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A Review Article on Formulation and Evaluation of Gels

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Abstract: *Topical gels, favored for their advantages over creams and ointments, are a common dosage form in cosmetics and skin disease treatments, delivering drugs directly to the application site for prolonged action. These gels consist of a gelator, solvent, active drug, and other excipients, and are categorized as either organogels or hydrogels, with their formulation and preparation contingent on the properties of the ingredients used. This review compiles recent literature, emphasizing a rational approach to topical formulation and the fundamental components of these systems. As the skin is an easily accessible organ for topical drug administration, this method is a main route for drug delivery, however, widely used topical agents like ointments and creams often present drawbacks such as stickiness, poor spreadability, the need for rubbing during application, and stability issues. Consequently, gels have gained popularity in both cosmetic and pharmaceutical applications within the realm of semisolid preparations. Gels are essentially colloids, primarily composed of liquid (typically 99% by weight), immobilized by surface tension within a macromolecular network of fibers formed by a small amount of a gelatinous substance..*

Keywords: Skin, Topical drug delivery system: types, Gels: classification, Gel formulation ingredients, formulation and evaluation

I. INTRODUCTION

As the largest organ in the human body, the skin covers roughly 2 square meters and receives about a third of the body's blood flow. Despite being only a few millimeters thick (approximately 2.97 ± 0.28 mm), it's a readily accessible organ that creates a protective barrier, preventing the absorption of chemicals and biological substances while also separating the internal circulation from the external world.

The skin serves as a barrier, guarding the body from physical trauma, chemical exposure, and microbial invasion.
The skin acts as a thermostat, helping maintain a stable internal body temperature.
The skin participates in the complex mechanism.
Contributing in regulate blood pressure.
The skin provides a protective shield against harmful UV radiation.
The skin is significantly involved in drug delivery, specifically affecting.
How medications penetrate and are absorbed through the dermal layers.
The skin's structural organization at both the anatomical and ultrastructural levels greatly affects.
Its resistance to the diffusion of substances.

Topical drug delivery System :-

Topical drug delivery involves applying a drug-containing formulation to the skin or mucous membrane to treat localized conditions like acne or skin manifestations of systemic diseases like psoriasis. The goal is to limit the drug's effect to the surface or layers of the skin or mucous membrane.

Types of Topical Drug Delivery System :-

Includes two types of Topical Drug Delivery System:

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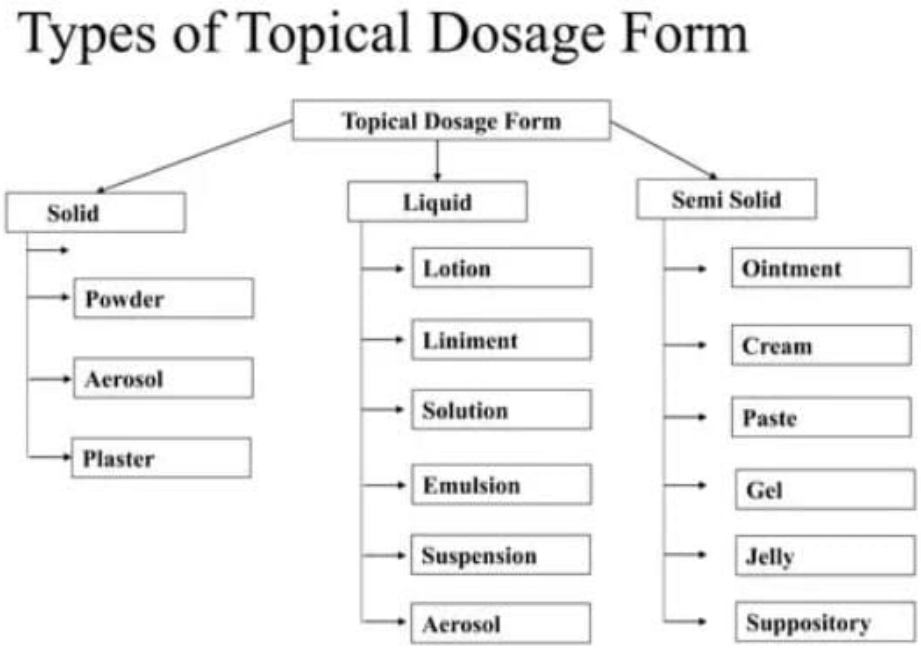
External- that are spread or dispersed on the cutaneous surface covering the affected area.
Internal-that are applied to the mucous membrane of eye (conjunctiva), ear, oropharyngeal cavity, nasal cavity, vagina or anorectal region for local activity.

Classification Based on physical state-
Solid: Powder, Aerosol, Plaster
Liquid: Lotion, Liniment, Solution, Emulsion, Suspension, Aerosol
Semi-solid: Ointment, Cream, Paste, Gel, Jelly, Suppository



Advantages of Topical Drug Delivery System:

- Bypasses first-pass metabolism.
- Simple to administer.
- Circumvents the challenges of absorption and the risks associated with enteral or parenteral routes, such as pH variations, enzymatic degradation, and variable gastric emptying.
- Allows for lower total daily drug doses to achieve efficacy through continuous delivery.
- Minimizes fluctuations in drug levels and reduces variability between patients and within the same patient.
- Facilitates easy discontinuation of treatment if necessary.

Disadvantages of Topical Drug Delivery System:

- Drug or excipient components can cause skin irritation or contact dermatitis.
- Certain drugs exhibit limited skin permeability, hindering absorption.
- Allergic reactions are a potential risk with topical drug application.
- Transdermal delivery is only suitable for drugs effective at low plasma concentrations.
- Enzymes present in the epidermis may degrade or inactivate certain drugs.
- Drugs with large particle sizes often face absorption challenges through the skin.

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Gels

Gels are defined as semi rigid systems in which the movement of the dispersing medium is restricted by an interlacing three-dimensional network of particles or solvated macromolecules of the dispersed phase.

The word ‘‘gel’’ is derived from ‘‘gelatin,’’ and both ‘‘gel’’ and ‘‘jelly’’ can be drawn back to the Latin gelu for ‘‘frost’’ and gel are, meaning ‘‘freeze’’ or ‘‘congeal.’’ This origin indicates the essential idea of a liquid setting to a solid-like material that does not flow, but is elastic and retains some liquid characteristics. Use of the term ‘‘gel’’ as a classification originated during the late 1800s as chemists attempted to classify semisolid substances according to their phenomenological characteristics rather than their molecular compositions. At that time, analytical methods needed to determine chemical structures were lacking.

The USP defines gels (sometimes called jellies) as semisolid systems containing either suspensions made up of small inorganic particles, or large organic molecules interpenetrated by a liquid. Where the gel mass contains a network of small separate particles, the gel is classified as a two-phase system. In a two-phase system, if the particle size of the dispersed phase is relatively large, the gel mass is sometimes called as a magma. Single-phase gels consist of organic macromolecules uniformly circulated throughout a liquid in such a way that no apparent boundaries occur between the dispersed macromolecules and the liquid. In pharmaceutical applications, water and hydroalcoholic solutions are most common. Many polymer gels exhibit reversibility between the gel state and sol, which is the fluid phase containing the dispersed or dissolved macromolecule. However, the formation of some polymer gels is irreversible because their chains are covalently bonded. The three-dimensional networks formed in two-phase gels and jellies are formed by several inorganic colloidal clays. The formation of these inorganic gels is reversible. Gels are generally considered to be more rigid than jellies because gels contain more covalent crosslinks, a higher density of physical bonds, or simply less liquid. Gel-forming polymers produce materials that span a range of rigidities, beginning with a sol and increasing in rigidity to a mucilage, jelly, gel, and hydrogel. Some gel systems are as clear as water, and others are turbid because the ingredients may not be completely molecularly dispersed (soluble or insoluble), or they may form aggregates, which disperse light. The concentration of the gelling agents is mostly less than 10%, usually in 0.5% to 2.0% range, with some exceptions.

Classification of Gels

Gels can be classified based on colloidal phases, nature of solvent used, physical nature and rheological properties, etc.

Based on colloidal phases:

They are classified into:

a. Inorganic (Two phase system)

b. Organic (Single phase system)

Inorganic (Two phase system)

If the partition size of dispersed phase is relatively large and form the three-dimensional structure throughout gel, such a system consists of floccules of small particles rather than larger molecules and gel structure, in this, system is not always stable. They must be thixotropic-forming semisolid on standing and become liquid on agitation.

Organic (Single phase system)

These consist of large organic molecules existing on the twisted strands dissolved in a continuous phase. This larger organic molecule either natural or synthetic polymers are referred as gel formers, they tend to entangle with each other their random motion or bound together by Vander walls forces.

Methods of Formulation of Gels:

Gels can be prepared by following methods:

1. Thermal changes:

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Solvated polymers (lipophilic colloids) when subjected to thermal changes causes gelatin. Many hydrogen formers are mere soluble in hot than cold water. If the temperature is reducing, the degree of hydration is reduced and gelatin occurs.
E.g., Gelatin, agar sodium oleate, guar gummod, cellulose derivatives, etc.

2. Flocculation:
Hare gelation is produced by adding just sufficient quantity of salt to precipitate to produce age state, but inadequate to bring about complete precipitation. It is essential to ensure quick mixing to avoid local high concentration of precipitant.
Eg. Soktion of ethyl cellulose, polystyrene in benzene can be gelled by rapid mixing with suitable amounts of a non-solvent such as petroleum ether. The addition of salts to hydrophobic solution brings about coagulation and gelation is rarely observed.

3. Chemical reaction:
In this method gel is produced by chemical interaction between the solute and solvent.
E.g., Alumiman hydroxide gel can be prepared by interaction in aqucous solution of an alurninum salt and sodium carbonate, an increased concentration of reactarns will produce a gel structure.

Gel Formulation Ingredients
The formulation of topical gels requires careful consideration of several key factors, including their appearance, odor, spreadability, extrudability, viscosity, pH, texture, potential for microbial contamination, and bioavailability. The vehicle's components should enhance drug penetration through the skin. Gel characteristics like consistency and viscosity, which are influenced by the formulation design, are critical for adhesion and retention at the application site, ensuring effective drug delivery.
Topical gel formulations generally comprise four main ingredient categories: gelators, solvents, the drug itself, and excipients.
a) Gelator: Gelators function as stabilizers and thickeners, increasing the viscosity of the gel solution while preserving its flexibility. When dispersed colloidally within the solvent, gelators provide a stable internal structure. The choice of gelator depends on its affinity for the solvent and the gel's intended purpose. The gelator dictates the gel's rigidity. Carbomers are frequently used due to their thickening capabilities across a broad pH range. Gelators can be categorized by polymer type: natural (e.g., tragacanth, gelatin, collagen, guar gum), semi-synthetic (e.g., methylcellulose and other cellulose derivatives), and synthetic (e.g., carbomers, polyvinyl alcohol, polyethylene and its copolymers).
b) Solvent: Solvent selection is guided by the gel's intended application and can be hydrophilic, lipophilic, or organic. Solvents can be used individually or in mixtures. Examples include purified water, glycerin, glycols, alcohols, sucrose, toluene, and mineral oils.
c) Drug: Topical delivery is a viable option for drugs susceptible to degradation in the gastrointestinal tract or to significant first-pass hepatic metabolism. Additionally, topical gels can be suitable for drugs requiring prolonged administration or those capable of inducing adverse effects beyond the targeted area. A drug's physicochemical and biological properties play a crucial role in determining its suitability for topical delivery via a gel dosage form.

Physicochemical properties : -
Have a molecular weight smaller than 500 daltons.
Be adequately lipophilic.
Have a pH value greater than 5 and smaller than 9 when saturated in an aqueous solution.
Not be highly acidic or highly alkaline
Biological properties :-
The drug should be non-irritantand non-allergenic.
Under a constant rate of delivery (zero order release profile), tolerance to the drug must not be developed.

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Excipients: Excipients are inactive ingredients added to drug formulations to enhance the overall quality and performance of the dosage form. They play a crucial role in ensuring the stability, efficacy, and patient acceptability of the final product. Examples of common excipients include antioxidants, sweetening agents, stabilizers, dispersing agents, penetration enhancers, buffers, and preservatives.

Types of excipients:

i. **Penetration Enhancers:** These excipients are used to increase the permeability of the skin, facilitating drug absorption. Several classes of compounds can act as penetration enhancers, including glycerin, sulfoxides and related analogs, pyrrolidones, fatty acids, ethanol, and surfactants.

ii. **Buffers:** Buffers are added to aqueous or hydroalcoholic gels to maintain a stable pH. Common examples of buffers used in these formulations include phosphate and citrate.

iii. **Preservatives:** Due to their antimicrobial properties, preservatives are vital, particularly in hydrogels, to prevent microbial growth and maintain product sterility. Parabens and phenolics are frequently used preservatives.

iv. **Antioxidants:** Antioxidants prevent the oxidation of gel ingredients, which can degrade the product. When selecting an antioxidant, the solvent system of the gel is an important consideration. Because most gels are aqueous-based, water-soluble antioxidants like sodium metabisulfite and sodium formaldehyde sulfoxylate are often preferred.

v. **Sweetening Agents:** Sweetening agents are used exclusively in gels designed for oral application, such as dental gels, to improve palatability. Common examples include sucrose, glycerol, and sorbitol.

Evaluation Parameters of the Formulated Gels

Homogeneity:

All developed gels are tested for homogeneity by visual inspection after the gels have been set in the comminer. They are tested for their appearance and presence of any aggregates

Grittiness:

All the formilations are evaluated microscopically for the presence of particles if any no appreciable particulate matter seen under light microscope.

Measurement of pH:

One gram of gel dissolved in 100 ml of distilled water and stored for two hours. The measurement of pH of each formulation is done in triplicate and average values are calculated

Drug content:

1g of the prepared gel is mixed with 100kal of suitable solvent. After suitable dilation, absorbance recorded by using UV- visible spectrophotometer (UV-1700 at 222 nm). Drug content is determined using slope of standard curve

Viscosity study:

The viscosity of the different gel formulations determined at 25°C using a cone and plate viscometet or Brookfield Viscometer. The gels are rotated at 0.3, 0.6 and 1.5 rotations per minute. At each speed, the corresponding dial reading are noted

Spreadability:

Spreadability is expressed in terms of time in seconds taken by two slides to slip off from gel and placed in between the slides under the direction of certain load, lesser the time taken for separation of two slides, better the spreadability. It is calculated by using the formula:

$$S=M.L/T$$

Where M=weight tied to upper slide

L=length of glass slides

T=time taken to separate the slide

Extradability study:

The formulations are filled in the collapoble tubes after the ges set in the container. Extrudability are hused upon the quantity of gel in percentage and gel extruded from collapsible tube on application of weight in grams required to extrude at least 0.5 cm ribbon of gel in 10 seconds.

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Skin irritation study:

The allino mice of either weighing 20-22gms used for this test. The intact skin is used. The huirs are removed from the back of the mice 3 days before the experiment. The animals are divided into two butches and each batch is again divided into two groups. The gel containing drag is used on test animal. A piece of cotton wool soaked in saturated drug solution is placed on the back of albino mice taken as control. The animals daily upto seven days and finally the treated skin oxannned visually for erythema and edema tested.

In-vitro Diffusion study:

The In-vitro technique for studying skin penetration involves use of some variety of a diffinion cell like Franz cell and Flow through cell in which animal or human skin is fastened to a holder and the passage of compounds from the epidermal surface to a fluid bath is measured.

Stability:

It was carried out by freese-thaw cycling. Here, the product to a temperature of 4°C for 1 month, then at 25°C for 1 month and then at 40°C for 1 month, syneresis was observed. Then the gel is exposed to ambient room temperature.

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