable and effective than ointments. Fungal infections are common dermatological issues. Skin infections benefit from topical therapy. Azole antifungals treat most systemic and localized fungal infections. Topical fungal infection therapy has less systemic side effects. Formulation and optimization improve therapeutic effectiveness. Physiochemical properties and drug formulation improve topical pharmacology most. New skin-targeted antifungals have been tested. Study investigates antifungal gel research.*

Keywords: Topical antifungal therapy, Drug delivery systems.

I. INTRODUCTION

A medicine is administered topically to a bodily part. Topical administration refers to applying drugs to the skin or mucous membranes to treat ailments. The classifications include creams, foams, gels, lotions, and ointments. Many skin medicines are treated topically. Continuous medication administration, less side effects, and more patient compliance are benefits of topical/transdermal drug delivery. Topical drugs are applied externally. Localizing on one or more skin layers is their goal. Semisolids, liquids, sprays, and solid powders are used for topical medication administration. Gels, creams, and ointments are the most common semisolid topical medications.

GEL

The U.S.P. defines a gel as a semisolid structure of microscopic inorganic particles or large organic molecules surrounded by fluids. Gels are extremely diluted cross-linked systems without flow1822. They are semi-solid liquid-rich two-component systems. The continuous structure that provides them solid-like qualities distinguishes them. Gels are preferred for drug delivery formulations because to their network structure, biocompatibility, and bioactive component molecular stability.

Structure of GELS

Gel is a three-dimensional matrix of natural or synthetic polymers in a hydrophilic liquid or dispersion medium. A tiny layer of gel-forming matrix covers the skin when the liquid evaporates following delivery, trapping the medication. A gel is stiff because gelling agent particles form a network. Gel and network structure depend on linkage form and particle kind.

Topical formulations have three main functions

- They contribute to skin hydration because of their emollient properties.
- To shield the skin from the environment or to mend a section of skin that is either uninjured or damaged.
- To smear medication across the body.

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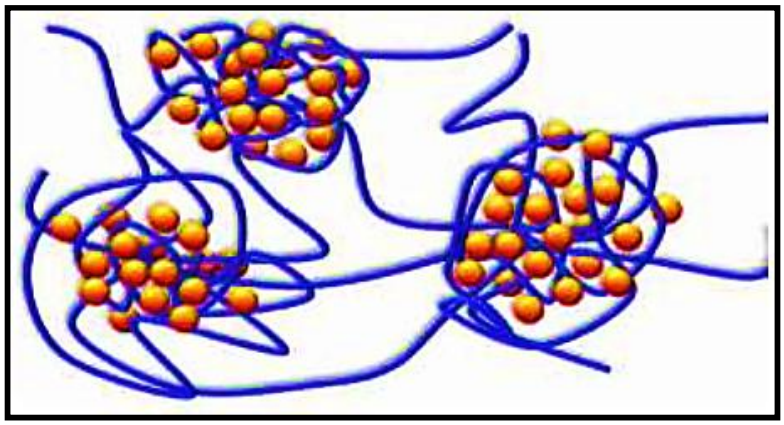

Figure 1: Structure of gels

Advantages of Topical Drug Administration

- Prevents GI medication absorption difficulties due to pH, enzymatic activity, and interactions with food, drink, and other oral medications.
- This technique is used when oral or intravenous delivery fails due to vomiting, swallowing problems, resistant youngsters, or diarrhea.
- Non-invasive medicine administration improves patient acceptability by minimizing parenteral treatment pain.
- Prevents digestive and hepatic enzyme inactivation from the first-pass effect.
- Reduced dose compared to oral versions.
- Dissolves an array of medications with diverse chemical properties, enabling combination therapy with a single transdermal gel.
- Enhanced compliance via extended therapy with a single application.
- Drug treatment may be terminated promptly by withdrawing the application from the skin.
- Lower in oil and easy to remove.

Disadvantages of Topical Drug Administrarion1

- This method is not suited for skin-irritating or sensitizing drugs.
- Topical medicines cost more than regular dosages.
- The delivery system's surface area and chronic sickness dosage limit the route.

Classification of GELS

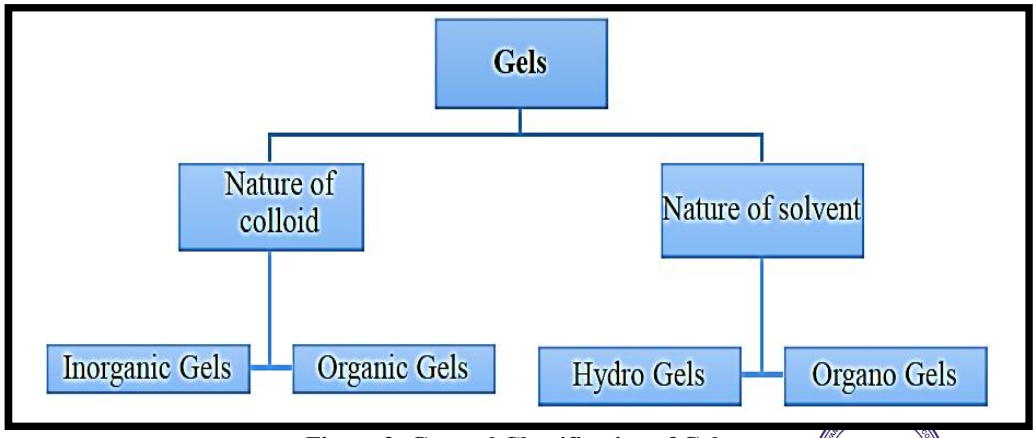

Figure 2: General Classification of Gels

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Two kinds of topically applied gels exist. Gel systems are divided into two types by the first method. Inorganic and organic gel systems exist. Two-phase inorganic hydrogels like aluminium hydroxide gel and bentonite magma are common. Ointments made with 10%–25% bentonite have been used. Single-phase organic gels may comprise gelling agents like carbomer and tragacanth and organic liquids like Plastibase. The second categorization divides gels into hydrogels and organogels, with various subclasses of organic hydrogels, natural and synthetic gums, and water-soluble inorganic hydrogels.

Characteristics of GELS

- Gels should have these properties: Pharmaceutical and cosmetic gelling agents should be inert, safe, and not react with other formulation ingredients.
- To maintain a solid-like consistency during storage, the gelling agent should resist shear pressures such as shaking the container, squeezing the tube, or applying it topically.
- Ensure enough antimicrobial protection against microbiological assault.
- Topical gel should not stick.

Swelling

The volume of a gelling agent increases as it absorbs a lot of solvated liquid. This is swelling. The solvent penetrates the matrix. Gel solvents function as gel-gel interactions. The quantity and intensity of gelling agent molecule bonds influence swelling.

Syneresis

Many gels compress and leak fluid when left standing. This is syneresis. As gelling agent concentration decreases, syneresis rises. Syneresis shows the original gel was thermodynamically unstable. Contraction is connected to gel setting's elastic tension release. Reducing these pressures reduces solvent interstitial space, forcing the liquid out.

Ageing

Colloids often aggregate slowly. This is aging. Gels develop a denser gelling component network with age. Gels develop a denser gelling component network with age.

This procedure is analogous to the first gelling phase and continues after the first gelation since the fluid medium is lost from the newly produced gel.

Structure

Gels are stiff because gelling agent particles form a network. The network architecture and gel properties depend on particle type and connection force. Individual hydrophilic colloid particles may be spherical or isometric small molecule or macromolecule groupings.

Rheology

Gelling agents and flocculated solid dispersion provide pseudo plastic solutions with non-Newtonian flow characteristics, decreasing viscosity with shear rate. N gels disrupt the delicate structure of inorganic particles distributed in water, and aging creates a denser gelling agent network.

Fungal Infection

Environmental and physiological factors may cause mycoses, common fungal diseases. Fungi may induce long-term infections, including lung or skin mycoses. As the fourth most common ailment in 2010, cutaneous fungal infections afflicted 984 million people. People with weak immune systems or on medications are more susceptible to fungal infections. Fungi are eukaryotic unicellular or multicellular creatures worldwide. The naked eye may see several yeasts and molds. Fungal diseases kill 1.5 million and injure billions. Avoidable fungal fatalities are ignored by public health officials. Moderate fungal infection may cause cancer, organ transplantation, asthma, and corticosteroid need. Many fungi are harmless, but others are poisonous. Inhaled or collected fungi spores infect. Fungus infections primarily affect the lungs, skin, and nails, but they may spread to organs and cause systemic illness. Unlike most bacteria, mycosis is fungal. Most severe mycoses can harm the host and need long-term therapy. Fungal infections are uncommon than viral and bacterial diseases, thus detection and prevention are less important.

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Antifungal Drugs Available in GEL

Sr. No.	Example
1	Fluconazole
2	Amphotericin B
3	Ketoconazole
4	Itraconazole
5	Terbinafine
6	Tioconazole
7	Clotrimazole
8	Mometasone
9	Fucidic acid

These drugs cure mycoses. Treatment may be topical or systemic, depending on the condition. Many over-the-counter antifungals include fluconazole. Amphotericin B, which is stronger, treats the most severe fungal infections that have been resistant to earlier treatments. Intravenous injection. Ketoconazole, itraconazole, and terbinafine treat skin infections. Candida albicans-caused vaginal yeast infections may be treated with tioconazole and pessaries, whereas cutaneous yeast infections are treated with ointments.

Antifungal Therapy Drug Delivery VIA Skin

Passive skin delivery needs 500-Da lipophilic molecule. Few drugs fulfill these percutaneous delivery requirements. Skin administration of such medications is mostly for systemic absorption or local therapy. Barrier layer-like topical preparations promote patient compliance and may be self-administered, whereas intravenous therapy avoids gastrointestinal adverse effects but is intrusive and onerous. Following cutaneous administration, antifungals should function in viable epidermis. Transdermal medication distribution is difficult due to stratum corneum and drug permeability. Many approaches are utilized. Solid-lipid nanoparticles, nanostructured lipid carriers, vesicular carriers like liposomes, ethosomes, niosomes, and transferosomes, and colloidal carriers like microemulsions, micelles, and nanoemulsions are new transdermal antifungal carriers

Physiochemical and Pharmacokinetic Properties of Antifungal Drugs

Physiochemical, pharmacokinetic, and intrinsic antifungal properties are crucial pre-development challenges for antifungal drugs. Fluconazole (8 mg/ml) is water-soluble and more polar than other azoles. Low protein binding, metabolically stable. Fluconazole is less active than ketoconazole in-vitro yet effective due to its body distribution and high blood drug levels. Poor water solubility, oxidation, and hydrolysis kill ketoconazole. While fluconazole is a weak base with a molecular weight of 306.3 Da, ketoconazole is a dibasic molecule with pKa values of 6.51 and 2.94. Patients with compromised immune systems may suffer oral infections from Candida species other than albicans. Polyene nystatin treats pharyngeal candidiasis. Nystatin binds to cell membrane sterols, leaking and permeating. We have ointment, powder, and cream. Works only against candida.

Preparation Available in Market

These categories used to according its site of infection

Preparation for Topical antifungal gels

These can be used to treat:

Infections from dermatophytes such tinea corporis, tinea cruris, tineafaciei, tineamanuum, and tineapedis.

An option to oral therapy for tinea barbae and capitis.

Yeast diseases: pityriasis versicolor and candida intertrigo.

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Nail plate infections and fungal skin disorders such tinea graeca.
The lotions are used twice a day to the affected area for two to four weeks, leaving several centimeters of healthy skin. After the last rash fades, continue for 1-2 weeks. Therapy must be repeated often.

Example along with brand name

Sr. No.	Brand Name	Example
1)	Whitfield's Ointment	Benzoic acid
2)	Batrafen® cream, powder, solution	Ciclopiroxolamine
3)	Nilstat® cream, ointment, paste	Nystatin
4)	Canesten® Once Daily Bifonazole Cream	Bifonazole
5)	Canesten® cream, powder and candid cream, solution	Clotrimazole
6)	Ecreme® cream, powder, foaming solution	Econazole
7)	Nizoral® cream and Daktagold® cream	Ketoconazole
8)	Daktarin® cream, dusting powder, lotion, thrush cream	Miconazole
9)	Lamisil® cream, gelsprey	Terbinafine

The azoles bifonazole, tioconazole, sulconazole, efinaconazole, and luliconazole, as well as the benzoxaborole tavaborole, are also accessible abroad.

Preparation for Scalp fungal infection

In addition to being used to treat tinea capitis and scalp psoriasis, antifungal shampoos are mostly used to treat dandruff and seborrheic dermatitis.

Example along with brand name

Sr. No.	Brand Name	Example
1)	Daktagold shampoo, Ketopine®shampoo, Nizoral®shampoo, Sebizole® shampoo	Ketoconazole
2)	HairScience® shampoo	Miconazole
3)	Stieprox® liquid	Ciclopirox

Drug Delivery System under Current Development for Improving Treatment of Fungal Diseases in Skin

Nanoparticulate Carriers

New topical colloidal drug carriers, nanostructure lipid carriers (NLC), are gaining interest. To circumvent SLN restrictions, NLC was created. SLN is solid lipids, whereas NLC is liquid (short chains) and well mixed solid (long chains), 70:30 to 99.9:0.1. The lipid particle matrix melts less than solid lipid but stays solid at body temperature. Dispersions of SLN have 70–99.9% water and low drug loading and ejection during storage. Active molecules are less likely to be expelled during storage because NLC may contain more medicines than SLN. Liquid lipid is more soluble in many medicines, making it ideal for drug loading. Numerous NLC characteristics facilitate topical usage. They have minimal cytotoxicity and systemic toxicity due to physiological and biodegradable lipids. The solid lipid matrix and compact size of lipid particles provide tight contact with the stratum corneum, which increases drug flow through the skin and controls carrier release.

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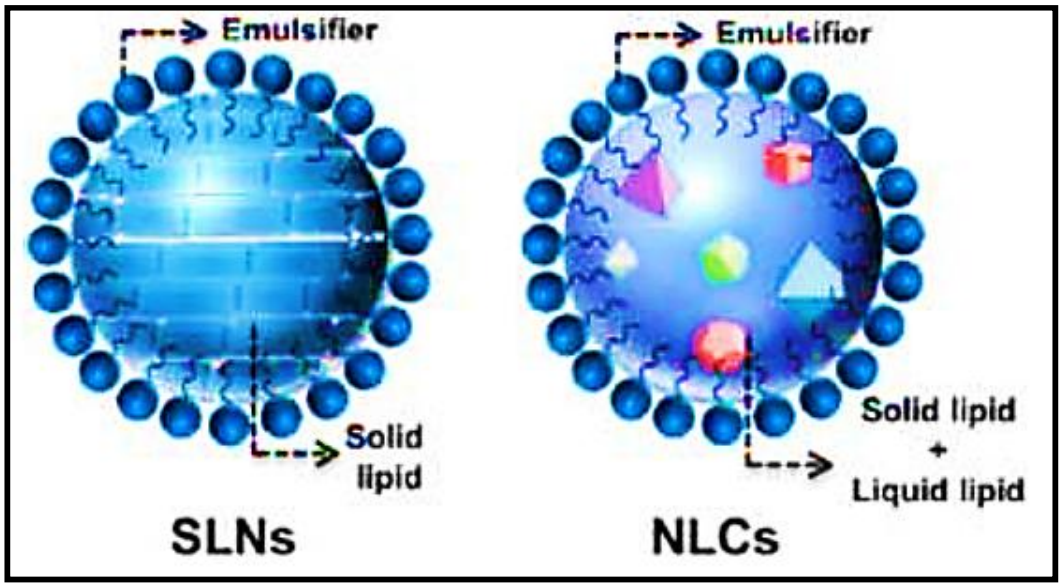

Figure 3: SLNs and NLCs.

Gelling Systems-polymeric Carriers

Nanosponges

Medication distribution methods have long been targeted to accomplish outcomes. Originally used solely on the surface, Nanosponges may now be injected orally and intravenously.

A new substance called a "nanosponge" has microscopic particles with a nanometer-wide hollow. These little holes may be filled with various materials. These tiny particles may transport hydrophilic and lipophilic therapeutic compounds, stabilizing weakly water-soluble molecules and medicines.

Polyester nanosponges are three-dimensional scaffolds that degrade biologically. Dissolving polyesters and a crosslinker creates Nanosponges. Since polyester is biodegradable, it dissolves gradually in the body. The loaded drug molecules are discharged harmfully when the nanosponges scaffold collapses.

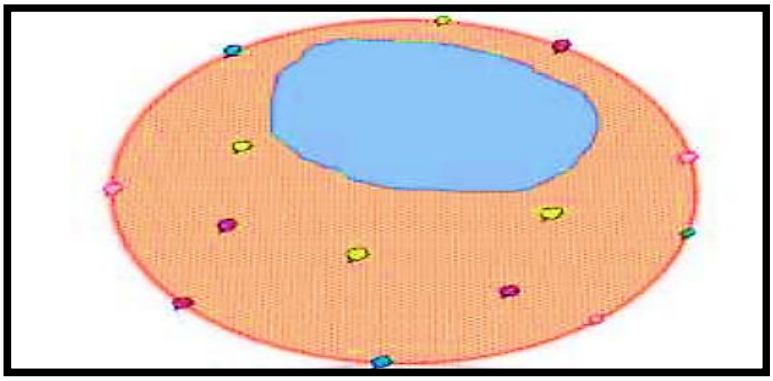

Figure 4: Structure of a Nanosponge showing a cavity for drug.

Amphiphilic GELS

Amphiphilic macromolecule-based self-assembly methods enable nanotechnology-based material construction. Recent investigations show that thermodynamic incompatibility between blocks organizes nanoscale space into ordered morphologies with specific structural features. Biosystems may execute particular biological functions via amphiphilic macromolecular assemblages and coordinated operations. Soft contacts like hydrogen bonds, steric effects, hydrophobic, and electrostatic interactions assemble conventional head/tail(s) amphiphiles. Effects electrostatic, hydrophobic, steric. We also discuss key scenarios where complicated processes, such as structure-directing

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interactions modifying and controlling morphology, may boost biological, pharmacological, and materials research. Chirality, signal processing, and identification are possible with precision chemical structure and noncovalent force. Finally, we describe the distinctive structural properties.

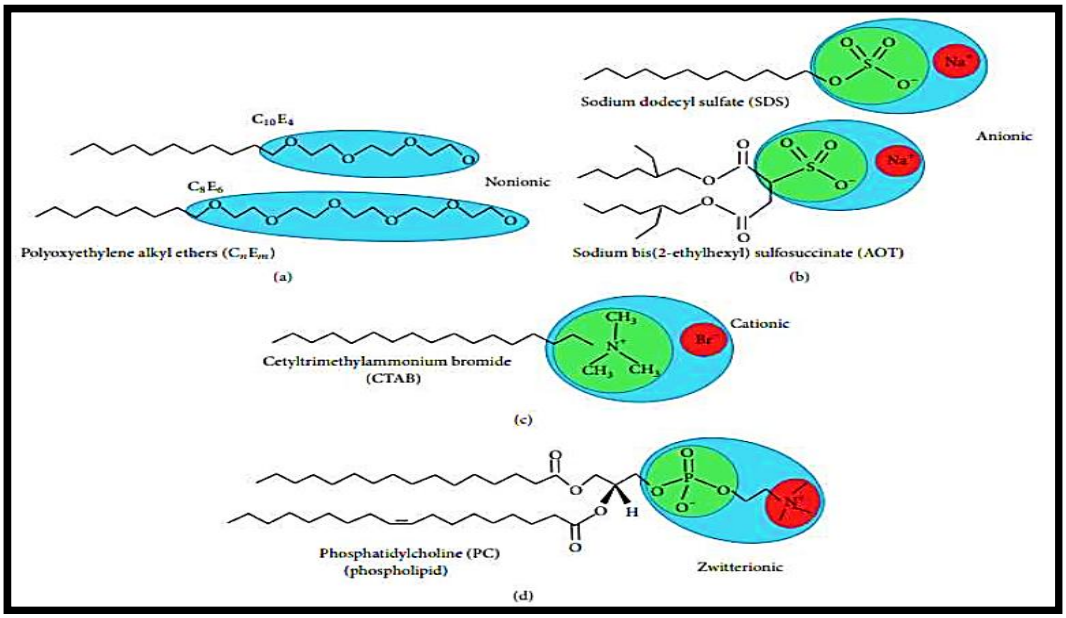

Figure 5: Example of most common Nonionic (a), Anionic (b), Cationic (c), and Zwitterionic (d) Amphiphilic molecule.

Emulgels

Over the last decade, academia and industrial researchers have focused on pharmaceutical semisolid dosage forms, particularly emulgels. Systemic and local medication delivery need skin. Despite their convenience, certain medications cannot enter the skin. Simple ointments to multiphase nanotechnology treatments are topicals. Patient compliance will be improved by widespread topical drug delivery. Emulgel combines emulsion with gel. A gelling agent with oil-in-water (O/W) or W/O emulsions generate an emulgel. Recent topical formulations provide hydrophobic drugs. Emulgel may also be used to add hydrophobic drugs to gels. Emulgel offers dual-control drug release due to its emulsion-gel features. These advantages have drawn pharmaceutical companies to emulgel production. Such as Diclofenac sodium.

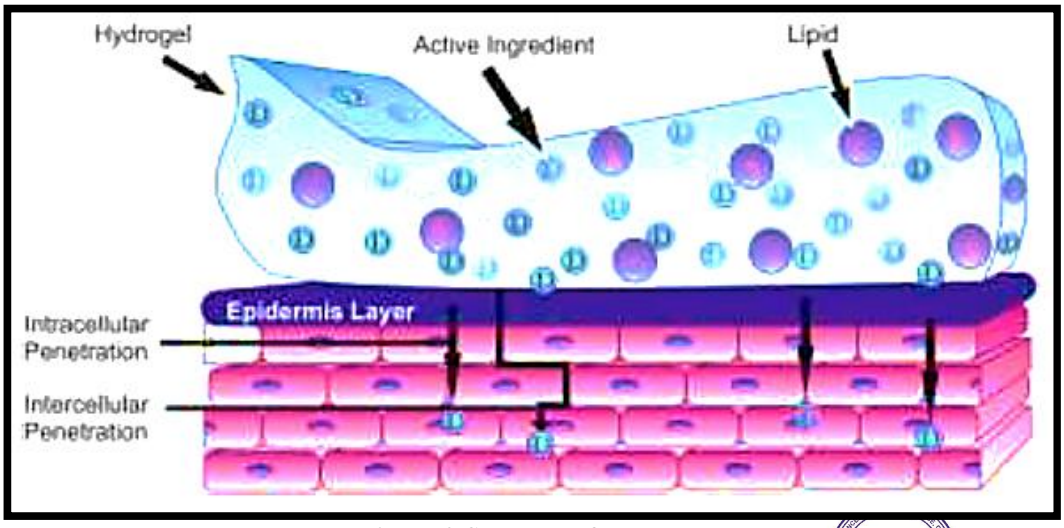

Figure 6: Structure of Emulgels

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Colloidal Carriers

Microemulsion

A "micro emulsion" is an optically isotropic, thermodynamically stable colloidal dispersion with droplet sizes between 10 and 100 nm. Plenty of oil, aqueous, surfactant, and co-surfactant. Microemulsions' poorly soluble pharmaceutical bioavailability has been widely studied. Their advice is realistic. Small droplets and low surface tension allow microemulsions absorb and penetrate. Flexible carriers are becoming used for more than oral delivery. They may deliver innovative medications due to their unique solubilization and thermodynamic stability. Research shows microemulsions outperform suspensions, micellar solutions, and colloidal systems and may transport drugs. Prolonged or modulated parenteral, topical, transdermal, ocular, percutaneous, and oral drug release are promising methods.

Bioavailability, spontaneous synthesis, thermodynamic stability, hydrophobic drug solubilization, and manufacturing and scaling ease. Microemulsions with inverted micellar structure may be less comedogenic than creams or solutions. Oil, water, surfactants, and cosurfactants form a microemulsion. Self-made systems are transparent, optically isotropic, low-viscosity, and thermally stable. Dispersed phase droplets may reach 150 nm, one-fourth of the visible light wavelength, making these systems transparent. A "micro emulsion" is misleading since stable ones have droplets of 10–100 nm (100–1000°A). Numerous in vitro and in vivo studies reveal micro emulsions distribute better transdermally and dermally.

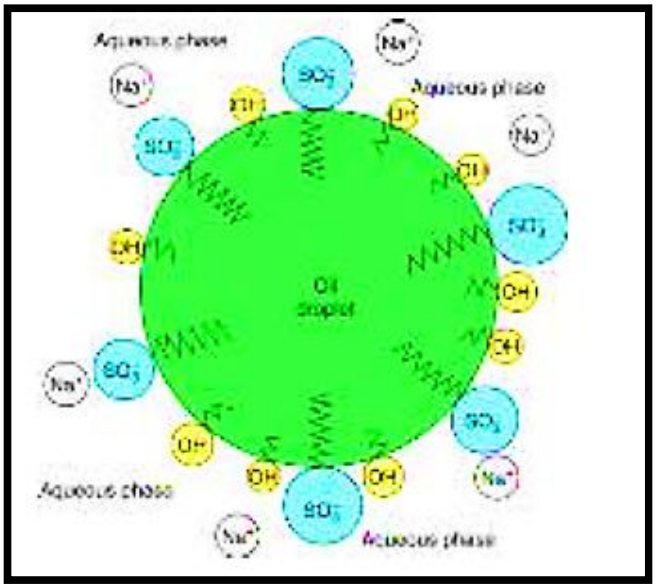

Figure 7: Microemulsion

Nanoemusion

Nanoemulsions are isotropic dispersions of two immiscible liquids, such water and oil, stabilized by a surfactant and co-surfactant interfacial layer to form a single phase. They are also called submicron, ultrafine, and miniemulsions. In thermodynamics and kinetics, submicron colloidal particle systems are assumed to be Various ionic and non-ionic surfactants have been utilized with these nanoemulsions. Zitterions, nonionic, anionic, and cationic surfactants were most often utilized. The earliest nanoemulsions were oil-in-water (O/W) with droplet diameters of 50–1000 nm. Recently discovered nanoemulsions include water-in-oil (W/O), bi-continuous, and O/W. By changing emulsion components, all three kinds may be created. Multiple nanoemulsions combine O/W and W/O emulsions. Both emulsions are stabilized by hydrophilic and lipophilic surfactants. The following are some benefits of nanoemulsions over conventional dosage forms:

A higher absorption rate,

A lower absorption variability,

Defense against hydrolysis and oxidation in O/W nanoemulsions,

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Lipophilic drug delivery after solubilization,
Aqueous drug dosing form for medicines insoluble in water,
Increased drug absorption for several medications
The capacity to combine hydrophilic and lipophilic medications,
Delivery methods that increase effectiveness while lowering the overall dosage,
Drug permeation via a liquid film, whose hydrophilicity or lipophilicity as well as thickness may be precisely controlled, to control drug release, is a safe, non-irritating technique of delivering medication to skin and mucosal membranes.

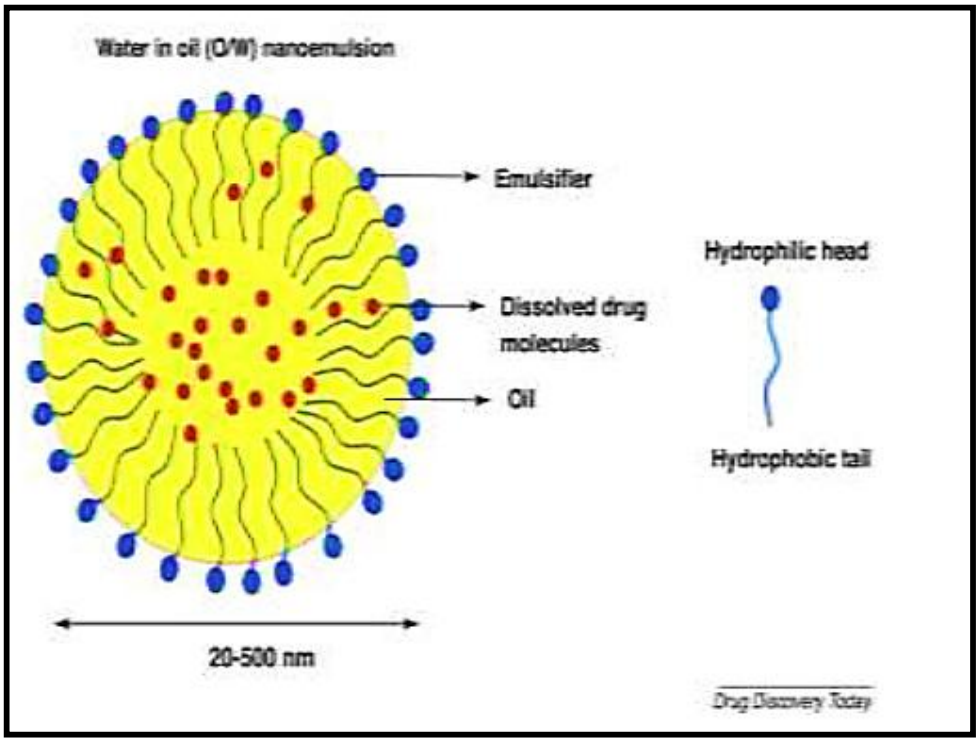

Figure 8: Nanoemulsion.

Different Types of Polymers Used to Prepare Topical Antifungal GEL:

Gelling agents

These compounds may also be used to thicken any dosage form in order to enhance its consistency.

Sr. No.	Gelling agent	Quantity [%]
1)	Carbopol-934	0.5 to 2
2)	Carbopol-940	0.5 to 2
3)	HPMC-2910	2.5
4)	HPMC	3.5
5)	Sodium CMC	1

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Permeation enhancers

These are chemicals that penetrate the skin and interact with its constituents to temporarily and reversibly increase skin permeability.

Sr. No.	Penetration Enhancer	Quantity [%]
1)	Oleic acid	1
2)	Lecithin	5
3)	Urea	10
4)	Isopropyl myristate	5
5)	Linoleic acid	5
6)	Linoleic acid	8
7)	Menthol	5
8)	Cinnamon	8

Emulsifier

In order to maintain stability throughout the course of a shelf life that might vary from days for spontaneously produced emulsions to months or years for commercial preparations, emulsifying chemicals are utilized. They are also used during creation to improve emulsification.

Sr. No.	Emulsifier
1)	Polyethylene glycol 40 stearate
2)	Sorbitan monooleate (span 80)
3)	polyoxyethylene sorbitan monooleate (tween 80)
4)	Stearic acid
5)	Sodium stearate

The choice of vehicle/solvent

Frequently, solvents consist of purified water. Alcohol, glycerol, PG, PEG 400, and other co-solvents may be utilized to enhance the solubility of the therapeutic agent in the dosage form and/or to facilitate drug transdermal absorption.

Inclusion of buffers

In the formulation of gels containing aqueous and hydroalcoholic bases, buffers may be used to control the pH. Hydraulic-based vehicles have a reduced solubility of buffer salts.

Preservatives

To decrease the amount of unbound (antimicrobially active) preservative present in the solution, specific preservatives form an alliance with the hydrophilic polymers employed in the fabrication of gels.

In order to compensate for this, the initial concentration of these preservatives must be increased.

Evaluation of GELS

Homogeneity

Using a visual inspection, the homogeneity of each generated gel was assessed subsequent to its placement in the container. They were inspected for the presence of aggregates and apparent indications of condition.

Grittiness

In an effort to detect the presence of particles, a light microscope analysis was performed on each of the formulations but none were observed. Hence, it is evident that the gel formulation meets the requirements for the absence of particular substances and particulate, both of which are essential qualities for a topical medication.

Measurement of pH

The pH was computed utilizing digital pH meters. After dissolving 1g of gel in 100 ml of purified water, the solution should be left for two hours. Perform the pH measurement in triplicate and calculate the mean value of the results.

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Drug content

A volume of 100 mL of the appropriate solvent was mixed with 1 gram of the gel. The stock solution should be cleaned. The absorbance is then measured after serial dilutions of various concentrations are prepared using the appropriate dilutions. Utilizing the equation derived from a linear regression analysis of the calibration curve, the drug concentration was computed.

Viscosity study

Utilizing a Brookfield Viscometer, the viscosity of the prepared gel was determined. The spindle bearing 64 was utilized to induce 20 and 30 revolutions per minute of gel rotation. The dial reading corresponding to each pace was recorded.

Spreadability

It displays the size of the area where the gel distributes readily on the skin. Spreading value impacts therapeutic efficacy. Spreadability is assessed in seconds by how long it takes two slides to separate from the gel sandwiched between them when a force is applied. Shorter sliding gaps improve spreadability. The formula below calculates spreadability.

Spreadability (S) = M × L / T

Where,

M = weight tied to upper slide

L = length of glass slides

T = time taken to separate the slides

Extrudability study

After setting in the container, the formulations are filled in collapsible tubes. Extrudability is the weight in grams needed to extrude a 0.5 cm gel ribbon in 10 seconds.

Skin irritation studies

For this test, 20–22g albino mice of either sex were employed. We utilized dorsal skin. Mice's hair was removed three days before the study. The animals were divided into two batches and two groups within each batch. The drug-containing gel was tested on animals. Albino mice were given cotton wool soaked in treatment solution as a control. Animals were treated daily for seven days before erythema and edema were visually assessed.

Globule size and its transport in gel

The Malvern zeta sizer determines globule size and course. To homogenize distribution, dissolve a 1.0 gram gel game plan test in refined water and aggressively mix. Test diffusing will be added to the zeta sizer photocell.

In-vitro Diffusion studies

A Keshary-Chien diffusion cell with a cellophane membrane was used to test the gel's in-vitro diffusion. The receptor compartment contained 100 ml of phosphate buffer and 500 mg of gel uniformly distributed over the cellophane membrane. The donor and receptor compartments were kept in touch and maintained at 37±0.5 0C. The receptor side solution was agitated by externally driven Teflon-coated magnetic bars at preset intervals, and 5 ml of solution was pipetted out and replaced with fresh 5 ml phosphate buffer right away. The receptor fluid drug concentration was evaluated spectrophotometrically against a blank. The experiment was repeated three times.

II. CONCLUSION

Gels are more stable and may discharge regulated amounts than creams, ointments, pastes, etc., making them popular. The gel formulation may increase medication bioavailability by improving absorption. A long-term study of gel formulation stability may allow its therapeutic use in patients. The water-soluble polymer creates a washable gel and has greater promise as a topical medicine delivery method. Topical medication application increases tissue and surrounding drug concentrations for better drug action. This is helpful for drugs with short biological half-lives and narrow therapeutic windows. Topical gel treats skin diseases safely and effectively, according to clinical evidence.

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