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FORMULATION AND EVALUATION OF LIPOSOMAL GEL CONTAINING *CLITORIA TERNATEA* EXTRACT FOR TOPICAL DRUG DELIVERY SYSTEM

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ABSTRACT

The word 'Cosmetic' derived from a Greek word – 'kosmetikos'that means to adorn. From that time any materials used to beautification or promoting appearance is known as cosmetic. Cosmetics are used to enhance appearance. Makeup has been around for many centuries. The first known people who used cosmetics to enhance their beauty were the Egyptians. Makeup those days was just simple eye colouring or some material for the body. Now-a-days makeup plays an important role for both men and women. The importance of cosmetics has increased as many people want to stay young and attractive. Cosmetics are readily available today in the form of creams, lipstick, perfumes, eye shadows, nail polishes, hair sprays etc. Other cosmetics like face powder give glow to the skin after applying the base cream. Then we have lipsticks, which are applied by many women of all ages. They are made from wax and cocoa butter in the desired amount. Herbal cosmetics are widely used when compared to synthetic cosmetics. Herbal Cosmetics referred as Products, they are formulated, using various cosmetic ingredients to form the base in which one or more herbal ingredients are used to provide defined cosmetic benefits only, shall be called as "natural cosmetics". The demand of herbal medicines is increasing rapidly due to their lack of side effects. Cosmetic products are used to protect exogenous and endogenous harmful agents and enhance the beauty and attractiveness of skin. Cosmetics are developed to reduce wrinkles, fight acne and to control oil secretion. For various types of skin ailments formulations like skin protective, sunscreen, antiacne, antiwrinkle and antiaging are designed using varieties of materials, either natural or synthetic. Both men and women use cosmetics like colognes, gels, and lotions on a daily basis.

KEYWORDS: Cosmetics, hair spray, hair polishes, eye shadow etc.

INTRODUCTION

The skin is the largest organ of the body, accounting for regarding 15% of the overall weight. It performs several very important functions, together with protection against external physical, chemical, and biological assailants, similarly as prevention of excess water loss from the body and a role in thermoregulation. The skin is continuous, with the mucous membranes lining the body's surface. The skin composed of three layers: the epidermis, the dermis, and subcutaneous tissue. The outermost level, the epidermis, consists of a selected constellation of cells called keratinocytes, that perform to synthesize albuminoid, along, threadlike supermolecule with protecting role. The middle layer, the dermis, is fundamentally made up of the fibrillar structural protein known as collagen. The dermis lies on the connective tissue that contains tiny lobes of fat cells called lipocytes. The thickness of those layers varies significantly, betting on the geographic location on the anatomy of the body. The eyelid, for instance, has the thinnest layer of the epidermis, measure but 0.1 mm, whereas the thickest stratum layer, measure approximately1. 5mm.The dermis is thickest on overlying epidermis, wherever it's 30–40 times as thick because the suprajacent epidermis.

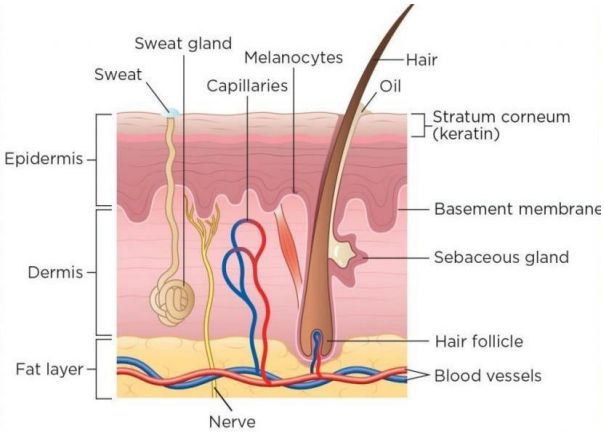

Fig. no 1: Structure of skin.

EPIDERMIS

Definition: The outermost layer of the skin that provides a barrier and protects against environmental damage.

Structure: Composed primarily of keratinized stratified squamous epithelium

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Cell types

Keratinocytes: Produce keratin for protection.

Melanocytes: Produce melanin for pigmentation.

Langerhans cells: Act in immune response.

Merkel cells: A type of cell in the skin that are involved in touch.

Layers of the epidermis (From outer to inner)

A) Stratum basale (Basal layer)

Location: The deepest layer of the epidermis.

Structure: A single row of cuboidal to columnar cells

B) Stratum spinosum (Prickly layer)

Location: Just above the stratum basale.

Structure: 8-10 layers of keratinocytes connected by desmosomes (protein structure).

C) Stratum granulosum (Granular layer)

Location: Middle layer of the epidermis.

Structure: 3-5 layers of flattened keratinocytes containing.

D) Stratum lucidum (Clear layer)

Location: Found only in thick skin (Palms, soles, fingertips).

Structure: Thin, transparent layer of dead keratinocytes filled with eleidin, tightens the connection between the cells, facilitating the protective and water-repellent function of the skin a precursor to keratin.

E) Stratum corneum (Horny layer)

Location: Outermost layer of the epidermis.

Structure: 15-30 layers of dead, flat keratinized cells (Corneocytes) embedded in a lipid matrix.

Topical drug delivery offers the advantages of ease of delivery, a cooperative patient, increased compliance as well as the avoidance of first-pass metabolism. Disadvantages are the lack of, or reduced rates of absorption and cosmetic considerations. New drug delivery technology and penetration enhancers may help to obviate some of these objections. There are important issues to consider as you contemplate development of a topical dermatological product. You may already have experience with oral or parenteral products, but there are challenges and issues which are unique to development of topical formulations.

A successful topical dermatological formulation can be considered to be one that satisfies the target product profile and is.

1) Physically and chemically stable having adequate shelf life,
2) Releases drug from the formulation and delivers it into the skin as required for the target indication,
3) Is cosmetically elegant and acceptable to patients,
4) Contains only excipients that are necessary, FDA-approved or acceptable from a regulatory perspective, and acceptable for the disease state,
5) Is easy to apply and compatible with the desired packaging, and
6) Can be manufactured with a process that is scalable to commercial levels.

There are challenges during almost every development program. It is important to be able to anticipate problems, prevent them where possible, and to understand how to correct those that do occur.

Following are the advances in the topical drug delivery systems

1. Aerosol foams
2. Liposomes
3. Nanoemulgel
4. Microsponge
5. Solid lipid nanoparticles
6. Ethosomes
7. Microneedles
8. Aquasomes
9. Dynamic foams
10. Polymers

Liposomes are now considered the most commonly used nanocarriers for various potentially active hydrophobic and hydrophilic molecules due to their high biocompatibility, biodegradability, and low immunogenicity. Liposomes also proved to enhance drug solubility and controlled distribution, as well as their capacity for surface modifications for targeted, prolonged, and sustained release. Based on the composition, liposomes can be considered to have evolved from conventional, long-circulating, targeted, and immune-liposomes to stimuli-responsive and actively targeted liposomes. Many liposomal-based drug delivery systems are currently clinically approved to treat several diseases, such as cancer, fungal and viral infections; more liposomes have reached advanced phases in clinical trials Liposomes were firstly discovered in the 1960's by Bengham.

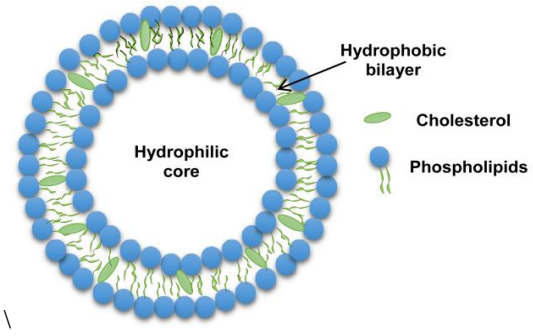

Fig. no 2: Structure of Liposomes.

Typically, gels are constructed from a fluid stage that has been thickened with various components. They are frequently prepared under the direction of qualified gelling experts like HPMC, Carbopol, Sodium CMC, and others. In the detailing of gels, extra ingredients including stabilisers, antibacterial additives, and cancer-prevention compounds are used. The term "gel" comes from "gelatin," and both "gel" and "jam" may be traced back to the Latin words "gelu" for "ice" and "gel" for "freeze" or "harden." This introduction demonstrates the basic concept of a fluid setup to key regions of strength for a texture that doesn't drift but is adaptable and retains certain fluid aspects. Gels are described as semi-unbending structures in which the growth of the scattering medium is restrained by a three-layered arrangement of intertwined waste products or solvated dispersed section macromolecules. Gels are frequently viewed of as being more rigid than jams because they have more covalent crosslinks, thicker real bonds, or just less fluidity. Gel-shaping polymers provide materials with a variety of rigidities, ranging from a sol to an adhesive, jam, gel, and hydrogel as the rigidity increases. Due to the fact that the compounds in some gel structures are either soluble or insoluble, or because they may form totals that scatter light, some gel structures are nearly as transparent as water while others are turbid. For certain exceptions, the attention paid to the gelling specialists is frequently much less than 10%, typically ranging from 0.5 to 2.5 percent.

Route of penetration: Drug molecules come into touch with cellular waste, bacteria, and other substances on the skin's surface, which has an impact on penetration.

Three routes connect the administered medication to the living tissue.
1. Through the hair follicles.
2. sweat ducts.
3. Continuous stratum corneum between the appendages, in that order (hair follicles, sebaceous glands, eccrine, apocrine glands and nails).

The essential border is the perfect layer corneum, and several upgrade techniques aim to disrupt or avoid this layer. Possible layers may start a prodrug or take a medicine. In general, deeper dermal regions seldom impact retention in a substantial way again. This method of medicine delivery has gained popularity since it prevents oral organization-related metabolic degeneration, gastrointestinal distress, and first-pass impact. The skin course of organisation has been employed to provide fundamental pharmacological outcomes or to give local results for treating skin problems. The primary purpose of putting medicine to the skin to treat skin conditions is to cause a local reaction where it is applied. Most of the time, only a small percentage of the total quantity really makes it to the activity site, which results in constrained neighbourhood mobility. The very intriguing boundary qualities of the skin have made this a challenging effort.

Fig no.3: Structure of Liposomal gel.

MATERIALS AND METHODS

Excipients

Sr.no	Chemical	Role
1.	*Clitoria Ternatea*	API
2.	Phospholipids	Vesicle formation
3.	Carbopol 940	Gelling agent
4.	Stearic acid	Sustain release, Penetration enhancement
5.	Cholesterol	Membrane stabilization
6.	Purified water	Vehicle

Equipment

Sr.no	Name of Equipment	Use
1.	Beakers	For preparing oil and aqueous phases
2.	magnetic stirrer	For heating and stirring phases separately
3.	pH meter	To measure and adjust PH
4.	Water bath	Gentle heating
5.	Viscometer	To measure the viscosity

Formulation table

Formulation	*Clitoria ternatea*	Phospholipids	Cholesterol	Stearic acid	Carbopol 934
F1	100 mg	100 mg	500 mg	500 mg	500 mg
F2	100 mg	100 mg	500 mg	500 mg	500 mg
F3	100 mg	100 mg	500 mg	500 mg	500 mg

METHODOLOGY

In order to extract the butterfly pea blossoms' components.

Maceration entails immersing them in a solvent for an extended amount of time at room temperature.

Steps

The blossoms of butterfly peas are selected
↓
Drying (Air-dry/Shade-dry to remove moisture)
↓
Powdering (Grind to coarse or fine powder)
↓
Weighing of Powdered Material
↓
Addition of suitable solvent
(Ethanol, methanol, water)
↓
For a few days, the combination in kept at room temperature
↓
Store in cool and dark place (24-72 hours)
↓
Filtration
(Remove the solid residue to collect liquid extract)
↓
Concentration of Extract
(Use rotary evaporator or water bath to remove solvent)
↓
Drying (if needed)
(Air dry or vacuum dry to obtain semi-solid or solid extract)
↓
Storage of Extract
(Store in an airtight container for further formulation use)
↓
The extract is obtained by filtering the liquid.

Method of formulating liposomal gel

THIN FILM HYDRATION METHOD

Different weight ratio of phospholipids (soya lecithin) : cholesterol and stearic acid weighed
↓
Dissolved in chloroform : methanol mixture (2:1 v/v) in 250 ml round bottom flask
↓
Organic solvent evaporated under vacuum using rotary evaporator at 45–50 °C
↓
Thin lipid film formed on inner side of round bottom flask
↓

Flask kept overnight under vacuum for complete removal of residual solvent

↓

Dry lipid film hydrated with 20 ml phosphate buffer solution (pH 7.4) containing *clitorea ternatea* extract at 60 ± 2 °C

↓

Dispersion kept undisturbed at room temperature for 2–3 hr

↓

Complete swelling of lipid film

↓

Formation of vesicular dispersion (Liposomes)

Liposomal gel

RESULTS AND DISCUSSION

Phytochemical Screening of Extract

Phytochemical Screening of Ethanol Extract of Butterfly Pea Flowers. The secondary metabolite compounds of ethanol extract of butterfly pea flowers screened in this study were flavonoids, saponins, and alkaloids. The secondary metabolite compounds were selected based on previous studies which stated that these compounds have antibacterial activity in butterfly pea flower extract. The results of the phytochemical screening carried out were in accordance with the literature obtained.

Physicochemical Evaluation of liposomal gel

1. Physical examination: The prepared Liposomal gel was evaluated for colour, smell and form; the prepared gel was in acceptable limit.

Observation	Base	Formula 1	Formula 2	Formula 3
Colour	White	Light bluish white	Pale blue	Bluish voilet
Smell	Odourless	Distinct smell of extract	Distinct faint odour	Distinct smell of extract
Form	Semi solid	Semi solid	Semi solid	Semi solid

2. pH: The pH values of 1% aqueous solutions of the prepared gels were measured by pH meter, the average pH of formulations were comes to 7.3 pH.

Formula	PH	Literature
Base	7.1	5.5-7.5
Formula 1	7.2	5.5-7.5
Formula 2	7.3	5.5-7.5
Formula 3	7.4	5.5-7.5

3. Drug Content uniformity: The gel sample (100 mg) withdrawn and drug content was determined using a UV spectrophotometer at 260 nm. Similarly, the content uniformity determined by analyzing the drug concentration in gel taking from 3 to 4 different points from the container. In case of liposomal gel, it will be shaken with adequate quantity of methanol to extract the drug and then analyzed by using a UV spectrophotometer at 260 nm. There was no significant difference observed in the % drug at various locations, indicating that the method used to disperse the liposomal dispersion in the gel base is satisfactory.

4. Rheological study: The semisolid preparations should flow or deform after applying the force and regain its elasticity as the force is removed. Thus, to understand the rheological properties of liposomal gels and for selection of optimum concentration of carbopol having desired rheological properties, different concentrations (1, 1.5, 2% w/w) of carbopol 934 were used to prepare liposomal gels at 25 °C with neutralization method.

5. Homogenicity: Developed gel was experienced for homogenicity by visual inspection after the gel has been set in the container. This tested for their appearance and presence of any aggregates that comes in acceptable range.

Formula	Homogenicity	Literature
Base	Homogenous	Homogenous
Formula 1	Homogenous	Homogenous
Formula 2	Homogenous	Homogenous
Formula 3	Homogenous	Homogenous

6. Viscosity Studies: Viscosity of prepared gel was carried out by using Brookfield Viscometer. The rotation was varied from 30 to 50 rpm at 25±1 ◦C.

7. Spreadability: It was determined by wooden block and glass slide apparatus. Weights were added to the pan and the time noted for upper slide (movable) to separate completely from the fixed slides. Spreadability intended by using the **formula: S = M.L / T** Where, S = Spreadability M = Weight tide to upper slide L = Length of glass slide T = Time taken to separate the slide completely from each other.

Formula	Spread power	Literature
Base	12.1	Good spreadability
Formula 1	13.4	Good spreadability
Formula 2	14.2	Good spreadability
Formula 3	15.0	Good spreadability

RECOMMENDATION

Liposomal and gel-based formulations represent two of the most innovative and effective drug delivery systems in dermatology, offering significant advantages over conventional topical treatments. Their ability to enhance drug stability, control release profiles, and improve skin penetration makes them valuable tools for treating a wide range of dermatological conditions. Liposomal formulations stand out due to their biocompatibility and structural similarity to biological membranes, allowing them to encapsulate both hydrophilic and lipophilic drugs while facilitating deeper skin penetration.

Recent advancements, including 3D printing, lyophilization techniques, and hybrid formulations combining liposomes with gels, have demonstrated significant potential in enhancing drug stability, prolonging therapeutic effects, and improving precision in drug delivery. By leveraging the unique strengths of both systems, researchers are working toward formulations that optimize treatment efficacy while minimizing side effects and maximizing patient adherence.

CONCLUSION

The present work on the preparation of topical liposomal gel containing *clitoria ternatea* is an attempt to utilize the immense potential of liposomes as a carrier to increase the permeability. Liposomal encapsulation showed more drug retention compared with plain drug gel . Further, the physicochemical modification in the drug by means of phospholipid membrane also promises to prolong the drug action. A number of problems associated with drug molecule such as bioavailability, degradation, stability and side effects can be overcome by incorporating it into liposomes. The liposomes of *clitoria ternatea* was prepared by film hydration method and evaluated.

Creation of reservoir effect for drug in skin due to deposition of other components of liposomes with drug into the skin and thereby increasing the drug retention capacity into the skin. Liposomal formulations were more spherical with stable zeta potential and mono-disperse with no clumping. with drug into the skin and thereby increasing the drug retention capacity into the skin. Due to constant exposure of human skin to the UV radiations present in sunlight causes several pathobiological alterations in cells occur such as increased wrinkling, irregular pigmentation, loss of elasticity and roughness, dryness. For the protection of this symptom of aging herbal cosmetic are used as a therapy. Various active constituents such as phenolic acids and flavonoids appear efficient against UV radiation-induced damage the evaluation test reveals that the formulated anti-aging cream from Clitoria Ternatea extract showed that it is safe to be used in the skin to protect from intrinsic and extrinsic aging. In experiments (F1 –F5), different batches of polyherbal anti aging cream were created using *clitoria ternatea* among other plants and components. Based on physical properties, homogenicity pH, viscosity, spreadability, type of emulsion, washability, accelerated stability studies as well as the fact that it meets all the criteria needed for a high –quality cream, F3 was chosen as the best formulation out of all of the others.

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