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Research Article

Formulation, Development And Evaluation Of Polyherbal Wound Healing Gel

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ABSTRACT

The current study set out to create and assess a herbal gel with antibacterial and wound-healing properties that contained marigold, garlic, honey, cocoa powder, and aloe vera. The preparation included marigold, garlic, honey, cocoa powder, and aloe vera, all of which have excellent anti-inflammatory, antioxidant, and healing properties. Carbopol 934 was the gelling agent used in this study, and five formulations with various concentrations of honey and Carbopol were created and optimized for the study. A subset of the optimal formulations was chosen for additional research.

The active medication was then added to the optimized gel. In order to assess toxicity or adverse effects, the formulations were first assessed using physicochemical criteria such as surface pH, spreadability, viscosity, and antimicrobial susceptibility test. The outcome showed that the skin's pH range was within the surface PH.When administered topically, the formulations did not cause any skin irritation, such as erythema or oedema, for around a month. They were stable under standard storage conditions.

INTRODUCTION

A wound is just a break in the skin that occurs to humans frequently during regular activity. Skin tissue injury can result from a variety of reasons, including physical friction and high temperatures that can disturb the normal arrangement of mucosa or epithelial cells on the skin. The skin's ability to protect the body is crucial for wound healing, which allows for an instant restoration of that function. The process of healing a wound involves multiple stages, commencing with inflammation and progressing through proliferation, epithelialization, angiogenesis, and skin remodeling.Maintaining the wound's sterility, shielding it from contamination that could lead to infection, preventing dehydration (since moisture is vital for the new tissue arrangement), and absorbing or getting rid of wound exudate are all

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important during those intricate procedures. The Food and Drug Administration (FDA) classifies wound dressing preparations—also referred to as wound dressing combination with drugs—into three categories: solid wound dressings, semisolid wound dressing preparations (ointments, creams, gels), and wound cleaning fluid. To hasten the healing phase of wounds, the right dose forms and formulations must be applied in the wound therapy. A gel is one of the appropriate dose forms for this use. A gel is a stiff structure made of a three-dimensional cross-linking network that expands in the right solvent; hydrogels are those in which water is the solvent. The gel formula's high water content is appropriate for the environment required for wound healing. In order to speed up the healing process, it collects wound exudates and produces a moist environment. Additionally, when the gel is put to the wounded skin, it might produce a cooling feeling that helps lessen the patient's agony. In addition, it is simple to apply and remove from the skin. The market is flooded with topical wound healing solutions. The majority of them include active medicinal compounds, such Neomycin, that fall within the antiseptic and antibacterial categories. Bacitracin, Mupirocin, Hydrogen Peroxide, and Povidone Lodine. Because of the high potential of bacterial resistance, the use of antimicrobials in medicine has recently become a topic of discussion. It sets off a variety of studies aimed at discovering novel pharmacological compounds with potential as medicines for wound healing. Utilizing natural wealth is one area of the searches. Many plants that are found in nature have the ability to heal wounds. The African marigold, or yellow marigold (Tagetes erecta), is one of the plants. In the past, Tageteserecta leaves were chewed or diced and applied to wounds to promote healing until the area healed. The pharmacological effects of Tagetes erecta leaf include antibacterial and anti-inflammatory properties that are related to the healing of wounds. Numerous investigations have demonstrated this plant's efficacy in the healing of wounds. Tagetes erecta leaf ethanol extract has demonstrated the capacity to quicken wound healing.

TOPICAL DRUG DELIVERY SYSTEM

The goal of any drug delivery system is to provide a therapeutic amount of drug to the proper site in the body to promptly achieve and then maintain the desired drug concentrations. The route of administration has a significant impact on the therapeutic outcome of a drug. One of the human body's easiest organs to administer topically is the skin, which serves as the primary route for topical medication delivery systems. Topical delivery is the process of applying a drug formulation topically to treat cutaneous conditions directly or the skin-related symptoms of a general illness (like psoriasis) with the goal of limiting the drug's pharmacological or other effects to the skin's surface or inside the skin.The most common topical delivery method is semi-solid formulation in all its forms, although foams, sprays, medicated powders, solutions, and medicated adhesive systems are also in use.External topicals are applied to the cutaneous tissues by spreading, spraying, or in some other way to cover the diseased area.Internal topicals are administered orally, vaginally, or on the tissues of the anorectum to provide local action on the mucosal membrane.

MATERIALS AND METHODS

Plant material

Plant material used includes marigold leaves, aloevera leaves, cocoa powder, and garlic.

Preparation of extract

Preparation of ethanolic extract of Marigold , aloevera ,Cocoa powder, Garlic etc.by using Soxhlet extraction method.

Preformulation studies

Incompatibility study

It is important to detect any possible chemical or physical interactions since they can affect the bioavailability and stability of the drug.

Physicochemical Properties

Assess the physicochemical properties of individual herbal extracts and the gel formulation. This includes solubility, pH, viscosity, and compatibility of herbal extracts with gel base components.

Safety Evaluation

Evaluate the safety profile of herbal extracts. Ensure they do not cause irritation, sensitization, or toxicity when applied topically. Perform skin irritation tests if necessary.

Formulation Optimization

Adjust the formulation based on pre-formulation study results to enhance stability, efficacy, and safety. Optimize the concentration of herbal extracts and gel base ingredients to achieve desired therapeutic effects.

Preparation of gel

Accurately weighed 0.6gm Carbopol 934 was taken in a beaker and dispersed in 25 ml of distilled water. Kept the beaker aside to swell the Carbopol for half an hour and then stirring should bedone using mechanical/lab stirrer at 1200 rpm for 30 min.

Take required quantity of Extract. Stirr continuously while you add 1ml of honey and 4 drops of coconut oil. Add 4 drops of clove oil and with constantly stirring and Add a 1ml rose water.

Evaluation

The gel has been evaluated using the following criteria.

Homogeneity

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

PH of the gel

The pH of various gel formulations were determined by using digital pH meter. 2.5gm of gel was accurately weighed and dispersed in 25ml of distilled water and stored for two hours. The measurement of pH of each formulation was carried out in triplicate and the average values are represented. The pH of dispersions was measured using pH meter.

Spreadibility

Spreadibility was determined by the apparatus which consists of a wooden block, which was provided by a pulley at one end. By this method spreadibility was measured on the basis of slipand drag characteristics of gels. An excess of gel (about 2 g) under study was placed on this ground slide. The gel was then sandwiched between this slide and another glass slide having the dimension of fixed ground slide and provided with the hook. Excess of the gel was scrapped off from the edges. The top plate was then subjected to pull of 80 g.With the help of strring attached to the hook and the time (in seconds) required by the top slide to cover a distance of 7.5 cm be noted. A shorter interval indicates better spreadibility. Spreadibility was calculated using the following formula: SMXL/T Where, S Spreadibility, M-Weight in the pan (tied to the upper slide),1,Length moved by the glass slide and T-Time (in sec.) taken to separate the slide completely each other.

Viscosity

Viscosity of herbal gel was determined by using Brookfield viscometer at 5, 10 20, 30 and 50rpm using spindle no.64. Each reading was taken after equilibrium of the sample at the end of two minutes. The viscosity determination of samples was repeated three times.

Grittiness

All the formulations were evaluated microscopically for the presence of any appreciable particulate matter which was seen under light microscope

Stability Study

Accelerated stability studies indicated that the physical appearance, theological properties, spreadability in the prepared gel remained unchanged upon storage for 1 month.

Antimicrobial study

This parameter evaluates the ability of the gel to prevent or control the growth of microorganism in the wound area.

Stability Study

Accelerated stability studies indicated that the physical appearance, rheological properties, spreadability in the prepared gel remained unchanged upon storage for 1 month.

Wound healing rate

This parameter measures the speed at which the wound heals with the use of the gel.

Wound closure

The wound closure parameter measures the extent to which the gel helps to close the wound.

Tissue regeneration

This parameter evaluates the ability of the gel to promote the regeneration of new tissue in the wound area.

RESULT AND DISCUSSION

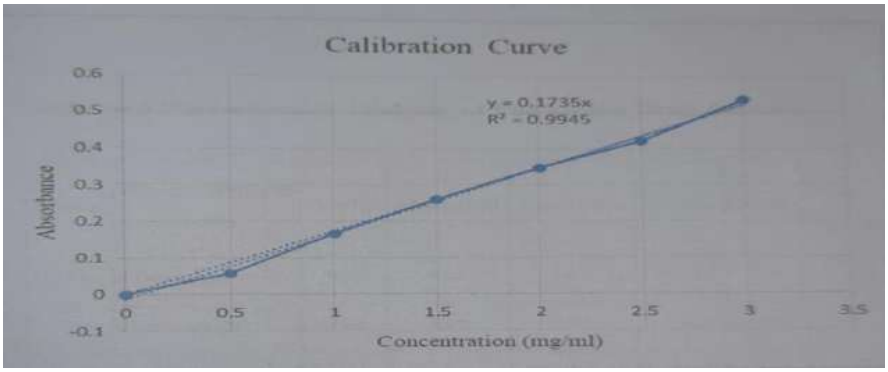
The present work aimed to increase stability of gel formulation with Carbopol 934. The prepared formulations were characterized for physical appearance, pH, spreadability, viscosity.greasiness, homogeneity, etc.

Table No 1. .Data of Calibration curve

Sr.No	Drug Concentration	Absorbance
1	0	0
2	0.5	0.058
3	1	0.167
4	1.5	0.261
5	2	0.348
6	2.5	0.422
7	3	0.536
	Slope=y-0.1735x-0.1450	R^2 =0.9945

Table No.2. Result of Calibration

Parameter	Result
Absorbance	400-500nm
Correlation coefficient	0.9945
Slope	y- 0.1735 x- 0.1450
Concentration of Allicin	0.08gm w/w
Concentration of Leutin	0.045 gm w/w



Calibration curve

Table No.3. Formulation of Gel

Sr.No	Ingredient	A1	A2	A3	A4	A5	A6
1	Ethanolic extract	1gm	1gm	1gm	1gm	1gm	1gm
2	Carbopol 934	1gm	1.5gm	0.6gm	0.8gm	1.4gm	1.2gm
3	Coconut oil	1 drop	2 drops	4 drops	2drops	4drops	3drops
4	Clove	4 drops	4 drops	4 drops	4 drops	4 drops	4 drops
5	Honey	1ml	1ml	1ml	1ml	1ml	1ml

6	Rose water	1ml	1ml	1ml	1ml	1ml	1ml
7	Distilled water	Upto 25ml	Upto 25ml	Upto 25ml	Upto25ml	Upto25ml	Upto25 ml

Fig No.1. Gel Formulation

Table 4: Data showing physicochemical

Formulation code	Appearance	PH	Spreadability(g.cm/sec)	Viscosity(cps)/rpm
A1	++	6.2±0.04	Good	110300 /5
A2	++	5.5±0.02	Excellent	112500 /10
A3	+++	6.4±0.03	Excellent	132700 /20
A4	+++	6.3±0.03	Excellent	110200 /30
A5	++	6.5±0.01	Good	120100 /40
A6	++	6.1±0.02	Good	130600 /50

All values are expressed as mean±SD++= fair,+++=good

Stability Studies:

Accelerated stability studies indicated that the pshysical appearance, theological properties, spreadability in the prepared gel remained unchanged upon storage for I motth. The pH observed of prepared gel through I month storage was in between 6-7. Rheological propertiesand spreadability was obtained uniformly. Gel formulation was maintaining drug level after Imonth of accelerated stability.

Evaluation	Initial	After
Physical apperance	Yellowish	Yellowish
Homogenicity	Homogeneous	Homogeneous
PH	6.2	6.5
Spreadability	15.75	19.78
Viscosity	110300	132700

Wound closure

The wound healing capabilities of the Samples: gel was assayed by performing in vitro cell migration studies on 1929 cells by a previously described method. Briefly, 2105 cells/ml, were seeded in 6-well plates and were cultured overnight. Cells were then washed with Delbucco's Phosphate Buffered Saline (DPBS) and a scratch was made with a sterile 200µl. tip. The detached cells and other cellular debris were removed by washing the cells with DPBS. The cells were treated with 1000 µg/ml. of sample code F8 and 5 µg/mL, of positive control, Cipladine and incubated for 24 h. Cipladine is a standard drug that is used in wound healing. Untreated cells were negative control. The cell migration and morphological changes of cells were observed in the images taken by inverted microscope, equipped with digital camera. The

experiments were performed in triplicate (n % 3). The width of the scratch and wound closure at different time intervals (0, 48hrs) was analyzed by SAGLO software.

Table no.1 Percentage (%) of cells migrated towards the wound and involved in wound closure.

Groups	0 hrs(mm)	48(mm)
Control	00	47
Standard cipladine(5 µg/mL)	00	67
Sample: Cream	00	50

Microscopical images representing the In vitro wound healing nature of Samples:

Cream: L929 cells were incubated in presence or absence of Samples: Cream and standard drug Cipladine and images were captured at 0 and 48 hrs.

Control or Untreated

Standard(Cipladine)

Sample Gel (1000 µg/mL)

At the concentration (1000mu*g / m * L) Samples: Gel: showed the Good wound healing activity as compared to standard.

CONCLUSION

From the above observations, it can be concluded that all the monographic parameters of the selected herbs were within in the Pharmacopeial limit indicates the good quality of raw materials. The microbiological studies indicated that the formulations possess wound healing activity. The wound contraction studies revealed that the wound contraction increases on increasing the concentration of herbal extract. The study also reveals the better activity of polyherbal formulation may be due to the synergistic action of the plant's constituents present in the formulation. Thus, the prepared topical gels possess a multifaceted approach in healing the wound.

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