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RESEARCH ARTICLE

FABRICATION AND EVALUATION OF HERBAL OINTMENT FORMULATIONS OF *MORINGA OLEIFERA* FOR TOPICAL DELIVERY

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Abstract

Objective: Traditional medicine is an important source of potentially useful new compounds for the development of chemotherapeutic agents. *Moringa oleifera* Lam. is a multipurpose and exceptionally nutritious vegetable tree with a variety of potential uses. It is distributed in many countries of the tropics and subtropics. Ointments are semisolid systems which behave as viscoelastic materials when shear stress is applied. They contain medicaments and are intended to be applied externally to the body or to the mucous membrane.
Methods: In present study the *Morenga oleifera* leaves extract was used to formulate four different ointment formulations with different bases like cetostearyl alcohol, hard paraffin, and liquid paraffin. Formulations were evaluated for different parameters such as general appearance, spreadability, pH, extrudability, centrifugation, irritancy, loss on drying, stability study *etc*.
Results: All formulations were found to be free of grittiness, homogeneous, without phase separation with green colour with a smooth homogeneous texture and glossy appearance. Viscosity of the ointment formulations was in the range of 32.21±0.51 to 35.3±0.4. Formulations were found to be stable at different temperature.
Conclusion: On the basis of results it can be concluded that ointment preparations with extract of *Morenga oleifera* leaves indicated the suitability of method for the production of ointments.
Keywords: Herbal ointment leaves extract, *Moringa oleifera* Lam, semisolid systems.

INTRODUCTION

Ointments are topical formulations that offer better patient compliance and hence become more acceptable to patients[1]. It is a semisolid dosage form that contains <20% water and volatiles and >50% hydrocarbons, waxes or polyethylene glycols as the vehicle for external application to the skin[2]. Ointments are used topically for several purposes, *e.g.*, as protectant, antiseptics, emollients, antipruritic, kerotolytic, and astringents[3]. Plants had been used for medicinal purposes long before recorded history. According to survey report by WHO, about 25 per cent of prescribed human medicines are derived from plants and 80 per cent people still depend on traditional system of medicines[4]. The World Health Organization (WHO) has appreciated the importance of medicinal plants for public health care in developing nations and has evolved guidelines to support the member states in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation, safety, and efficacy[5].

Figure 1: Leaves of *M. oleifera.*

Herbal medicine, also called botanical medicine or phytomedicine, refers to the use of any plant's seeds, berries, roots, leaves, bark, or flowers for medicinal purposes. Long practiced outside of conventional

medicine, herbalism is becoming more main stream an up-to-date analysis and research shows their value in the treatment and prevention of disease[6].

M. oleifera is one of the vegetables of the Brassica order and belongs to the family *Moringaceae.* Moringa trees have been used to combat malnutrition, especially among infants and nursing mothers[7]. *M. oleifera* is a small native tree of the sub-Himalayan regions of North West India, which is now indigenous to many regions in West India, Africa, Arabia, South East Asia, Islands and South America[8].

Traditionally, besides being a daily used vegetable among people of these regions, the Moringa is also widely known as 'the miracle tree' and used for its abilities for various ailments and even some chronic diseases including anemia, skin infections, blackheads, anxiety, bronchitis, catarrh, chest congestion, asthma, blood impurities, cholera, glandular, swelling, headaches, conjunctivitis, cough, diarrhea, eye and ear infections, fever, abnormal blood pressure, hysteria, pain in joints, pimples, psoriasis, respiratory disorders, scurvy, semen deficiency, sore throat, sprain, tuberculosis, for intestinal worms, lactation, diabetes and pregnancy[9]. The healing properties of Moringa oil have been documented by ancient cultures. Moringa oil has tremendous cosmetic value and is used in body and hair care as a moisturizer and skin conditioner. Moringa oil has been used in skin preparations and ointments since Egyptian times. Moringa is especially promising as a food source in the tropics because the tree is in full leaf at the end of the dry season when other foods are typically scarce. They contain high amount of vitamin C, vitamin A, calcium, potassium, and proteins, the basic building blocks of all our body cells. Another important point is that *M. oleifera* leaves contain all of the essential amino acids in a good proportion, which are the building blocks of proteins[10]. Leaves can be eaten fresh, cooked, or stored as dried powder for many months without refrigeration, and reportedly without loss of nutritional value. Leaves were also used for food fortification. Spoonful of the powder can then be added to baby food, soups, and vegetables, adding nutrition but not changing the taste.

The delivery of drug through the skin has long been a promising concept because of the ease of access, large surface area, vast exposure to the circulatory and lymphatic networks and non-invasive nature of the treatment. In present study four different ointment formulations of *M. oleifera* were prepared and evaluated for different parameters[11].

MATERIALS AND METHODS

Fresh leaves of *M. oleifera* was collected from local Area Buldana, Maharashtra, India and transported to laboratory, authenticated from Center for Biodiversity Jijamata Mahavidyalaya, Buldana, Maharashtra, India.

Extraction of Plant Material

Collected leaves are washed in running tap water till the removal of dirt. After this leaves are soaked in 1% saline solution (NaCl) for 5 minutes to remove microbes. Leaves are further washed with 70 % ethanol followed by twice washing with distilled water. This step plays a substantial role in removal of dust, pathogens as well as microbes present on the leave surface. The excess water can be removed by spreading the leaves in sunlight for a brief period till the removal of water present on the leaf surface[12-15].

The leaves (1 kg) were crushed with little amount of water to obtain the leaf juice. The leaf juice was filtered through a muslin cloth and later through Whatman filter paper to obtain a greenish brown juice. The juice was shade dried and a little amount of absolute alcohol was added to the juice to prevent the growth of microorganisms. The dried leaf juice was collected as a brown colored powder (about 30 g). It was refluxed at 50°C for 5-6 hours with absolute alcohol. The alcohol fraction was separated from the residue and dried to obtain the alcoholic fraction of *M. oleifera* leaf juice.

Preparation of Ointment

Four topical ointment formulations were prepared by means of different ingredients as shown in Table 1. The constituents of the base were placed together in a melting pan and allowed to melt together at 70°C. After melting, the ingredients were stirred gently maintaining temperature of 70°C for about 5 minutes and then cooled with continuous stirring. Formulation of ointment was done by incorporating 10 % w/w of the semisolid extract of *M. oleifera* into the various bases by triturating in a ceramic mortar with a pestle to obtain 100 g of herbal ointments containing 10 % w/w of *M. oleifera.* The prepared herbal ointments were put in ointment jars, labelled and were stored at room temperature pending the evaluation[16-18].

Table 1: Composition of *M. oleifera* ointment formulations.

Ingredients	Formulation code			
(% w/w)	F1	F2	F3	F4
Extract	10	10	10	10
Cetostearyl alcohol	5	5	-	-
Chlororesol	-	-	5	5
Wool fat	-	5	5	-
Liquid Paraffin	20	20	-	-
Hard Paraffin	5	-	-	5

Evaluation of formulations

Prepared *M. oleifera* ointment formulations were evaluated for the following parameters.

Organoleptic Parameters

M. oleifera ointment formulations were evaluated based on their appearance, texture and consistency. Texture was determined on the basis of grittiness/ smoothness. Texture was found to be smooth; it can be spreadable and washable easily.

pH

Total 2.5 gm *M. oleifera* ointment formulations of each batch was taken in 100 ml dry beaker, 50 ml water was added to it. Beaker was heated on water bath maintained at about 60ºC to 70ºC for 10 minutes, cooled to room temperature, and then centrifuged at 3000 rpm for 10 minutes. The pH of water extract was measured by using pH meter. The pH measurements

were done by using a digital type pH meter by dipping the glass electrode into the ointment formulation[19].

Spreadability

The spreadability is expressed in terms of time in seconds taken by two slides to slip off from ointment, placed in between two slides under the direction of certain load. Lesser the time taken for separation of two slides, better the spreadability of ointment[20].

Spreadability of *M. oleifera* ointment formulations was determined by using the formula-

$$S = \frac{MxL}{T}$$

Where S=spreadability, M=Weight tied to upper slide, L =Length of glass slides and T=Time taken to separate the slides.

Viscosity

The measurement of viscosity of prepared ointments was carried out with Brookfield Viscometer (model LV -DV-II, Helipath spindle type S-96). The values of each *M. oleifera* ointment formulation were done in triplicate[21].

Extrudability

Extrudability test is the measure of the force required to extrude the material from a collapsible tube when certain amount of force has been applied on it in the form of weight. In the present study the quantity in percentage of ointment extruded from the tube on application of certain load was determined. The extruadibility of prepared *M. oleifera* ointment formulations was calculated by using following formula[22].

$$\text{Ext.} = \frac{\text{Amount of ointment extruaded from the tube x 100}}{\text{Total amount of ointment filled in the tube}}$$

Loss on drying

The loss in weight, in the sample so tested, principally is due to loss of water and small amount of other volatile material from it. Loss on drying was determined by placing the 1 gm of *M. oleifera* ointment formulations of different batches in a petri dish on a water bath and dried until constant weight was obtained[23].

Centrifugation

It is believed to be a unique tool for the evaluation of accelerated deterioration of ointments. It was determined by using Remi centrifuge in 10ml graduated cylinder at 10,000 rpm for 10 min[24].

Washability

M. oleifera ointment formulations were applied on the skin and then ease extend of washing with water was checked. Washability was checked by keeping applied skin area under the tap water for about 10 min[25].

Stability study

M. oleifera ointment formulations were evaluated for their stability at an ambient condition of pressure and temperature for two weeks. Formulations were observed for phase separation and particle agglomeration[26].

Acute skin irritation study

This test was performed on albino rats weighing between 150-200 g. The animals were given standard animal feed and had free access to water *ad libitum*. The total mass was separated into four groups, each batch containing five animals. Dorsal hair at the back of the rats were removed one day prior to the commencement of the study and kept individually in cages to avoid contact with the other rats. Two groups of each were used for control and standard irritant. Other two groups were used as test. The 50mg of *M. oleifera* ointment formulations were applied over one square centimeter area of whole and abraded skin to different animals. Aqueous solution of 0.8 % formalin was used as standard irritant. The animals were observed for seven days for any signs of oedema and erythema[27].

RESULTS AND DISCUSSION

Four different ointment formulations were prepared using *M. oleifera* extract in different ratio (Table1). All formulations were found to be free of grittiness, homogeneous, without phase separation with green colour with a smooth homogeneous texture and glossy appearance (Table 2). The mechanical evaluation parameters are important tests to evaluate pharmaceutical ointment formulations. Formulations complied with the physical evaluation parameters like pH, physical stability, centrifugation, viscosity, spreadability, extrudability was found to be acceptable. The pH of the formulations was in the range of 5.5 to 6.5, which lies in the normal pH range of the skin and would not produce any skin irritation.

Table 2: Evaluation of formulation.

Parameters	F1	F2	F3	F4
Colour	Green	Green	Green	Green
Odour	Characteristic	Characteristic	Characteristic	Characteristic
Consistency	Smooth, soft semisolid	Soft semisolid	Smooth, Soft semisolid	Soft semisolid
Viscosity (cps)	34.5±0.8	35.3±0.4	33.5±0.21	32.21±0.51
pH	5.5	6.5	5.0	5.6
Spreadability (sec)	9	10	8	7
Extrudability (gm)	0.5	0.4	0.9	0.8
Centrifugation	No phase separation	No phase separation	No phase separation	No phase separation
Loss on drying	20%	35%	38%	25%
Washability	Good	Good	Good	Good
Non irritancy	Non irritant	Non irritant	Non irritant	Non irritant
Stability study	Stable	Stable	Stable	Stable

There was no significant change in pH values as a function of time for all formulations**.** Loss on drying was determined by placing the 1gm of *M. oleifera* ointment formulations was found to be in the range of 20-38%. The results of viscosity gives an idea about measurement of strength and the result of spreadability denote the extent of area to which the prepared formulations readily spreads on application to skin or affected part and homogeneity confirms no lumps. Viscosity of the ointment formulations was in the range of 32.21±0.51 to 35.3±0.4. As per results of spreadability studies, the spreading area was found to decrease with increase in viscosity, as spreadability and viscosity are inversely proportional. All the formulations did not produce any skin irritation, i.e. erythema and oedema for about a week when applied over the skin. All formulations were found to be safe for clinical practice. No phase separation was observed during centrifugation among all ointment formulations. Formulations were found to be stable at different temperature i.e. 20ºC, 25ºC, 37ºC.

CONCLUSIONS

Since ancient time, herbs plays major role in the treatment because of less side effects, low cost and easy availability. The *M. oleifera* leaves extract was used to formulate four different ointment formulations with different bases like cetostearyl alcohol, hard paraffin, and liquid paraffin. Formulations evaluated for physical parameters and standardize as per pharmacopoeial standards. The results of the physical evaluation of ointment preparations with extract of *M. oleifera* leaves indicated the suitability of method for the production of ointments. Further investigations are necessary to determine the therapeutic efficiency of the prepared *M. oleifera* ointment formulations.

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AUTHOR'S CONTRIBUTION

Shaikh SC: writing original draft, methodology, investigation. **Sanap D:** formal analysis, data curation, conceptualization. **Bhusari DV:** writing, review and editing. **Jain S:** methodology, formal analysis. **Kochar PP:** data curation, conceptualization. **Memon FS:** writing, review, and editing. All authors read and approved the final manuscript for publication.

DATA AVAILABILITY

Data will be made available on request.

CONFLICT OF INTEREST

No conflict of interest is associated with this work.

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