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EMULGEL: TOPICAL DUAL CONTROL RELEASE SYSTEM

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ABSTRACT

The review was carried about emulgel formulations used for delivering non-steroidal anti-inflammatory drugs (NSAIDs) through the skin. Emulgels are a new type of topical medicine that is applied to the skin as a semi-solid form and works by coming in contact with the outer skin layer. Using emulgels for drug delivery has many benefits. It avoids the livers first past metabolism, can be used without a doctor, improves patient comfort, targets specific areas, allows the use of water-insoluble drugs, and offers better drug loading, stability, and controlled release. Its also cheaper and easier to make compared to other delivery systems. The creation of emulgels involves mixing oil and water phases with emulsifiers, polymers, and agents that help the drug absorbed through the skin. The review discusses the types of emulgels, their pros and cons, ingredients, how they are made, how they are tested, how NSAIDs work in them, different marketed emulgel products, and ongoing research in this field.

Key Words: *Topical drug delivery system, Emulgel, Emulsion, Gel, Incorporation method*

INTRODUCTION

Emulgels are a type of emulsion (a mix of oil and water), either oil-in-water or water-in-oil, that is turned into a gel using a gelling agent. This gel form is stable and works well for carrying drugs that don't dissolve easily in water (hydrophobic drugs). In simple terms, emulgels are mix of an emulsion and gel. While gels have many benefits, one major drawback is their difficulty in delivering hydrophobic drugs.[1,2,3]. To solve the problem of delivering that don't dissolve well in water, an emulsion-based method is used. This allows such drugs to still benefits from the special qualities of gels. In recent years, new types of polymers have become important. These can act as emulsifiers and thickeners. Their ability to form gels helps create stable emulsions and creams by lowering surface tension and increasing the thickness of the water part. When a gelling agent is added to the water phase, it turns a regular emulsion into an emulgel. Emulgels used on the skin have several good qualities-they are thixotropic, not greasy, easy to spread, non-staining, greater shelf life, bio-friendly,

comfortable to use, clear & pleasant appearance. Non-steroidal anti-inflammatory drugs (NSAIDs) are common and widely used to treat pain and swelling. They are often used to treat different types of arthritis.[4,5]

Advantages of Topical Drug Delivery System [5]

- Targeted to specific site.
- Better stability.
- Controlled release.
- Termination of medication is easy when needed.
- Better compliance.
- It is convenient to use and easy to apply.
- Providing utilization of medication with a brief biological half-life and a limited therapeutic range.

Disadvantages of Topical Drug Delivery System [6]

- Drug with larger particle size is difficult to penetrate.
- Possibility of allergic reactions.
- Some drugs may poor permeability through skin.
- Skin irritation on contact dermatitis.

Classification of Topical formulation

1. **Solid:** Powders, Poultices, Plasters
2. **Liquid:** Solution, Lotion, Suspension, Colloidions, Liniments, Emulsion
3. **Semi-solid:** Ointments, Creams, Pastes, Gels, Suppositories
4. **Miscellaneous:** Transdermal delivery system, Rubbing alcohol, Gouzes, Surgical tapes

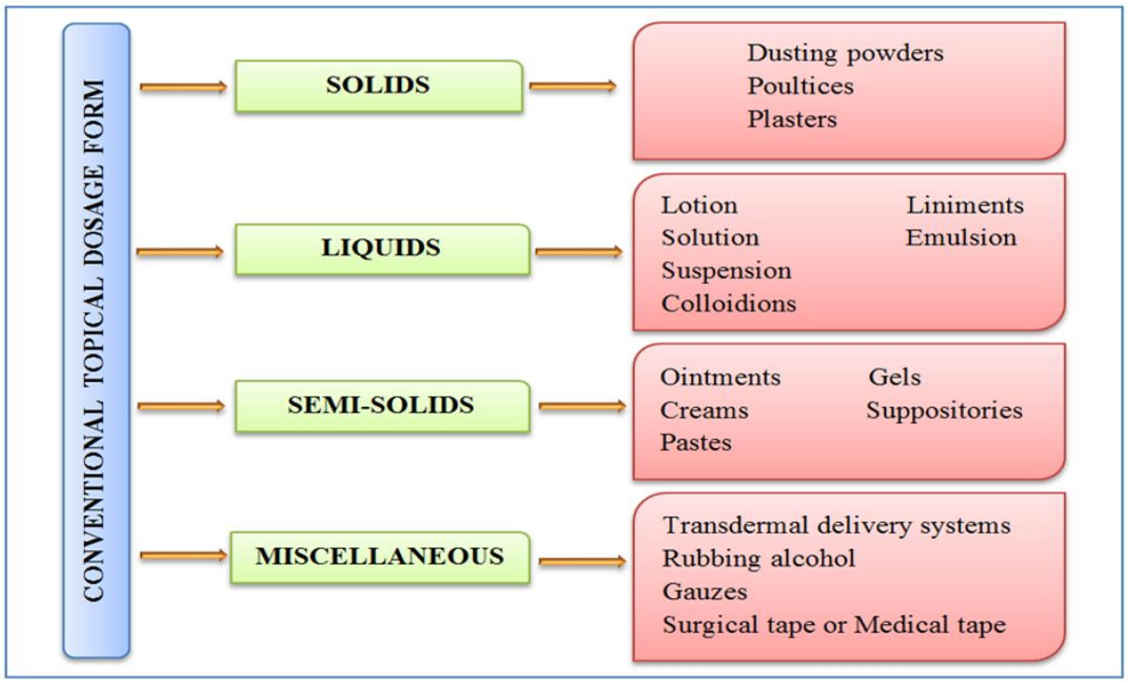


Figure 1: - Classification of Topical Formulations

Factors Affecting Topical Absorption of Drug [12]

A. Physiochemical Factors of Drug Substance

1. Molecular weight (400 Daltons)
2. Partition coefficient
3. Diffusion coefficient
4. Drugs that are not ionized (uncharged) are absorbed better through the skin.
5. Protein binding capacity.

6. **Physiological Factors**
   - **A.** Lipid content
   - **B.** Skin thickness
   - **C.** Blood flow
   - **D.** Skin pH
   - **E.** Sweat gland density
   - **F.** Hair follicle density
   - **G.** Skin hydration and Inflammation of the skin

Physiology Of Skin [4,5]

Most medicines that are used on the skin (called topical preparations) are applied directly to the surface. To make these medicines work well, it's important to understand how the skin works. The skin of an average adult covers about 2 square meters and gets about one-third of the blood flowing in the body. The skin has different layers. The top layer is called the epidermis, and the layer below it is called the dermis. On average, human skin has about 40 to 70 hair follicles and 200 to 300 sweat ducts in each square centimetre. The skin's pH (a measure of how acidic or basic it is) usually ranges from 4 to 6.5, which means it's slightly acidic. This helps protect the body from germs.

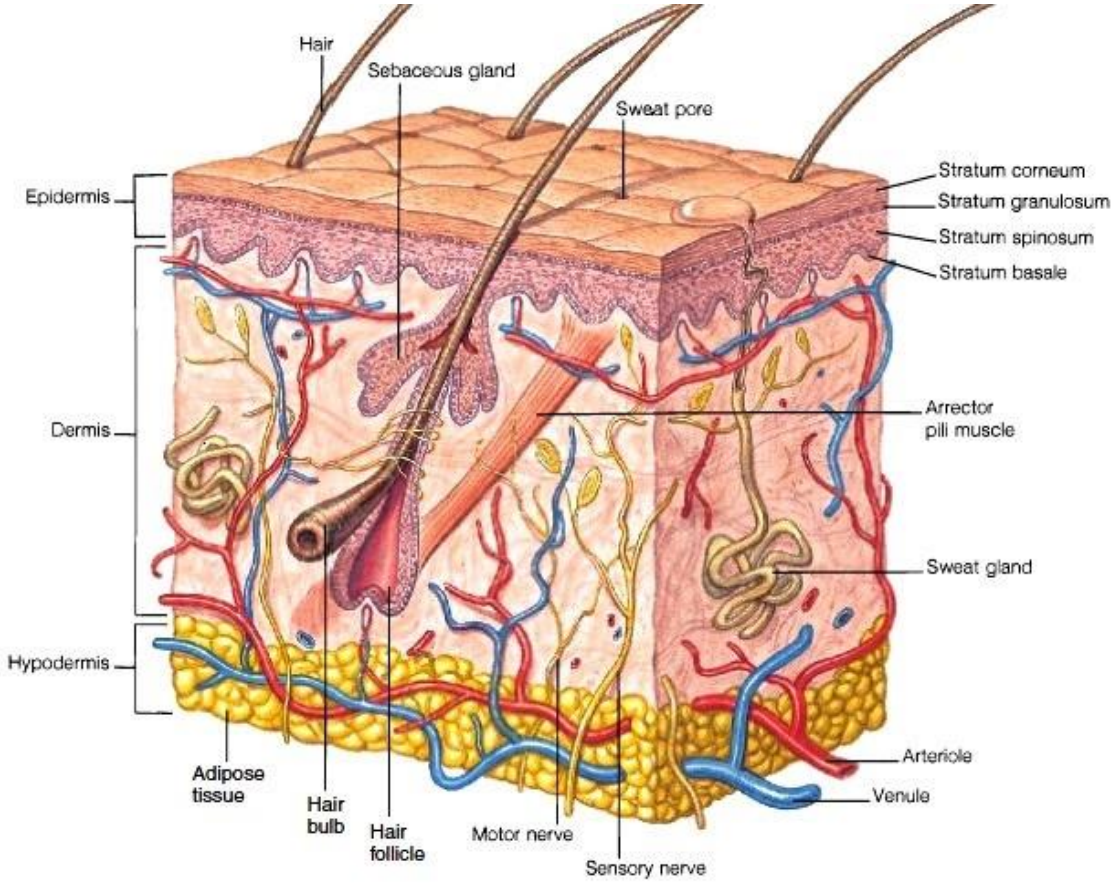


Figure 2: - Structure of Skin

Epidermis :- The epidermis is the outer layer of the skin. It is the first part that touches any cream or medicine put on the skin. The epidermis works like a shield to protect the body. It is made of many flat skin cells stacked in layers.

Epidermis divided into 5 layers: -

- Stratum Corneum
- Stratum lucidum
- Stratum granulosam
- Stratum spinosum
- Stratum basale

.Dermis: - The dermis is the layer under the epidermis. Its main job is to support the epidermis and provide it with nutrients. The dermis has two parts: the papillary layer and the reticular layer. These layers contain important substances like elastin, fibrillin, and collagen, which help keep the skin strong and stretchy.The dermis also contains important parts of the skin, such as sebaceous (oil) glands, sweat glands, blood vessels, and nerve endings. Blood vessels (veins) in the dermis bring nutrients to both the dermis and the epidermis.

3. Hypodermis and Subcutaneous tissue: - Hypodermis is internal layer of the skin. The subcutaneous tissue, or hypodermis, is not really part of the main skin structure. It has tough tissue with blood vessels, lymph vessels, sweat gland openings, and nerves. Most medicines that go through the skin enter the blood before reaching the hypodermis.

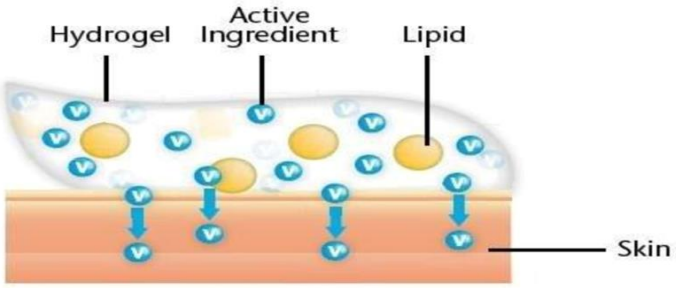
EMULGEL

Emulgels are very effective skin preparations used for treatment and diagnosis. They are a mix of gel and emulsion, making a two-part (biphasic) system The emulsion is the inner part, and it is mixed into a gel base made with water. In simple terms, the emulsion is a combination of emulsion and gels. Emulgels is developing field of topical drug delivery, and with few products on the market to date, it is thoughtful and challenging to focus on emulgels formulations. [13]

Emulgels are a mix of oil and water used to put medicine on the skin. They can be oil in water or water in oil. To keep them mixed well, a special mixing agent is added.

Emulgels are easy to wash off and help the medicine go deep into the skin. To turn a regular mix into an emulgel, a gel-making ingredient is added to the water part.

Some medicines in emulgels can even go into the blood through the skin. Emulgels are safe, easy to spread, not sticky or oily, do not leave marks, look clear, and last a long time without spoiling. [14]



Advantages of Advantages of Emulgel [18]

- Avoidance of first pass metabolism.
- Avoidance of gastrointestinal incompatibility.
- Enhance patient compliance.
- Better penetration and stability.
- Controlled release.
- Both hydrophilic and hydrophobic enhance skin permeation.
- Convenient and easy to apply.
- Self-medication.
- Improve bioavailability.
- Provides targeted drug delivery.

Disadvantages of Emulgel [19]

- Skin irritation on contact dermatitis.
- Possibility of allergic reaction.
- Poor permeability of some drugs through skin.
- Bubbles may occur during formulation of emulgel.
- Large particles of drugs easily not absorbed through skin.

Emulgels are classified into 3 types on the basis of type of emulsion [15,16,17]

1. Macroemulgel
2. Microemulgel
3. Nanoemulgel

Macroemulgel

These are the most common types of mixing helpers (emulsifiers). The tiny droplets in them are bigger than 400 nanometres. They look milky and you can see the droplets under a microscope.These mixtures, called macroemulsions, are not stable, but they can be made stable by adding a special mixing ingredient called a surfactant.

Microemulgel

Microemulsions are clear and stay stable. The tiny droplets in them are very small, between 10 to 100 nanometers. They are made by mixing oil, a helper ingredient, and water in the right amounts.

Nanoemulgel

When nano emulsion is incorporated into gel it is known as nanoemulgel. The thermos stable transparent dispersion of water and oil with a droplet size less then 100nm, known as nanoemulsion. Nanoemulsion are stabilized by an interfacial film of surfactant and co-surfactant. Nanoemulsion formulation has improved transdermal and dermal delivery properties in vitro as well as in vivo.

Emulgel consists of two components.

Emulsion [11]

Emulsion are biphasic liquid dosage forms that are separated into components-Emulsion involves a combination of two or more liquids that are usually immiscible, forming a stable mixture. Two liquids can form different type of emulsions. As an example, oil and water can form, first, oil-in-water emulsion, in which the oil phase is the dispersed phase, and water is the continuous phase. Second, they can form a water dispersed phase and oil is the continuous phase.

Classification of Emulsion [15]

- Oil in water (o/w)
- Water in oil (w/o)
- Multiple emulsion (w/o/w) or (o/w/o)

Gel [16]

The gel refers to enhancing the viscosity of liquid preparation without changing other properties. Gels are used as thickening agent and also to improve homogeneity and consistency of a formulation. They are made from special materials (polymers) that swell up when they absorb liquid. How firm the gel is depends on how much liquid it holds. These gels are wet and smooth, with being solid appearance. These are capable of significant physical deformation, from solid-state to liquid state.

ESSENTIAL INGREDIENT IN THE FORMULATION OF EMULGEL

Active pharmaceutical Ingredient

Aqueous Material [7]

This formed the water phase of the emulsion. Commonly used agents e.g., water, alcohols.

Oils [9]

These agents formed an oil phase. For topically applied emulsion, mineral oil is often used by itself or mixed with soft or hard paraffin. When taken by oral, some oils like mineral and castor

oils, such as fish liver oil or plant-based oils (e.g., peanut, cottonseed, or corn oil), are used in the diet.

Name of Oils	Properties
Clove oil	Anti-inflammatory, Antioxidant
Castor oil	Topical NSAIDs, Antioxidant
Olive oil	Antioxidant, Antimicrobial
Balsam oil	Antifungal, Topical Antibiotics
Light liquid paraffin	Emollient

Emulsifiers [17]

Emulsifiers are surfactant that help mix things like oil and water together during production. They also keep the mixture from separating while its stored.

Chemical	Formulation
Polyethylene glycol 40 stearate	Emulgel and Emulsion
Sorbitan monoolate (span 40)	Emulgel and Emulsion
Stearic acid agent	Emulsion
Sodium sterate agent	Emulsion

Preservatives [19]

Preservatives are added to formulations to prevent the growth of harmful microbes like bacteria, fungi, and molds. They help to extend the shelf life of the products, ensuring it remains safe and effective for longer period. By protecting the active ingredients from degradation, preservatives maintain the stability and quality of the formulation.

Preservatives	Concentration
Methyl paraben	0.03-0.16
Propyl paraben	0.03-0.06
Phenoxy ethanol	0.2

Gelling Agent [3]

They are the substance used to enhance the viscosity of any dosage form can also be used as a thickening agent.

Gelling agents	Type	Uses
Carbopol 934	Synthetic	Emulgel
Carbopol 940	Synthetic	Emulgel
HPMC-2910	Semi-Synthetic	Emulgel
Sodium CMC	Semi-Synthetic	Gel
Xantham Gum	Natural	Gel
Guar Gum	Natural	Gel

Penetration Enhancer [5]

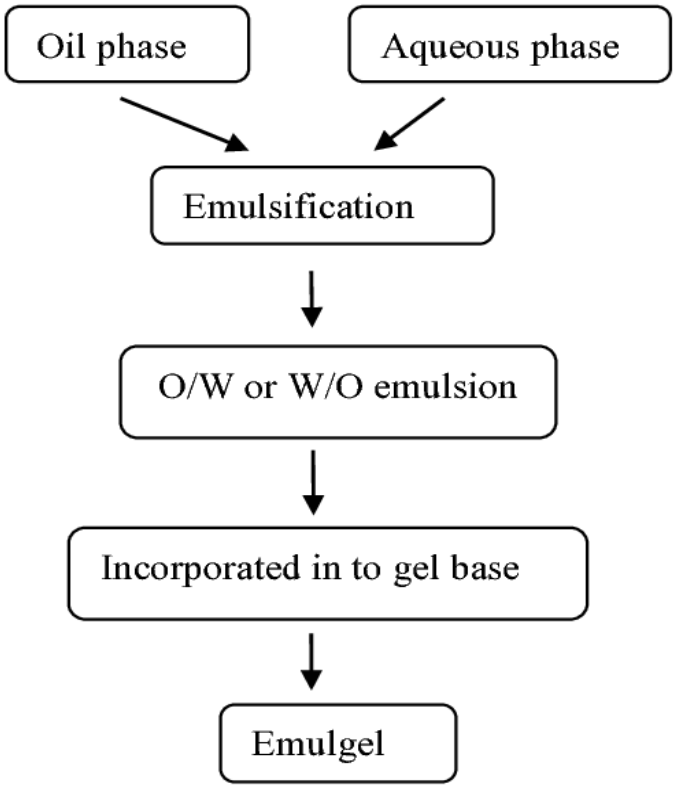
These are substance that mix with the skin and help it temporarily more absorbent. This allows other substances to pass through the skin more easily for a short time.

Penetration Enhancer	Formulation
Oleic acid	Emulgel
Lecithine	Gel
Urea	Gel
Menthol	Emulgel
Clove oil	Emulgel
Linoleic acid	Gel

pH Adjustment [3]

These ingredients is used to maintain the pH stability of the formulation. E.g., triethanolamine, NaOH, etc.

EMULGEL PREPARATION METHOD [20]



Emulsion Preparation

- 10 ml of distilled water was dissolved 0.5% w/w tween 20 in order to create an aqueous phase.
- Then propylene glycol was combined with propyl paraben and methyl paraben they were eventually mixed in with the aqueous phase.

- 1% w/w spam 20 was mixed with liquid paraffin in order to create an oil phase, and this oil phase 0.25 drug was dissolved in ethanol.
- The oil phase and water phase were heated in water bath upto 80°C.
- The oil phase and aqueous phase were mixed to create the emulsion by using a mechanical stirrer for 20-25 minutes.
- The mixture was cooled at room temperature after being stirred.

Gel Preparation

- In a 100-ml beaker, add 40 ml of water where'd mix at a speed of around 800 rpm.
- A precisely measured amount of Carbopol 934 was added pinch by pinch to the stirring solution mention above and stirred for 10 to 15 minutes.

Emulgel Preparation

- Add gel solution to the emulsion drop by drop, stirring continuously at moderate speed.
- Continued stirring for 5 minutes, led to create of emulgel that were more consistent.

Evaluation of Emulgels

Physical Appearance [15]

The prepared emulgel formulation are visually observed color, phase separation and uniformity.

Determination of pH [18]

Emulgel was correctly weight and mixed in 25 ml of distilled water. The pH of dispersion was measured with digital pH meter. This process was repeated 3 times.

Rheological Studies [2]

20 grams of the emulgel was put into a 25 ml beaker. To check how thick the emulgel is (called viscosity), a machine called a Brookfield viscometer with spindle number 63 was used.
The emulgel was left to settle for 30 minutes at a temperature of 25°C (plus or minus 1°C) before testing. The spindle was carefully placed straight into the middle of the gel, making sure it didn't touch the bottom of the beaker.
Then the spindle was spun at a speed of 50 rounds per minute for 10 minutes, and the thickness (viscosity) was written down.

Spreadability [18,20]

To check how well the gel spreads, two glass slides of the same size were used.
Some gel was put on one slide. Then, the second slide was placed on top, so the gel was in the middle like a sandwich. The slides were pressed together to remove any air, and the extra gel on the sides was cleaned off.
Next, the slides were placed on a stand. The bottom slide was held tight, and the top slide could move freely. A 20-gram weight was gently tied to the top slide.
The time it took for the top slide to slide off completely was noted.

To find out how well the gel spreads, this formula was used:

Spreadability (S) = M × L / T

Where:
M = weight (20g)
L = length of the slide
T = time taken for the top slide to move

Swelling Index [2,3]

Take 1 gram of the emulgel and put it on a piece of aluminium foil with tiny holes. Then place it into 10 ml of 0.1 N NaOH solution.
At different times, take the gel out, place it on a dry surface, and weigh it again.
This tells us how much the gel has soaked up the liquid and grown (swelled).

Use this formula to find the swelling:
Swelling Index (SW%) = [(Wt. – Wo) / W0] × 100
Where:
SW% = Swelling percentage
Wt. = Weight after swelling
W0 = Original weight (1 gram)
Wo = Original weight of emulgel at zero time
Wt. = Weight of swollen emulgel after time

Fourier Transforms Infrared Spectroscopy (FTIR) [2]
The purpose of this was to identify stable storage surroundings for drug in solid state and determine compatible excipient for formulations.
Drug content Assessment [20]
To find out how much medicine is in the emulgel, a machine called a spectrophotometer was used. First, 2 grams of the emulgel was mixed with methanol (a type of liquid) using sonication (shaking with sound waves to mix well). Then the liquid was diluted (made thinner), and its absorbance (how much light it takes in) was checked using a UV-Visible Spectrophotometer (model 1700 CE, made by Shimadzu in Japan).
The amount of drug was calculated using this formula:
Drug Content = (Concentration × Dilution × Volume taken) × Conversion factor

Skin Irritation Test [5]
With agreement the skin irritation test was performed by human volunteer's skin. The produced medication is applied to the hand skin and any negative effect are monitored.
In-Vitro Drug release study [3]
In-Vitro Drug release study done with the Franz diffusion cell in emulgel. In figuring out the medication release.
Emulgel Globule Size and Distribution [3]
The size and spread of globules are measured using a Malvern zeta sizer. A 1.0 g. sample is mixed with clean water and stirred until evenly mixed. The mixture is then put into the zeta sizer machine. This gives the average size of the globules and how they are spread out.
Microbiological Assay [20]
The ditch plate method was used to check if the gel can stop bacteria or fungi from growing. This test is often used for thick products like gels.
Plates were made using Saburou's agar, which is a jelly-like food that helps fungi grow. Then, 3 grams of the gel was put into a small cut (ditch) in the middle of the plate.
A tool called a loop was used to spread the germs from the edge of the plate toward the gel to see if the gel can stop them.

PACKAGING OF EMULGEL [18]
Emulgels are usually packed in aluminium tubes with a special coating inside to protect the gel. The tubes are closed with a plastic screw cap or a sealed lid.

Marketed emulgels

S.no	**Product Name**	**Drug**	**Manufacture**	**Use**
1.	Diclomax Emulgel	Diclofenac Sodium	Torrent Pharma	Anti-inflammatory
2.	Voveron Emulgel	Diclofenac	Dr. Reddy ś Laboratories	Anti-inflammatory
3.	Sorobet Emulgel	Clobetasol	Geluk Pharma	Anti-inflammatory
4.	Nucoxia Emulgel	Etoricoxib	Zydus Cadila	Anti-inflammatory

CONCLUSION

Topical drug delivery systems will be used more because they are easier for patients to use. Emulgels are great because they spread easily**,** stick well, are the right thickness, and are easy to squeeze out. They are used in both medicine**s** and cosmetic**s**, and can also include herbal ingredients. Emulgels are likely to become a popular way to deliver medicine.

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