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Formulation and Evaluation of Herbal Gel Containing Leaf Extract of *Tridax Procumbens*

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Abstract

Herbal medicine has become an item of global importance both medicinal and economical. Although usage of these herbal medicines has increased, their quality, safety and efficiency are serious concerns in industrialized and developing countries. Herbal remedies are getting increasing patient compliance as they are devoid of typical side effects of allopathic medicines. The present research has been undertaken with the aim to formulate and evaluate the herbal gel containing Tridax procumbens leaf extract. The gel formulation was designed by using Carbapol 940, Tridax procumbens leaf extract, propylene glycol, methyl paraben, propyl paraben and required amount of distilled water. The skin pH was maintained by drop wise addition of Tri-ethanolamine. The physicochemical parameters of formulations (pH, spreadibility, viscosity etc.) were determined. Herbal medications are considered safer than allopathic medicines as allopathic medicines are associated with the side effects. One of the method for its survival is preparation of extract and their formulations for better absorption and penetration of the active moiety into the systemic circulation.

Keywords: Tridax procumbens, leaf extract, Carbapol 940, Gel.

INTRODUCTION

Medicinal plants have been a major source of cure for human diseases since time immemorial. It is no wonder that the world's one-fourth population i.e. 1.42 billion people, are dependent on traditional medicines for the treatment of various ailments [1]. Recently considerable attention has been paid to utilize eco-friendly and bio-friendly plant based products for the prevention and cure of different human diseases. It is documented that most of the World's population has taken in traditional medicine, particularly plant drug for the primary health care [2]. The Indian flora offers a variety of plants having medicinal properties. These plants can be exploited to find out effective alternative to synthetic drugs [3]. Plants play a vital role in curing various ailments of the man and herbal remedies are getting increasing patient compliance as they are devoid of typical side effects of allopathic medicines. The allopathic system of medicine includes two conventional line of the treatment for rheumatoid arthritis, which come along with certain side effects. Hence, turning to safe, effective and time tested ayurvedic herbal drug formulations would be a preferable option. So there is need to investigate such drugs and their effective formulation for the better patient acceptance [4]. In India, medicines based on herbal origin have been the basis of treatment and cure for various diseases [5]. Moreover, Indian folk medicine comprises numerous prescriptions for therapeutic purposes such as healing of wounds, inflammation, skin infections, leprosy, diarrhea, scabies, venereal disease, ulcers, snake bite, etc [6]. More than 80% of the world's population still depends upon traditional medicines for various skin diseases [7]. Herbal medicines in wound management involve disinfection, debridement and providing a moist environment to encourage the establishment of the suitable environment for natural healing process [8]. Research on medicinal plants is one of the leading areas of research globally [9]. Topical antimicrobial therapy is one of the most important methods of wound care. In folklore medicine, medicinal plants have been used widely in facilitating wound healing with high degree of successes. This has inspired many researches which are aimed at validating the claims and discovering mechanisms which possibly explains the potentials of these herbs on wound repair processes & eliminating infections [10,11]. Drug delivery

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via skin to achieve systemic effect of drug is commonly referred to as transdermal drug delivery. Transdermal drug delivery systems (TDDS) provide a means to sustain drug release as well as reduce the intensity of action and thus reduce the side effects associated with its oral therapy. Semisolids available as a wide range of dosage forms each having unique characteristics.

Skin Infection

An intact stratum corneum prevents invasion of skin by normal skin flora or pathogenic microorganisms. Skin diseases that are usually complicated by secondary bacterial invasion can be broadly classified into itchy skin conditions in which scratching provides a portal of entry to microorganisms such as scabies and pediculosis, and those characterized by absence of skin barrier, such as eczema, pemphigus and ulcers [12]. Secondary infections to skin lesions can be potentially life threatening and may progress rapidly; therefore, their early recognition and proper medical and surgical management are important [13].

Bacterial Skin Diseases

Only a few species of bacteria commonly invade the intact skin directly, which is not surprising in view of the anatomical and physiological features discussed earlier. Hair follicle infections exemplify direct invasion.

Hair Follicle Infections

Infections originating in hair follicles commonly clear up without treatment. In some instances, however, they progress into severe or even life-threatening disease.

Causative Agent

Most furuncles and carbuncles, as well as many cases of folliculitis, are caused by Staphylococcus aureus, a staphylococcus that produces coagulase and is therefore called “coagulase-positive.” It is much more virulent than the staphylococci normally found on the skin. The name derives from staphyle, “a bunch of grapes,”referring to the arrangement of the bacteria as seen on stained smears, and aureus, “golden,” referring to the color of the S. aureus colonies [14].

Scalded Skin Syndrome

Staphylococcal scalded skin syndrome (SSSS), is a potentially fatal toxin-mediated disease that occurs mainly in infants but can also occur in children and adults.

Causative Agent

Staphylococcal scalded skin syndrome is caused by toxins called exfoliatins produced by certain strains of Staphylococcus aureus. called exfoliatin, produced by certain strains of Staphylococcus aureus, causes the outer layer of skin to separate. These toxins destroy material that binds together the layers of skin. At least two kinds of exfoliatins exist: one is coded by a plasmid gene, and the other is chromosomal [15].

Streptococcal Impetigo

A skin infection characterized by pus production is called pyoderma. Pyodermas can result from infection of an insect bite, burn, scrape, or other wound. Sometimes, the injury is so slight that it is not apparent. Impetigo is the most common type of pyoderma.

Causative Agent

Although Staphylococcus aureus often causes impetigo, many cases, even epidemics, are due to Streptococcus pyogenes. These Gram-positive, chain-forming cocci are b-hemolytic and are frequently referred to as b-hemolytic group A streptococci because their cell walls contain a polysaccharide called group A carbohydrate.

Rocky Mountain Spotted Fever

Rocky Mountain spotted fever was first recognized in the Rocky Mountain area of the United States thus its name. The disease is representative of a group of serious rickettsial diseases that occur worldwide and are transmitted by certain species of ticks, mites, or lice.

Causative Agent

Rocky Mountain spotted fever is caused by Rickettsia rickettsii, an obligate intracellular bacterium. The organisms are tiny, Gram-negative, non-motile coccobacilli. Rickettsia rickettsii is difficult to see well in Gram-stained smears but can be seen using special stains such as Giemsa. Rickettsia rickettsii can sometimes be identified early in an infection by demonstrating the organisms in biopsies bits of tissue removed surgicallyof skin lesions. Also, their DNA can be magnified by the polymerase chain reaction and identified with a probe [16].

Gel Forming Polymers

Polymer is simply a compound made up of repeating units. Polymers are used to give the structural network which is essential for the preparation of gels.

Gel forming bases or polymers is classified as follows: -

Natural polymers – Natural polymers are those polymers which exist naturally and can be synthesized by living bodies, e.g. proteins like collagen, gelatine etc and polysaccharides like agar, tragacanth, pectin and gum etc.

Semi synthetic polymers – These polymers are mostly derived from natural polymers by chemical modification, e.g. cellulose derivatives like carboxymethylecelulose, methylcellulose, hydroxypropyl cellulose and hydroxyethyle cellulose.

Synthetic polymers – The polymers which are prepared in laboratories are called synthetic polymers. These are also called man made polymers, e.g. carbomer carbopol 940, carbopol 934, poloxamer, polyacrylamide, polyvinyl alcohol and polyethylene [17].

Herbal Gel

The use of medicinal plants as raw materials in the production of new drugs is ever increasing because of their potentials in combating the problem of drug resistance in micro-organisms. For topical treatment of dermatological disease as well as skin care, a wide variety of vehicles ranging from solids to semisolids and liquid preparations is available to clinicians and patients. Within the major group of semisolid preparations, the use of transparent gels has expanded both in cosmetics and in pharmaceutical preparations [18]. Numbers of medicated products are applied to the skin or mucous membrane that either enhance or restore a fundamental function of a skin or pharmacologically alter an action in the underlined tissues [19].

MATERIAL AND METHODS

Preparation of Plant Extract

The collected fresh leaves of Tridex procumbens were dried in shade. After drying plant material were coarsely powderd and kept in well closed container. About 100gm of powder of plant leaf was taken in soxhlet apparatus and extracted with (45-550C) ethanol. The collected extracts were concentrated on rotary evaporator and concentrated extract were kept in vacuum dryer until used [20].

Formulation of Placebo Gel

For the preparation of gel formulation, firstly take carbopol 940 which was then dispersed in distilled water (methyl paraben, propyl paraben) and glycerine overnight. Take the extract of Tridax procumbens in propylene glycol which was then added in polymer dispersion. Remaining quantity of water was then added and neutralized to pH 7 with triethanolamine by constant stirring for 10 minutes [21]. On the basis of evaluation parameters such as appearance, viscosity, pH, spreadability, the placebo gel formulation of the control batch was selected (Table 1).

Development of Formulation

For the preparation of gel formulation, firstly take carbopol 940 which was then dispersed in distilled water (methyl paraben, propyl paraben) and glycerine overnight. Take the extract of Tridax procumbens in propylene glycol which was then added in polymer dispersion. Remaining quantity of water was then added

and neutralized to pH 7 with triethanolamine by constant stirring for 10 minutes (Table 2).

Table 1. Control batch

Ingredients	F2
Carbopol 940	1.0gm
Propylene glycol	10.0ml
Methyl paraben	0.2ml
Propylparaben	0.1ml
Glycerine	1.0ml
Triethanolamine	Q.S.
(To maintain pH7)	
Water	100ml

Table 2. Developed herbal gel formulation

Ingredients	F1	F2	F3	F4
Extract	0.20gm	0.40gm	0.80gm	1.0gm
Carbopol 940	1.0gm	1.0gm	1.0gm	1.0gm
Propylene glycol	10.0ml	10.0ml	10.0ml	10.0ml
Methyl paraben	0.2ml	0.2ml	0.2ml	0.2ml
Propylparaben	0.1ml	0.1ml	0.1ml	0.1ml
Glycerine	1.0ml	1.0ml	1.0ml	1.0ml
Triethanolamine	Qs	Qs	Qs	Qs
Water	100ml	100ml	100ml	100ml

Characterization of Herbal Gel Formulation

Physical Evaluation: Physical parameters such as color and appearance were evaluated.

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: 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 [22].

Spreadability: Spreadability was determined by the apparatus which consists of a wooden block, which was provided by a pulley at one end. By this method spreadability was measured on the basis of slip and 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. Weight of 1 kg was placed on the top of the slide for 5 minutes to expel air and to provide a uniform film of the gel between the slides. Excess of the gel was scrapped off from the edges. The top plate was then subjected to pull of 50 g. With the help of string attached to the hook and the time (in seconds) required by the top slide to cover a distance of 6.5 cm be noted. A shorter interval indicates better spreadability [23].

Spreadability was calculated using the following formula:

$S = M \times L / T$

Where, S = Spreadability,

M = Weight in the pan (tied to the upper slide),

L = Length moved by the glass slide and

T = Time (in sec.) taken to separate the slide completely each other.

Microbial growth: Nutrient agar media was used in microbial growth study. In this method the blank and sample petriplates were used and gel sample were aseptically transferred on to the sample plates in a cross pattern. The microbial growth observed [24].

Viscosity: Viscosity of herbal gel was determined by using Brookfield rotational viscometer at 5, 10 20, 30 and 50 rpm 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.

Antimicrobial activity: Antimicrobial study of the formulated gel was conducted by ditch plate technique. It is a technique used for evaluation of bacteriostatic and fungistatic activity of compound and is mainly used for semisolid formulation. Agar plate were prepared and sterilized as per standard procedure.A ditch was made in centre of agar plate and was filled by test formulation. The prepared culture loops were streaked across the agar at a right angle from the ditch to the edge of the plate. After incubation for 18-24 hours at 250 C, The bacterial growth was observed and inhibition was measured.

RESULTS AND DISCUSSION

Characterization of polymer

Colour and appearance:

Colour and appearance of the polymer is checked and is as mentioned below in table 3.

Table 3. Colour and appearance

Test	Result
Colour	White
Appearance	Powder

Physico-chemical evaluation of Tridex procumbens leaf

Different physico-chemical evaluation tests of Tridex procumbens leaf are done and results of the tests are as mentioned below in table 4.

Table 4. Physico-chemical evaluation of Tridex procumbens leaf

Sr. N0.	Test	Result
1	Description	Green
2	Determination of moisture	0.4mg
3	Total ash value	10%
4	Acid insoluble ash value	4.0%
5	Water soluble ash value	3.0%

Preliminary phyto-chemical screening:

Different preliminary phyto-chemical screening tests are done and results of the tests are as mentioned below in table 5.

Table 5. Preliminary phyto-chemical screening

Sr. No.	Test	Result
1	Tests for carbohydrates	(+)ve
2	Test for steroid	(+)ve
3	Test for alkaloids	(-)ve
4	Test for saponins	(+)ve
5	Test for flavonoids	(+)ve
6	Test for Tannins and Phenolic compounds	(+)ve

Evaluation of Topical Gel Formulation

Physical Evaluation

Physical parameters such as color and appearance were checked (Table 6).

Table 6. Physical parameters such as color and appearance

Sr. No.	Batch	Colour	Appearance
1	F1	Light green	Green
2	F2	Light green	Green
3	F3	Green	Green
4	F4	Dark green	Green

Homogeneity

All developed gels were tested for homogeneity by visual inspection after the gels have been set in the container (Table 7).

Table 7. Homogeneity of formulation

Sr. No.	Batch	Homogeneity
1	F1	Homogeneous
2	F2	Homogeneous
3	F3	Homogeneous
4	F4	Homogeneous

pH

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 (Table 8). The pH of dispersions was measured using pH meter [22].

Table 8. pH of the formulation

Sr. No.	Batch	PH
1	F1	6.8
2	F2	7.2
3	F3	6.9
4	F4	6.9

Spreadability

Formulation placed between two glass slides and 100gm weight was placed on the upper glass slide for 5 min to compress the formulation to uniform thickness. Weight 50 gm was added to the pan. The time in seconds require to separate the two slides was taken as measure of spreadability (Table 9).

Table 9. Spreadability of formulation

Sr. No.	Batch	Spreadability
1	F1	16.25
2	F2	15.47
3	F3	15.47
4	F4	14.13

Microbial growth

Nutrient agar media was used in microbial growth study. In this method the blank and sample petriplates were used and gel sample were aseptically transferred on to the sample plates in a cross pattern, the microbial growth was observed (Table 10). Antimicrobial activity was assessed against staphylococcus aureus strain and found to exhibit significant antimicrobial activity.

Viscosity

Viscosity of gel was determined by using Brookfield rotational viscometer at 5,10,20,30 and50 rpm. Each reading was taken after equilibrium of the sample at the end of two minutes. The samples were repeated three times (Table 11).

Table 10. Microbial growth of formulation

Batch	Observation
F1	No microbial growth
F2	No microbial growth
F3	No microbial growth
F4	No microbial growth

Table 11. Viscosity value of herbal gel

RPM	cp
5	**45000**
10	**32160**
20	**19560**
30	**7890**
50	**4820**

CONCLUSION

In Indian system of medicine majority of herbal products are made by using crude plant or portion of plant parts and their extracts. The leaves extract of Tridax procumbens plant belongs to family asteraceae was taken for this present study and formulated for the topical gel and its properties. The gel prepared using Tridax procumbens leaf extract was found to be good gel characteristics with respect to homogenecity, spredability, pH, viscosity, microbial growth, antimicrobial activity. Herbal gel formulation containing leaf extract of Tridax procumbens was successfully prepared with carbopol 940 as a gelling agent. The contents of developed herbal extract based gel were propylene glycol as plastisizer, methyl and propyl paraben as preservative and double distilled water and carbopol 940 as gelling agent. The extract of Tridax procumbens exhibited strong antimicrobial activity especially with 1% of the extract concentration. The

results of different chemical and physical tests of gel showed that the formation could be used topically in order to protect skin against damage caused by Staphyllococcus aureus. Thus it can be concluded that there is a growing demand for herbal formulation in the world market and they are invaluable gift of nature. Herbal medications are considered safer than allopathic medicines as allopathic medicines are associated with the side effects. One of the method for its survival is preparation of extract and their formulations for better absorption and penetration of the active moiety into the systemic circulation.

In this different gelling agents can be used to formulate topical herbal gel of Tridax procumbens. Long term stability studies as per ICH guidelines and also the clinical trials if the earlier works yield encouraging results can be performed. The formulated topical herbal gel can be incorporated into a suitable dosage forms such as cream, lotion.

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