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(54) Title: HERBAL COMPOSITION FOR THE TREATMENT OF BURNS

(57) Abstract: The present invention relates to a herbal composition for the treatment of burns. Specifically, the present invention relates to a synergistic herbal composition comprising of *Sesamum indicum* oil, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more one pharmaceutically acceptable additive, preparation of the herbal composition and use of the herbal composition in the treatment of burns and burning sensation in hemorrhoids.



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HERBAL COMPOSITION FOR THE TREATMENT OF BURNS

FIELD OF THE INVENTION

[0001] The present invention relates to a herbal composition for the treatment of burns.

5 Specifically, the present invention relates to a synergistic herbal composition comprising of *Sesamum indicum* oil, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more pharmaceutically acceptable additive agents having an excellent burns treatment effect and also useful in the treatment of burning sensation caused in hemorrhoids.

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BACKGROUND OF THE INVENTION

[0002] Background description includes information that may be useful in understanding the present invention. It is not an admission that any of the information provided herein is prior art or relevant to the presently claimed invention, or that any publication specifically or implicitly referenced is prior art.

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[0003] Burns are damages to the tissues, typically the skin, caused by heat, friction, electricity, radiation, or chemicals. Burns are classified as first, second, third-degree, or fourth-degree depending on how deeply and severely they penetrate the skin's surface. First-degree (superficial) burns affect only the outer layer of skin, the epidermis. The burn site is red, painful, dry, and with no blisters. Mild sunburn is an example. Long-term tissue damage is rare and often consists of an increase or decrease in the skin color. Second-degree (partial thickness) burns involve the epidermis and part of the lower layer of skin, the dermis. The burn site looks red, blistered, and may be swollen and painful. Third or fourth -degree (full thickness) burns destroy the epidermis and dermis. They may go into the innermost layer of skin, the subcutaneous tissue. The burn site may look white or blackened and charred.

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[0004] Various treatments are available for burns depending on the nature of degree of burns. First-degree burns can be treated at home and usually heal within couple of weeks. Second degree burns can be treated using water based treatment, taking over-the-counter pain medication and applying antibiotics cream to prevent infection. Severe burns may require treatment like fluids to prevent dehydration, pain and anxiety medications, burn creams and ointments, dressings, antibiotics for infection and tetanus shot.

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[0005] Creams and ointments which are used most extensively for the treatment of burns come with the disadvantages of delayed separation of mark, delayed re-epithelization, and staining of the skin and even the allergic manifestations. Although various treatments are available, the drugs and the associated treatment methods pose a serious side effects and
5 chemical toxicity which in turn affects patient health. Currently, burn treatment requires a long stay in hospital or burn centers which impose huge treatment cost as well as longer treatment time.

[0006] There is, therefore, an urgent need to develop a herbal composition for the treatment of burn which is safe, economical, easily available, effective and faster in therapeutic
10 action.

OBJECTS OF THE INVENTION

[0007] An object of the present invention is to provide a synergistic herbal composition for the treatment of burns.

15 [0008] Another object of the present invention is to provide a synergistic herbal composition for the treatment of burns which is highly safe and cost effective.

[0009] Another object of the present invention is to provide a synergistic herbal composition having faster therapeutic action in the treatment of burns and related conditions.

20 [0010] Another object of the present invention is to provide a synergistic herbal composition for the treatment of burning sensation in hemorrhoids.

[0011] Another object of the present invention is to provide a synergistic herbal composition having antiseptic and antibacterial property for the treatment of burns.

[0012] Another object of the present invention is to provide a synergistic herbal composition having antiseptic and antibacterial properties.

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SUMMARY OF THE INVENTION

[0013] The present invention relates to a herbal composition for the treatment of burns. Specifically, the present invention relates to a synergistic herbal composition comprising of

Sesamum indicum oil, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more one pharmaceutically acceptable additive.

[0014] The herbal composition of the present invention surprisingly shows faster onset of action when compared with the currently available formulations such as burnol and silver sulfadiazine in the market. The herbal composition of the present invention reduces the burning sensation caused almost completely even in third degree burns within 15 minutes of application in such a way that even a 9 month old baby can sleep peacefully after topical administration. Also, treating burns with the herbal composition of the present invention does not require oral pain killer but most of the currently available treatment requires pain killer.

10 [0015] In one aspect, the present invention relates to a herbal composition comprising combination of:

- (a) *Sesamum indicum* oil from seeds of *Sesamum indicum*;
- (b) leaves of *Bryophyllum pinnatum*;
- (c) stem and leaves of *Ayapana triplinervis*;
- 15 (d) roots of *Glycyrrhiza glabra*;
- (e) leaves of *Aloe barbadensis*; and
- (f) optionally one or more pharmaceutically acceptable additive agent (s).

[0016] In another aspect, the present invention relates to a herbal composition comprising combination of:

- 20 (a) *Sesamum indicum* oil in an amount ranges from about 5% to about 80% by weight of the composition;
- (b) leaves of *Bryophyllum pinnatum* in an amount ranges from about 5% to about 40% by weight of the composition;
- (c) stem and leaves of *Ayapana triplinervis* in an amount ranges from about 5% to
- 25 about 80% by weight of the composition;
- (d) roots of *Glycyrrhiza glabra* in an amount ranges from about 5% to about 40% by weight of the composition;
- (e) *Aloe barbadensis* gel in an amount ranges from about 5% to about 40% by weight of the composition; and
- 30 (f) optionally one or more pharmaceutically acceptable additive agent (s).

[0017] In another aspect of the present invention, the herbal composition comprises the *Sesamum indicum* oil from seeds of *Sesamum indicum* in an amount ranges from about 5% to about 80% by weight of the composition.

[0018] In another aspect of the present invention, the herbal composition comprises the leaves of *Bryophyllum pinnatum* in an amount ranges from about 5% to about 40% by weight of the composition.

[0019] In another aspect of the present invention, the herbal composition comprises the stem and leaves of *Ayapana triplinervis* in an amount ranges from about 5% to about 80% by weight of the composition.

[0020] In another aspect of the present invention, the herbal composition comprises the roots of *Glycyrrhiza glabra* in an amount ranges from about 5% to about 40% by weight of the composition.

[0021] In another aspect of the present invention, the herbal composition comprises the leaves of *Aloe barbadensis* in an amount in an amount ranges from about 5% to about 40% by weight of the composition.

[0022] In another aspect of the present invention, the pharmaceutically acceptable additive agents is selected from the group consisting of polyethylene glycol bases, hydro emulsifying bases, water-soluble bases, gelatin, tragacanth, bentonite and pectin, either alone or in combination.

[0023] In yet another aspect, the present invention relates to a process for preparation of herbal composition comprising combination of:

- (a) *Sesamum indicum* oil from seeds of *Sesamum indicum*;
- (b) leaves of *Bryophyllum pinnatum*;
- (c) stem and leaves of *Ayapana triplinervis*;
- (d) roots of *Glycyrrhiza glabra*;
- (e) leaves of *Aloe barbadensis*; and
- (f) optionally one or more pharmaceutically acceptable additive agent (s).

[0024] In another aspect of the present invention, the process for preparation of the herbal composition comprising the step of:

- (a) cleaning dried leaves and stems of *Ayapana triplinervis* and dried leaves of *Bryophyllum pinnatum*;
- (b) adding distilled water to the cleaned herbs and boiling the mixture to obtain concentrated mixture;
- (c) filtering the concentrated mixture to obtain filtrate;

(d) adding *Aloe barbadensis* gel, crushed root of *Glycyrrhiza glabra* and *Sesamum indicum* oil to the filtrate obtained in step (c) to obtain a concentrated herbal mixture;

5 (e) boiling the concentrated herbal mixture obtained in step (d) to obtain oily extract; and

(f) cooling the oily extract at temperature in the range of 25-30 °C to obtain oily herbal composition.

[0025] In another aspect of the present invention, the steps of adding distilled water to the herbs, boiling and filtering is repeated for two or three times to obtain the complete extract of
10 herbs in the process of preparing herbal composition.

[0026] In yet another aspect, the present invention relates to a herbal composition in the form of oil, solution, lotion, cream, ointment, gel, paste, powder, solid, transdermal patch, advanced wound dressing, oil emulsion dressings, therapeutic dressings and the like.

[0027] In another aspect of the present invention, the herbal composition is in the form of
15 oil.

[0028] In another aspect of the present invention, the herbal composition is administered in combination with advanced dressings to heal the burns by continuous supply of the medication to the site and keep the wound moist and offer microbial control.

[0029] Various objects, features, aspects and advantages of the inventive subject matter
20 will become more apparent from the following detailed description of preferred embodiments.

DETAILED DESCRIPTION OF THE INVENTION

[0030] The following is a detailed description of embodiments of the disclosure. The
25 embodiments are in such detail as to clearly communicate the disclosure. However, the amount of detail offered is not intended to limit the anticipated variations of embodiments; on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the present disclosure as defined by the appended claims.

[0031] Unless the context requires otherwise, throughout the specification which follow,
30 the word “comprise” and variations thereof, such as, “comprises” and “comprising” are to be construed in an open, inclusive sense that is as “including, but not limited to.”

[0032] Reference throughout this specification to “one embodiment” or “an embodiment” means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, the appearances of the phrases “in one embodiment” or “in an embodiment” in various places throughout this specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments.

[0033] As used in this specification and the appended claims, the singular forms “a,” “an,” and “the” include plural referents unless the content clearly dictates otherwise. It should also be noted that the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

[0034] In some embodiments, the numbers expressing quantities of ingredients, properties such as concentration, reaction conditions, and so forth, used to describe and claim certain embodiments of the invention are to be understood as being modified in some instances by the term “about.” Accordingly, in some embodiments, the numerical parameters set forth in the written description are approximations that can vary depending upon the desired properties sought to be obtained by a particular embodiment. In some embodiments, the numerical parameters should be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of some embodiments of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as practicable.

[0035] The recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein.

[0036] All processes described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g. “such as”) provided with respect to certain embodiments herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

[0037] The headings and abstract of the invention provided herein are for convenience only and do not interpret the scope or meaning of the embodiments.

[0038] The following discussion provides many example embodiments of the inventive subject matter. Although each embodiment represents a single combination of inventive
5 elements, the inventive subject matter is considered to include all possible combinations of the disclosed elements. Thus if one embodiment comprises elements A, B, and C, and a second embodiment comprises elements B and D, then the inventive subject matter is also considered to include other remaining combinations of A, B, C, or D, even if not explicitly disclosed.

10 [0039] All publications herein are incorporated by reference to the same extent as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference. Where a definition or use of a term in an incorporated reference is inconsistent or contrary to the definition of that term provided herein, the definition of that term provided herein applies and the definition of that term in the reference does not apply.

15 [0040] Groupings of alternative elements or embodiments of the invention disclosed herein are not to be construed as limitations. Each group member can be referred to and claimed individually or in any combination with other members of the group or other elements found herein. One or more members of a group can be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion
20 occurs, the specification is herein deemed to contain the group as modified thus fulfilling the written description that follows, and the embodiments described herein, is provided by way of illustration of an example, or examples, of particular embodiments of the principles and aspects of the present disclosure. These examples are provided for the purposes of explanation, and not of limitation, of those principles and of the disclosure.

25 [0041] It should also be appreciated that the present invention can be implemented in numerous ways, including as a system, a method or a device. In this specification, these implementations, or any other form that the invention may take, may be referred to as processes. In general, the order of the steps of the disclosed processes may be altered within the scope of the invention.

30 [0042] Various terms as used herein are shown below. To the extent a term used in a claim is not defined below, it should be given the broadest definition persons in the pertinent art have given that term as reflected in printed publications and issued patents at the time of filing.

[0043] The term, "pharmaceutically acceptable additive" as used herein refers to the pharmaceutically acceptable additive or excipient. The pharmaceutically acceptable additive or excipient is an inactive ingredient in the composition which has no role in the therapeutic effect of the composition however helps in controlling the bio-availability, maintaining the viscosity and improving the stability of the composition.

[0044] As used herein, the term "treatment," "treating," "palliating" and "ameliorating" are used interchangeably. These terms refer to an approach for obtaining beneficial or desired results including but not limited to therapeutic benefit and/or a prophylactic benefit. By therapeutic benefit is meant eradication or amelioration of the underlying disorder being treated. Also, a therapeutic benefit is achieved with the eradication or amelioration of one or more of the physiological symptoms associated with the underlying disorder such that an improvement is observed in the subjects, notwithstanding that the subject may still be afflicted with the underlying disorder. For prophylactic benefit, the compositions may be administered to a subject at risk of developing a particular disease, or to a subject reporting one or more of the physiological symptoms of a disease, even though a diagnosis of this disease may not have been made.

[0045] In a general embodiment, the present invention relates to a herbal composition for treatment of burn. Specifically, the present invention relates to a synergistic herbal composition comprising of *Sesamum indicum* oil, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more one pharmaceutically acceptable additive agents.

[0046] The source of the herbs as used in the present invention is given in the table below.

S. No.	Botanical name	Common Name	Parts Used	Geographical Distribution	Source
1	<i>Sesamum indicum</i>	Gingelly oil/Sesame oil	Seeds	Rajasthan, U.P., Assam and West Bengal.	HaridasBhandarkar and sons, No. 10/10/461, JM Road, Bunder, Mangalore - 575001, Near Jumna masjid Spice Food Product

					Distributors.
2	<i>Bryophyllum pinnatum</i>	Life-plant, Ghamari	Leaves	Assam, Kerala, Tamilnadu and U.P.	No. III-885, BANA, Opp. Raghavendra Mutt, Kallare, Puttur, Dakshin Kannada - 574201, Karnataka, India.
3	<i>Ayapana triplinervis</i> (<i>Eupatorium Ayapana Vent., Eupatorium Triplinerve M.V ahl.</i>)	Gadimaddu	Leaves and Stems	Assam and Maharashtra	III-885, BANA, Opp. Raghavendra Mutt, Kallare, Puttur, Dakshin Kannada - 574201, Karnataka, India.
4	<i>Glycyrrhiza glabra</i>	Licorice	Root	North West India	Haridas Bhandarkar and sons, No.10/10/461, JM Road, Bunder, Mangalore - 575001, Near Jumna masjid Spice Food Product Distributors.
5	<i>Aloe barbadensis</i>	<i>Aloe vera gel</i>	Leaf	Assam, Mizoram, Tamilnadu, Andhra Pradesh, Across India and Maharashtra	No. III-885, BANA, Opp. Raghavendra Mutt, Kallare, Puttur, Dakshin Kannada - 574201, Karnataka, India.

[0047] In an embodiment, the present invention relates to a synergistic herbal composition for the treatment of burns and burning sensation of hemorrhoids.

[0048] In another embodiment, the present invention relates to a herbal composition comprising of (a) *Sesamum indicum* oil from seeds of *Sesamum indicum*; (b) leaves of *Bryophyllum pinnatum*; (c) stem and leaves of *Ayapana triplinervis*; (d) roots of

Glycyrrhiza glabra; (d) leaves of *Aloe barbadensis*; and(e) optionally one or more pharmaceutically acceptable additive.

[0049] In another embodiment, the present invention relates to a herbal composition comprising of (a) *Sesamum indicum* oil; (b) leaves of *Bryophyllum pinnatum*;(c) stem and
5 leaves of *Ayapana triplinervis*; (c) roots of *Glycyrrhiza glabra*; (d) *Aloe barbadensis*gel; and(e) optionally one or more pharmaceutically acceptable additive.

[0050] In another embodiment, the herbal composition of the present invention comprises(a) the seeds of *Sesamum indicum oil* in an amount ranges from about 5% to about 80% by weight of the composition; (b) the leaves of *Bryophyllum pinnatum* in an amount
10 ranges from about 5% to about 40% by weight of the composition; (c) the stem and leaves of *Ayapana triplinervis*in an amount ranges from about 5% to about 80% by weight of the composition; (d)the roots of *Glycyrrhiza glabra* in an amount ranging from about 5% to about 40%by weight of the composition; and (e) the leaves of *Aloe barbadensis* in an amount in an amount ranging from about 5% to about 40%by weight of the composition.

15 [0051] In another embodiment, the herbal composition of the present invention comprises (a) *Sesamum indicum* oil in an amount ranges from about 30% to about 60% by weight of the composition; (b) leaves of *Bryophyllum pinnatum*in an amount ranges from about 5% to about 10% by weight of the composition;(c) stem and leaves of *Ayapana triplinervis*in an amount ranges from about 25 % to about 55% by weight of the composition; (c) roots of
20 *Glycyrrhiza glabra*in an amount ranges from about 5% to about 10% by weight of the composition; and (d) *Aloe barbadensis*gelin an amount ranges from about 5% to about 10% by weight of the composition.

[0052] In another embodiment, the herbal composition of the present invention comprises (a) *Sesamum indicum* oil in an amount of about 50% by weight of the composition; (b) leaves
25 of *Bryophyllum pinnatum*in an amount of about 5% by weight of the composition;(c) stem and leaves of *Ayapana triplinervis*in an amount of about 5% by weight of the composition; (c) roots of *Glycyrrhiza glabra*in an amount of about 30% by weight of the composition; and (d) *Aloe barbadensis*gelin an amount of about 10% by weight of the composition.

[0053] In another embodiment, the herbal composition of the present invention comprises
30 (a) *Sesamum indicum* oil in an amount of about 40% by weight of the composition; (b) leaves of *Bryophyllum pinnatum*in an amount of about 5% by weight of the composition;(c) stem and leaves of *Ayapana triplinervis*in an amount of about 40% by weight of the composition;

(c) roots of *Glycyrrhiza glabra* in an amount of about 5% by weight of the composition; and
(d) *Aloe barbadensis* gelin an amount of about 10% by weight of the composition.

[0054] In another embodiment, the herbal composition of the present invention comprises the *Sesamum indicum* oil in an amount ranges from about 10 % to about 80 %, about 20 % to
5 about 80 %; about 30 % to about 80 %, about 40 % to about 80 %, about 50 % to about 80 %, about 60 % to about 80 %, about 20 % to about 60 %; about 20 % to about 50 %; about 20 % to about 40 %; about 20 % to about 30 %, about 30 % to about 40 % or about 40 % to about 50 % by weight of the total composition.

[0055] In another embodiment, the herbal composition of the present invention comprises
10 the leaves of *Bryophyllum pinnatum* in an amount ranges from about 5 % to about 40 %, about 10 % to about 40 %; about 20 % to about 40 %, about 5 % to about 10 %, about 5 % to about 15 %, about 5 % to about 20 %, about 10 % to about 15 %, about 10 % to about 20 %, about 10 % to about 30 %; about 20 % to about 30 % or about 30 % to about 40 % by weight of the total composition.

[0056] In another embodiment, the herbal composition of the present invention comprises
15 the stem and leaves of *Ayapana triplinervis* in an amount ranges from about 10 % to about 80 %, about 20 % to about 80 %; about 30 % to about 80 %, about 40 % to about 80 %, about 50 % to about 80 %, about 60 % to about 80 %, about 20 % to about 60 %; about 20 % to about 50 %; about 20 % to about 40 %; about 20 % to about 30 %, about 30 % to about 40 % or
20 about 40 % to about 50 % by weight of the total composition.

[0057] In another embodiment, the herbal composition of the present invention comprises
the roots of *Glycyrrhiza glabra* in an amount ranges from about 5 % to about 40 %, about 10
% to about 40 %; about 20 % to about 40 %, about 5 % to about 10 %, about 5 % to about 15
%, about 5 % to about 20 %, about 10 % to about 15 %, about 10 % to about 20 %, about 10
25 % to about 30 %; about 20 % to about 30 % or about 30 % to about 40 % by weight of the total composition.

[0058] In another embodiment, the herbal composition of the present invention comprises
the *Aloe barbadensis* gelin an amount ranges from about 5 % to about 40 %, about 10 % to
about 40 %; about 20 % to about 40 %, about 5 % to about 10 %, about 5 % to about 15 %,
30 about 5 % to about 20 %, about 10 % to about 15 %, about 10 % to about 20 %, about 10 % to about 30 %; about 20 % to about 30 % or about 30 % to about 40 % by weight of the total composition.

[0059] In another embodiment, the pharmaceutically acceptable additive agent is selected from the group consisting of polyethylene glycol bases, hydro emulsifying bases, water-soluble bases, gelatin, tragacanth, bentonite and pectin, either alone or in combination.

[0060] In an embodiment, the weight fraction of the pharmaceutically acceptable additive agent or combination of excipients in the pharmaceutical composition may be about 75% or less, about 70% or less, about 65% or less, about 60% or less, about 55% or less, about 50% or less, about 45% or less, about 40% or less, about 35% or less, about 30% or less, about 25% or less, about 20% or less, about 15% or less, about 10% or less, about 5% or less, about 2%, or about 1% or less of the total weight of the pharmaceutical composition.

[0061] The general process for preparing the herbal composition of the present invention comprises the following steps:

(a) cleaning and mixing the dried leaves and stems, roots and whole parts of herbs to obtain clean herbal mixture;

(b) adding water to the clean herbal mixture obtained in step (a) and boiling the mixture to obtain extract of herbal mixture;

(c) filtering the extract of herbal mixture obtained in step (b) to obtain filtrate and adding water to the residue to obtain residual solution;

(d) boiling the residual solution and filtering and combining the filtrate to obtain a concentrated herbal mixture; and

(e) heating the concentrated herbal mixture to eliminate water and cooling the final solution to obtain the herbal composition of the present invention.

[0062] The pharmaceutically acceptable additives shall be added in the final step of the process for preparing the herbal composition of the present invention.

[0063] In another embodiment, the process of preparing herbal composition of the present invention shall include conventional herbal extraction methods known to the person skilled in the art and mixing the extract to arrive at the herbal composition comprising the combination of extract of herbs.

[0064] In another embodiment, the extract of the herbs of the present invention is obtained by any extraction techniques as known to or appreciated by a person skilled in the art, for example utilization of Soxhlet extractor apparatus or by simple maceration. Any extraction techniques can be utilized to serve its intended purpose as laid down in the present invention without departing from the scope and spirit of the present invention.

[0065] In another embodiment, the process for preparation of the herbal composition comprising the step of:

- (a) cleaningdried leaves and stems of *Ayapana triplinervis* and dried leaves of *Bryophyllum pinnatum*;
- 5 (b) addingdistilled water to the cleaned herbs and boiling the mixture to obtain concentrated mixture;
- (c) filtering the concentrated mixture to obtain filtrate;
- (d) adding *Aloe barbadensis* gel, crushed root of *Glycyrrhiza glabra* and *Sesamum indicum* oil to the filtrate obtained in step (c)to obtain a concentrated herbal
- 10 mixture;
- (e) boiling the concentrated herbal mixture obtained in step (d)to obtain oily extract; and
- (f) cooling the oily extract at temperature in the range of 25-30 °C to obtain oily herbal composition.

15 [0066] In an embodiment, the extraction of herbs from boiling with water and filtering shall be carried out repeatedly until the complete extraction has been done. In an embodiment, the boiling with distilled water and filtering shall be carried out two to three times.

20 [0067] In yet another embodiment, the present invention relates to the herbal composition in the form of oil, solution, lotion, cream, ointment, gel, paste, powder, solid, transdermal patch and the like. Preferably, the herbal composition is in the form of oil.

[0068] In another embodiment of the present invention, the different forms of the herbal pharmaceutical composition shall be prepared using the conventional methods known to a person skilled in the art based on the common knowledge available in the art.

25 [0069] In another embodiment, the oil herbal composition of the present invention shall be administered directly on to the burn site. In another embodiment, the oil herbal composition of the present invention shall be administered directly on to the burn sitefor every 2 hours for the first 7days, followed by 3times daily till complete healing takes place.

30 [0070] In another embodiment, the oil herbal composition of the present invention shall be administered directly on to the burn site without covering or dressing the burn siteafter administration in any sort of way.

[0071] In yet another embodiment, the present invention relates to a herbal composition useful in the treatment of burns. In another embodiment, the herbal composition of the present invention is useful in the treatment of first-degree burns. In another embodiment, the herbal composition of the present invention is useful in the treatment of second-degree burns. In another embodiment, the herbal composition of the present invention is useful in the treatment of third or fourth-degree burns.

[0072] In another embodiment, the present invention relates to a herbal composition in combination with administration of intravenous (*i.v.*) fluids for treating fourth degree burns in order to monitor the dehydration level.

10 [0073] In another embodiment, the present invention relates to a method of treating burns comprising administering a therapeutically effective amount of a herbal composition comprising of *Sesamum indicum oil*, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more one pharmaceutically acceptable additive agents to a subject in need thereof.

15 [0074] In another embodiment, the present invention relates to a use of a herbal composition comprising of *Sesamum indicum oil*, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more one pharmaceutically acceptable additive agents for the treatment of burns to a subject in need thereof.

20 [0075] In another embodiment, the present invention relates to a herbal composition comprising of *Sesamum indicum oil*, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more one pharmaceutically acceptable additive agents for use in the treatment of burns to a subject in need thereof.

25 [0076] In another embodiment, the present invention relates to a herbal composition comprising of *Sesamum indicum oil*, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more one pharmaceutically acceptable additive agents for the manufacture of medicament for the treatment of burns to a subject in need thereof.

30 [0077] In another embodiment, the present invention relates to a herbal composition comprising of *Sesamum indicum oil*, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more one pharmaceutically acceptable additive agents for use in the treatment of burning sensation in hemorrhoids.

[0078] In another embodiment, the present invention relates to a method of treating burning sensation in hemorrhoids comprising administering a therapeutically effective amount of a herbal composition comprising of *Sesamum indicum oil*, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more one pharmaceutically acceptable additive agents to a subject in need thereof.

[0079] The herbal composition of the present invention also shows antimicrobial, bactericidal and antiseptic activity. In view of these activities, treatment of burn using the herbal composition of present invention does not require antibiotics and other separate drugs for treating infection and inflammation.

[0080] In another embodiment, the present invention relates to a herbal composition comprising of *Sesamum indicum oil*, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more one pharmaceutically acceptable additive agents having antibacterial activity and useful as an antibacterial agents for treatment of infection.

[0081] In another embodiment, the present invention relates to a herbal composition comprising of *Sesamum indicum oil*, *Bryophyllum pinnatum*, *Ayapana triplinervis*, *Glycyrrhiza glabra*, *Aloe barbadensis* and optionally one or more one pharmaceutically acceptable additive agents having antiseptic activity and useful as an antiseptic agents.

[0082] While the foregoing describes various embodiments of the disclosure, other and further embodiments of the disclosure may be devised without departing from the basic scope thereof. The scope of the invention is determined by the claims that follow. The invention is not limited to the described embodiments, versions or examples, which are included to enable a person having ordinary skill in the art to make and use the invention when combined with information and knowledge available to the person having ordinary skill in the art.

EXAMPLES

[0083] The present invention is further explained in the form of following examples. However, it is to be understood that the following examples are merely illustrative and are not to be taken as limitations upon the scope of the invention.

[0084] **Example 1: Preparation of 1 litre of oil herbal composition**

Composition:

S. No.	Ingredients	Parts used	Quantity
1	<i>Sesamum indicum oil</i>	Seeds	1 litre
2	<i>Bryophyllum pinnatum</i>	Leaves	100 grams
3	<i>Ayapana triplinervis</i>	Leaves, stems	2 kilograms
4	<i>Glycyrrhiza glabra</i>	Root	100 grams
5	<i>Aloe barbadensis</i>	Leaf	100 grams
6	<i>Distilled Water</i>		q.s.

[0085] *Sesamum indicum* oil:

The *Sesamum indicum* oil was obtained from the seeds of *Sesamum indicum* oil through conventional methods.

5 [0086] *Aloe barbadensis* gel:

The *Aloe barbadensis* gel was obtained from the leaves of *Aloe barbadensis* through conventional methods.

[0087] The dried leaves and stems of *Ayapana triplinervis* (2 Kg) and dried leaves of *Bryophyllum pinnatum* (100 g) were cleaned using water and distilled water (8 litres) was added to the cleaned leaves and stems and boiled down to 2 litres. Filtered the boiled mixture, filtrate was separated and the residue was added with distilled water (2 litres) and heated to boil. Filtered the boiled mixture and the filtrate obtained was collected and combined first filtrate. *Aloe barbadensis* gel (100 g), crushed roots of *Glycyrrhiza glabra* (100 g) and *Sesamum indicum* oil (1 litre) were added to the filtrate and boiled till the aqueous part is completely evaporated to obtain oil. Cooled the oil obtained in room temperature and stored the oily herbal composition in an amber colored bottle.

[0088] Efficacy of the oil herbal composition

1. Herbal composition of the present invention was applied to a 3 year old child burnt with 2nd and 3rd degree burns when boiling sambar fell on her as she pulled a table cloth, where the large blisters and scalded area of the hands and fingers were prominent. The oil herbal composition of the present invention was applied immediately after piercing and draining the blisters thereafter every 2 hours for 7 days followed by 3 times daily till complete healing took place. Child stopped crying after 15 to 20 minutes of initial application.

2. A nine month baby who got burnt when boiled milk fell on her was taken to a hospital where she was bandaged and dressed for 3 days after which the doctors rejected the case saying they could not do anything and there is no hope. The oil herbal composition of the present invention was applied to the burnt areas accumulated with pus and infected. Oil
5 herbal composition of the present invention was applied every 2 hours for 7 days followed by 3 times daily till it healed completely. Child stopped crying after 15 to 20 minutes of initial application.

Results:

10 It was observed that the oily composition of the present invention surprisingly relieves the burning sensation within 15-20 minutes to the extent that the child stopped crying and slept due to relieve from the pain and burning sensation. The test results clearly demonstrate that the oil herbal composition of the present invention has synergistic unexpected effect.

[0089] A skilled artisan will appreciate that the quantity and type of each ingredient
15 including the medicinal plant can be used in different combinations or singly. All such variations and combinations would be falling within the scope of present disclosure

[0090] The foregoing examples are merely illustrative and are not to be taken as
20 limitations upon the scope of the invention. Various changes and modifications to the disclosed embodiments will be apparent to those skilled in the art. Such changes and modifications may be made without departing from the scope of the invention.

We Claim:

1. A herbal composition for the treatment of burns comprising combination of:
 - (a) *Sesamum indicum* oil from seeds of *Sesamum indicum*;
 - (b) leaves of *Bryophyllum pinnatum*;
 - 5 (c) stem and leaves of *Ayapana triplinervis*;
 - (d) roots of *Glycyrrhiza glabra*;
 - (e) leaves of *Aloe barbadensis*; and
 - (f) optionally one or more pharmaceutically acceptable additive.

2. The herbal composition as claimed in the claim 1, wherein the composition comprises
10 combination of:
 - (a) *Sesamum indicum* oil in an amount ranges from about 5% to about 80% by weight of the composition;
 - (b) leaves of *Bryophyllum pinnatum* in an amount ranges from about 5% to about 40% by weight of the composition;
 - 15 (c) stem and leaves of *Ayapana triplinervis* in an amount ranges from about 5% to about 80% by weight of the composition;
 - (d) roots of *Glycyrrhiza glabra* in an amount ranges from about 5% to about 40% by weight of the composition;
 - (e) *Aloe barbadensis* gel in an amount ranges from about 5% to about 40% by
20 weight of the composition; and
 - (f) optionally one or more pharmaceutically acceptable additive.

3. The herbal composition as claimed in the claim 1, wherein the *Sesamum indicum* oil is present in an amount ranges from about 5% to about 80% by weight of the composition.

4. The herbal composition as claimed in the claim 1, wherein the leaves of *Bryophyllum pinnatum* is present in an amount ranges from about 5% to about 40% by weight of the
25 composition.

5. The herbal composition as claimed in the claim 1, wherein the stem and leaves of *Ayapana triplinervis* is present in an amount ranges from about 5% to about 80% by weight of the
30 composition.

6. The herbal composition as claimed in the claim 1, wherein the roots of *Glycyrrhiza glabra* is present in an amount ranges from about 5% to about 40% by weight of the composition.
7. The herbal composition as claimed in the claim 1, wherein the leaves of *Aloe barbadensis* is present in an amount in an amount ranges from about 5% to about 40% by weight of the composition.
8. The herbal composition as claimed in any one of the claims 1 to 7, wherein said composition is in the form of oil, solution, lotion, cream, ointment, gel, paste, powder, solid, transdermal patch, advanced wound dressing, oil emulsion dressings and therapeutic dressings.
9. The herbal composition as claimed in any one of the claims 1 to 7, wherein said composition is in the form of oil.
10. A process for preparation of the herbal composition as claimed in claim 1, wherein the process comprising the steps of:
- (a) cleaning dried leaves and stems of *Ayapana triplinervis* and dried leaves of *Bryophyllum pinnatum*;
 - (b) adding distilled water to the cleaned herbs and boiling the mixture to obtain concentrated mixture;
 - (c) filtering the concentrated mixture to obtain filtrate;
 - (d) adding *Aloe barbadensis* gel, crushed root of *Glycyrrhiza glabra* and *Sesamum indicum* oil to the filtrate obtained in step (c) to obtain a concentrated herbal mixture;
 - (e) boiling the concentrated herbal mixture obtained in step (d) to obtain oily extract; and
 - (f) cooling the oily extract at temperature in the range of 25-30 °C to obtain oily herbal composition.

11. The herbal composition as claimed in any one of the claims 1 to 7, wherein said composition shows antiseptic activity, antibacterial activity and reduces the burning sensation in hemorrhoids.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2020/051464

A. CLASSIFICATION OF SUBJECT MATTER A61K36/00 Version=2020.01		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) A61K		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) TotalPatent One, IPO Internal Database, TKDL		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	IN101MUM2003A (SHANTARAM GOVIND KANE) 04 Feb 2005 (04.02.2005). claims; page 51; para 01; table 2; page 29, para 05-page 30, para 06	1-11
Y	Pattanayak, Shibabrata, Tapan Kumar Mandal, and S. K. Bandyopadhyay. "A study on use of plants to cure enteritis and dysentery in three southern districts of West Bengal, India." Journal of Medicinal Plants 3.5 (2015): 277-283. page 178, column right, para 4	1-11
Y	WO2002005830A2 (SHANTARAM GOVIND KANE) 24 Jan 2002 (24.01.2002). claims; Table 1	11
Y	IN100MUM2003A (SHANTARAM GOVIND KANE) 04 Feb 2005 (04.02.2005). The whole document	1-11
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "D" document cited by the applicant in the international application "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 24-06-2020	Date of mailing of the international search report 24-06-2020	
Name and mailing address of the ISA/ Indian Patent Office Plot No.32, Sector 14,Dwarka,New Delhi-110075 Facsimile No.	Authorized officer Suresh Kumar Telephone No. +91-1125300200	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
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Citation	Pub.Date	Family	Pub.Date
WO 2002005830 A2	24-01-2002	AU 8008701 A	30-01-2002
		IN 188857 B	16-11-2002
		US 2004156920 A1	12-08-2004