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REVIEW ON NANOEMULGEL

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ABSTRACT
In contrast to other semisolid preparations, gels are now often used in both medicinal and cosmetic formulations. Emulgel is the name given to the combination of gel and emulsion. The promising drug delivery method for hydrophobic medicines is emulgel. An emulsion can be turned into emulgel by combining it with gelling agents. The fundamental restriction of gels' many benefits is the delivery of hydrophobic medicines. Therefore, the emulsion-based technique is being employed to get around this restriction. Emulgel is used to relieve aches and pains brought on by colds, headaches, muscle aches, backaches, arthritis, and other ailments. In chronic skin illnesses such fungal infections, acne, and psoriasis, patient adherence to topical formulations is critical. Emulgels are thixotropic, greaseless, readily spreadable, easily removed, emollient, nonstaining, long shelf life, clear, and have a beautiful look, all of which are beneficial for dermatological use. Emulgels are a type of emulsion that has gained popularity in recent years. Emulgels, which contain a dual release control mechanism (Gel and Emulsion), have emerged as one of the most intriguing topical delivery technologies.

KEYWORDS: Nanoemulsion, Emulgel, Gelling agents, Topical drug delivery.

INTRODUCTION
Topical medication delivery is the application of a drug-containing formulation to the skin in order to deliver the drug directly to the patient. When other routes (Such as oral, sublingual, rectal, and transdermal) are ineffective, the topical medication delivery mechanism is commonly used.[1] The primary benefit of the topical delivery technique is that it avoids first-pass metabolism. Another advantage is the avoidance of the hazards and inconveniences of intravenous therapy, as well as the various circumstances of absorption, such as pH fluctuations, the presence of enzymes, and gastric emptying time. When other methods of drug administration fail, the topical drug delivery system is commonly used.[2]

There are a range of drug carriers utilised in topical therapies, including niosomes, liposomes, NLCs, SLNs, microemulsions, and topical gels, however they are mainly confined to the skin surface, which leads to a variety of side effects. As a result of its increased penetration into the skin and hair shaft, Nanoemulgels (Figure1) will prove to be the ideal topical preparation due to its long-lasting effects at the site of application.[3]

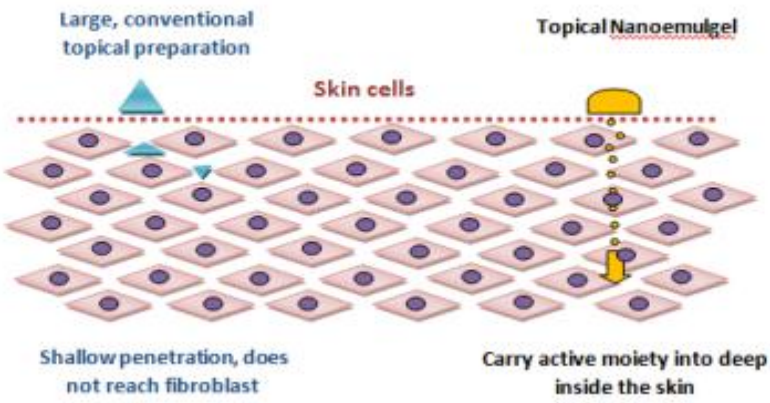

Fig. 1: Comparison of topical nanoemulgel with other topical preparations.

Each skin cell is separated by 70nm. Normal emulsified products take a long time to permeate the skin. Topical Nanoemulgel penetrates quickly and delivers active ingredients deeper and faster. Furthermore, nanoemulgel's gel-based formulation has improved qualities such as being non-greasy, easily spreadable, easy to remove, and having a longer shelf life.

Nanoemulsion

Nanoemulsions are submicron-sized colloidal particle systems that act as medication carriers. Their diameter ranges between 10 and 1,000 nanometers. These carriers are solid spheres with an amorphous, lipophilic, and negatively charged surface.[4] Nanoemulsions (NEs) are metastable dispersions of nano-sized particles that are non-equilibrium, thermodynamically stable, and optically transparent having a predetermined surface tension created by a certain shear, which is made up of a certain oil and blend of surfactant and co-surfactants being capable of dissolving huge amounts of hydrophobic medicines.[5]

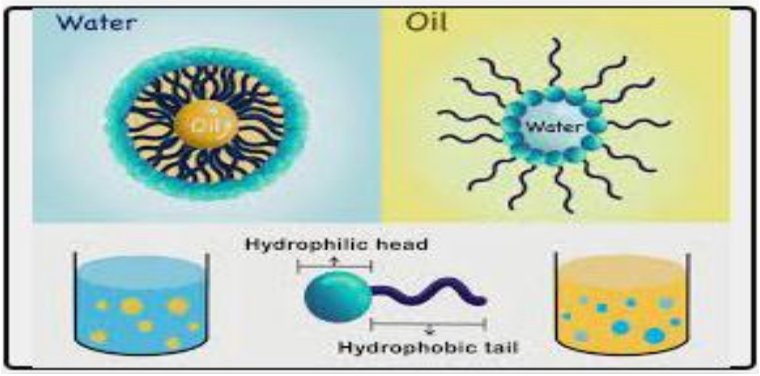

Fig. 2: Representation of nanoemulsion.

Emulgel

Emulgels are a combination of gel and emulsion, as their name suggests. Both oil-in-water and water-in-oil emulsions have been used to administer medications to patients.[6] Emulgels have advantages like Thixotropic, greaseless, easily spreadable, readily removable, emollient, non-staining, biodegradable, attractive, transparent, and non-toxic as well as having a lengthy shelf life and penetration. The characteristics of the emulsion and gel formulations are different. However, the gels have some drawbacks in terms of hydrophobic drug delivery. This constraint is being overcome by use of emulgel. The use of a gelling ingredient in a traditional emulsion can be made into an emulgel.[7]

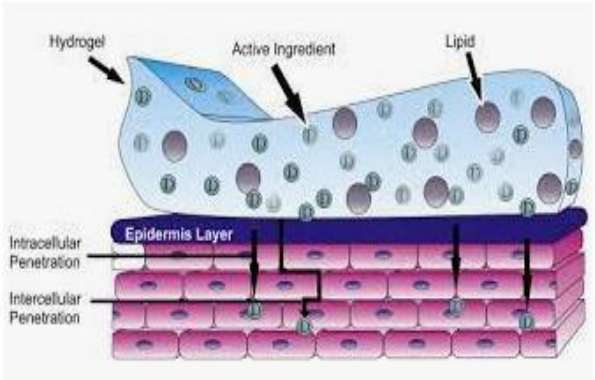

Fig. 3: Structure of emulgel.

Rational

Topical dose forms such as creams, lotions, and ointments have a number of drawbacks. One of them is stickiness, which can be difficult for patients to apply and has low spreading qualities. The demand for rubbing is sometimes considered a drawback. In addition, the stability of the formulation for hydrophilic medicine revealed several issues. As a result of these flaws with the largest number of people,The usage of gelled formulations in semisolid preparations has increased both in pharmaceutical and cosmetic preparations. Gel is a colloid that contains 99 percent liquid and is immobilised by a macromolecular network of fibres made from a gelling material. They're held together by surface tension Regardless of the benefits, there is a significant disadvantage.The issue with hydrophobic

medicines is their delivery. To circumvent this difficulty, an emulsion-based technique can be employed to include lipophilic medicinal moiety in a gel-based system.[8]

Advantages

- Hydrophobic medicines can be easily integrated into gels.
- Improved stability.
- Greater capacity for loading.
- Possibility of production and cheap preparatory cost.
- There will be no intensive sonication.
- It gets rid of the first-pass metabolism.
- Possible to avoid GI incompatibility.[9,10]

Disadvantages

- This causes an issue with macromolecule absorption.
- Air bubble entrapment during formulation.
- Only hydrophobic medicines are suitable for this type of delivery.[11]

Components

The components used in the preparations are as follows;

1. Aqueous materials

The aqueous phase of the emulsion is formed by the addition of aqueous materials.[12]

2. Oils

Oils contribute to the oily phase of the emulsion. Externally applied emulsions can be supplemented with non-biodegradable mineral castor oils, fish liver oils, or other fixed vegetable oils.[13]

3. Emulsifier

Emulsifiers are substances that help to regulate and stabilise the emulsification process. Because the application of an appropriate emulsifying agent can increase emulsion stability. Nonionic surfactants (spans, tweens) with HLB values greater than 8 are employed in the formulation of o/w emulsions, whereas mineral surfactants with HLB values less than 8 are used. Liquid paraffin has an HLB value of less than 8, and is therefore utilised to make water-in-oil emulsions. Combinations of span 20 and tween 20 result in increased emulsion stability when compared to standalone span or tween systems.[14]

4. Antioxidants

E.g. Ascorbyl palmitate, Butylated hydroxyanisole (BHA), Butylated Hydroxy Toluene (BHT).

5. Gelling agents

These are thickening agents that are used to enhance the consistency of any dose form.[15]

Eg. Carbopol 934, Carbopol 940, HPMC

6. Penetration enhancer

They interact with a number of skin constituents to generate a reversible transient increase in permeability. They can act in a variety of ways, including,

i. Disrupting SC's highly tight structure.
ii. Optimizing drug, solvent, or co-enhancer partitioning in the SC.
iii. A protein that interacts between cells.[16]

Method of preparation[17,18,19]

It consists of three steps

Step-1: Preparation of emulsion

Preparation of aqueous phase: The aqueous phase of the emulsion was prepared by dissolving tween 80 in purified water.

Preparation of oil phase: Methyl paraben and propyl paraben were dissolved in propylene glycol where as drug was dissolved in ethanol and both solution were mixed with aqueous phase. Both the aqueous phase were separately heated to 75°C. The oil phase was then added to the aqueous phase and stirred continuously until it reached room temperature.

Step-2 formulation of gel base: The pH was adjusted to 6-6.5 using tri ethanolamine after dispersing polymer in filtered water with steady stirring at a moderate speed using a mechanical shaker.

Step-3 incorporation of emulsion into gel base: To make emulgel, add glutaraldehyde in a 1:1 ratio to the gel and emulsion during mixing.

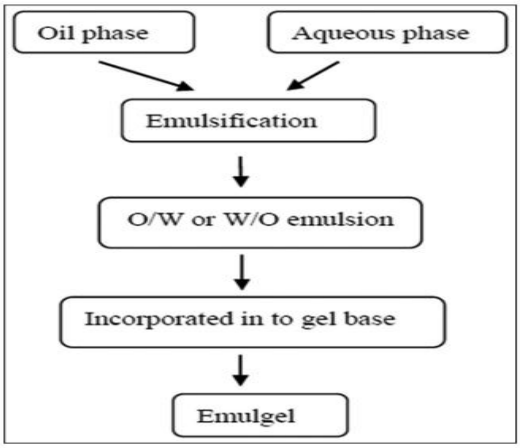

Fig. 4: Formulation of emulgel.

Characterization of nanoemulsion

Appearance

The prepared formulation's physical appearance is checked, including colour, clarity, and homogeneity.[20]

Solubility

A little amount of medication is added to the solvent at room temperature and left for 24 hours with just minor agitation for solubility purposes. The supernatant was collected and analysed using a double beam spectrophotometer.[21]

pH

A pH meter was used to determine the pH of the solution. An acidic pH buffer solution and a neutral buffer norm (pH 7.01) are used to calibrate the electrode (pH 4.01). Then electrode is immersed in nanoemulsion. The pH value is recorded on the toll. Calculations are conducted at room temperature.[22]

Centrifugation

The formulated formulas are centrifuged at 5000rpm for 30 minutes using the centrifuge. Further investigation was performed on the formulations that showed no symptoms of phase separation.[23]

Heating cooling cycle

Nanoemulsion compositions were subjected to six cycles at temperatures ranging from 4°C in the refrigerator to 45°C in the freezer. The formulations that had proven to be stable were next put to the test of centrifugation.[24]

Determination of % transparency and drug precipitation

To choose formulas in different ratios, the ternary phase diagram is employed. A transparency analysis is carried out to find the optimum percent transparency and drug precipitation between oil, surfactant and co-surfactant combinations, and water containing 1% drug. (The nanoemulsion device is clear and transparent when diluted with pure water.)[25]

Melting point

The melting point is calculated using the capillary technique. One end of a capillary tube is sealed shut with the sample. After that, the capillary was inserted into Thiele's drain, which was heated. The melting point temperature of a medication sample is the temperature at which it begins to melt. The average of three readings was calculated, and the result was compared to the value discovered in the scientific literature.[26]

Viscosity

A Brookfield-type rotational viscometer is used to measure the viscosity of nanoemulsions at various shear rates and temperatures. A thermobath must be used to keep the sample room of the instrument at 37± 0.2°C, and the samples for measurement must be immersed in it prior to testing.[27]

Drug content

The goal of the drug content analysis was to figure out how much drug was in a particular amount of the formulation. 1 g of the formulation was put into a 10 ml volumetric flask, which was then filled with methanol and thoroughly agitated. The volumetric flask was kept in a shaker for 2 hours and completely blended After filtering the mixer and putting the solution through the filter paper, the absorbance was measured with a spectrophotometer set at 257nm.[28]

Compatibility study by FTIR

The drug-excipient connection was explored using FTIR spectroscopy till the formulation was designed. A Jasco Fourier Transform Infrared spectrometer was used for infrared analysis. Formulation stability and molecular interactions between the medicine and the excipients utilised are two of the most significant aspects to consider. With roughly 1-2mg of sample mixed with dry potassium bromide, the samples were screened over a spectrum of 4000 to 400cm^{-1}.[29]

Particle size

This is a parameter that has to be calculated. After 1.0gm of gel had been dissolved in water and agitated to produce dispersion, the sample was injected into the photocell of a Malvern zetasizer.[30,31]

Surface morphology

The morphology and composition of the nanoemulsion were studied using a TEM (Jeol, JEM-100 CX electron microscope, Japan). Selected samples are diluted in water (1:25) and placed on a carbon coated copper grid for 30 seconds before staining with a 2% uranyl acetate solution.[32,33]

In-vitro permeation study

In vitro release tests were carried out with a bichambered donor recipient compartment model (Franz diffusion cell) that was placed on a magnetic stirrer at 37.5º C. Himedia dialysis membrane (cut-off molecular weight: 12000-14000) a receptor cell was placed at one end of the chamber, and 2.5 mL of the formulation was put on a dialysis membrane in contact with the receptor medium and carefully calibrated after being soaked in phosphate buffer pH 7.4. Phosphate buffer pH 7.4 was used to adjust the medium, and samples were taken at predetermined intervals. To look for drugs in the samples, a UV-Vis spectrophotometer with the maximum setting was utilised.[34]

Characterization of nanoemulgel

Physical appearance

The prepared nanoemulgel compositions were visually examined for colour, homogeneity, consistency, and pH.[35]

Viscosity

The viscosity of emulgel was measured using a Brookfield viscometer (LVDV II + prime model) with S64 spindle.[37]

pH

When evaluated using a pH metre, many topical preparations have a pH range of 5-6. To determine the pH, dissolve 1 gram of product in 10 ml water. Each formulation's PH is tested three times to reduce inaccuracies.[36]

Spreadability

Spreadability is calculated using the "Slip" and "Drag" qualities of emulgels. A ground glass slide is included with this block. This ground slide has an oversupply of emulgel (approximately 2 gram) that is being investigated. The emulgel, which is a liquid, is sandwiched between this slide and a second glass slide that has the dimensions of a permanent ground slide and can be delivered with a hook. A 1 kg weight is placed on top of the two slides for 5 minutes to release air and ensure a constant emulgel coating between them. At the edges, excess emulgel is scraped away. After that, 80 gms of pull was given to the top plate. With the use of string linked to the hook, note the time (in seconds) required for the top slide to traverse a distance of 7.5 cm. The better the spreadability, the shorter the interval.[38]

Spreadability was calculated by using the formula,

S= M.L/T

Where, S = spreadability, M = Weight tied to upper slide, L = Length of glass slides T = Time taken to separate the slides completely from each other.

Extrudability

The force required to extrude the material from the tube is commonly measured using an empirical test. The method used to determine the amount of applied shear in the rheogram's region. corresponding to a shear rate that is higher than the yield value displaying plug flow. The present approach used to evaluate emulgel formulations for extrudability is based on the quantity in percentage of total weight of emulgel and emulgel extruded from lacquered aluminium on the application of weight in grams, a collapsible tube is necessary in 10 seconds, extrude at least a 0.5 cm emulgel ribbon. The more the quantity extruded, the greater the extrude ability.[39]

Extrudability calculated by using the formula,

Extrudability = Applied weight to extrude Emulgel from the tube (in g)/Area (in cm2)

Swelling index

To calculate the swelling index, 1 gram of emulgel is placed on porous aluminium foil and then placed separately in a 50 ml beaker containing 10 ml 0.1 N NaOH. Then, at various time intervals, samples are removed from beakers and reweighed.[40]

Swelling Index (SW) % = $[(Wt - W_0) / W_0] \times 100$

Where,

(SW) % = Equilibrium percent swelling, W_0 = Weight of emulgel at zero time,

Wt = Weight of swollen emulgel after time t

Drug content determination

It takes 1 gram of emulgel. It must be combined in an appropriate solvent. Filter the solution to obtain a clear result. Calculate its absorbance with a UV spectrophotometer. A conventional drug plot is prepared in the same solvent. By entering the value of absorbance into the same standard plot, the amount of medication in a sample can be determined.[41]

Skin irritation study

For this study, emulgel is applied to the shaved skin of rats, and its adverse effects, such as colour change and skin shape change, are monitored for up to 24 hours. A total of 8 rats can be used in the experiment. The test is passed if there is no irritation. If the test fails, it is repeated two times.[42]

In-vitro permeation study

The in vitro drug release studies were performed using a modified vertical Franz diffusion cell (effective diffusion area 1.44 cm2 and 15.5 ml cell volume). The recipe was applied to a 0.45 m Nylon membrane that was inserted between the donor and receptor franz diffusion cell compartments (after being soaked for 24 hours in Phosphate buffer pH 7.4). Phosphate buffer pH 7.4 + ethanol were used as the dissolving media (80:20). A water bath was used to keep the cell at 370.2 degrees Celsius. The solution was continuously swirled at 50 rpm using a magnetic bead, and the entire assembly was placed on a magnetic stirrer. The samples (1.0 ml aliquots) were extracted at appropriate time intervals and analysed for drug content after proper dilutions.[43]

Stability study

The emulgels were packaged in 5 g aluminium collapsible tubes and subjected to three months of stability testing at 5°C, 25°C/60 percent RH, 30°C/65 percent RH, and 40°C/75 percent RH. Physical appearance, pH, rheological features, drug content, and drug release profiles are all aspects to consider. Samples were taken and evaluated at 15-day intervals.[44]

Marketed product[45]

Product	Drug	Manufacturer
Voltaren emulgel	Diclofenac-diethyl ammonium	Novartis pharma
Miconaz-H-emulgel	Miconazole nitrate, hydrocortisone	Medical union pharmaceuticals
Excel gel	Clindamycin, adapalene	Zee laboratories
Pernox gel	Benzoyl peroxide	Cosme remedies Ltd.
Lupigyl gel	Metronidazole,Clindamycin	Lupin pharma

CONCLUSION

Because of increased patient compliance, the topical drug delivery system will be employed extensively. Emulgels will grow more popular as they have an advantage in terms of spreadability, adhesion, viscosity, and extrusion. A widely used medication delivery method. They will also become a solution for loading hydrophobic medicines into water soluble gel bases.

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