Research Article

Formulation And Characterization Of Aloe Vera Based Polyherbal Emulgel For Topical Drug Delivery

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Abstract

Background: Herbal medicines have gained considerable attention as potential alternatives for topical therapy because of their diverse phytoconstituents and therapeutic properties. Emulgels offer several advantages as topical drug delivery systems, including improved spreadability, stability, patient acceptability, and the ability to incorporate both hydrophilic and lipophilic components. The present study was undertaken to formulate and evaluate a polyherbal emulgel containing Aloe vera and selected herbal essential oils for topical drug delivery. **Methods:** The polyherbal emulgel was prepared by incorporating selected herbal components, including Aloe vera, Tulsi (Ocimum sanctum), lemongrass (Cymbopogon citratus), clove (Syzygium aromaticum), coconut (Cocos nucifera), and eucalyptus (Eucalyptus globulus). The formulation was prepared through sequential development of a gel base, emulsion, and final emulgel using suitable gelling and emulsifying agents. The developed formulation was evaluated for physical appearance, homogeneity, pH, viscosity, spreadability, drug content, and stability. **Results:** The prepared Aloe vera-containing emulgel exhibited acceptable physical characteristics and was reported as a translucent, semisolid formulation. The pH was 6.8 ± 0.3, while viscosity was reported as approximately 27,000 cP. The spreadability was 3.7 ± 0.26 cm, indicating satisfactory application characteristics. The drug content of the formulation was 85.30 ± 0.38%. During the stability study, formulation showed only slight changes in appearance and pH, with drug content decreasing from 97.18 ± 0.02% initially to 94.56 ± 0.24% after 90 days. **Conclusion:** The findings indicate that the developed Aloe vera-containing polyherbal emulgel possesses suitable physicochemical properties, satisfactory spreadability, drug content, and stability, suggesting its potential as a topical drug delivery system. Further comprehensive investigations, including therapeutic efficacy and skin permeation studies, are warranted to establish its clinical applicability.

Keywords: Aloe vera; Polyherbal emulgel; Topical drug delivery; Spreadability; Viscosity; Drug content; Stability.

1. Introduction

The active ingredients found in medicinal plants are responsible for their therapeutic effects. The use of traditional medicines and medicinal plants as a means of health care in the majority of developing nations has been well-documented [1]. World Health Organisation data shows that in low-income countries, 80% of the population relies on traditional medicines, which mostly include herbal plant remedies, for their primary healthcare needs. It is possible that a plant's anti-oxidant, antibacterial, and antipyretic actions are due to the phytochemicals found in the plant [2]. Because of this misconception, herbal remedies have long been used by both the general public and medical professionals as a secure substitute for pharmaceuticals. Neither the general public nor organisations engaged in traditional medicine have recognised the potential toxicity of herbs, even though there has been many documentation of varying toxicity consequences from herb use in the literature [3]. Medicinal plants are attracting more attention as a potential pharmaceutical industry raw material source.

The vast variety of medicinal and ornamental plants found in India has earned the country the nickname "Botanical Garden of the World." Herbal remedies have a long history of usage in traditional Indian medicine, including Ayurveda, Siddha, and Unani. India is home to about one-quarter of the world's medical plant species, or 1.4 million out of 3.6 million. Traditional medicine makes use of an estimated 70,000 herbs, according to recent studies. All around the globe, ancient peoples relied on plants as their principal medicinal resource. At the outset, with the rise of modern western medicine, the idea that man-made chemicals were the best way to treat and cure sickness was common across all cultures [4]. Due to a resurgence of interest in health and wellbeing, people are learning about the effectiveness of herbs again. A growing number of individuals are

turning to herbal medicines in an effort to better themselves and the world around them. Especially in Western countries, this is the case. A lot of the harmful side effects of contemporary medications aren't present in herbal treatments, however they nonetheless work [5].
People are turning back to traditional medical techniques in search of more effective alternatives. In the future, people everywhere will choose to get treated via traditional medical methods. This is due to the fact that there is still a shortage of suitable applications for modern medicine, even if there is a mountain of evidence demonstrating its effectiveness. Modern medicine has its flaws, so researchers have been exploring alternative systems, especially traditional and ancient medicine [6,7].

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

India is home to numerous plant bioresources that have important cultural and medical uses. Numerous medical systems have recorded the usage of medicinal plants; they include Siddha, Ayurveda, Unani, and the British and American pharmacopoeias [9]. Himachal Pradesh, as one of the original Himalayan states, is rich in medicinal plants. A plethora of medicinal herbs and traditional treatment methods can be found in this Himalayan region. Numerous medicinal plant populations have drastically decreased or vanished in the last several decades as a result of careless harvesting from the wild and the degradation of their natural environment. In order to meet their most fundamental medical requirements, many people living in these rural areas depend on medicinal plants. On a global scale, the demand for medicinal plant species has increased due to the resurgence of interest in herbal medicine [10]. The fastincreasing demand for plant-based medications is putting a tremendous strain on certain wild populations of valuable medicinal plants due to overharvesting. Medicinal plants are a primary source of care for many people in these areas' rural areas[11]. Worldwide, medicinal plant species are in high demand due to the resurgence of interest in herbal therapy. The fast increasing demand for plant-based medications is putting a tremendous strain on certain wild populations of valuable medicinal plants due to overharvesting.

Figure 1: Flow diagram showing the medicinal plant discovery

3. Traditional Medicinal Plants[12,13]

In the context of health treatment, "traditional medicine" means methods that have been around since before modern medicine. These traditional medical practices have evolved through the years and are as distinct as the countries that practice them, as the name implies. A system is said to be traditional if it has been in use for many generations by the same group. Ancient Indian medicine predates both the Vedic era and human civilisation as a whole [14]. Despite many changes throughout the years, it continues to serve as the foundation for medical care for a large portion of the country's population. Traditional medicine is still widely practiced in several Asian countries, such as Pakistan, India, Japan, and China. Medicinal plants have been around longer than any other type of medicine. An ancient Indian medical technique known as Ayurveda[15]
There has likely been continuous practice of Ayurveda, the ancient Indian science of life, for at least five thousand of those years. This is among the most famous forms of modern medicine. Space, air, energy, liquid, and solid are the five basic components of all things, according to Ayurveda. Within the human body, the three elements vata (space/air), pitta (energy/liquid), and kapha (solid/liquid) each have finite manifestations. The

three elements of existence, vata, pitta, and kapha, form what is known as the tridosha. When balance is disturbed, illness might develop.

Traditional Unani medical practices[16]

Many people believe that the illustrious Greek philosopher Hippocrates was the founder of the system. "Father of Natural History" It was heavily influenced by Aristotle Golem. These theoretical foundations are Hippocrates' theory of the four humours and Pythagoras' theory of the four proximate qualities. The four humours are hot, cold, moist, and dry, while the four characteristics are blood, phlegm, yellow bile, and black bile. They are symbolised by the four elements: earth, water, fire, and air. In Unani medicine, the focus is on getting to the root of an illness rather than just alleviating its symptoms. To obtain a comprehensive view of the patient's health, it is necessary to take his pulse, have him pee, and have him squat. The patient is treated according to the belief that an imbalance of humours is the fundamental cause of their illness.

Medical practice based on homoeopathy[17]

The German physician and chemist Samuel Hahnemann laid the groundwork for homoeopathy in the seventeenth century; the practice is considered to be relatively contemporary. He proposed diagnosing and treating illnesses by getting to the bottom of what was causing them. The idea behind his "like cures like" law was that remedies for different ailments are essentially the same. His proof that cinchona can imitate malaria's effects was based on same logic. A patient's symptoms and present state of health are the primary indicators of the homoeopathic system's optimal prescribed medication. This is based on the concept of a prover. Taking note of the change in a healthy person's mental, emotional, and physical state brought on by different doses of drug extracts is called proving. Therefore, these symptoms are intensified by adding them to those of another patient who is also suffering similar symptoms, and then giving both of them the same extract. Many medicinal plants are used in homeopathy, including Arnica, Belladona, Camomile, Colchicum, Hyocyamus, Ipecacuhna, Lycopodium, Opium, Ergot, Nux-vomica, etc.

Traditional Indian medicine (Siddha)[18]

In Sanskrit, "Siddha" means "accomplishment," and the "Siddhars" were revered individuals who mastered the healing arts via devotion to Bhakti and Yoga. This system, whose main emphasis is on medicine, is linked to the pre-Vedic Dravidian culture. The five elements of earth, water, sky, fire, and air are the building blocks of everything, according to this school of thought, just as they are in Ayurveda. Some helpful diagnostic tools include reading pulses, analysing body colours, listening to voices, analysing urine, evaluating digestive health, and analysingtongue.

Yoga and natural medicine [19].

Naturopathy is a system of medicine that emphasises the body as a whole and the need of restoring harmony with nature. Hydrotherapy, mud packs, baths, massage, and other purgative methods are highlighted, along with dietary and activity considerations. All aspects of one's being, including mental, moral, and spiritual health, are addressed in yoga's eightfold path.Its progression is linear, starting with the animal condition and ending with the divine. Samadhi, physical postures, austerity, breathing exercises, contemplation, meditation, and restraint of sense organs are the eight limbs that make up Yoga.

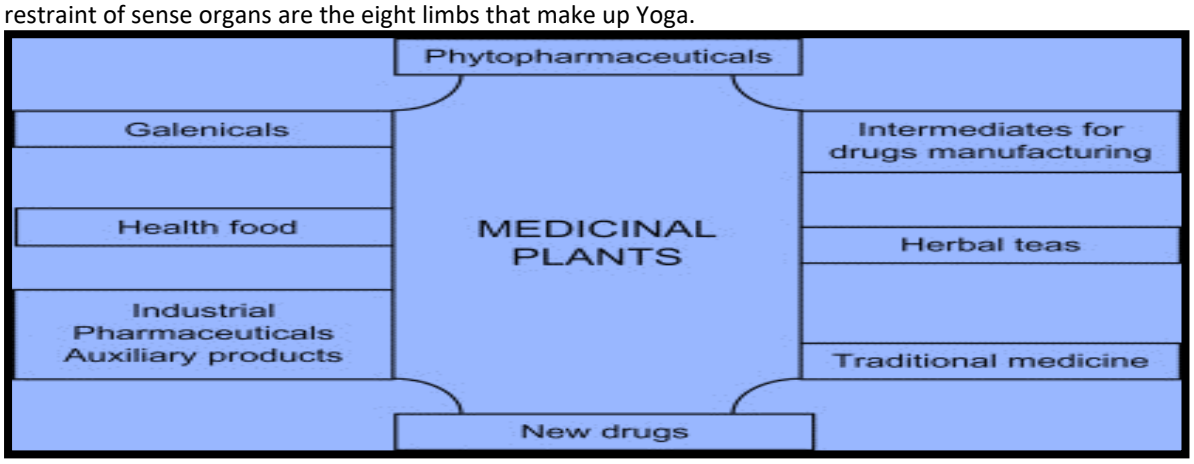


Figure 2: Medicinal plants derived from a wide variety of sources

4. Modern uses of herbal medicine [20]

Modernised herbal therapy is nothing more than the rediscovery of ancient, widely disseminated knowledge. Many turned to alternative treatments after becoming disillusioned with traditional medicine and surgical procedures. Many individuals still use herbal remedies since they are usually believed to be safe due to their all-natural composition. Pharmacologists extract the active ingredients from plants rather than consuming the whole plant. In addition to the active components, other plant chemicals such as minerals, vitamins, volatile oils, glycosides, alkaloids, bioflavonoids, and others are essential for a herb's medicinal actions [21]. All of these things work together to provide an important natural barrier. To be toxic, you need a lot more of a whole plant—including all of its parts—than you would with a single active molecule, whether it be manufactured or isolated. Having said that, herbs are medications and, when administered correctly, can have significant advantages. Take care not to mistreat them.

5. Introduction of Topical Gel [22]

The process of delivering medication to specific parts of the body, like the skin, eyes, rectum, or vagina, is called topical administration. This technique allows for localised drug delivery by applying a gel directly to the target area. An estimated one-third of the blood volume circulating throughout the body reaches the integumentary system, which in an average adult covers an area of about 2 square metres. What we call "transappendageal penetration" happens when things go into the skin via the hair follicles, sweat glands, and sebum glands.

6. The Emulgel Primer [23]

A gelling agent is used to create an emulgel when an emulsion is treated with it. They come in two varieties, open and closed. Pharmaceuticals that are not very water-soluble can be stabilised and enhanced by adding them to an emulgel system. In brief, emulgel is a combination of emulsion and gel. Despite their numerous advantages, gels have a big downside when it comes to the distribution of hydrophobic medications. An emulsion-based solution is now under development to circumvent this limitation and take advantage of the gel's unique properties. Emulgel can transport medications that are hydrophilic as well as those that are lipophilic. In recent years, they have become increasingly popular as a formulation for controlled release. These biphasic systems may load more drugs and are more stable overall. Superior spreadability, thixotropy, stability, odorlessness, and aesthetic appeal are just a few of the many benefits that Emulgel offers over conventional topical formulations.

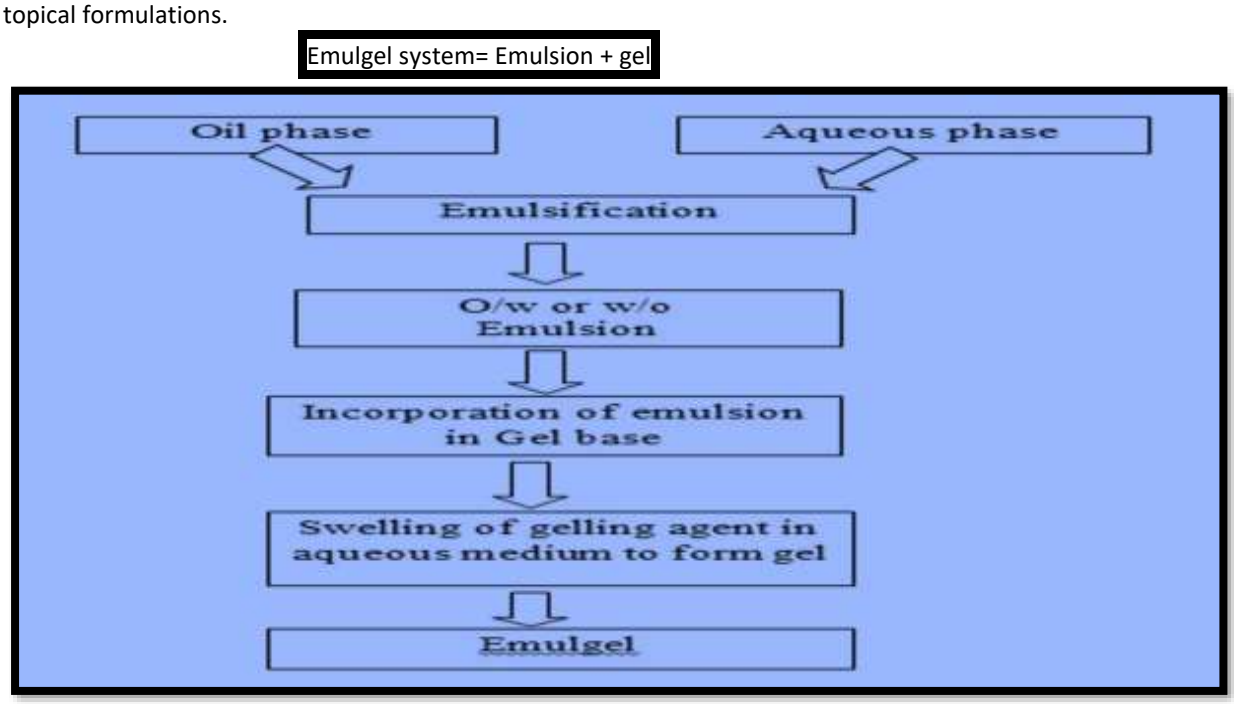


Figure 3: Diagrammatic depiction of the steps involved in the creation of emulgel formulation

7. Materials and methods

Purchase of essential oils and test strains

The essential oils of plants will be sourced from nearby markets in order to formulate the polyherbal emulgel. We will select the following plants and essential oils from those plants.

Table.No.1: List of plant and plant essential oil used in Emulgel Formulation [24]

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 (Syzygium aromaticum) [22]	Myrtaceae
05	Coconut (Cocos nucifera) [23]	Arecaceae
06	Eucalyptus (Eucalyptus globules) [24]	Myrtaceae

Emulgel Ingredients

Oils are used as the oil phase in emulsions. Mineral oil and hard or soft paraffin are common components in topical emulsions. For example, due to their laxative effects, castor and mineral oils are commonly used as ingredients in oral and topical therapy. Solvents such as water or alcohol are commonly used as carriers in aqueous phase emulsions.

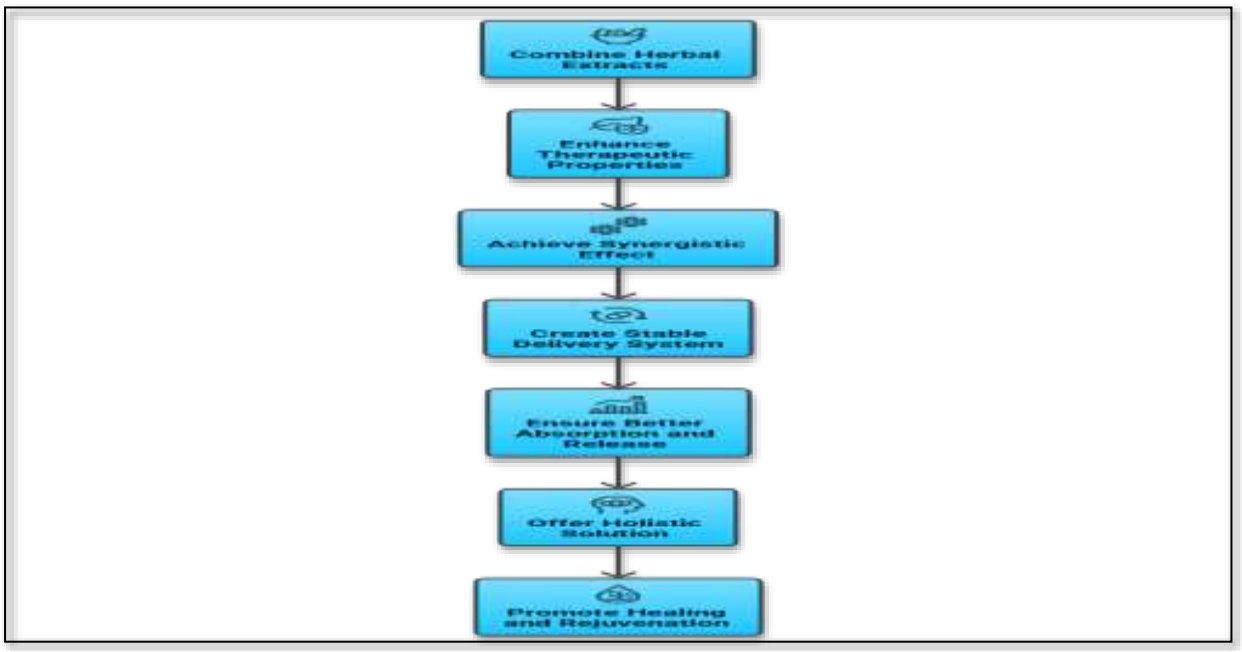
Emulsifiers

The introduction of an emulsifier enhances the preparation's emulsification, making it more stable at room temperature and with time. We can find emulsifying agents such as Tween 80, Span 80, Tween 20, stearic acid, and many more.

Constituent of a Gelling agent

Gelling agents are utilised to produce a gel that can be used in therapeutic dose forms. It's an excellent method for maintaining uniformity in your composition. Carbopol 940, Carbopol 934, HPMC-2910, and similar substances are examples of gelling agents. pH-balancing chemical With these compounds, the pH of the formulation can be regulated.

8. Polyherbal emulgel preparation [25]



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

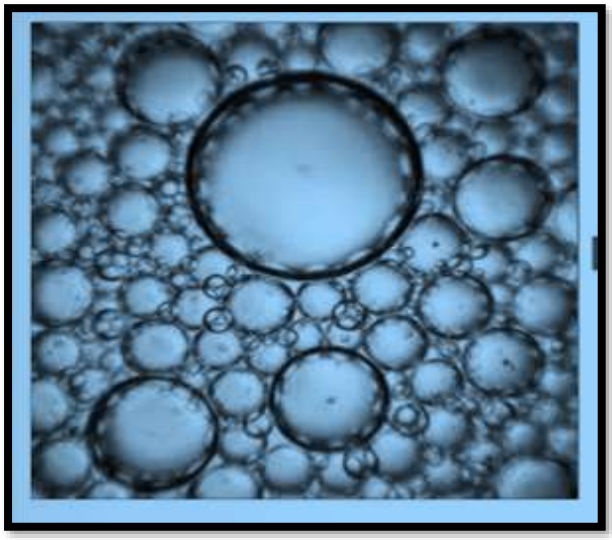
To make the gel base, dissolve the polymer in DDW using a magnetic stirrer set to a moderate speed. Then, use Triethanolamine and NaOH to adjust the pH to a range of 5-6.5.

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

(C) Emulgel Formation

Figure 4: Step involve the formation of Emulgel Formulation[26]

9. Evaluation parameter of Aloe vera contain Emulgel[27,28]

1. Physical Examination of Emulgel

The developed Emulgel formulations were visually evaluated for a variety of physicochemical properties, including colour, homogeneity, consistency, and phase separation. Emulgel, which is present in aloe vera, is a translucent, semisolid substance.

2. Determination of pH of Emulgel

The pH was measured using a digital pH metre from Thermo-scientific, which was calibrated using standard buffer solutions. For each system, we measured the pH three times independently.
The aloe vera in Table No. 2 has an emulgel formulation with a pH

Table No. 2: An emulgel formulation with a pH

Formulation	pH (Mean ±SD) *
Aloe vera contain Emulgel	6.8±0.3

3. Viscosity of the Emulgel [30]

The viscosity of the compositions was measured using a Brookfield digital viscometer at room temperature. The viscosity of the Emulgel optimised formulation was shown in Table No. 3. The Emulgel's viscosity was measured to be 27,00 cp.

Table No. 3: The Emulgel's viscosity

RPM	Aloe vera contain Emulgel
8	**25000cp**

4. Spreadability of Emulgel [21]

To determine the spreading ease of Emulgel, 0.5 g of the substance was evenly distributed across a pre-marked 1 cm diameter glass plate in a circular pattern. Subsequently, a second plate was placed on top. After 5 minutes of resting under 500 mg of weight, the top glass plate was removed. The spreading was identified and the diameter grew because of Emulgel. The results regarding the spreadability of the generated gel are shown in table no. 4.

Table No.4: The spreadability of the generated gel

Formulation	Spreadability (Mean cm ±SD)*
Aloe vera contain Emulgel	3.7±0.26

5. Stability studies of Emulgel [22]

When a medication remains mostly unchanged in a certain container with respect to its physical, chemical, therapeutic, and toxicological characteristics, we say that the drug is stable. The essential stability tests for medications to be registered in the US, EU, and Japan are specified in the Tripartite guideline "stability testing of new drug substance and products" provided by the International Conference of Harmonisation (ICH). Having said that, it has no plans to handle the testing requirements for registration in other nations with different climates. An expansion of the ICH tripartite guideline outlining stability criteria in an effort to standardise and simplify stability testing on a worldwide scale was published.

Table No.5: Data of stability study of Aloe Vera contain Emulgel

No. of days	Physical Appearance	pH evaluation	% drug content (Mean cm ±SD) *
Initial	++	6.7	97.18±0.02
30	++	6.7	97.18±0.03
60	+	6.6	95.25±0.16
90	+	6.5	94.56±0.24

*** Average of three trails**

++ No change in color
+ Slight change in color

6. Drug Content determination of Emulgel [23]

One gram of formulation was diluted with 6.8 pH phosphate buffer using a 50 ml volumetric flask. Using a phosphate buffer with a pH of 6.8, the solution was further diluted from one millilitre to ten millilitres. Two wavelengths, 310 nm and 274 nm, were used in a UV-Vis spectrophotometer to evaluate the drug content. With a range of 86.4% to 103%, the medication concentration was consistent across all formulations.

Formulation	Drug content (Mean % ±SD) *
Aloe Vera contain Emulgel	85.30±0.38

Results and Discussions

The anti-inflammatory medicine emulgel, derived from aloe vera, has a shorter half-life in the body. It is impervious to water due to its hydrophobic properties. The gastrointestinal system, kidneys, and liver can all become infected if swallowed. Therefore, to avoid the issues mentioned before, the medicine must be applied topically. We utilised Sodium Alginate, Guar Gum, and Xanthan Gum, which are gelling agents, in the formulation of Emulgel. After its creation, the aloe vera topical emulgel underwent a battery of physicochemical testing, including assessments of its spreadability and viscosity and in vitro release. Based on the results, we know that the drug concentration in the formulation was between 86% and 103% and that its pH was 6-7. It was found that the formulation contained a range of medication contents. This mixture showed a remarkable ability to disperse. The stability test, which was carried out in compliance with ICH guidelines, was applied to the optimised formulation. Accelerated testing was conducted on an aloe vera Emulgel formulation at 40°C ñ 2°C and 70.5% relative humidity. The data assumes a baseline skin hydration of 40 corneometer arbitrary units (AU), with a 20–30% improvement after 3–7 days of daily Aloe vera gel application. Neither the pH level nor the appearance of the medicine changed noticeably. It was reasonable to conclude that the produced emulgel formulation was an effective drug delivery mechanism. Testing led to this conclusion. Further studies are required to prove the formulation's usefulness in a therapeutic context.

Conclusion

The present study successfully demonstrated the formulation and evaluation of an Aloe vera-containing polyherbal emulgel as a potential topical drug delivery system. The developed formulation exhibited satisfactory physicochemical characteristics, including acceptable appearance, homogeneity, pH, viscosity, and spreadability. The formulation showed a pH of approximately 6–7, making it suitable for topical application, while its satisfactory spreadability indicated ease of application over the skin. The drug content was within an acceptable range, demonstrating reasonably uniform distribution of the active constituents within the formulation. The optimized formulation also demonstrated acceptable stability characteristics during the stability study, with only minor changes in appearance, pH, and drug content over the study period. These findings suggest that incorporation of Aloe vera and other selected herbal ingredients into an emulgel system can provide a suitable and stable platform for topical delivery. Overall, the developed polyherbal emulgel may serve as a promising topical formulation; however, further studies, particularly therapeutic efficacy and comprehensive skin-permeation investigations, are required to establish its potential clinical usefulness.

Conflict of Interest

Declared None

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