FORMULATION OF ANTI-INFLAMMATORY AND ANALGESIC SIDDHA TOPICAL OIL USING SOME TRADITIONAL SIDDHA HERB

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Abstract

India has various traditional ways of medicines. One of the most popular among them is Siddha Medicine. These medicines are made out of different kinds of poly herbal formulations which are used for curing many diseases. Siddha medicines become popular nowadays because of various outbreaks of chronic diseases like various types of arthritis etc. Arthritis is a disease-causing painful inflammation and stiffness of the joints. Inflammatory conditions are the common afflictions irrespective of ages. Numbers of NSAIDs are commonly used to treat arthritic conditions and the most widely cited side-effect of NSAIDs includes gastrointestinal ulcers etc. Hence it makes it desperate to look for other ways for the management of arthritic conditions. In order to avoid the gastric irritation, minimize the systemic toxicity and achieve a better therapeutic effect, one promising method is to administer the drug via skin. Some traditional herb could be the best answer to this quest as anti-inflammatory herbal formulation cause much less adverse effects. Siddha preparation has been classified into different categories of medicinal forms as 32 internal and 32 external medicines. Out of these some herb used as an external application for the treatment of arthritis. Topical siddha oil using some traditional Siddha herb can be used to develop stable micro-dispersion system with better skin permeation and promising anti-inflammatory activity without any skin irritation.

INTRODUCTION

Arthritis a disease-causing painful inflammation and stiffness of the joints. Inflammatory conditions are the common afflictions irrespective of ages. Numbers of NSAIDs are commonly used to treat arthritic conditions and the most widely cited side-effect of NSAIDs includes gastrointestinal ulcers etc. Hence it makes it desperate to look for other ways for the management of arthritic conditions. In order to avoid the gastric irritation, minimize the systemic toxicity and achieve a better therapeutic effect, one promising method is to administer the drug via skin. There are reports available in the literature about the existence of various topical medicines for the management of arthritic condition.
US 6444238B1 discloses a pain relief composition for relieving pain in a human body, the pain relief composition consisting essentially of a mixture of aloe Vera oil, eucalyptus essential oil, lemon essential oil, orange essential oil, peppermint essential oil, and rosemary essential oil; wherein the peppermint essential oil is between about 65 and 84 per cent by weight.

US 7282224B1 discloses a pain relief composition comprising an effective amount of a nerve inhibiting component, including capsaicin, a capsaicinoid or a capsaicin analogue, which numbs or inhibits the nerve endings that signal pain, in combination with at least one of the following: an effective amount of an inflammation control component which is designed to reduce immediate pain and discourage future pain in the joints and muscles; an effective amount of a cooling component; an effective amount of a heat minimizing or blocking component; an effective amount of a circulation increasing component which effectuates better penetration of the actives to the skin and nerves; and an effective amount of a soothing and anti-inflammatory complex for the joints and/or muscles comprising Glucosamine sulfate or HCl, Zingiber officinale (Ginger Root) extract, Methyl sulfonylmethane (MSM), Polygonum cuspidatum (Mexican Bamboo) extract, Aloe barbadensis leaf, and Salix alba (white willow) bark extract. Additionally, the composition includes an encapsulation or entrapment system for a timed release delivery.

US 8,865,234 discloses a topical pain formulation the ingredients of which comprise: wrightia tinctoria in an amount ranging between 20% and 40% by weight, coconut oil, and at least one of the following additional ingredients taken from the group consisting of: eucalyptus oil in an amount ranging between 8% and 15% by weight, menthol in an amount ranging between 2% and 15% by weight, clove oil in an amount ranging between 2% and 10% by weight, peppermint oil in an amount ranging between 5% and 12% by weight, and methyl salicylate in an amount ranging between 10% and 25% by weight. Indian Patent 241583 discloses an herbal pain-relief composition comprising therapeutically effective amount of at least one essential pain relief oil, lemon grass oil, winter green oil camphor, menthol and at least one non-petroleum base.

However the available pain relief composition possess various drawbacks which includes, skin irritation, skin impermeable, ineffective in pain relieved and the like. Thus there exists a need in the state of art to formulate a novel anti-inflammatory and analgesic herbal formulation which is devoid of above said drawbacks.

AIMS OF THE STUDY

The main aim of the present invention is to develop a novel process of preparation of anti-inflammatory and analgesic herbal formulation.
Another aim of the present invention is to employ Vitex negundo, Withaniasomnifera, Hyosoyamusnige, and Gingelly oil, Alkannatinctoria, Menthol and Thymol for the preparation of the anti-inflammatory and analgesic herbal formulation.

Yet another aim of the present invention is to formulate a novel anti-inflammatory and analgesic herbal formulation with better skin permeation and promising anti-inflammatory activity without any skin irritation.

Further aim of the present invention is to utilize the developed anti-inflammatory and analgesic herbal formulation for the management of arthritic condition.

**MATERIALS AND METHODS**

**Combination of traditional Siddha Herb in Topical Oil**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Name of the Herb</th>
<th>Quantity</th>
<th>Image of the Herb</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Withaniasomnifera</td>
<td>100gms</td>
<td><img src="image1" alt="Image" /></td>
</tr>
<tr>
<td>2</td>
<td>Vitex Negundo</td>
<td>100gms</td>
<td><img src="image2" alt="Image" /></td>
</tr>
<tr>
<td>3</td>
<td>Hyosoyamus Niger</td>
<td>100gm</td>
<td><img src="image3" alt="Image" /></td>
</tr>
<tr>
<td>4</td>
<td>Alkanna tinctoria</td>
<td>50gms</td>
<td><img src="image4" alt="Image" /></td>
</tr>
<tr>
<td>5</td>
<td>Menthol</td>
<td>5gms</td>
<td><img src="image5" alt="Image" /></td>
</tr>
</tbody>
</table>
Preparation of Oil:

To collect the above said three herbs (Withaniasomnifera, Vitex Negundo and Hyosoyamusniger,) dried and make it coarse powder. Then add 4 litres of water and mix to boil leave it for 2 litres. After the extraction, filter and add 2 litres of Gingelly oil, again to boil it. Make it to 2 litres and filter it. At last, add the above said quantity of Alkanna tinctoria, Menthol and Thymol in it to get cool.

The formulation of present invention was next subjected to clinical studies and found to be very effective in alleviation of severe pain. Immediate relief from severe pain occurred with only one application. Several test subjects reported that severe arthritis pain was completely cured following continuous applications of the formulation. Thus Topical Oil of the present invention was successfully developed using widely accepted safe excipients and reproducible methodology.

The Oil has shown acceptable parameters with better skin permeation. The Topical pain oil shown promising anti-inflammatory and analgesic activity. This Oil proved to be non-irritant to skin and stable. The synergistic effect of combining the ingredients in formulations was entirely unexpected. The above formulations fulfil a long-felt and unfulfilled need for a topical analgesic preparation that relieves mild, moderate, and severe pain.

In one of the preferred embodiment, the present invention shall disclose a process of preparation of anti-inflammatory and analgesic herbal formulation. The process of the present invention comprises of following steps;

a. Procuring predetermined amounts of dried plant part of Withaniasomnifera, dried plant part of Vitexnegundo and dried plant part of ofHyosoyamusniger followed by mixing and grinding to form a coarse powder,

b. Extracting the coarse powder by adding predetermined volume of solvent followed by mixing and boiling until the volume reduces to predetermined volume and filtered to form an extract;

c. Adding predetermined volume of Gingelly oil to the extract followed by mixing and boiling until the volume reduces to predetermined volume and filtered to form a mixture;
d. Adding predetermined amount of plant part of Alkannatinctoria, predetermined amount of Menthol and predetermined amount of Thymol to the mixture to form the anti-inflammatory and analgesic herbal formulation.

In another preferred embodiment, the present invention shall disclose an anti-inflammatory and analgesic herbal formulation prepared by the process discussed above.

In yet another preferred embodiment, the present invention shall disclose a process of preparation of anti-inflammatory and analgesic herbal formulation comprises of following steps;

a. Procuring 100gms of dried Root of Withania somnifera, 100gms of dried leaves of Vitex negundo and 100gms of dried seeds of Hyoscyamus niger followed by mixing and grinding to form a coarse powder;

b. extracting the coarse powder by adding 4 litres of water followed by mixing and boiling until the volume reduces to 2 litres and filtered to form an extract;

c. Adding 2L of Gingelly oil to the extract followed by mixing and boiling until the volume reduces to 2 litres and filtered to form a mixture;

d. Adding 50gms of bark of Alkannatinctoria, 5gms of Menthol and 10gms of Thymol to the said mixture to form the anti-inflammatory and analgesic herbal formulation.

CONCLUSION

Topical Siddha Pain Oil was successfully developed using widely accepted safe excipients and reproducible methodology. This Siddha Oil has shown acceptable parameters with better skin permeation. Siddha Topical pain oil shown promising anti-inflammatory and analgesic activity. This siddha Pain Oil proved to be non-irritant to skin and stable.