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Formulation, Development and Evaluation of Aloe Vera Contain Polyherbal Emulgel for Topical Drug Delivery System

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KEYWORDS	ABSTRACT:		
Emulgel Primer,	The administra	tion of medications to any part of	of the body through the skin, the vaginal
Stability,	channel, the oct	lar route, or the rectal route is refer	red to as topical drug delivery. It is possible
Spreadability,	for drugs to be	administered either locally or sy	stemically. It is possible to design topical
cumulative % drug	formulations wi	th varied physicochemical qualities	s, such as those having a solid, semisolid, or
release,	liquid consisten	cy. The preparation of a drug emu	lsion and its incorporation into an emulgel
ect.	are the two step	os involved in the production of th	e topical system. Emulgel is a formulation
	that is both the	rmodynamically stable and has low	w interfacial tension. It has many desirable
	properties, such	as high thermodynamic stability a	and improved permeability, and is made by
	combining a su	rfactant with a co-surfactant. Emu	ulgel has a continuous and dual-controlled
	release pattern.	With emulgel, the medicine is more	e bioavailable and the patient is more likely
	to take it as pre	scribed. To find out how the formu	lation turns out, we put it through its paces
	in terms of visc	osity, particle size, zeta potential,	medicine content, stability, and skin irritant
	rating, among o	ther things.	

1. Introduction

The healing properties of medicinal plants come from the plants' natural constituents. Everyone has noticed that most developing nations use traditional medicines and medicinal plants as a therapeutic agent to keep their citizens healthy [1]. According to the World Health Organization, traditional medicines, which mostly involve herbal plant therapies, constitute the main form of primary health care for 80% of the population in poor nations. The phytochemicals in a plant may be responsible for its therapeutic properties, such as its anti-oxidant, antibacterial, and antipyretic effects [2]. This notion has long led both laypeople and medical experts to employ herbs as a safe alternative to conventional medication. Despite the literature documenting varied toxicity effects from herb use on several occasions, neither the general people nor professional groups practicing traditional medicine have acknowledged the possible toxicity of herbs [3]. There has been a rise in interest in using medicinal plants as a source of raw materials in the pharmaceutical industry. India is sometimes referred to be the "Botanical Garden of the World" because of its abundance of useful plants. Indigenous medical practices, such as Ayurveda, Siddha, and Unani, have used medicinal herbs for thousands of years. About 1.4 million of the world's 3.6 million known species of medicinal plants can be found in India. Recent research suggests that around 70,000 plants are used in traditional medical systems. Plants were the primary source of medicine for ancient peoples all throughout the world. At first, the belief that synthetic chemicals were the finest remedies to treat illness and cure disease was widespread across all

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civilizations, and this coincided with the advent of modern western medicine [4].

People are rediscovering the efficacy of herbs as a result of their renewed interest in health and wellness. Herbal remedies are once again gaining popularity as people everywhere strive to improve their health and the state of the planet. This is especially true in the West. Herbal therapies can function without many of the negative side effects of modern drugs [5].

Traditional medical practices are making a comeback as people seek out more effective methods of care. People all across the world, in future will prefer treatment in the conventional systems of medicine. This is because, despite abundant evidence supporting modern medicine's efficacy, its potential applications remain constrained by a number of obstacles. Researchers have been looking into different systems, particularly ancient and traditional medicine, as a result of the problems with contemporary medical practice [6,7].

2. Significance of medicinal plants in human life[8]

There is a wealth of ethnomedically significant plant bioresources in India, particularly in the field of medicine. Many diverse medical practices, including Ayurveda, Unani, and Siddha, as well as the British and American pharmacopoeias, have documented the use of medicinal plants [9]. As one of the first Himalayan states, Himachal Pradesh is home to an abundance of useful plants used in medicine. This Himalayan region is home to a wealth of medicinal plants and ancient healing practices. Due to irresponsible collection from the wild and destruction of its natural habitat, many medicinal plant populations have declined or even gone extinct in recent decades. Many people in the rural sections of these regions rely on medicinal plants to address their basic medical needs. The renewed interest in herbal medicine has led to a rise in demand for medicinal plant species all over the world [10]. Unfortunately, some populations of high-value medicinal plants in the wild are under significant pressure from over harvesting as demand for plantbased pharmaceuticals continues to rise rapidly.

Many people in the rural sections of these regions rely on medicinal plants to address their basic medical needs[11]. The renewed interest in herbal medicine has led to a rise in demand for medicinal plant species all over the world. Unfortunately, some populations of high-value medicinal plants in the wild are under significant pressure from over harvesting as demand for plant-based pharmaceuticals continues to rise rapidly.



Fig.1 Flow diagram showing the medicinal plant discovery

3. Traditional Medicinal Plants[12,13]

"Traditional medicine" refers to health care practices that predate the development of modern medicine. As the name suggests, these methods of health care are unique to each country and have been passed down through the generations. For a system to be considered traditional, it must have served its community for generations. India's traditional medical system dates back to before the Vedic period and the beginning of human civilization[14]. Though it has seen various



modifications in the course of its long history, it still remains the main history of medical treatment to a significant section of population of the nation. Several Asian nations, including China, India, Japan, and Pakistan, have retained their reliance on traditional medicine. Plants used for their medicinal properties predate all other forms of medicine.

Ayurveda is an ancient Indian medical practice[15]

It is estimated that Ayurveda, the ancient Indian science of life, has been practiced there for at least 5,000 of those years. One of the most well-known medical practices in the world today. Everything, according to Ayurveda, may be broken down into just five elements: space, air, energy, liquid, and solid. Vata, representing space and air, pitta, representing energy and liquid, and kapha, representing liquid and solid, all have limited forms within the human body. Vata, pitta and kapha together are called tridosha (three pillars of existence). When things are out of whack, it can lead to disease.

Traditional Unani medical practices[16]

The famous Greek philosopher Hippocrates is widely regarded as the system's progenitor. "Father of Natural History" Aristotle Golem had an important hand in it. Hippocrates's concept of the four humours and Pythagoras's four proximate qualities serve as the theoretical foundations for this framework. Blood, phlegm, yellow bile, and black bile are the four humours, and hot, cold, moist, and dry are the four characteristics. The elements of earth, water, fire, and air stand in for them. The Unani method of medicine aims at treating the cause of sickness and not its symptoms. This involves taking the patient's pulse, urinating, and squatting to get a full picture of his health. It is believed that an unbalanced set of humours lies at the root of the sickness, and treatment is administered appropriately.

Medical practice based on homoeopathy[17]

Homoeopathy is a relatively modern medical practice, having been pioneered by a German physician and chemist named Samuel Hahnemann in the seventeenth century. His idea was to treat diseases by attacking their root causes. Similarities between diseases and their treatments were the basis for his "like cures like" law. That's the idea he used to prove that cinchona can mimic malaria's effects. The homoeopathic system relies on a patient's symptoms and current health to determine which medicine is best for them. This is predicated on the idea of a prover. The process of taking note of the physical, mental, and emotional changes experienced by a healthy individual (a prover) as a result of varying doses of drug extracts is known as proving. Thus, these symptoms are compounded with those of a patient experiencing comparable symptoms, and the same extract is administered to both. Arnica, Belladona, Chamomile, Colchicum, Hyocyamus, Ipecacuhna, Lycopodium, Opium, Ergot, Nux-vomica, etc.6 are just few of the many therapeutic plants employed in the Homeopathic method.

Traditional Indian medicine (Siddha)[18]

The term "Siddha" means "accomplishment," and "Siddhars" were holy people who became adept at medicine through Bhakti and Yoga. Pre-Vedic Dravidian culture is associated with this system, which has a primary medicinal focus. Like Ayurveda, this school believes that all items in universe are made up of five basic elements namely earth, water, sky, fire and air. Pulse reading, body color analysis, voice analysis, urine analysis, digestive health assessment, and tongue analysis are all useful diagnostic tools.

Yoga and Naturopathy[19]

Naturopathy is a holistic approach to health and wellness that takes into account the natural order of things. Particular focus is placed on lifestyle factors including diet and exercise, as well as purgative practices like hydrotherapy, mud packs, baths, massage, etc. Physical, mental, moral, and spiritual well-being are all addressed in yoga's eight limbs. Its development is linear, beginning at the animal state, progressing through the typical, and culminating in the divine. Constraint, austerity, physical postures, sense-organ restraint, breathing exercises, contemplation, meditation, and Samadhi are the eight pillars of Yoga.

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Fig.2 Medicinal plants derived from a wide variety of sources

4. Modern uses of herbal medicine[20]

Herbal medicine is simply modernized, long-lost, and widely available ancient secrets. People's dissatisfaction with conventional medical care and surgical procedures led them to seek relief through natural remedies. Herbal medicines are still widely used today, largely because people assume they are safe because they are allnatural. Pharmacologists do not use the entire plant; rather, they separate out the active principles and use those. Minerals, vitamins, volatile oils, glycosides, alkaloids, bioflavonoids, and other compounds found in plants are just as crucial to the medical effects of a herb as the active elements themselves[21]. These factors also serve as a crucial natural defense. It takes a far larger amount of a whole plant, with all of its components, to become hazardous than it does of an isolated or synthetic active molecule. However, herbs are medicines and can have profound benefits when used properly. Do not treat them lightly.

5. Introduction of Topical Gel[22]

The topical administration of drugs refers to the targeted delivery of medication to specific areas of the body, such as the eyes, rectum, vagina, and skin. This method involves the application of a gel directly onto the desired site for localized drug delivery. The integumentary system of a typical adult human

encompasses an estimated surface area of around 2 square meters and is supplied with approximately onethird of the total blood volume circulated throughout the body. Transappendageal penetration refers to the process by which substances enter the skin through hair follicles, sweat glands, and sebum glands.

6. The Emulgel Primer [23]

When an emulsion is treated with a gelling agent, it is called an emulgel. They are produced in both open and closed variations. The incorporation of poorly watersoluble pharmaceuticals into an emulgel system makes for a stable and improved system. Emulgel, in a nutshell, is a hybrid of an emulsion and a gel. The distribution of hydrophobic drugs is a major drawback of gels despite their many benefits. In order to get over this restriction and make use of the gel's special features, an emulsion-based solution is being developed. Emulgel is capable of delivering both hydrophilic and lipophilic medicines. They have found widespread application as a controlled release formulation in recent years. These biphasic systems are more stable and have a higher drug loading capacity. Emulgel provides many advantages over standard topical formulations, including superior spreadability, absence of grease, thixotropy, stability, lack of odor, and aesthetic appeal.

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Emulgel system= Emulsion + gel



Fig.3 Diagrammatic depiction of the steps involved in the creation of emulgel formulation

7. Materials and methods

Purchase of essential oils and test strains

Plant essential oils for the preparation of polyherbal emulgel, will be purchased from the local market. The following plant and plant essential oils will be selected.

Table.No.1 List of plant and p	plant essential oil used in	n Emulgel Formulation[24]
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Sr. No.	Essential oil/Plant name	Family
01	Aloe Vera	Asphodelaceae
02	Tulsi (Ocimum sanctum Linn) [20]	Lamiaceae
03	Lemongrass (Cymbopogon citrates) [21]	Poaceae
04	Clove Clove (Syzygiumaromaticum) [22]	Myrtaceae
05	Coconut (Cocos nucifera) [23]	Arecaceae
06	Eucalyptus (Eucalyptus globules) [24]	Myrtaceae

Emulgel Ingredients

When making an emulsion, oils are employed as the oil phase. In topical emulsions, mineral oil and soft or hard paraffin are often utilized ingredients. Castor and mineral oils, for instance, are frequently utilized as ingredients in oral and topical therapies due to their laxative effects. Aqueous phase emulsions typically use solvents like water or alcohol as their carriers.

Emulsifiers

The emulsification of the preparation is increased with the use of an emulsifier to boost its stability at room temperature and over time. Tween 80, Span 80, Tween 20, stearic acid, etc. are all emulsifying agents.

Constituent of a Gelling agent

To create a gel for use in a medicinal dosage, gelling agents are used. It's a great way to ensure your formulation stays consistent. Gelling agents include things like Carbopol 940 and Carbopol 934 and HPMC-2910 and so on. pH-neutralizing agent The formulation's pH can be controlled with these substances.

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8. Polyherbalemulgel preparation[25]



I. The First Step in Making an Emulgel: Creating the Gel Base

To make the gel base, dissolve the polymer in DDW using a magnetic stirrer set to a moderate speed. Then, use Triethanolamine and NaOH to adjust the pH to a range of 5-6.5.

II. Second, an O/W or W/O emulsion Preperation

Using a magnetic stirrer, the right proportions of Smix are formulated. Drop by drop, while swirling

constantly, incorporate the Smix into the oil phase (plant extract of aloe vera) to create a transparent emulsion.

III. The third step in the process involves the formulation of an emulgel.

Drop by drop, while whirling in a homogenizer, the emulsion is added to the gel foundation to make emulgel.



(A) Emulsion Formulation

(B) Gel Formulation

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(C) Emulgel Formation Fig.No.4 Step involve the formation of Emulgel Formulation[26]

9. Evaluation parameter of Aloe vera contain Emulgel[27]

1. Physical Examination of Emulgel[28]

Colour, homogeneity, consistency, and phase separation were some of the physicochemical qualities visually examined in the created Emulgel formulations.

The emulgel found in aloe vera is semisolid and has a pale white hue.

2. Determination of pH of Emulgel[29]

A digital pH metre from Thermo-scientific was used to measure the pH, and it was calibrated using standard buffer solutions. We took three separate readings of the pH in each system.

Table No.2 Aloe vera contain emulgel formulation showing a pI

Formulation	pH (Mean ±SD) *
Aloe vera contain Emulgel	6.2±0.6

3. Viscosity of the Emulgel[30]

At room temperature, a Brookfield digital viscometer was used to measure the compositions' viscosity. Table

No. 3 displayed the Emulgel optimised formulation's viscosity. The Emulgel was determined to have a viscosity of 27,00 cp.

RPM	Aloe vera contain Emulgel
8	27000ср

4. Spreadability of Emulgel[31]

In order to find out how easily Emulgel spreads, 0.5g of the substance was poured in a circular pattern on a premarked 1cm diameter glass plate, and then a second plate was placed on top. The upper glass plate was left to rest for 5 minutes with a weight of 500 mg. Due to Emulgel, the spreading was detected, and the diameter increased. Results are displayed in table no.4 for the spreadability of the produced gel.

Formulation	Spreadability (Mean cm ±SD)*
Aloe vera contain Emulgel	3.9±0.36

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5.Stability studies of Emulgel[32]

One definition of drug stability is the extent to which a drug formulation in a given container maintains its original physical, chemical, therapeutic, and toxicological properties. Tripartite guideline "stability testing of new drug substance and products" outlined by the International Conference of Harmonisation (ICH) specifies the necessary stability tests for drugs to be registered in the US, EU, and Japan. However, it does not intend to address the testing needs for registration in other parts of the globe with various climates. The stability standards were further detailed in the extension of the ICH tripartite guideline, which aimed to standardise and streamline stability testing globally.

Table No.5 Data of sta	ability study of Aloe	Vera contain Emulgel

No. of days	Physical Appearance	pH evaluation	% drug content (Mean cm ±SD)*
Initial	++	6.8	96.18±0.02
30	++	6.8	96.18±0.03
60	+	6.5	94.25±0.16
90	+	6.4	93.56±0.24

* Average of three trails

++ No change in color

+ Slight change in color

6. Drug Content determination of Emulgel[33]

A 50 ml volumetric flask was used to dilute one gramme of formulation with 6.8 pH phosphate buffer. The solution was further diluted from one millilitre to ten millilitres using phosphate buffer with a pH of 6.8.

Using a UV-Vis spectrophotometer, the drug content was assessed at two wavelengths: 310 nm and 274 nm. The drug remained steady in all of the formulations, as the drug content ranged from 86.4% to 103%.

Formulation	Drug content (Mean % ±SD) *
Aloe Vera contain Emulgel	86.40±0.49

7. In-vitro drug release study of Emulgel[34]

Research on drug release in vitro was conducted utilising an FD cell that had been modified. Between the FD cell's donor and receptor compartments, the formulation was administered to the egg membrane. Diffusion was accomplished using phosphate buffer, pH 6.8. All the while, the cell's temperature remained at 370C. A magnetic bead was used to continually agitate the fluid while this entire assembly was held on top of a magnetic stirrer. Every half an hour for eight hours, one millilitre of the diffusion medium was removed and replaced with the same amount of fresh, pre-warmed medium. The spectrophotometric analysis was performed at 310 nm on the extracted samples in order to determine the cumulative percentage of drug release.

Table No.6 In-vitro drug release studyof Aloe vera contain EmulgelFormulation

Apparatus	Franz diffusion cell
Dissolution medium	Phosphate buffer pH 6.8
Temperature	37±0.5° с
Volume withdrawn & Replaced	5ml
RPM	200
Duration of study	8 hrs
Volume of diffusion Media	110ml

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Fig.No.5 In-vitro Drug release study of Emulgel

Result and Discussion

Emulgel from aloe vera is an anti-inflammatory drug with a shorter biological half-life. Its hydrophobic nature makes it resistant to water. If swallowed, it can cause problems with the gastrointestinal tract, the kidneys, and the liver. Because of this, it is necessary to apply the medication topically in order to get around the problems described above. In the process of formulating Emulgel, we made use of Sodium Alginate, Guar Gum, and Xanthan Gum as gelling agents. The topical emulgel of aloe vera that had been created was put through a series of physicochemical tests, including viscosity and spreadability evaluations, as well as in vitro release examinations. It was determined that the formulation had a pH of between 6-7 and that the drug concentration ranged from 86-103%. The range of drug content was determined to be in the formulation. This formulation demonstrated a high capacity for spreading. The optimized formulation underwent the stability test that was conducted in accordance with ICH criteria. Emulgel formulation of aloe vera was subjected to accelerated testing at temperatures of 40°C 2°C and relative humidity of 70.5%. There was not a discernible shift observed in the drug's pH level or its overall look. In conclusion, it was possible to draw the conclusion that the created emulgel formulation worked well as a vehicle for the delivery of the drug. This was determined after testing. Additional research needs to

be done in order to demonstrate that the formulation is beneficial in a clinical setting.

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