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# Development and Characterization of Medicated Ointment Containing Extracts of *Dolichos biflorus, Cichorium intybus, Pterocarpus marsupium,* and *Crataeva nurvala*

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## ABSTRACT

The present research reflected towards exploring the plausible role(s) of extracts of *Dolichos biflorus* (seed), *Cichorium intybus* (root), *Pterocarpus marsupium* (bark), and *Crataeva nurvala* (bark) formulated as ointment product. The formulations were characterized by determining the pharmaceutical characteristics like pH, skin irritancy test, viscosity, appearance, extrudability, spreadability, washability, and swelling index. No specific edema or erythema symptoms were seen following treatment for a continuous seven days according to the skin irritation test investigation. The formulations' pH levels were determined to be 5.2 (F1) and 5.7 (F2). F1 displayed swelling of 1.29%, whereas F2 displayed swelling of 1.14%. The spreadability of the two ointment formulations (F1 and F2) was 6.9 g.cm/sec and 5.2 g.cm/sec. For F1 and F2, the extrudability of the formulations from the collapsible tubes was determined to be +++ and ++, respectively. The viscosity was determined to be 4550 cps (F1) and 5300 cps (F2) when examining the rheological features of the formulations. The formulations' washability was determined to be +++ for Formulation-1 and ++ for Formulation-2. The uses of polyherbal formulations in conventional medicine were revealed by this discovery, which also revitalized the concepts of ethnopharmacology in relation to contemporary medicine.

**Keywords:** Wound Healing, *Dolichos biflorus, Cichorium intybus, Pterocarpus marsupium, Crataeva nurvala*, Ointment

## INTRODUCTION

The skin or the injured organ can mend itself through a very complicated process called wound healing [1]. The dermis, which is deeper and forms a protective barrier against the outside environment, and the epidermis, which is the skin's outermost layer, exist in steady-state symmetry under normal circumstances [2]. The natural physiological function of wound healing is initiated right away if this protective barrier is compromised by any type of trauma or damage [3]. Growth factors work through endocrine, autocrine, and paracrine communication systems to start the healing of wounds [4]. In addition to these, there are several growth factors that promote wound healing via a variety of ways. The proliferation of connective tissue is induced by platelet-derived growth factor (PDGF), the proliferation of cutaneous tissue is induced by epidermal growth factor (EGF), and the proliferation of fibroblast cells is induced by fibroblast growth factor (FGF) [5]. There are several commercial treatments on the market that promise to speed up the healing of wounds, but after using them for a while, they caused a number of problems (hypo-pigmentation, the emergence of scars, etc.) [6].

Herbal treatment is popular in both conventional and alternative medicine in both developing and developed nations [7]. The World Health Organization (WHO) and India have been pushing the use of traditional medicines since they are more affordable, widely accessible, and have a strong following among communities in poor nations [8]. According to published research, common, traditional herbs can help with wound healing as well as a number of skin-related issues [9]. The assumption that plant-based products are reliable, safe, and have fewer adverse effects is the reason for the widespread interest in the uses of herbal-based active extracts or phytoconstituents [10]. Several herbal-based

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wound healing formulations have been studied recently, including creams, ointments, emulsions, gels, liquids, suspensions, jellies, sprays, wet dressing, carbogel, lipogels, and lotions [11–13].

The present research reflected towards exploring the plausible role(s) of extracts of *Dolichos biflorus* (seed), *Cichorium intybus* (root), *Pterocarpus marsupium* (bark), and *Crataeva nurvala* (bark) formulated as ointment product. The formulations were characterized by determining the pharmaceutical characteristics like pH, skin irritancy test, viscosity, appearance, extrudability, spreadability, washability, and swelling index.

## MATERIALS AND METHODS

### Chemicals

White wax and white petroleum, and other analytical-grade chemicals were purchased from SD Fine Chem Ltd., India. We bought PEG 300, cetostearyl alcohol, and chloroform from HiMedia Chemicals Ltd., India. Sigma Aldrich Ltd., Germany was the source for the purchases of propyl paraben and methyl paraben. We bought honey (99.96% pure) from Patanjali Ayurveda Ltd., India. Borosil® distilled water equipment was used to produce double distilled water.

### Instrumentation

All measurements were made with a Shimadzu® electronic balance (Model AUW220D, Japan). A digital pH meter made by VSI® (model VSI-1B) was used to monitor the pH. By utilizing a Brookfield Digital DV-II+ (USA) Viscometer, the viscosity was calculated (using spindle 6). Accelerated stability tests were carried out in a stability chamber (Bio-Technics, India).

### Animals

The Department's Ethical Committee and CPCSEA gave its consent before the Swiss albino rats were used for the wound healing experiment (5 to 6 weeks age and 150-200 g body weight). The rats were housed in the animal home at a temperature of 25°C to 26°C, a humidity of 50% to 65 %, and a cycle of light and dark lasting 12 hrs. The rats were housed in cages made of polypropylene, fed with regular pellets, and allowed unlimited access to food and water.

### Extracts

Standardized *D. biflorus* seed extract (NLT 45 percent Saponins) and standard *P. marsupium* bark extract (Tannins NLT 5 percent / 18:1) were both given by S.A. Herbal Bioactive, Mumbai. Standardized *C. intybus* root extract (Bitters NLT 1.5 percent / 10:1) and standard *C. nurvala* bark extract (Saponins 20–30%) were both made available by Green Heavens Private Limited, Nagpur.

### Formulation development

#### *Preparation of ointment base*

White wax was melted on a hot plate at a temperature of 70–75°C to create the ointment basis. White petroleum was added when the wax had completely melted, and the mixture was left to stay on the hot plate until it liquefied. The content was heated, then allowed to liquefy before being taken off the heat and allowed to congeal. It was swirled until the mixture started to solidify (**Table 1**) [14].

**Table 1: Composition of ointment base.**

| INGREDIENTS | QUANTITY (in gram) |
|---|---|
| White wax | 1.5 |
| White petroleum | 1.5 |
| Cetosteary alcohol | 1.5 |
| PEG 300 | 2.5 |
| Methyl paraben | 0.025 |
| Propyl paraben | 0.025 |

### Preparation of polyherbal formulation

To make ointment, the semi-dried extracts were employed. Using the ointment basis, the polyherbal formulations (F1 and F2) were created. The common trituration technique was applied, which involved melting and combining solid fats. The necessary amount of the ointment base was then added to the melted base at 40°C and properly mixed. The mixture was continually and gently swirled until a homogenous dispersion was achieved (**Table 2**) [15].

**Table 2: Composition of polyherbal ointment formulation.**

| INGREDIENTS | FORMULATION-1 (F1) QUANTITY (g) | FORMULATION-2 (F2) QUANTITY (g) |
|---|---|---|
| *Dolichos biflorus* | 2.5 | 2.5 |
| *Cichorium intybus* | 1.25 | 1.25 |
| *Pterocarpus marsupium* | 0.5 | 0.5 |
| *Crataeva nurvala* | 0.75 | 0.75 |
| Honey | - | 0.5 |
| Ointment base | 5 | 5 |

### Evaluation of polyherbal formulations

#### *Physical Evaluation*

The created compositions' color, overall look, and feel upon application were recorded, and the outcomes are discussed.

### pH

The digital type calibrated pH meter was used to measure the pH of the ointment formulations (F1 and F2), and it was further calibrated before each use using buffered solutions at pH-4 and pH-7. The glass electrode and the reference electrode were fully submerged in the ointment to determine the pH of the formulations [16].

### Spreadability

A unique instrument consisting of a flat wooden block held by a pulley at one end was used to measure the spreadibility of the formulas. By dropping 2 g of the polyherbal product on the ground slide, the formulations were tested based on the drag and slip characteristics. The formulation was sandwiched between two slides of the same dimensions, and the system was held up by a hook. A unit kilogram weight was placed over the slide in order to release the trapped air from the formulas and to create a consistent film between the two slides. The margins were cleaned of extra formulation that was protruding outside. The time needed for the top slide to travel 7.5 cm of distance was calculated with the aid of the hook after 50 g of weight was tied to create a pulling force [17]. Spreadibility of the formulation was determined from the formula:

$$\text{Spreadibility} = \frac{M \times L}{T}$$

where, M = weight tied to the upper slide (50 g); L = length of glass slide (6 cm); T = time taken (sec) to separate the glide slides from each other.

### Washability

By putting the ointments to the skin and personally observing how easily the polyherbal formulations could be washed with distilled water, the washability of the products was evaluated [18].

### Skin irritancy test

0.5 g of the formulation was placed over a 6 $cm^2$ area of skin, followed by a gauze piece that was loosely held in place by a dressing (semi-occlusive) for one hour. The leftover content was removed without changing the other conditions when the gauze was removed after 1 hour. Regarding sensitivity traits and other rash or response symptoms, a complete evaluation was conducted. The program was followed for seven days straight, and evaluations were completed [19].

### Viscosity

The manufacturer's manual's normal operating method was followed to test the apparent viscosity values of the ointment formulations using a Brookfield viscometer with spindle number 6 at 50 rpm at room temperature [20].

### Extrudability

The polyherbal ointment compositions were placed within a collapsible aluminum tube with a normal plastic cap, which was then crimped shut with ointment sealing equipment. The tubes were positioned in the space between the two slides and further clamped. The cap was instantly unfastened once a weight of 500 g was put over the slides. In 10 seconds, the formulation was extruded in a ribbon-like fashion. The extruded ribbon's length was noted [21].

### Swelling index

Since the ointment contained hydrophilic components, its swelling index was calculated by dissolving 2 grams of the substance in distilled water (10 mL). The mixture was taken out of the beaker and put on a Petri plate after one hour [22]. The content was weighed and the degree of swelling was established from the formula:

$$\text{Swelling index} = \frac{W_t}{W_o} \times 100$$

where, Wt = weight of swollen after 1 hr; Wo = original weight of ointment at zero hr.

### Accelerated Stability Studies

The stability of both F1 and F2 was investigated for a period of 90 days under accelerated temperature and moisture conditions (40°C ± 2°C / 75% ± 5% RH). The formulas were put into a PVC container that had been foil-wrapped. The formulations were removed from the stability chamber after 90 days and put through another round of testing for medicinal qualities such appearance, pH, spreadability, viscosity, washability, and extrudability [23].

## RESULTS AND DISCUSSION

Both ointment compositions are quite elegant, beautifully pigmented, extremely soft to the touch, devoid of grit, non-irritating, and no such flaws were found. While Formulation-2 is brownish in color and has a distinctive herbal odor, Formulation-1 has a brown look and a brown-red hue. Formulation-2 appeared to be more elegant than Formulation-1.

No specific edema or erythema symptoms were seen following treatment for a continuous seven days according to the skin irritation test investigation. Simple observation revealed that the Formulation-2 was far less irritating than the Formulation-1. In contrast, polyherbal formulations showed higher compatibility for human use with no local irritation. When examining the compatibility of usage, many synthetic cosmetics on the market now contain new synthetic excipients that irritate the skin in sensitive populations.

The viscosity was determined to be 4550 cps (Formulation-1) and 5300 cps (Formulation-2) when examining the rheological features of the formulations. It has been assumed

that when the torque increases, the shear stress increases, and the viscosity decreases as a result. Formulation-2's excessive viscosity can be attributed to the honey addition, which caused the Brookfield viscometer spindle to experience difficulty. The absence of a high emulsifier concentration may also be the cause, as it is well known that emulsifier concentration increases cause viscosity to decrease. The high viscosity also concentrated on the product's retention on the skin surface for a longer period of time and will continue to exert the activity.

The formulations' pH levels were determined to be 5.2 (Formulation-1) and 5.7 (Formulation-2), respectively. This indicates compatibility for dermal application because the formulation pH closely resembles the skin's pH (5.4-6.0).

Both formulations' swelling indices were relatively low. Formulation-1 displayed swelling of 1.29 percent, whereas Formulation-2 displayed swelling of 1.14 percent. Although the ointment contains hydrophilic excipients, there was very little swelling since there was a significant amount of extract component included in the formulation, which inhibited swelling. Although swelling can have both beneficial and negative consequences, it is necessary for dermal applications to have some degree of occlusive swelling.

It was discovered that the spreadability of the two ointment formulations (F1 and F2) was 6.9 g.cm/sec and 5.2 g.cm/sec, respectively. The spreadability of the formulated formulation rises as the viscosity lowers. Low spreadability is a result of Formulation 2's high viscosity. Formulation-2 may have a greater activity since it is less spreadable and more likely to stick to the injured region, resulting in a concentrated concentration of the product in the targeted location.

For Formulation-1 and Formulation-2, the extrudability of the formulations from the collapsible tubes was determined to be +++ and ++, respectively. The increased viscosity of Formulation-2, which prevented free extrusion from the collapsible tube, may be the cause of its lower extrusion when compared to Formulation-1.

The formulations' washability was determined to be +++ for Formulation-1 and ++ for Formulation-2. Formulation-2's greater viscosity, superior retention capacity, and increased stickiness led to a lower degree of washability (**Table 3**).

**Table 3: Results of evaluation parameters of ointment formulations.**

| PARAMETERS | FORMULATION-1 | FORMULATION-2 |
|---|---|---|
| Appearance | Brown colored, characteristic odor | Brown-Red colored, characteristic odor |
| Spreadability (g.cm/sec) | 6.9 | 5.2 |
| Extrudability | +++ | ++ |
| Skin irritancy test | Non-irritant | Non-irritant |
| pH | 5.8 | 6.4 |
| Viscosity (cps) | 4550 | 5300 |
| Washability | +++ | ++ |
| Swelling index (%) | 1.29 | 1.14 |

The polyherbal wound healing formulations (F1 and F2) showed no significant alterations in terms of washability, physical appearance, spreadability, viscosity, and extrudability under the accelerated stability conditions (40°C ± 2°C and 75% ± 5% RH for 90 days). The synthesis of some tiny fragmented acidic components under the accelerated condition may be to blame for the pH drop in Formulation-1. Formulation-2, in comparison, was discovered to be more resilient in terms of pH and viscosity (**Table 4**). The product's inclusion of honey, which slowed the breakdown of the compounds under rapid stress, may be the most likely explanation. As a result, it was found that the created ointment compositions were quite stable.

**Table 4: Results of accelerated stability studies of ointment formulations.**

| PARAMETERS | FORMULATION-1 | FORMULATION-2 |
|---|---|---|
| Appearance | No change | No change |
| Spreadability (g.cm/sec) | 6.4 | 4.8 |
| Extrudability | +++ | ++ |
| pH | 5.3 | 6.1 |
| Viscosity (cps) | 4150 | 4900 |
| Washability | +++ | ++ |

## CONCLUSION

Positively, this study has created new opportunities for treating wounds with various causes. Future application possibilities exist for the produced polyherbal formulations that comprise extracts of *Dolichos biflorus* (seed), *Cichorium intybus* (root), *Pterocarpus marsupium* (bark), and *Crataeva nurvala* (bark). The uses of polyherbal formulations in conventional medicine were revealed by this discovery, which also revitalized the concepts of ethnopharmacology in relation to contemporary medicine.

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## CONFLICT OF INTEREST

Authors state that there is no conflict of interest regarding the publication of this manuscript.

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