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Research Article

Film Forming Emulgel: An Overview

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ABSTRACT
Sustained release delivery system with features of both semisolid formulations And patches has been employed in the formulation of film forming emulgel. The concept of film forming formulation is very recent. Film forming formulations may be solutions, gel o emulsions. Film forming formulations are defined as non solid dosage forms that produce a substantial film in situ after application on the skin or any other body surface. Such a compositions can either be liquid or semisolids with a film forming polymers as basic materials for the matrix. He formed film is sufficiently substantial to provide a sustained drug release to the skin. Film forming emulgels are emulsions, either of the oil-in-water or water-in-oil type, which are gelled by mixing with a gelling agent. Film forming emulgel is stable one and better vehicle for hydrophobic or water insoluble drugs.

Keywords: film formation, emulsion, gel, polymer, sustained drug release.

INTRODUCTION

For treatment of skin infections, wide assortment of topical dosage forms are available. It comprises powders, lotions, emulsions, ointments, pastes, aerosoles, soaps ,plasters, shampoo and other preparations ointments like preparations covers about 80%. The applications of some ointments to the skin produces systemic actions, which means, hat certain degree of absorption occurs. After words, systemic drug administration by the transdermal route was achieved with some cream and ointments preparations for protection and treatment of certain diseases. None of these preparations was satisfactory; the major disadvantage was variable systemic absorption due to the absence of specific direction to the area expected to be covered. For such a reasons, medicated topical polymeric films are designed to deliver the drug to the skin surface at controlled rate[1]. The concept of film forming formulations is very recent. Film forming formulations may be solutions, gels or emulsions. Film forming formulations are defined as non solid dosage forms that produce a substantial film in situ after application on the skin or any other body surface. Such a compositions can either be liquid or semisolids with a film forming polymers as basic materials for the matrix. He formed film is sufficiently substantial to provide a sustained drug released to the skin[2]. Film forming emulgels have emerged as one of the most interesting topical drg delivery systems as I has dual release control i.e. emulsion and gel. Film forming emulgels are emulsions, either of the oil-in-water or water-in-oil type, which are gelled by mixing with a gelling agent. Hey have a high patient acceptability since they posses the previously mentioned advantages of both emulsion and gels. Therefore, have been recently used as vehicles to deliver various drugs to the skin. Film Forming Emulgel is stable one and better vehicle for hydrophobic or water insoluble drugs[3].

Dermatological product applied to the skin are diverse in formulation and range in consistency from liquid to powder but the most popular products are semisolid preparations. Within the major group of semisolid preparation, the use of transparent gels has expanded both in cosmetics and in pharmaceutical preparations. Gels are relatively newer class of dosage form created by entrapment of large amount of aqueous or hydro alcoholic liquid in network of colloidal solid particles. Gel formulations generally provide faster drug release compared with ointment and creams. In spite of many advantages of gel a major limitation is in the delivery of hydrophobic drugs. So to overcome this limitation emulgels are prepared and with their use even a hydrophobic drug can enjoy the unique properties of gels. Emulsion posses a certain degree of elegance and are easily washed off whenever desired. They also have a ability to penetrate the skin. Emulgels are dermatological use have several favorable properties such as being thixotropic, greaseless, easily spreadable, easily removable, emollient, nonstaining, watersoluble, longer shelf life, bio-friendly transparent and pleasing appearance[4]. by acting as a controlled formulation emulgel provide a defence against skin irritation.[7]

Rationale[8]

Various types of topical formulation are available like a ointment, cream, lotion have many disadvantages. They have very sticky causing uneasiness to the patient when

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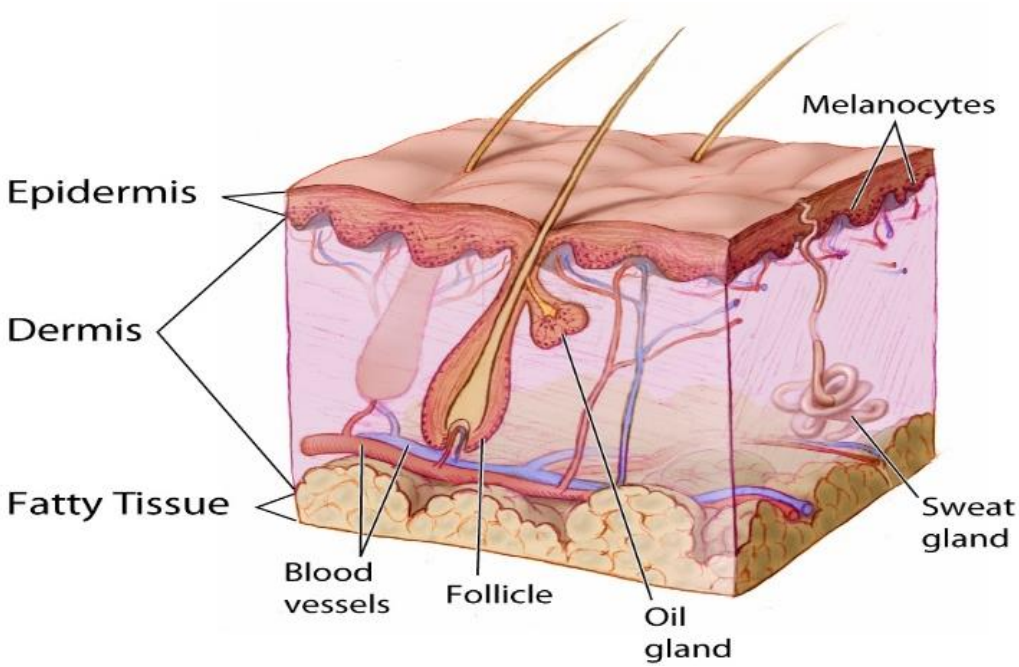

Figure 1: Cross section of skin.

applied. They exhibit the problem of stability also. Due to all these factors within the major group of semisolid preparatons, the use of gels has expanded both in cosmetics and in pharmaceutical preparations. A gel is colloid that is typically 99% wt liquid, which is immobilized by surface tension between it and a macromolecular network of fibers built from a small amount of gelling substance present. In spite of many advantages of gels a major limitation is in the delivery of hydrophobic drug. So to overcome this limitation an emulsion based approach is being use so that even a hydrophobic therapeutic moiety can be successfully incorporated and delivered through gels.

Drug delivery across the skin[9]

The skin has several layers. The outer layer is called epidermis; the layer below the epidermis is called dermis. The dermis contain a network of blood vessels, hair follicle, sweat gland and sebaceous gland. The most superfacial layer of the skin is a epidermis and is composed of stratified keratinized epithelium which varies in thickness in different part of the body. The skin forms a relatively waterproof layer that protects the deeper and delicate structures. Blood vessels are distributed profusely beneath the skin especially continuous venous plexus that is supplied by inflow of blood from skin capillaries. The most exposed areas of the body-the hands, feet, and ears blood is also supplied to the plexus directly from the small arteries through highly muscular arteriovenous anastomoses. There are three primary mechanisms of topical drug absorption: transcellular, intercellular and follicular. Drug passes through the torturous path around corneocytes and through the lipid bilayer to viable layer of the skin. The barrier in outer layer of the epidermis, the stratum corneum as evidenced by approximately equal rates of penetration of chemicals through isolated stratum corneum or whole skin. Gels and creams that are rubbed into the skin have been used for tears to deliver medication and infection fighting drug to an affected site of the body. New technologies not just the affected areas (for example, the skin) but the whole body[10].

Factors affecting topical absorption of drug[10]

Physiological factors

A. Skin thickness.
B. Lipid content.
C. Density of hair follicles.
D. Density of sweat glands.
E. Skin pH.
F. Blood flow
G. Hydration of skin.
H. Inflammation of skin

Physicochemical factors

A. Partition coefficient.
B. Molecular weight (<400 dalton)
C. Degree of ionization(only unionized drugs gets absorbed well)
D. Effect of vehicle

Advantages of Emulgels[5]

- Hydrophobic drug can be easily incorporated into gel using o/w emulsion.
- Better loading capacity
- Economical
- Control release
- Increase the stability of formulation.
- Increase contact time and mean residence time of the drug.
- Dual drug release from emulsion and gel.
- Emulgels used even for cosmetic purposes.

Disadvantages of Emulgel[12]

- Bubbles formed during emulgel formulation.
- Possibility of allergic reactions.
- Drugs having large particle size (>400 daltons) are not easily absorb or cross through the skin barrier.

Constituents of Emulgel Preparation[11-12]

Aqueous Material

This forms the aqueous phase of the emulsion commonly used agents are water, alcohols.

Oils

These agents forms the oily phase if the emulsion. For externally applied emulsion, mineral oils, either alone or combined with soft or hard paraffin are widely used both as the vehicle for the drug and for their occlusive and sensory chracteristics. Widely used oils in oral preparations are non biodegradable mineral and caster oils that provide a local laxative effect, and fish liver oils or various fixed oils of vegetable origin (e.g. arachis, cottonseed and maize oils) as nutritional supplements.

Emulsifiers

Emulsifying agents are used both to promote emulsifying at the time of manufacture and to control stability during a shelf life that can vary from day for extemporaneously prepared emulsion to months or years for commercial preparations. eg. Polyethylene glycol 40 steatate, sorbitan monooleate (span 80), polyoxyethylene sorbitan monooleate (Tween 80), stearic acid, sodium stearate.

Gelling Agent

These are agents used to increase consistency of any dosage form can also be used as thickening agent.

Permeation Enhancers

These agents that partition into and interact with skin constituents to induce a emporary and reversible increase in skin permeability

Polymers

The polymer is required to form films at skin surface temperature (28ºC-32ºC) and should have a certain inherent flexibility and affinity to the skin to avoid the usage of excessive amounts of plasticizer. It has to be soluble in a highly volatile, skin friendly solvent.

Plasticizers

In polymeric application the main purpose a plasticizer is to facilitate the film forming and to increase the flexibility of the resulting film. Additionally, the formulation experiment have shown that the skin adhesion of the film can be modulated with the help of plasticizers. The acrylate polymer poly (ethyl acrylate-co-methyl methacrylate) Eudragit NE 40D as well as the silicone gum formed adequate films without the help of a plasticizing agent.

Emulgel Preparation[3]

Step-1: Formulation of Emulsion either O/W or W/O.

Step-2: Formulation of gel base

Step-3: Incorporation of emulsion into gel base with with continuous stirring

Step-4: After formulation of emulgel addition of film forming solution.

Characterization of emulgel[10]

Physical appearance

The prepared emulgel formulations are inspected visually for their color, homogeneity, consistency and phase separation.

Rheological Studies

The viscosity of the different emulgel formulations are determined at 25ºC using a cone and plate viscometer with spindle 52 and connected to a thermostatically controlled circulating water bath.

Spreading Coefficient

Spreadabilty is determined by apparatus which is suitably modified in the laboratory and is used for the study. It concists of a wooden block, which is provided by a pulley at one end. Bt this method, spreadability is measured on the basis of 'slip' and 'drag' characteristics of emulgel. A ground glass slide is fixed on this block. An excess of emulgel (about 2 gm) under study is placed on this ground slide. The emulgel is then sandwiched between this slide and anather glass slide having the dimension of fixed ground slide and provided with the hook. A 1kg weight is placed on the top of the two slides for 5 minutes to expel air and to provide a uniform film of the emulgel between the slides. Excess of the emulgel is scrapped off from the edges. The top plate is the subjected to pull of 80 gms. With the help of string attached to the hook and the time (in seconds) required by the top slide to cover a distance of 7.5 cm be noted. A shorter interval indicates better spreadability.

Excrudability Study

It is a usual empirical test to measure the force required to extrude the material from tube. The method applied for determination of applied shear in the region of the rheogram corresponding to a shear rate exceeding the yield value and exhibiting concequent plug flow. In the present study, the method adopted for evaluating emulgel formation for extrudability is based upon the quantity in percentage of emulgel and emulgel extruded from lacquered aluminium collapsible tube on application of weight in grams required to extrude at least 0.5 cm ribbon of emulgel in 10 seconds. More quantity extruded better is extrudability. The measurement of extrudability of each formulation is in triplicate and the average values are presented. The extrudability is than calculated by using the following formula:

Extrudability = Applied weight to extrude emulgel from tube (in gm)/ Area (in cm^2)

Swelling Index

To determine the swelling index of prepared topical emulgel. 1 gm of gel is taken on porous aluminum foil and then placed separately in a 50 ml beaker containing 10 ml 0.1 N Naoh. Then samples were removed from beakers at different time intervals and put it on dry place for some time after it reweighed. Swelling index is calculated os follows:

Swelling index(SW)% = [(Wt-Wo)/Wo] ×100.

Where, (SW)%= Equilibrium percent swelling.

Wt= Weight of swollen emulgel after time t.

Wo= Original weight of emulgel at zero time.

Drug Content

Take 1 gm of emulgel. Mix mix it in suitable solvent. Filter it to obtain clear solution. Determine its absorbance using UV spetrophtometer. Standard plot of drug is prepared in same solvent. Concentration and drug content can be determined by using the same standard plot by putting the value of absorbance.

Drug content= (Concentration × Dilution Factor × Volume taken) × Conversion Factor

Skin Irritation Test (Patch Test)

The preparation is applied on the properly shaven skin of rat and its adverse like change in color, change in skin, morphology should be checked upto 24 hours. The total set of 8 rats can be used of the study. If no irritation occurs the test is passed. If the skin irritation symptom occurs in more than 2 rats the study should be repeated.

Ex-vivo bioadhesive strength measurement of topical emulgel

(Mice shaven skin): The modified method is used for the measurement of bioadhesive strength. The fresh skin is cut into pieces and washed with 0.1 N NaOH. Two pieces of skin were tied to the two glass slide separately from that one glass slide is fixed on the wooden piece and other piece is tied with balance on the right hand side. The right and left pans were balanced by adding extra weight on the left-hand pan. 1 gm of topical emugel is placed between these two slides containing hairless skin pieces and extra weight from the left pan is removed to sandwich the two pieces of skin and some pressure is applied to remove the presence of air. The balance is kept I this position for 5 minutes. Weight is added slowly at 200 mg/min to the left-hand pan until the patch detached from the skin surface. The weight (gram force) ewquired to detach the emulgel from the skin surface gave the measure of bioadhesive strength. The bioadhesive strength is calculated by using following

Bioadhesive strength= weight required(in gms) / Area (cm^2) .

In Vitro Release/ Permeation Studies

In vitro release studies were carried out using Franz diffusion cell.

Globule size and its distribution in emulgel

Globule size and distribution was determined by Malvern Zetasizer. A 1 gm sample was dissolved in purified water and agitated to get homeogeneous dispersion. Sample was injected to photo cell of zetasizer. Mean globule diameter and distribution was obtained.

Microbiological assay

A ditch plate technique is used in this method. This technique is used for the bacteriostatic and fungistatic activity of a compound. It is mainly applied for semisolid formulations. Previously prepared Sabouraud's agar dried plate were used. 3 gm of gellified emulsion is placed in a ditch cut in the plate. Freshly prepared culture loops are streaked across te agar at a right and left from the ditch to the edge of the plate. After incubation for 18 to 24 hours at 25^o C, the fungal and bacterial growth was observed and the percentage inhibition was measured as follows:

% inhibition = L2/L1× 100

Where, L1= Total length of streaked culture.

L2= Length of inhibition.

Stability Studies

The prepared emulgels were packed in aluminum collapsible tube (5gm) and subjected to stability studies at 5^{o}c, 25^{o}C/60% RH, 30^{o}C/65% RH and 40^{o}C/75% RH for a period ofh3 months. Samples were withdrawn at 15- day time intervals and evaluated for a physical appearance, pH, Rheological properties, drug content and drug release profiles.

CONCLUSION

In the recent years, topical drug delivery system will be used extensively due to better patient compliance. Film forming formulations is the recent technique for the topical drug delivery. Emulgels have better suitability for the both hydrophobic and hydrophilic drugs. Mainly the hydrophobic drug formulation can be developed with emulgel technique because it contain both iol and aquous (i.e. gel base) on the other hand hydrogel are not suitable for hydrophobic drugs. Since emulgel is enhancing spreadability, adhesion, viscocity and extrusion. This novel drug delivery becomes a popular formulation in future.

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