Bulletin of Environment, Pharmacology and Life Sciences
Bull. Env. Pharmacol. Life Sci., Vol 12 [5]April 2023 : 308-317

Online ISSN 2277-1808
Journal's URL:http://www.bepls.com
CODEN: BEPLAD

REVIEW ARTICLE **OPEN ACCESS**

Nanoemulsion for the Treatment of Psoriasis

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ABSTRACT

Psoriasis is a disease caused by hyperproliferation and abnormal keratinocyte differentiation. It has affected most of the population. It is characterized by skin patches that are red or pink and coated with silvery-white scales, the exact cause of this disease is unknown. Psoriasis is classified into many types, it affects the human skin and it targets the skin folds, groyne area, nails, between the buttocks, and many other areas. There are many drugs used to treat psoriasis-like dithranol and calcipotriol, nanoemulsion formulation is also used to treat psoriasis. Nanoemulsions contain an oil phase, surfactant, co-surfactant, and other excipients and have a number of benefits over conventional delivery systems, including increased drug bioavailability, reduced drug degradation, and loss, and prevention of toxic side effects. Nanoemulsions are more kinetically stable, avoid cream separation, have a significant impact on topical systems, and have a larger solubilization capacity than coarse emulsions. Antipsoriatic drugslike capsaicin and aceclofenac are loaded into the nanoemulsion. There are two ways to prepare nanoemulsions, they are high and low-energy emulsification.

Keywords: *Nanoemulsion, Psoriasis, Topical Therapy. Phototherapy, Skin Patches*

Received 13 .03.2023 Revised 17.04.2023 Accepted 26.04.2023

INTRODUCTION

Psoriasis is a chronic autoimmune inflammatory disease that affects 2%-5% of the world's population and is distinguished by skin macules and plaques produced by hyperproliferation and abnormal keratinocyte differentiation (1–4). Around the age of 40 when the syndrome initially manifests itself, and it lasts a lifetime. The disorder has a significant influence on a patient's quality of life, resulting in intense despair and suicide ideation, as well as a high mortality rate (5,6). Psoriasis is identifiable by its silvery-white, scaly, erythematous patches that itch the skin. The skin's structural and histological alterations that make the disorder more severe and painful have been linked to the immune system and concomitant inflammatory mediators like interferon, cytokines, tumor necrosis factor, and colony-stimulating factors (7). Although the exact cause of the disorder is unknown, a changein skin cell activity could be brought on by a number of things including stress, smoking, skin infections, climatic circumstances, and specific drugs (8). The severity of the disease, which is categorized as mild, moderate, or severe, determines the best course of treatment for this multifactorial ailment (9) Currently used drugs for treating psoriasis include pyrimidine antagonists, corticosteroids, retinoids, anthralin, calcineurin inhibitors, vitamin D analogs, folic acid antagonist, Janus kinase inhibitors, phosphodiesterase-4 inhibitors, radiation therapy and biologics (10). Most in the aforementioned classifications, with the exception of biologics, are applied topically and are advised for mild to moderate disorders. While reducing systemic damage, topical therapy has improved therapeutic responsiveness to the target location (11). Psoriasis treatment relies heavily on drugs anti- proliferative, immunosuppressive qualities, and anti-inflammatory. A class of drugs

known as corticosteroids possesses all of the therapeutic qualities (12). One of the oldest and most efficient therapies for dermatologic conditions is topical corticosteroids. The anti-inflammatory, immunosuppressive, vasoconstrictive, and antiproliferative properties of topical corticosteroids contribute to their clinical effectiveness in the managementof atopic dermatitis and psoriasis. Psoriasis is classified into many types which are discussed in **Table 1.**

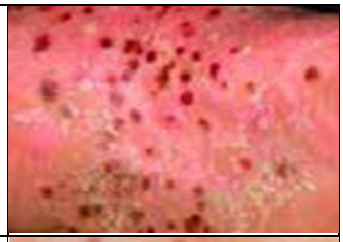
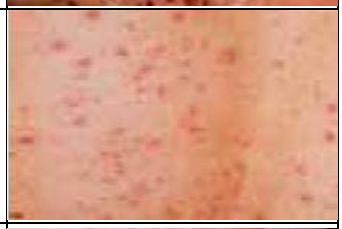
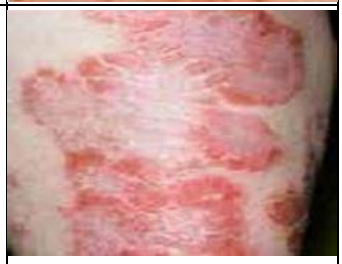
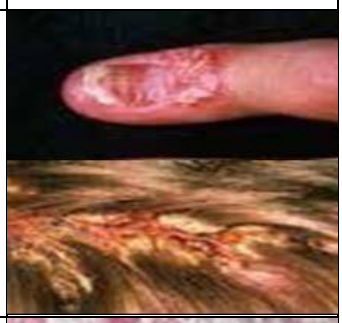
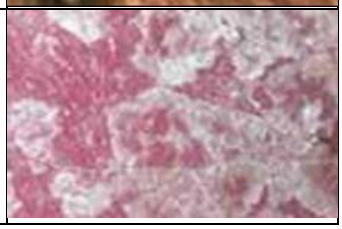
Pustularpsoriasis	This type of psoriasis is severe in which numerous tiny blisters occuron your skin. It requires immediate medical intervention.	
Guttate psoriasis	This appears as a smattering of little red scaly areas on your skin. These patches are able to cover up a considerable portion of your skin.	
Plaque psoriasis	Plaque psoriasis affects the majority of people. This manifests as skin patches that are red or pink and coated with silvery-white scales. The patches protrude a little bit from the surface of the skin.	
Flexural, nail,and Scalp psoriasis	This psoriasis manifests itself in skin folds, groyne area, andbetween the buttocks, where the genitals may be affected.	
Erythrodermicpsoriasis	In this type of psoriasis, the whole body will become red andinflamed.	

Table 1: Classification of Psoriasis

A colloidal carrier system called a nanoemulsion is composed of a surfactant, water, and oil. These nanoemulsions are good for a variety of dermatological applications because of their low viscosity, great kinetic stability, and optical clarity (13). Droplets that are as small as 500 nm might be referred to as nanoemulsions (14,15). Nanoemulsions are made up of extremely tiny and uniform-sized droplets. Different dosage forms, such as liquids, creams, sprays, gels, foams, and aerosols, can be formulated using nanoemulsions. They can also be given via a number of different delivery systems, including oral, intravenous, topical, intranasal, ocular, and pulmonary. Nanoemulsions are more kinetically stable, avoid cream separation, have significant impact on topical systems, and have a larger solubilization capacity than coarse emulsions (16,17). Nanoemulsions have a number of benefits over other conventional formulations including increased drug bioavailability, reduced drug degradation, and loss, prevention of toxic side effects, increased drug accumulation in the target region, versatility and improved patient

compliance, and flexibility in drug handling. The long-term physical stability of nanoemulsions is directly related to their tiny droplet size, which prevents common destabilizing phenomena including creaming, sedimentation, and coalescence. **Figure 1** illustrates how the miniscale size of nanoemulsion droplets and their tendency to solubilize hydrophobic drugs when applied topically can significantly increase systemic bioavailability via the transcellular route and rate of drug dissolution. By partitioning the drug from the oil into the surfactant layer andthen into the aqueous phase, the drug is released from a nanoemulsion while avoiding occlusive effects (18,19). Since macroemulsions frequently exhibit inherent creaming, flocculation, sedimentation, and coalescence, nanoemulsions are an advantageous choice as a carrier for anti-psoriatic drugs.

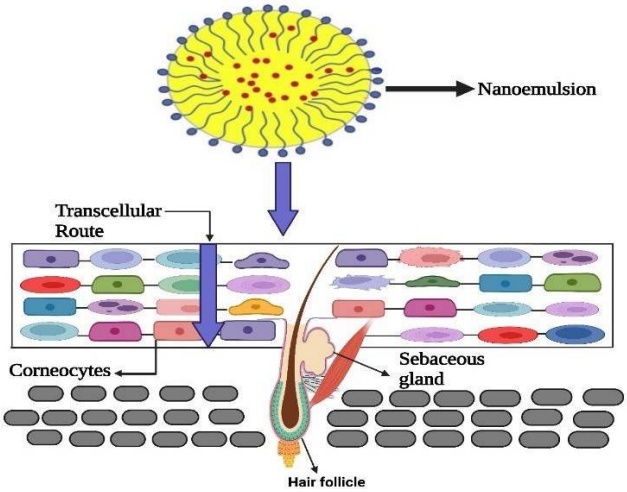


Figure 1: Mechanism of absorption of Nanoemulsion

PATHOGENESIS OF PSORIASIS

Four irregularities set psoriasis apart from other skin conditions: Acanthosis is characterized by the following four abnormal epidermal differentiation processes: (1) Redness or erythema occurs due to vascular changes, in whichcapillary blood vessels become dilated and tortuous, (2) Inflammation, during which polymorphonuclear leukocytes from dermal vessels invade the epidermis, (3) Hyperproliferation of the keratinocytic layer, and (4) Abnormal epidermal differentiation, during which corneocytes maintain their ability to differentiate **Figure 2** (20,21). The activation of circulating immune cells and the signaling molecules they emit, which promote hyperkeratosis and neovascularization in psoriatic skin are usually required for the development of psoriasis in contrast to the development of normal skin (22).

TREATMENT STRATEGIES FOR PSORIASIS

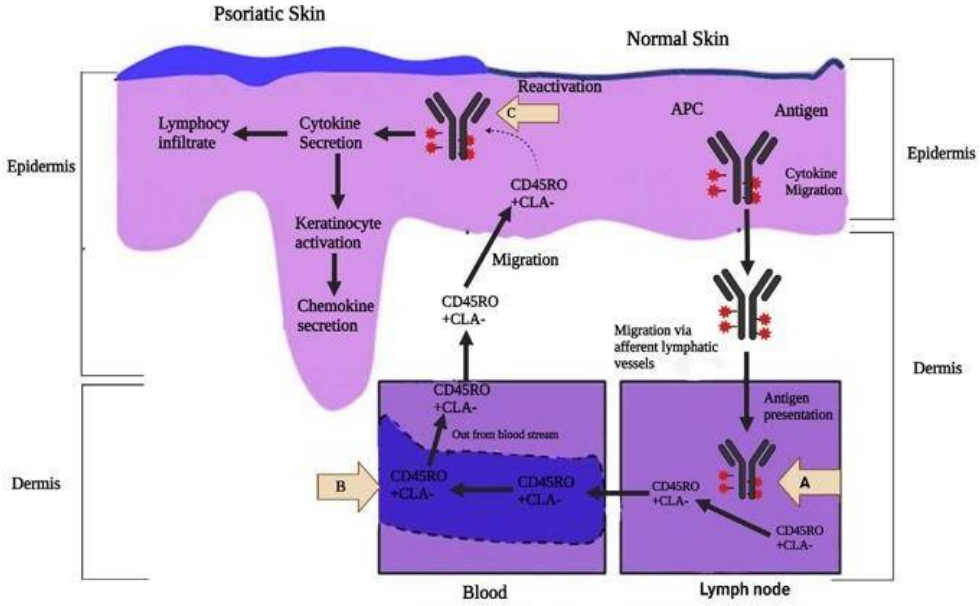


Figure 2: The major pathway of psoriasis pathology.

Psoriasis can be treated using a variety of approaches. Systemic therapy, phototherapy, and topical therapy are the most regularly used treatments for psoriasis. Topical therapies are prioritized in the treatment of psoriasis. In the case that topical therapy is ineffective or the psoriasis disease is persistent, phototherapy is advised. Systemic drugs are then prescribed. Therapies used to treat psoriasis are given in **Table 2.** None of the psoriasis treatments that are currently available have been proven to be completely safe and can cure the condition. Additionally, there are toxicities associated with the treatment alternatives that contribute to poor patient compliance over time. Numerous negative consequences of phototherapy and systemic drugs include renal toxicity and hepatotoxicity. Furthermore, there are issues with the currently available psoriasis formulations including increased side effects, and higher dose frequency. It is necessary to develop and execute fresh approaches in order to increase the therapy's usefulness and acceptability because there is now no effective or safe treatment for psoriasis (23,24).
Formulation development aims to create the drug formulation demonstrating the ease of administration topsoriatic patients.

Table 2: Therapies used to treat psoriasis

Class	Drugs	Type of Therapy
Psoralens	Trioxysalen – Methoxsalen	Topical
Antracens	Dithranol	
Tars	Tar	
Others	Calcipotriol, Tacalcitol	
Psoralen	Trioxysalen	Systemic
Retinoids	Etretinate – Acitretin	
	Artificial or natural light sources	Phototherapy

The localized effect and reduced systemic side effects of topical delivery systems are extremely advantageous. Drug delivery to the targeted site in the skin may be facilitated by novel colloidal carriers. Major topical delivery carriers include ethosomes and liposomes. The use of nanoemulsions as topical delivery systems presents a potential strategy because they are the most straightforward transparent kinetically stable systems with globule sizes in the 20-200 nm range. Recently, Kaur *et al.* developed and optimized the calcipotriol (CT) and clobetasol propionate (CP) loaded nanoemulsion-based gel for the topical treatment of psoriasis. In comparison to free drugs, HaCaT cell lines displayed improved drug uptake from nanoemulsion in conjunction with improved drug penetration in the stratum corneum (SC) and viable layer. Nanoemulsion gel had much greater anti-psoriatic action as compared to free drugs. In another study, the non-aqueous nanoemulsion (NANE) of Alpinia galanga extract (AGE) was created utilizing Palmester 3595 as the oil phase, glycerine as the non-aqueous polar continuous phase, and Cremophor RH 40-Transcutol P® as the surfactant-co-surfactant (Smix). Confocal laser scanning microscopy (CLSM) demonstrated that the trans-follicular transport mechanism allowed AGE NANE to penetrate the stratum of the skin. AGE-NANE at 30 2 C/75 5% RH and 53 C showed greater stability. The effectiveness was assessed *in vivo* using a mouse model induced by imiquimod (IMQ). The psoriasis was significantly improved in the mice treated with low and high dosages of AGE NANE (groups VI and VII; p 0.05). In mice treated with AGE NANE, histopathological findings showed a decrease in the psoriasis area severity index (group VI and group VII)(25).
Another study revealed that the addition of CP in NEs might improve CP delivery, enhancing anti-psoriatic activity. The drug was incorporated into a dispersed phase of oil when the topical O/W nanoemulsion was produced, and several *in vivo* research studies were used to assess the efficacy of the formulation. They considerably increased their anti-inflammatory activity. According to a study, CP-loaded nanoemulsion markedly enhanced lymphocyte NTPDase (Nucleoside triphosphate phosphohydrolase) activity. Extracellular ATP (Adenosine triphosphate), which is responsible for cell proliferation, and inflammatory processes, is hydrolyzed by this membrane protein. Despite having a large level of surfactant, in vivo irritation testing did not demonstrate any irritation (26). Another study, using tween 80 and ethanol as surfactants, has developed a methotrexate-loaded nanoemulsion based on chaulmoogra oil via an emulsification approach. FTIR and TEM studies were used to characterize the formulation. By using the MTT assay, the formulation was found to be cytocompatible with mouse dermal fibroblast L929 cells and stable in the refrigerator for the 3 months it was tested for. When compared to the control drug solution, the *ex-vivo* skin permeation investigations carried out using Franz diffusion cell apparatus employing porcine skin indicated better skin permeation and retention of the drug in deep skin layers. When

compared to an oral methotrexate tablet, the *in vivo* anti-psoriatic tests on the imiquimod psoriatic model showed greater anti- psoriatic activity with less serum and tissue build-up and effective skin retention (27). The multiple-drug approach can also be employed in a single nanoemulsion for the synergistic effect of combinatorial formulation and for the enhancement of therapeutic activity. In this regard, recently a research group designed and optimized a nanoemulsion gel formulation for the simultaneous delivery of three drugs: Curcumin, Resveratrol, and Thymoquinone. On A-431 cells, the optimized formulation showed a higher proportion of growth inhibition and demonstrated anti-angiogenic efficacy in the HET-CAM test. Finally, *in vivo* research using the Balb/c mouse model demonstrated enhanced anti-psoriatic conditions, proving that the nanoemulgel formulation's triple natural bio- actives combination is effective in treating psoriasis (28).

METHOD OF PREPARATION OF NANOEMULSION

Fundamentally there are two ways to prepare nanoemulsions, they are high and low-energy emulsification which is depicted in **Figure 3** (29).

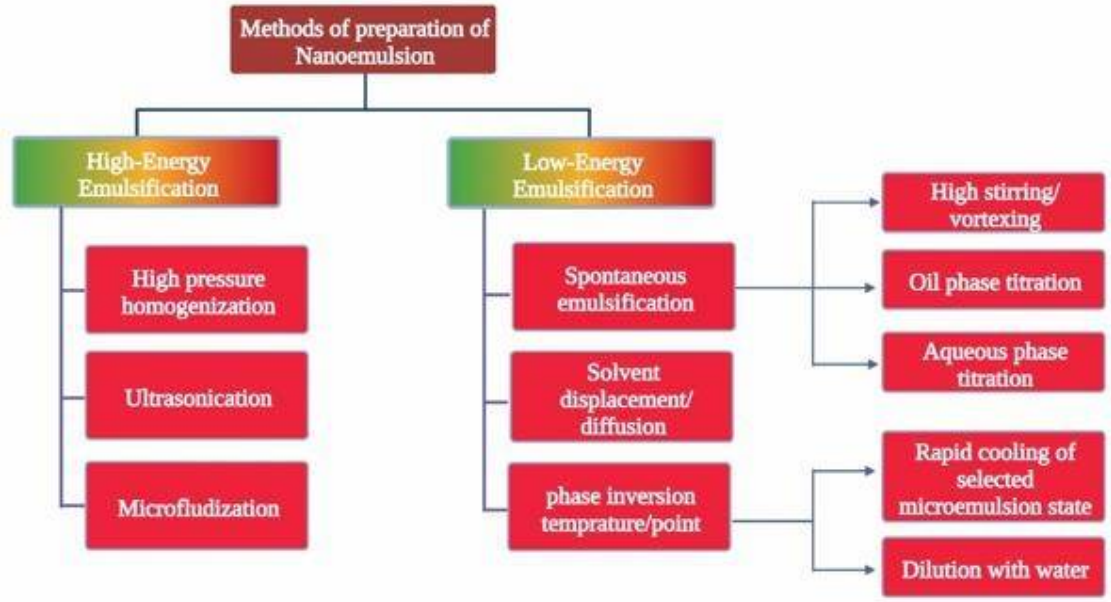


Figure 3: Methods of Preparation Nanoemulsion

High-pressure Homogenization:

This is a very effective technique for the preparation of nanoemulsions, requiring the forceful entry of water, oil, cosurfactants, and surfactants through a tiny hole under intense pressure. The dispersed phase makes up a high- volume fraction of the initial emulsion, which may later be diluted. Surfactants are applied in excess to prevent coalescence (30).

Micro fluidisation:

Oil and water are delivered into the mixing region using a pressure pump through a small opening in the opposite direction, where they combine with other high-shear ingredients to form tiny droplets that are then employed to formulate a nanoemulsion (31).

Sonication:

A probe sonicator is used to provide mechanical force, causing the dispersion to form tiny droplets in a mixture of water, oil, cosurfactants, and surfactants (32).

Phase inversion temperature technique:

Before the temperature is raised and the surfactant is coupled with the oily phase, the water, oil, and surfactants are combined at room temperature. As a result of temperature changes, phase inversion inhibits coalescence andproduces stable nanoemulsions (33).

Solvent displacement method:

An aqueous phase containing surfactants is combined with an organic phase containing oil that has been dissolved in a solvent at room temperature. To prepare the nanoemulsion, a vacuum-evaporated organic solvent is dispersed. The correct solvent-to-oil ratio can be employed to make nanoemulsion droplets (30).

Spontaneous emulsification:
O/W nanoemulsions are produced by slowly adding water to a combination of oil and surfactant. Concentration, the phase transition region, and the surfactant structure are the variables in the preparation of nanoemulsion (34,35).

COMPONENTS USED IN THE TOPICAL ANTIPSORIATIC NANOEMULSION FORMULATIONS

Oil Phase:
This phase can be penetrated by both unsaturated and saturated fatty acids. Since the majority of antipsoriatic drugs are lipophilic, they can be encapsulated in emulsions. Examples of unsaturated and saturated fatty acids include coconut oil, and castor oil (30).

Surfactant:
In order to prepare stable emulsions with the proper particle size and minimal skin irritation, the interfacial tension is reduced by using the right surfactant. The four primary types of surfactants are anionic, cationic, zwitterionic, and nonionic. Typical surfactants include Tween® and Cremophor® (35).

Co-surfactant:
These are widely employed to alter the fluidity and curvature of the interfacial layer, hence reducing interfacial tension. These also include short- and medium-chain alcohols (30).

Other Excipients:
The product is supplemented with antioxidants (ascorbic acid, a-tocopherol), tonicity Modifiers (sorbitol, glycerol), pH adjusting substances (HCl or NaOH), aqueous phase ingredients (sodium chloride), Gelatin and other viscosity-enhancing substances (Carbopol® and Aerosil®), and penetration promoters (36).

CHARACTERIZATION OF NANOEMULSION

Drug-excipients compatibility studies:
In order to determine the interactions between excipients and drugs, Fourier Transform Infrared Spectroscopy (FTIR) is used. It has been suggested that drug-excipient interactions occur most frequently when the drug and excipient are used in a 1:1 ratio, which also makes it simpler to spot incompatibilities (32).

Polydispersity index and Globule size distribution:
Size of the nanoemulsion's average globules can be find out by using a zeta sizer and photon correlation spectroscopy (PCS). The particle's mean diameter at 25 °C and a 90 ° angle are shown in this analytical finding (n=10). The polydispersity index, which is a measurement of the width of the dispersion of globule sizes, and the mean diameter (z-average), which is the size of the bulk population and is weighted by light intensity, are both produced by the PCS analysis (37).

Zeta potential:
The electrophoretic mobility is measured using a Laser Doppler Anemometer connected to the zeta sizer apparatus. Potential set at 150 mV, add 5 ml of water (0.45 m) and a sufficient amount of sample (50–100 mL) to the instrument's electrophoretic cell. The Smoluchosky equation can be used by the instrument software to calculate the zeta potential values (32).

Transmission electronmicroscopic (TEM):
With TEM, it is possible to observe each globule's internal matrix and form. One drop of the sample is put on a grid of copper that had a holey carbon layer, and it was then left aside for 10 minutes. The grid was then exposed to phosphotungstic acid (PTA) for 10 seconds while being held upside-down. The grid can then be examined under specific magnification by soaking any extra PTA on filter paper (38).

pH:
A pH meter can be used to measure the formulation's pH (31).

Viscosity:
Using a Brookfield viscometer, which spins for 10 minutes at a speed of 100 maximum rotations per minute, the viscosity of the nanoemulgel can be measured (39).

Drug content:
Drug content is estimated by adding 5g of nanoemulgel in 25ml of a phosphate buffer solution with a pH of 7.4. The solution is sonicated, filtered, and then adequately diluted. Then measure the absorbance at 273 nm in a UV- Visible spectrophotometer (40).

Spreadability:
In the center of a glass plate, weigh 0.5g of the sample. Insert a second glass plate between the two slides and place it on top of the first one after five minutes to assess the gel's spreadability in cm (37).

Pseudo-Ternary Phase Diagrams:

It stands out because it possesses a wide range of physical traits that are essential to determine its stability, structure, and drug release. To show how the oil, water, cosurfactant, and surfactant components impact the borders of the various phases, pseudo-ternary phase diagrams are frequently made. The aqueous solution is diluted by mixing the surfactant, oil, and cosurfactant in specified weight ratios at room temperature. By employing polarised light microscopy or a visual examination of the phase diagram, as illustrated in **Figure 4**, it is possible to identify the combinations of the three components that lead to clear emulsions after equilibrium. (41).

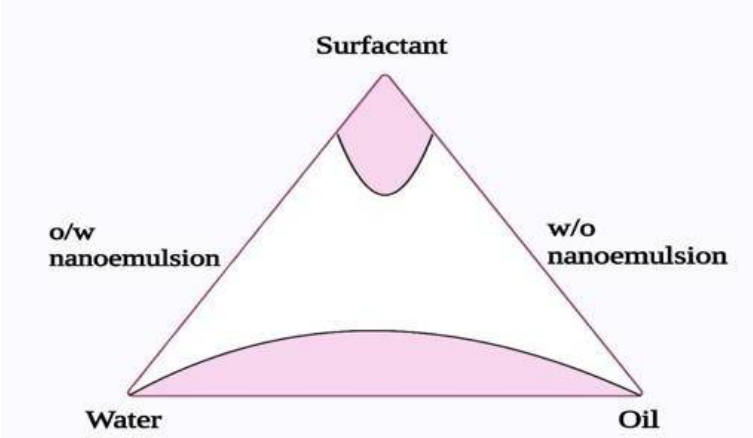


Figure 4: Phase diagram for the nanoemulsion formulation

CHALLENGES IN THE TOPICAL TREATMENT OF PSORIASIS

The hindrance preventing drug from being absorbed through the skin when they are applied topically is the stratum corneum. Recently, solid lipid nanoparticles and nanostructured lipid bilayers have been identified as promising colloid carrier systems for topical delivery. How well these systems work as drug delivery systems is greatly influenced by the drug release, stability at the nanoscale, and ability of these systems to pass through the various barriers of the skin. For *in vitro* and *in vivo* research, there is no acceptable animal model with a fully developed psoriatic illness (42). The advance of a delivery system for topical psoriasis treatment faces a number of substantial challenges, but there are also some particular issues with anti-psoriatic topical drugs that need to be fixed. (1) Psoriatic lesions have substantially thickened or reduced epidermis. Different skin morphologies may complicate drug absorption, making formulation development more challenging. (2) Most people with psoriasis think the current course of treatment is either ineffective or not aggressive enough. The development of a unique therapy that can be taken once every day and has quick benefits is thus another concern. (3) In order to enhance response and minimize adverse effects, combining drugs is essential for effective psoriasis treatment. Any innovative topical therapy must therefore be secure and efficient enough to be combined with an already available topical medication, like phototherapy. (4) Patients with plaque psoriasis favor formulations that can be applied to various body parts, including areas where hair grows. (5) The competitive pricing of any new drug is the most significant factor influencing product selection given the variety of therapies and the accessibility of generic goods on the market (43).

STABILITY OF NANOEMULSION

Emulsion stability is influenced by surfactant function, composition, and drop size distribution. Coalescence, which happens when droplets merge by rupturing the film between the two globules, increases the size of the nanoemulsion and is what causes major instability. Another is Ostwald ripening, where emulsions deteriorate over time as a result of molecular diffusion and modifications to the size of the nanoemulsion droplet. From the dispersed phase to the continuous phase, mass transfer occurs. The complete mechanism that causes the instability of the nanoemulsion is depicted in **Figure 5** (44).

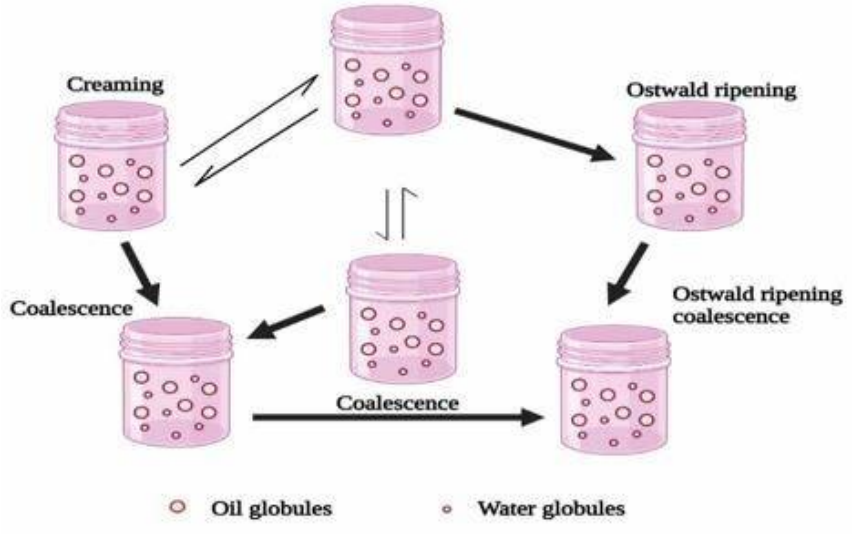


Figure 5: Mechanism causes instability of nanoemulsion

ANTIPSORIATIC DRUGS LOADED INTO NANOEMULSION.

Substantial research has already been conducted on nanoemulsion-loaded antipsoriatic drugs. The antipsoriatic drugs have been loaded into nanoemulsion is given in **Table 3.**

Table 3: Antipsoriatic drugs have been loaded into nanoemulsion.

Drug	Excipients	Preparation method	Ref
Capsaicin and Aceclofenac	Polyethylene glycol, dichloromethane, Polyvinyl alcohol,sodium tripolyphosphate,tween 80,	High-pressure homogenization and Solvent evaporation method	(30)
Turmeric oil	isopropyl alcohol, tween 80, Tween 20, lecithin, labrasol,	Emulsification method	(34)
Calcipotriol and Clobitasol propionate	Capmul MCM C8 EP, Labrafil 1944 CS and Cremophor RH 40,	Emulsification method	(35)
Betamethasone dipropionate	Eucalyptus Oil, Babchi oil, ethanol, tween 20	Spontaneous Emulsification method	(45)
salicylic acid and Betamethasone dipropionate	Sefsol, Oleic acid, isopropylalcohol tween 20,	Aqueous phase titration method	(46)
Clobetasol propionate	Eucalyptus oil, ethanol, Tween 20, distilled water,	Aqueous phase titration method	(46)
Betamethasone valerate	Sefsol, transcutol p, Tween 20,	Aqueous phase titration method	(26)
Cyclosporine	virgin coconut oil, xanthan gum, Nutmeg oil, tween 80,	High-shear homogenizer	(47)

CONCLUSION

There are many types of antipsoriatic formulations are available in the market but the nanoemulsion formulation shows increased drug bioavailability, reduced drug degradation and loss, prevention of toxic side effects, increased drug accumulation in the target region, versatility and improved patient compliance, and flexibility in drug handling. In comparison to coarse emulsions, nanoemulsions are more kinetically stable, prevent cream separation, significantly affect topical systems, and have a higher solubilization capacity. There are many drugs are loaded in the nanoemulsion formulation and these formulations are used to treat the psoriasis and it shows greater bioavailability.

DECLARATIONS

This review has not received any funds from funding agencies

CONFLICT OF INTEREST

All the authors have contributed equally to the work done and there is no conflict of interest

Ethics approval and consent to participate

This review has not involved studies such as human participants, human data, or human tissues

ACKNOWLEDGMENT

The authors express heartfelt gratitude towards the JSS College of Pharmacy, JSS Academy of Higher Educationand Research (JSSAHER), Mysuru, for providing all the obligatory facilities for completion of this piece of writing.

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CITATION OF THIS ARTICLE

Praveen H, Mohit A, Arjun H.R, Hemanth P. R V, Soundaryashree NR, Preethi S. Nanoemulsion for the Treatment of Psoriasis. Bull. Env.Pharmacol. Life Sci. Vol 12[5] April 2023: 308-317.