RESEARCH ARTICLE
DEVELOPMENT AND EVALUATION OF HERBAL OINTMENT FOR SKIN BURN

SUBMITTED TO

SCHOOL OF PHARMACEUTICAL SCIENCES,
FACULTY OF HEALTH SCIENCES,

ATMIYA UNIVERSITY, RAJKOT

BY

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8TH SEMESTER B.PHARM

UNDER THE GUIDANCE OF

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DECLARATION

We, all hereby declare the Work is presented in the project report entitled Development and evaluation of herbal ointment for skin burn. It is an authentic record of work carried out by us during the studying period of semester 8 at and under the guidance of Atmiya University, Rajkot, and is being submitted for partial fulfillment of the requirement for the award of a bachelor's degree in B.Pharm. This is not submitted anywhere else for the award of any other degree/diploma.

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Abstract

Skin burns are frequent injuries that need to be treated quickly and efficiently in order to encourage recovery and reduce discomfort. For decades, traditional herbal therapies have been utilized to relieve burn symptoms and promote the healing of damaged skin. This abstract describes a new herbal ointment formulation that is enhanced with ingredient like green gram (mung) and ghee. That have antibacterial and wound-healing qualities. The ointment is a potential option for the treatment of skin burns because of its ability to effectively reduce pain, inflammation, and promote tissue repair. It also provides a safe and natural substitute for traditional treatments. To confirm its therapeutic advantages and determine its place in burn care procedures, more clinical research is necessary. We evaluate ointment pH, Physical appearance, Spreadability, skin irritation studies, anti-microbial activity.

Key words : skin burn, ointment, green gram, ghee, evaluation.

Burn Introduction

In past few years burns are treatment is very difficult so it is important to make formulation to give better effects and easy to treat burns and related burn effects. Millions of individuals worldwide are afflicted with skin illnesses, which account for a sizable portion of all diseases globally. They can affect part or all of the skin layers and have a number of different etiologies, such as inflammation, infection, or malignancies. Non-topical application routinely used medications to treat skin conditions; nonetheless, there are restrictions on its use, such as the medications' inability to reach skin tissues and their buildup elsewhere, which leads to the emergence of off-target adverse events. The topical approach has been extensively used in order to avoid this from occurring. considered as a very promising port for medication delivery, yet there are significant restrictions that need to be addressed and removed to allow for the topical administration of medications enhance the therapeutic effects of medications delivered topically. Skin structure and topical drug delivery though skin.

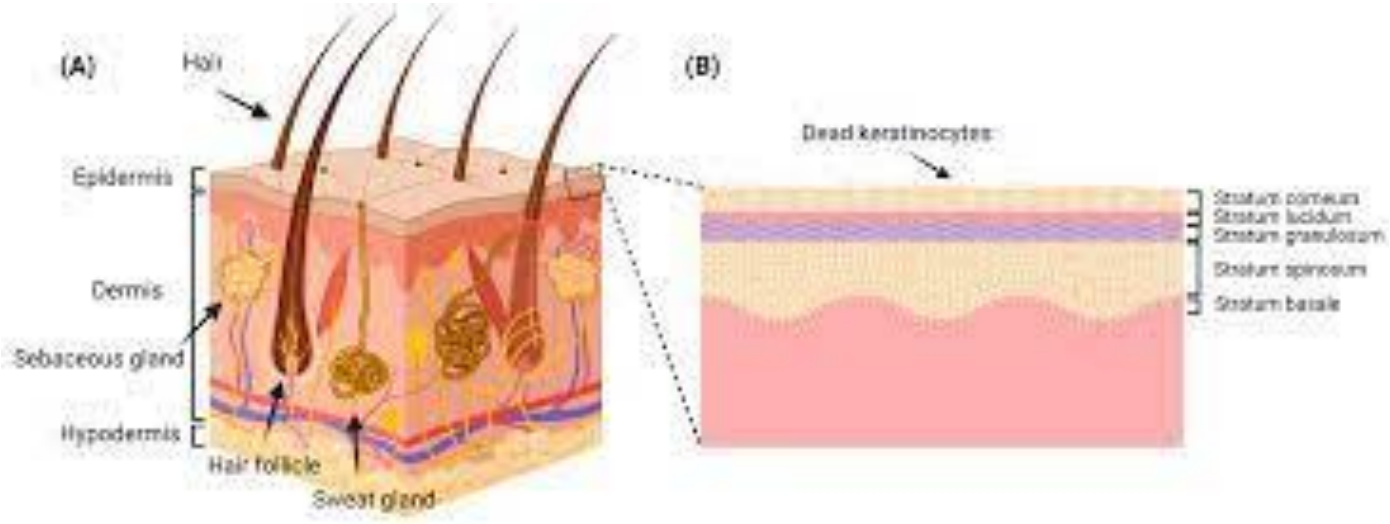


Figure: 1 (A) Skin structure
(B) Epidermis structure

(A) Skin structure showing the three distinct layers of epidermis, dermis, and hypodermis, and skin appendages including hair follicle and shaft, sebaceous gland, sweat gland, and arrector pili muscle; and (B) epidermis structure showing the five distinct layers of stratum corneum, stratum lucidum, stratum granulosum, stratum spinosum, and stratum basale (Madawi, E.A.; Al Jayoush, A.R.; Rawas-Qalaji, M.; Thu, H.E.; Khan, S.; Sohail, M.; Mahmood, A.; Hussain, Z.et al.,2023).

The skin is regarded as the largest organ in relation to other body parts since it covers the largest surface area of the body, which is roughly 1.8–2.0 m2. Being first-rate the skin serves

as a vital component of the body's defense system as a protective barrier to the environment. Against different chemicals, radiation, and infections. The skin is composed of three primary the upper or exterior layer is the epidermis; the second layer is the hypodermis, which the dermis, which lies between the epidermis and the layer that is deepest, Hypodermis The epidermis also consists of five unique layers: the stratum corneum (SC), the stratum lucidum, the stratum granulosum, the stratum spinosum, and the stratum basale. The SC is the outermost layer. The For all permeants (such as medications, chemicals, radiation, etc.), SC acts as a significant utermost barrier. Infections, etc. that frequently penetrate the skin because cholesterol, free fatty acids, and ceramides are abundant in the intracellular matrix of SC; it has a hydrophobic lamellar structure that significantly enhances the barrier qualities of SC. The epidermis is made up of four main types of cells as well (1) keratinocytes, first (dead), which are in charge of creating a water-proof barrier and controlling the body maintain skin's warmth and stop trans epidermal water loss; (2) melanocytes, which are primarily responsible for the production of melanin, which serves as a sunscreen barrier that protects against UV radiation; (3) Langerhans cells, one type of immune cell that helps in displaying and eliminating antigens (such as infections); and (4) Merkel cells, which are in charge of the skin's sensory processes.

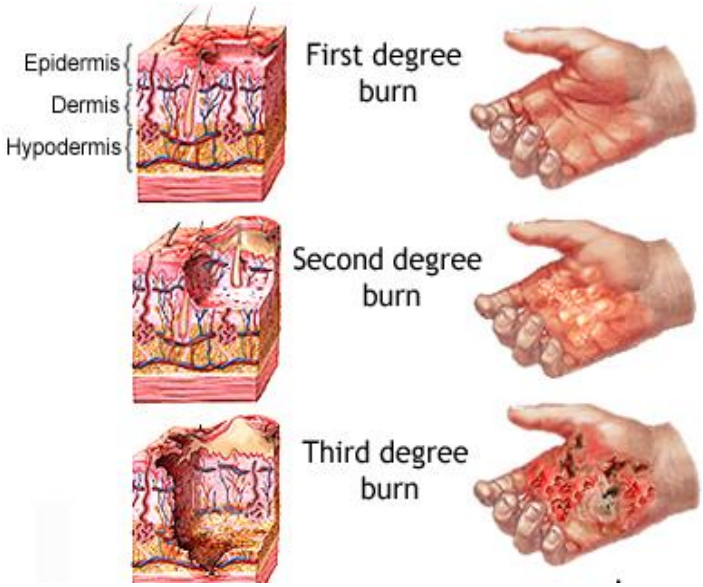


Figure : 2 Burn Level

There is a substantial layer of dermal tissue behind the epidermis, and depending on the thickness of collagen in each layer, there are two distinct layers of connective tissue underneath that layer. The lower dermal layer, referred to as the reticular dermis, is somewhat thicker than the upper dermal layer, known as the papillary dermis, since it has a higher collagen thickness. Furthermore, the dermis is home to a variety of complementary structures, including blood vessels, neurons, oil and sweat glands, hair follicles, and other structures. The third layer of the skin is called the hypodermis, or subcutaneous tissue. It is the lowest layer and is mainly composed of adipose tissue, which has a high fat content, and some connective tissue.

Table 1: Burn classification and healing response

Burn classification	depth	Wound appearance
1st degree superficial	epidermis	Red, dry, painful. turns white when pressed
2nd degree Superficial partial thickness deep partial thickness	Papillary(superficial) dermis ,reticular (deep) dermis	Red, moist, blistering, painful, turns white when pressed red and white, blistering, painful
3rd degree Full thickness	Dermis and sub dermal tissues	White, leathery or charred, No pain

Pathophysiology of Burn Injuries:-

1. Local Effects of Burn Injuries:-

A burn injury can result in coagulative necrosis of the skin's surface layers and underlying tissues. Owing to its primary role as a physiological barrier shielding subcutaneous structures, the skin typically prevents damage from spreading to deeper layers; nevertheless, temperature, the energy the causative agent transmits, and the length of exposure all affect how much damage is done. A cutaneous burn injury site can be separated into three zones, in theory:
Zone of coagulation: this is the area where there was irreversible tissue damage at the moment of injury and necrosis; the zone of stasis, which surrounds the coagulation zone, is considerably damaged due to local inflammatory responses, increased vasoconstricting agents, and vascular transudate. This results in poor tissue perfusion. The zone may heal or advance to necrosis based on the wound surroundings; Zone of hyperaemia, characterized by dilated vessels caused by inflammation. Unless there is severe sepsis or persistent hypo perfusion, it is characterized by increased blood flow to healthy tissues with little risk of necrosis. Research from both experimental and clinical settings has shown that severe burns, independent of their underlying cause, result in the development of a highly deregulated inflammatory response. Response from the host within a few hours of the injury. Increased levels of cytokines, chemokine's, and acute phase proteins, as well as a hyper metabolic condition that is associated with the inflammatory and stress responses driven beyond the acute period of care by a constant sympathetic tone . Cardiovascular changes - An increase in capillary permeability causes a loss of intravascular fluids and proteins into the interstitial

region. Splanchnic and periphery Vasoconstriction takes place. Respiratory changes - Bronchoconstriction is a result of inflammatory mediators, and serious burns can result in adult respiratory distress syndrome. Immunological changes - Both cell-mediated and humoral immune responses are down regulated in a non-specific manner.

Introduction of Ointment

Ointments are semisolid solutions that, when subjected to shear stress, typically exhibit viscoelastic behavior. Their main purpose is to be applied topically to the body or mucous membrane, and they usually contain medications. Often known as ointment bases, non-medicated ointments are used as such to provide lubricating or emollient properties, or they can be prepared as medicated ointments. Other terminology are also used as such in prescription practice to refer to emollients in a variety of variations, such as creams, pastes, and cerates. (Gupta k.Ashok et al., 2006)

Every ointment has a foundation that serves primarily as a vehicle for the medications. Its performance is also dictated by the nature of the base. Therefore, choosing an ointment base is a crucial step in the formulation process. Understanding skin anatomy in relation to medication absorption is crucial for a scientific understanding of the percutaneous absorption of ointment bases.

Additionally, herbal medications are prepared as ointments. The ointment base is prepared and the ointment is formulated by incorporating the active ingredients in the base at most effective ratio by trituration. After the completion of formulation, quality of the ointment is assessed in terms of irritancy, Spreadability, diffusion and stability. Traditional medicine is an important source of potentially useful new compounds for the development of chemotherapeutic agents. The first step towards this goal is the screening of plants used in popular medicine. Along with other dosage forms, herbal drugs are also formulated in the form of ointment. An ointment is a viscous semisolid preparation used topically on a variety of body surfaces. These include the skin and the mucus membranes of eye, vagina,

Ointments are applied topically for a variety of uses, including as astringents, keratolytics, Protestants, antiseptics, emollients, and antipruritic.

Characteristics of an ideal ointment

1. It must be stable both chemically and physically.
2. The ointment's basis shouldn't have any medicinal properties.
3. The finely split active component in the ointment base needs to be dispersed evenly.
4. The ointment ought to be smooth and devoid of gritty particles. (Aulton M.E. et al., 1988)

Advantages of ointment

1. They offer ways to apply medication only to the diseased area, preventing needless drug exposure that could lead to adverse consequences.
2. They avoid the drug's first pass metabolism.
3. Easy for people who are unconscious and have trouble taking pills orally.
4. Compared to liquid dose forms, they are easier to handle and have a more stable chemical composition.

5. For medications with an unpleasant taste, these dose forms work well.

Disadvantages of ointments

1. These semisolid, greasy formulations discolor easily and have a less appealing appearance.
2. Using your fingertip to apply could contaminate the mixture or irritate it.
3. Handling semisolid preparations is bulkier than handling solid dose forms.
4. Despite the fact that semisolids offer greater dosage flexibility, uniformity in the amount to be administered determines dose accuracy.
5. Less stable physically and chemically than solid dose forms.

Selection of the appropriate base depends on

1. Desired rate at which the specific medicinal material will release from the base of the ointment.
2. Desirability for improvement based on the drug's percutaneous absorption base.
3. The wisdom of blocking the base's capacity to absorb moisture from the skin.
4. The medication's both short- and long-term stability in the ointment base
5. Any impact the medication may have had on the ointment base's consistency or other characteristics. (Ansel‟s 1981)

Other additives in Ointments

The ointments may include any combination of the following groups of additives in addition to base and medications:

A. Preservative

The microbial compounds and their quantities should be carefully decided upon if the same are being used to prevent contamination, deterioration or spoilage of ointment bases by bacteria and fungi. The first consideration in selection is the irritancy or toxicity of compound to the tissue to which the ointment is to be applied. For, instance methyl and propyl parabens are irritants to nasal passages. Boric acid may be toxic. Quaternary ammonium compounds or phenyl mercuric nitrates are better tolerated by nasal tissues. On occasions the plastic containers or rubber closures may „take up‟ some amount of preservatives thus reducing their availability for antimicrobial action. Sometimes the preservatives get complexed by other ingredients and are thus not available in sufficient concentration for microbial action. In the presence of tween 80, methyl paraben, benzalkonium chloride, benzoic acid, etc. get inactivated to appreciable extents. The bacterial activity also depends upon the partition coefficient of antimicrobial compound between aqueous and oily phase. If both phases are to be protected additional amount may be needed.

B. Antioxidants

Whenever there is a chance that the base will oxidatively degrade, antioxidants should be added. It might be better to choose two antioxidants as opposed to only one. The partition coefficients of antioxidants between the aqueous and oil phases, when both phases are present in a base, determine the concentration of these compounds. Examples of ointment bases are propyl gallate and butylated hydroxyl anisole.

C. Chelating agents

If it is expected that the presence of metallic ions may cause oxidative degradations, a modest quantity of chelating agents, such as citric acid, maleic acid, phosphoric acid, etc., might be added.

D. Perfumes

Nowadays, the majority of ointment bases have a nice scent that is imparted by the use of certain blends. Choosing the right perfume blend is a really difficult task, and every producer wants to give their product a unique odor.

Preparation of the Ointments

Two type of method for preparation of ointments. Mechanical method and Fusion method.

1. Mechanical Method

A flexible steel spatula should be used in conjunction with white porcelain or marble ointment, which should not contain more than 50 g of ointment. It is not advisable to use a steel spatula when handling medication as the metal may react. The material reacts with metals like iodine, tannic acid, salicylic acid, and mercury compounds.

2. Fusion method

To produce the ointment, melt the components in a porcelain dish over a water bath. The ingredients include hard paraffin, beeswax, emulsified wax, and wool alcohol. Higher melting point materials should be melted first in this process, and then the other base elements should be added in the order that they melt. (Gaud R.S., Gupta G.D et al., 200).

Factors governing selection of the ointment base:

type of factors governing selection of the ointment base. Dermatological factors and pharmaceutical factors.

A. Dermatological factors:

- dermatological factors are sub divided.

1. Absorption and penetration.
2. Effect on skin function.
3. Miscibility with skin secretion and serum.
4. Compatibility with skin secretions.
5. Irritant effect.
6. Emollient properties.

Rational

- The rationale behind using herbal ointments for skin burns, such as those made with ghee and green gram, often involves their natural soothing and healing properties. Ghee is known for its moisturizing and anti-inflammatory properties, while green gram contains antioxidants and can help promote skin regeneration.

- Allopathic ointments contain chemical ingredients which can damage the skin and environment with prolonged use.

- While all the ingredients of herbal ointment are taken from natural sources so that it is more acceptable for body and environment and does less harm.

- Synthetic Isolated chemicals are not only harmful for the human body but they cause serious damage to our ecosystem.

Aim and Objective

- The aim of the current work is development of the herbal formulation for topical use and evaluate it for its burn site activity.
- To Identify the appropriate drugs or herbs having burn reliving activity.
- To select the proper method of preparation and to optimize process parameters and concentration of ingredients.
- To evaluate the Formulation by some standard reference which include the general appearance, PH, Spreadability, Washability etc.

Literature Review

1. Mung Beans (Vigna radiata L.) effect on skin burn

Figure 3: Histology of green gram (Mung Beans (Vigna radiata L.))

(A) plant of green gram (Vigna radiata L.) (Ref: Mung bean | Description, Origin, Uses, Nutrition, & Facts | Britannica)
(B) Leaf and flower of green gram (Ref: 22,578 Mung Bean Plants Images, Stock Photos, 3D objects, & Vectors | Shutterstock)
Kingdom: Plant

Division: Magnoliophyta

Class: Magnoliopsida

Scientific name of Mung beans: Vigna radiata L.

Biological source: Mung bean (Vigna radiata) is a plant species

Family: Febaceae

The mung bean (Vigna radiata L.), a traditional soy cuisine, has been used as a herbal cure and nutritional supplement for over 2,000 years. Polysaccharide, one of the main active components of mung beans, has biological characteristics including immunomodulatory, hypoglycemic, antioxidant, and antibacterial effects. (Qin, L., Chen, S., Xie, L., Yu, Q., Chen, Y., & Xie, J. et al., 2022)
According to scientific research, there are benefits to using mung beans as a food, medicine, and cosmetic when done so in an extremely effective way. (Golob P et al., 1999).
The hot water extraction method yielded a polysaccharide with antioxidant and antibacterial activity of 208 kDa when it was extracted from mung bean skins grown in Harbin, but only 146.22 kDa when it came to the same polysaccharide extracted from mung bean skins grown in Nanchang. (A.E. Mubarak et al., 2005).

Traditional Chinese medical ideas suggest that mung beans have physiological effects that include digestion, cleansing, and disinfection. (Y. Yao et al., 2016).
Mung beans are becoming more and more well-liked on the global market mainly because they are hypolipidemic, anticancer, anti-inflammatory, and detoxifying. While mung beans' primary active constituent, polysaccharides, is being thoroughly studied for its range of biological activities, including immunomodulation, antioxidant, and antibacterial properties, which sets the stage for its potential application in medicine and other domains in the future. (Y.P. Zhu et al., 2018)
The ability of green gram powder to naturally exfoliate the skin and remove dead cells leaves the skin looking more radiant and supple. However, the texture and radiance of the skin are improved by the abundance of vitamins A and C found in green gram powder. With its cooling and restorative qualities, green gram dal powder helps protect skin from the damaging effects of UV radiation. (Sowmya Binu et al., 19 July, 2020).
There are 105 calories in 100 grams of the bean. They include 0.577 milligrams of niacin, 0.41 milligrams of pantothenic acid, 0.38 grams of fat, 0.164 milligrams of thiamine, 0.061 milligrams of riboflavin, 0.577 milligrams of vitamin B6, 0.15 milligrams of vitamin E, 0.298 milligrams of manganese, and ***0.84 milligrams of zinc.*** (By Amritha KFriday et al., March 15, 2019).
From membrane repair, oxidative stress, coagulation, inflammation and immunological defense, tissue re-epithelialization, angiogenesis, to fibrosis/scar formation, zinc is essential for controlling each stage of the wound healing process. (Lin PH, Sermersheim M, Li H, Lee PHU, Steinberg SM, Ma J. et al., 24 December,2017).

2. Ghee (An hydrous milk fate) EFFECT ON SKIN BURN:

Figure 4 : Ghee (an hydrous milk fat)

Scientific name of ghee: clarified butter or anhydrous milk fat.
Biological source: ghee is made from the milk of domesticated ungulates such as cows, buffalos, goat and sheep.
Clarified butter, or ghee, is a medicinal herb used in Ayurveda. In addition to improving skin, respiratory, ocular, and mental health, it also helps with wound healing, digestion, and inflammation reduction.
Ghee is basically a form of clarified butter commonly used in Indian cuisine and Ayurvedic medicine, is rich in several essential nutrients. It has significant concentrations of fat-soluble

vitamins, including A, D, E, and K, which are essential for maintaining bone health, immune system function, and skin integrity, among other body processes.

The antibacterial and anti-inflammatory qualities of ghee help promote the healing of wounds. Topically applying ghee to small burns, cuts, or abrasions can help reduce inflammation and expedite the healing process.

Vitamins A, D, E, and K are abundant in ghee and nourish and support skin health and vitality. Ghee applied topically helps enhance skin tone and texture, relieve inflammation, and moisturize dry skin. (Times of India indiatimes.com).

Material and method

1. Mung beans (Green Gram):

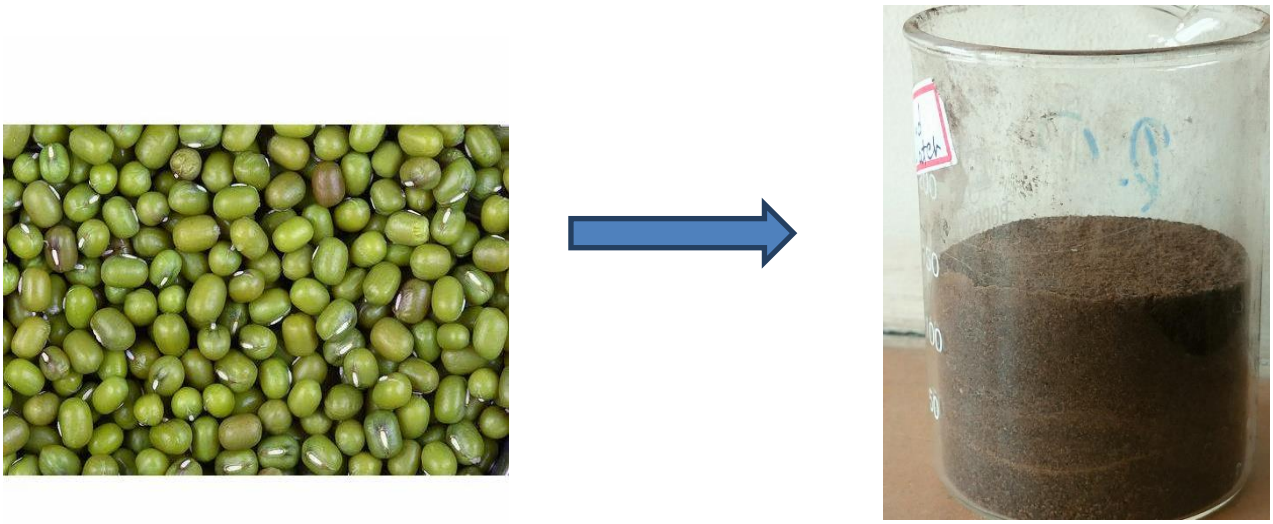


Figure 5: (A) Mung beans (B) Rosted Mung Powder

Kingdom: Plant

Division: Magnoliophyta

Class: Magnoliopsida

Scientific name of Mung beans: Vigna radiata

Biological source: Mung bean (Vigna radiata) is a plant species

Family: Febaceae

Chemical constitution: Polyphenolics are abundant in mung beans. Phenolic acids (1.81–5.97 mg rutin equivalent/g), flavonoids (1.49–1.78 mg catechin equivalent/g), and tannins (1.00–5.75 mg/g) are the main phenolic components of mung beans.
The green gram, sometimes called the mung bean, is made up of a variety of chemical components, such as:
Minerals: zinc, sodium, potassium, selenium, calcium, copper, iron, magnesium, manganese, and manganese Phenolic acids include shikimic acid, cinnamic acid, caffeic acid, gallic acid, vanillin acid, and protocatechuic acid.
Flavonoids: Isoflavonoids, isflavones, and flavones
Polyphenols: Three acids: Gallic, ferulic, and Sinapic Leucine, phenylalanine, lysine, valine, and isoleucine are the amino acids both fibres and oligosaccharides: high concentrations of bioactive phytochemicals.

Antioxidants: found in green grams also include flavonoids, phenolic acids, caffeic acid, and cinnamic acid. Free radicals, which can interact with biological components and cause issues, are countered by antioxidants. The germination process and cooking techniques of green gram seeds can impact their antioxidant content.

Minerals, fibre, and protein can all be found in abundance in green grams. Moreover, it has anti-inflammatory properties such as zinc, magnesium, calcium, thiamine, riboflavin, niacin, and pyridoxine. Among the various health advantages of green grams are:

- Cardiovascular well-being
- bringing down blood pressure
- advantages for skin care
- qualities that build bones
- vigor of the immune system
- beneficial for losing weight

2. Ghee (An hydrous milk fate):

Figure: 6 Ghee

Scientific name of ghee: Clarified butter or anhydrous milk fat.

Biological Source: ghee is made from the milk of domesticated ungulates such as cows, buffalos, goat and sheep.

Chemical Constitution: *Fatty acid*: the major lipid fraction representing 85.1% for buffalo and 83.65% of cow ghee. Vitamin A, Saturated fatty acids, unsaturated fatty acids, Cholesterol.

A wound is characterized as the loss or disruption of a living tissue's cellular, anatomical, or functional continuity. (Ayello, 2005). Wound healing is a biological process that is triggered by trauma and frequently culminates in the production of scars. (Rubin and Fabrex, 1996). The possibility of using natural substances derived from plants and animals to create medications with the ability to cure wounds, as taught in the widely practiced Ayurvedic system of Indian medicine, has sparked attention in India. (Biswas and Mukherjee, 2003). Since ancient times, natural products have been vital to the continuation of life, and their use as complementary and alternative therapies is growing. Whether used as herbal remedies for long-term health issues or as starting points for the synthesis of more or less complex chemical compounds with specific biological properties, the long-held convictions about the effectiveness of natural products and herbs can and ought to be validated through scientific research that integrates experience and tradition from ancient knowledge with modern

science. (Duke et al., 2002). The adverse effects of synthetic substances and allopathic medications have spurred interest in herbal and natural remedies. (Govindarajan et al., 2004). In Ayurveda, the five major products of cows—milk, curd, ghee, urine, and dung are referred to as panchgavya. Several ayurvedic literature with medicinal claims record several formulations based on each of these ingredients. Each of these constituents has also been assigned multiple therapeutic properties, as stated in Ashtangahriday Chikitsasthan, Kushta Chikista Shlok. 768. Several old ayurvedic scriptures describe formulations based on panchgavya. There aren't many scientific research about panchgavya published in contemporary literature or journals. Ghee was chosen because it is inexpensive, abundantly available, and utilized throughout the subcontinent. Ghee is used to cook food in underdeveloped nations, and it was also utilized to roast vegetables. Regarding its capacity to improve memory, it has also been demonstrated in a number of clinical investigations to be clinically useful. (Murray, 1996). One essential panchgavya ingredient is ghee. Several medical benefits of ghee have been documented in ancient books, as have the several ways it can be used with plants. Nonetheless, there is glaringly little comprehensive chemical and clinical investigation in this field. The ability of ghee to heal wounds is one of its most well-known and extensively discussed qualities.

The goal of the current study is to methodically assess this assertion in relation to ghee and antibiotics. Butyric, hexanoic, and octanoic acids found in ghee are eliminated as much as feasible through the distillation of mixed fatty acids. Oleic acid, palmitic acid, myristic acid, stearic acid, and a characteristic proportion of butyric, caproic, caprylic, and capric acids, along with small amounts of lauric and arachidionic acid and a large amount of unsaturated and saturated fatty acids, are the volatile acids and mixture of glycerides that make up ghee. Butyric, caproic, caprylic, capric, lauric, myristic, palmitic, stearic, and araeludic acids are examples of saturated fatty acids. Deconic, dodeconic, tetradeconic, hexadecane, and octadedienoic acids are the unsaturated fatty acids. (Murray and Watt, 1972).

One product that was purchased was ghee from Go-Vighyan Kendra, an institution that deals with products derived from bovine animals. The goal of this work is to test the hypothesis that, if given concurrently, preferably in a single formulation, cow's ghee, which promotes better tissue formation, and neomycin (Katzung, 1995), which protects against invasion, would prove to be a superior treatment for healing wounds. It also aims to determine whether such a formulation satisfies the standard requirements for a formulation to be accepted as a medicinal agent. (Mukerjee et al., 2000). Ghee is made up of lipids that keep the skin's moisture balance, vitamins A and E, which have antioxidant qualities, and fatty acids that moisturize and nourish the skin to give it a healthy appearance. (Ghee Cosmetic Cream et al., 2020).

3. Shea butter

Figure 7: shea butter

Scientific name of Shea butter: Butyrospermum parkii

Biological source: Nut of the African Shea tree (vitellaria paradoxa)

Family: Sapotaceae

Chemical constitution: Shea butter is composed of five principal fatty acids: palmitic, stearic, oleic, linoleic, and arachidic (see Table below). About 85 to 90% of the fatty acid composition is stearic and oleic acids.

Shea butter is becoming an increasingly important ingredient on a global scale in the multibillion dollar markets for confections and cosmetics. Although nothing is known about its carbon footprint, it has been seen as an environmentally friendly option because it does not have the same detrimental environmental effects of fertilizer use and land use change as alternative vegetable oils. An investigation into the greenhouse gas (GHG) emissions of one kilogram of Shea butter used in cosmetic items was conducted through a life cycle assessment (LCA). When Shea butter was added to a final cosmetic product, the LCA of the traditionally produced ingredient yielded an emission value of 10.374 kgCO2eq per kg of Shea butter. (Glow, D., & Lovett, P. N. et al., 2014).

Shea butter has been used in traditional medicine to treat a variety of illnesses. It lessens skin irritation and promotes the healing of wounds. In addition, Shea butter is used as an anti-inflammatory and to treat ulcers, dermatitis, chapping, and child rashes. (Hong T.D, Linington S, Ellis R.H. Rome et al., 1996)
Shea butter is used in cosmetics, particularly in lipsticks and moisturizers. Consequently, this component is used in soap, shampoo, and skin cream preparations sold in the cosmetic sectors. (Hall J.B, Aebischer P.D, Tomlinson H.F et al., 1996) A burn is a type of skin damage brought on by chemicals or extreme heat. Chemicals and heat exposure are the main causes of burn damage. Usually, full-thickness burns occur, which result in instantaneous cell

death and matrix damage. The wound surface sustains the most harm. (Williams W. et al., 2001). The loss of normal skin barrier function is the common cause of burn damage complications. These include illness, altered touch and appearance, increased evaporative water loss, and loss of body heat.
Depending on the patient's age, size, location, and burn depth, the severity of the burn can be assessed. The percentage of the entire body surface area that is exposed to the burn can be used to describe the size of the burn. One of the main factors influencing a patient's prognosis is thought to be their age. Compared to older children and young and middle-aged adults, infants and the elderly are more vulnerable and have a higher death rate. (Monafo W, Bessy et al., 2001). The amount of skin layer destruction caused by the heat source is known as burn depth, and it is the defining factor that impacts wound care. Burn injuries were once divided into four degrees: first, second, third, and fourth. Nonetheless, it is more accurate to determine the depth of a burn wound based on the skin's anatomic thickness in the following ways: The outer epidermal layer is all that is burned in a superficial burn; the inner dermis and part of the epidermal layer are burned in a partial-thickness burn; the destruction of the dermis and epidermis is burned in a full-thickness burn; and the lower tissues, such as fat, tendons, muscle, and bone, are burned in a subdermal burn that includes the destruction of both layers. (DeSanti B. S. Pathophysiology et al., 2005).

4. Rose Oil:

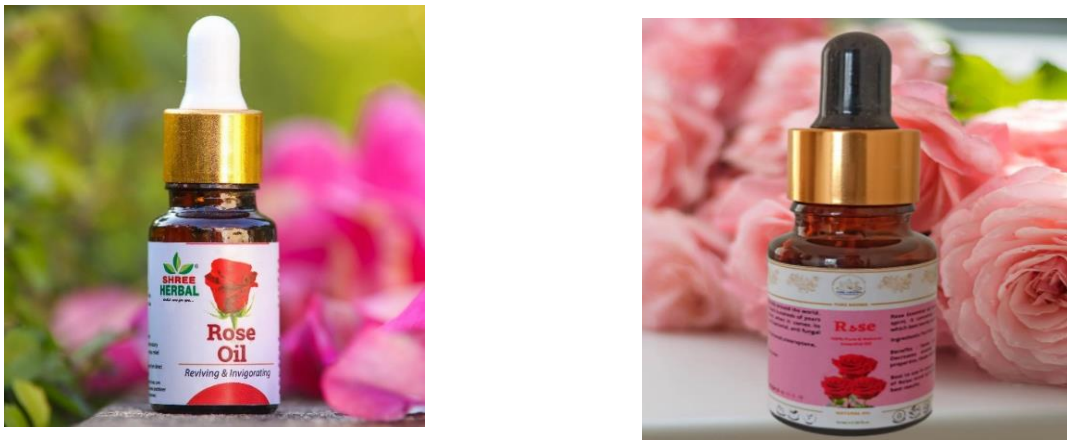


Figure 8: Rose oil

Kingdom: Plantae kingdom

Scientific name of Shea butter: Rosa damascena

Biological Source: the petals of roses, especially the Rosa damascene and Rosa centifolia species.

Family: Rocaceae

Order: sweet, floral, characteristic aroma

Chemical constitution: Citronellal: 34–55%, Geraniol: Around 14%, Nerol: Around 7%, other compounds: Phenyl ethyl alcohol, linalool, β-phenyl ethyl alcohol (PEA)

Skincare: Rose oil has antiseptic, antibacterial, and anti-inflammatory properties that can help with eczema, allergic rashes, and other skin irritations. It can also help with acne, hydration, and tone improvement. Anti-aging: Rose oil can help tighten skin and prevent fine lines and wrinkles, which can make you look younger for longer.

Hair care: Rose oil can nourish hair.

Stress relief: Rose oil can help alleviate stress and anxiety.

Pain relief: Rose oil can help relieve stomach pain, menstrual cramps, and fatigue.

Wound healing: Rose oil has been used throughout history as a cicatrisant (wound-healing) ingredient.

Infection prevention: Rose oil can be effective against a wide range of microbes that cause infections, including E. coli, staph infections, strep throat, and Candida albicans.

5. Aloe Vera:

Figure 9: Aloe Vera gel

Scientific name of Aloe Vera: Aloe barbadensis miller

Biological source: aloe Vera is the dried latex of the leaves of the plant.

Family: Asphodelaceae

Chemical constitution:

Anthraquinones/anthrones: Aloe-emodin, aloetic-acid, anthranol, barbaloin, isobarbaloin, emodin, ester of cinnamic acid.

Carbohydrates: Pure mannan, acetylated mannan, acetylated glucomannan, glucogalactomannan, galactan, galactogalacturan, arabinogalactan, galactoglucoarabinomannan, pectic substance, xylan, cellulose.

Chromones: 8-C-glusoly-(2'-O-cinnamoly) -7-O-methlyaloediol A, 8-C-glucosyl-(S)-aloe sol, 8-C-glucosyl-7-O-methylaloediol A, 8-C-glucosyl-7-0-methylaloediol, 8-C-glucosyl-noreugenin, isoaloeresin D, isorabaichromone, neoalosin A

Enzymes: Alkaline phosphatese, amylase, bradykinase, carboxypeptidase, catalase, cyclooxidase, cyclooxygenase, lipase, oxidase, phosphoenolpyruvate, carboxylase, superoxide dismutase

Inorganic compounds: Calcium, chlorine, chromium, copper, iron, magnesium, manganese, potassium, phosphorous, sodium, Zinc

Vitamins: Vitamin A, B12, C, E, choline and folic acid.

Formulation Procedure

Take the Green gram beans (Mung), and roast on the burner while green grams are become black.

Roasting by high temperature causes higher water Evaporation than other pretreatment methods.

After the cooling of seeds convert into powder form by using mortar pestle.

This powder is sieving by sieve method (sieve no.22). And to take fine particle of powder. And after add ghee (anhydrous milk fat).

After add the rose oil for smelling purpose.

Added much Ghee that it has a consistency like cream or ointment.

Table 2: Therapeutic Effect of Ingredient

Ingredients	Therapeutic effect
Green gram (mung)	• Green gram powder has the powder to naturally exfoliate. • Vitamin A, C and zinc are present in green gram. • While the richness of vitamin A and C in Green gram powder helps to enhance the skin texture. • Vitamin C it give wound healing and ventilation requirements in patients with burns. • Zinc may improve burn outcome as a result of its antioxidant and immunomodifier effect and its beneficial Effect on wound healing. • Clear of dead cells making the skin look brighter. Vitamin C and ZINC are most used in burn healing.
Anhydrous milk fat (ghee)	• Vitamin E is present in this ghee. • Studies have shown that vitamins significant antioxidant Properties. • Vitamin E and Care antioxidant. • They help reduce the body's Stress response after an injury. • Ghee is also use as a binder.

Table 3: Formulation B1 to B4

Ingredient	B1(17gm)	B2(17gm)	B3(17gm)	B4(17gm)
Green gram powder	12gm	11gm	7gm	9gm
Ghee	5gm	6gm	10gm	8gm
Rose oil	-	1-2 Drop	1-2 Drop	1-2 Drop
Aloe Vera	-	-	-	-
Shea butter	-	-	-	-

Table 4: Formulation B5 to B8

Ingredient	B5(30gm)	B6(30gm)	B7(30gm)	B8(30gm)
Green gram powder	15gm	14gm	14gm	15gm
Ghee	13gm	14gm	14gm	13gm
Rose oil	-	1-2 Drop	1-2 Drop	1-2 Drop
Aloe Vera	2 ml	-	2 ml	-
Shea butter	-	2gm	-	2gm

Table 5: Formulation B9 to B12

Ingredient	B9(25gm)	B10(25gm)	B11(34gm)	B12(51gm)
Green gram powder	13gm	17gm	20gm	30gm
Ghee	12gm	8gm	14gm	21gm
Rose oil	1-2 Drop	-	1-2 Drop	1-2 Drop
Aloe Vera	-	-	-	-
Shea butter	-	-	-	-

Figure 10: final formulation (herbal ointment)

Evaluation Parameter

1. **Physical appearance:** The color of the herbal ointment formulation was assessed and visually checked. The product was smelled to determine its odor. By rubbing the paste formulation between the finger, the smoothness was evaluated.
2. **pH:** The pH of herbal ointment was determine using a pH paper, the pH of the developed herbal formulations was measured.
3. **Physical stability:** The physical changes that affect the stability and other desired features of ointment formulations, such as phase separation and changes in color, odor, consistency, etc., were assessed. Periodically, they were checked for physical changes such as phase separation and the emergence of disagreeable colors and odors.
4. **Spreadability:** The Spreadability method is determined by involving the drag and slip characteristics of the herbal ointment. Weighing out one to two grams of herbal ointment, we sandwiched in between two 10-by-10-cm glass slides (sliding is not allowed) and pulled the slides in the opposite direction. After three minutes, measure the ointment's spreading (in centimeters). Performing the experiment again and recording the mean of the three readings.

   S=M ×L/T

   Where, S = Spread ability M = Weight tide to the upper slide L = Length of glass slide
   T = Time taken to separate the slides.

5. **Skin irritation studies:** Herbal ointment formulation was evaluated for the non-irritancy test. Apply the ointment on skin and Observation of the sites was done for 30mins.

6. **Rheological Properties:** The viscosity of the preparation should be such that the product can be easily removed from the container and easily applied to the skin.

7. **Anti-Microbial Activity:** In-vitro anti-bacterial study of formulated ointment was performed by disc diffusion method by using Soybean casein digest medium against a pathogenic bacterial strain E coli and staphylococcus initially, the cells in the E coli and staphylococcus were cultured and tended to multiply in agar plates. Plates were first spread with inoculum, and sterile cork borer was used to create 5 mm diameter holes in the medium. Next, the commercial antibacterial formulation and the prepared paste were inserted into the bores on the cultured plates. The plates underwent a 24-hour incubation period at 37°C after being labeled and wrapped in paraffin. Both plates were inspected following a 24-hour incubation period. The zone of inhibition's (ZOI) diameter was measured in millimeters (mm) with scale.

Result and Analysis

1. Physical appearance

parameter	Formulation
color	Black
odor	Rose like
Texture	Smooth
State	Semisolid

2. pH

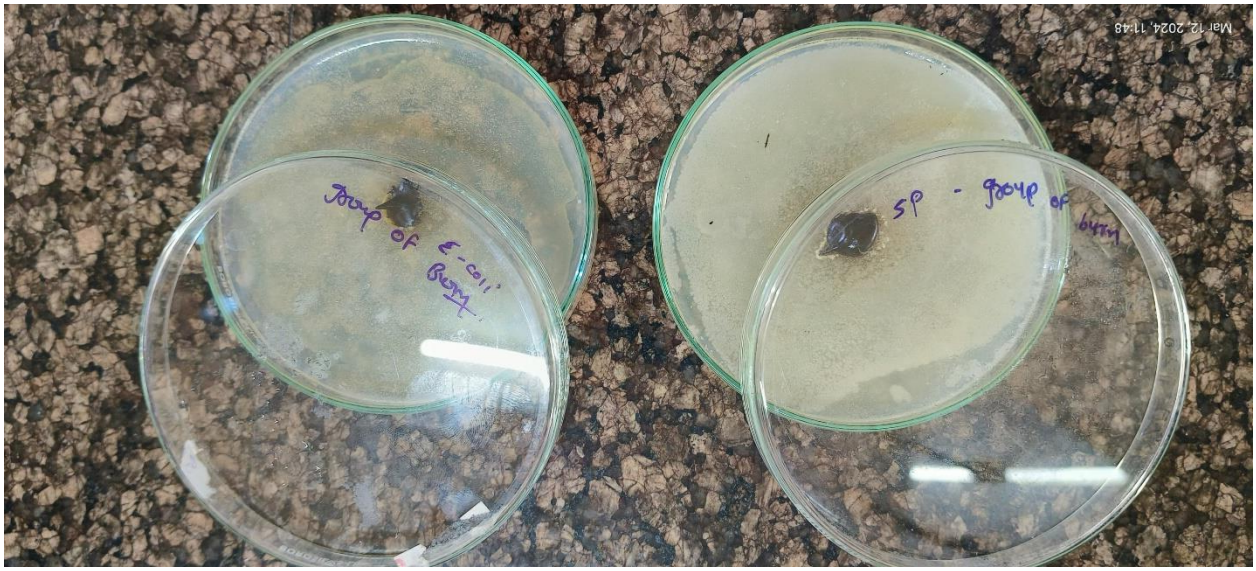
Normally the pH of the herbal ointment has been mostly found between 6.30 to 7.50.

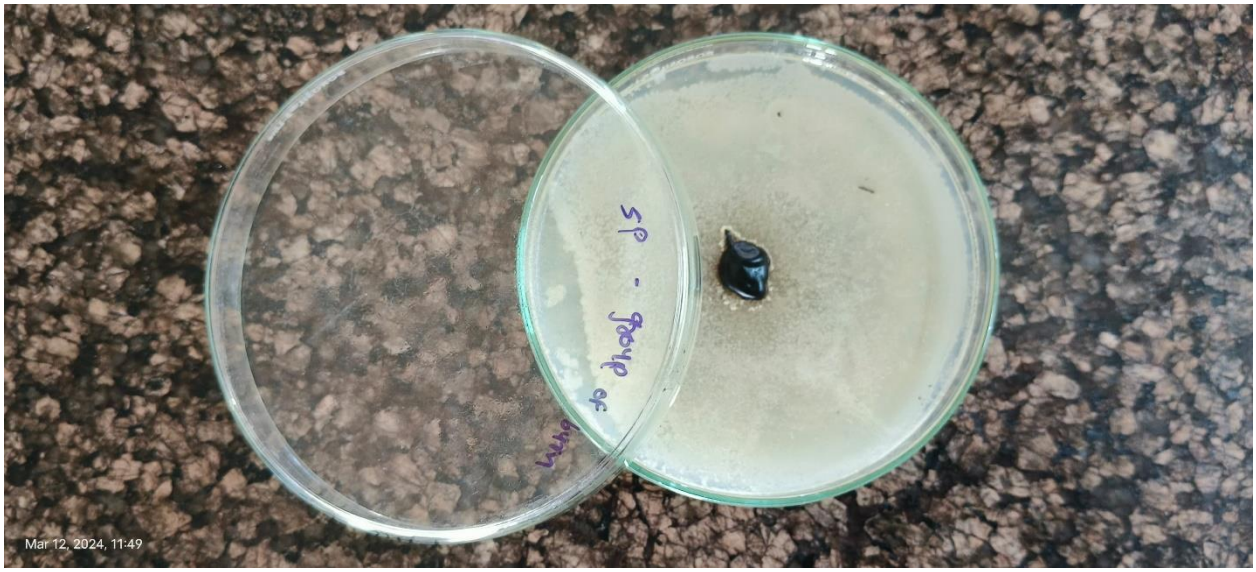
Parameter	Formulation
pH	5.5-6.5

3. Spreadability

parameter	Formulation
Spreadability	11.05 gm.cm/sec.

4. Anti-Microbial Activity



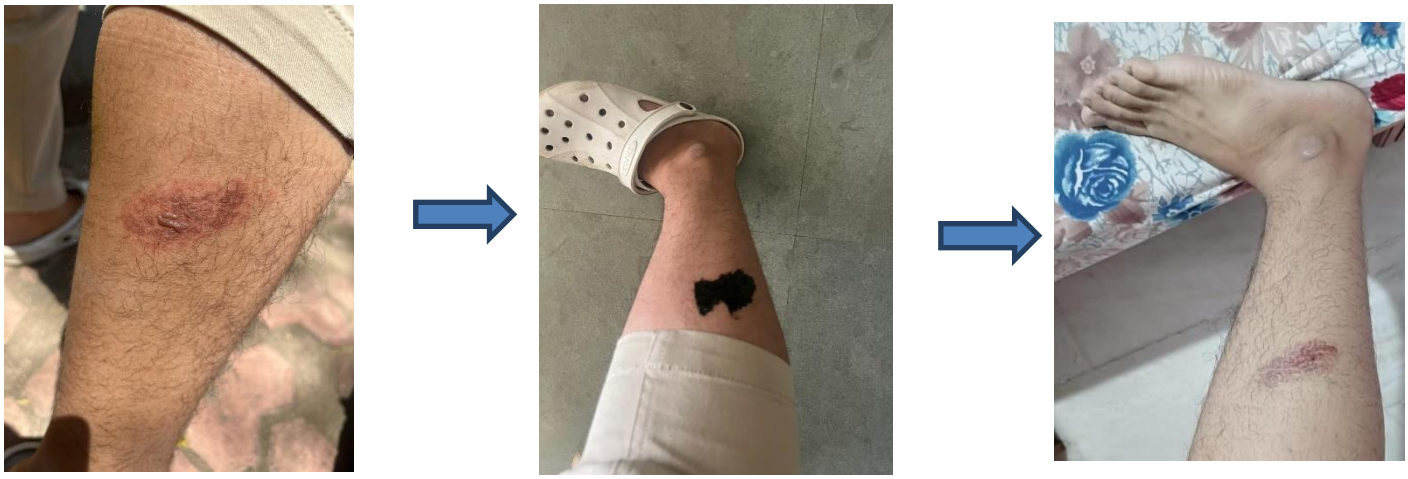


Area of zone of inhibition is large so formulation ointment is give more effect against bacterial activity.

5. Phase separation

No phase separation is observed in our formulation and Ointment.

6. Skin Irritation Test: Minor or No irritation observe



1. Burn Injury **2. Applied Formulation** **3.observation**

Result and Conclusion

Table 6: Evaluation of Formulation B1 to B4

Evaluation parameter	B1(17gm)	B2(17gm)	B3(17gm)	B4(17gm)
Color	Black	Black	Black	Black
Odor	Unpleasant	Rose like	Rose like	Rose like
Texture	Harden	Harden	Smooth(acceptable)	Smooth(But not acceptable)
State	Semisolid	Semisolid	Semisolid	Semisolid
pH	6.5-7	6.5-7	6-6.5	6.5-7
Particle size	Large(Not acceptable)	Large(Not acceptable)	Small(Acceptable)	Medium (Not acceptable)
Spreadability	-	-	9.35 gm.cm/sec.	-
Washability	Easily	Easily	Easily	Not Easily
Skin irritation	-	-	Not irritated	-
Phase separation	-	-	-	-

Formulation 1, 2: More harden, because more Green gram powder material passed through sieve no. 120 so particle size was extra-large.

Formulation 3: small particles of green gram observed in formulation. Drugs powder passed through sieve no. 240 and suitable amount of ghee. But observed less Spreadability with compare final formulation.

Formulation 4: Continuously reducing amount of green gram powder and increased amount of ghee till obtain not acceptable consistency of formulation.

Table 7: Evaluation of Formulation B5 to B8

Evaluation parameter	B5(30gm)	B6(30gm)	B7(30gm)	B8(30gm)
color	Black	Black	Black	Black
odor	Unpleasant	Rose like	Rose like	Rose like
Texture	Smooth(But not acceptable)	Smooth(But not acceptable)	Smooth(But not acceptable)	Harden
State	Semisolid	Semisolid	Semisolid	Semisolid
pH	6.5-7	6-7	7.5-8	7
Particle size	Medium (Not acceptable)	Medium (Not acceptable)	Medium (Not acceptable)	Large(Not acceptable)
Spreadability	-	-	-	-
Washability	Easily	Not Easily	Not Easily	Easily
Skin irritation	Not irritated	-	-	-
Phase separation	-	-	-	-

Formulation 5: Continuously reducing amount of ghee and increased amount of green gram powder (Medium particle size) And also add little amount of aloe Vera Gel till obtain not acceptable consistency of formulation.

Formulation 6: same amount of ghee and green gram powder (Medium particle size) And also add little amount of Shea butter till obtain not acceptable consistency of formulation.

Formulation 7: same amount of ghee and green gram powder (Medium particle size) And also add little amount of Aloe Vera Gel till obtain not acceptable consistency of formulation. But observed less Spreadability.

Formulation 8: Increase the amount of ghee and add green gram powder (Large particle size) and also add little amount of Shea butter till obtain not acceptable consistency of formulation.

Table 8: Evaluation of Formulation B9 to B12

Evaluation parameter	B9(25gm)	B10(25gm)	B11(34gm)	B12(51gm)
color	Black	Black	Black	Black
odor	Rose like	Unpleasant	Rose like	Rose like
Texture	Smooth(But not acceptable)	Harden	Smooth(acceptable)	Smooth(acceptable)
State	Semisolid	Semisolid	Semisolid	Semisolid
pH	7.5-8	6.5-7	6-6.5	5.5-6.5
Particle size	Medium (Not acceptable)	Large(Not acceptable)	Small(acceptable)	Small(acceptable)
Spreadability	-	-	10.03 gm.cm/sec.	11.05 gm.cm/sec.
Washability	Easily	Easily	Easily	Easily
Skin irritation	-	-	Not irritated	Not irritated
Phase separation	-	-	-	-

Formulation 9: Increase the amount of ghee and add green gram powder (Medium particle size) and till obtain not acceptable consistency of formulation.

Formulation 10: Increase the amount of green gram powder (Large particle size) and add ghee and till obtain not acceptable consistency of formulation.

Formulation 11: That formulation was prepared with acceptable criteria. But observed less Spreadability with compare final formulation.

Formulation 12: Final formulation was prepared with acceptable criteria.

Table 9: Evaluation of Final Formulation

Sr.no.	Parameter	Ideal Characteristic	Result
1.	Appearance	Greasy and smooth	Smooth
2.	Color	-	Black
3.	PH	5.6- 6.9	6.2
4.	Spreadability	9.0 to 31.02 g cm /sec	11.05 gm.cm/sec.
5.	Washability	Good	Good
6.	Non irritancy test	Non irritant	Non irritant
7.	Stability test	Stable	Stable

Conclusion

The prepared ointment shows good pharmaceutical properties, which is yet to be evaluated for its pharmacological activity.

This innovation is more specifically an ayurvedic composition for treating burns that is not only free from any negative side effects but also provides very rapid impact that is visible but leaves no scars within a very limited time frame, specifically within 15 to 20 days of applications two or three (not to be removed in between) and the intensity of the burn, in addition to all the components used are reasonably priced and easily accessible in local stores.

Many burn ointments and creams are readily available in the market but mostly, these known products are chemical based, thereby having harmful effects or side effects as well as time taking to show the results. Most of them have been found totally un-effective or treats leaving scar mark. Thus, it is better than other burn ointments.

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