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Formulation and Evaluation of *Ficus benghalensis* and *Ficus racemosa* Aquoues Extracts

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ABSTRACT

We intended to develop a desired ointment for treatment of wound. Main objective of this study was to formulate the ointment with different ointment bases having good consistency, better diffusion and antiseptic properties. To assess the efficacy of uniformity, viscosity, diffusivity, rheology, stability, spreadability, permeability and other physical characteristics were evaluated. Two Formulations, formulation A (Aq. extract of *Ficus racemosa*) and B (Aqueous extract of *Ficus benghalensis*) were prepared with same bases. Both the Formulation A and B contains hard paraffin, cetostearyl alcohol, Light liquid paraffin and microcrystalline wax. Formulation B was found better than formulation A in all aspects like spreadability, viscosity, consistency, stability, diffusibility. In conclusion, it was clearly observed that Formulation B was better than formulation A.

Keywords: Aq. Extract, *Ficus Racemosa*, *Ficus Benghalensis*, Formulation, Ointment, Stability Testing, Cetostearyl Alcohol

1. INTRODUCTION

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 noninvasive nature of the treatment. This is true whether the bioavailability desired is systemic or local. Formulations suitable for skin delivery are ointment, cream, gels. Ointments are homogeneous, semisolid preparations intended for external application to the skin or mucous membranes. They are used as emollients or for the application of active ingredients to the skin for protective, therapeutic, or prophylactic purposes and where a degree of occlusion is desired (Cooper and Guns, 1975).

A wound may be defined as a break in the epithelial integrity of the skin or may also be defined as a loss or breaking of cellular and anatomic or functional continuity of living tissue (Ramzi *et al*., 1994). Wound healing studies are mainly aim to detect various means and factor influencing healing process, so they could be either used or avoid in clinical practice to favorably alter the healing process (Stuart and Patricia, 2004).

Ficus benghalensis (Moraceae, Mulberry family) is commonly known as Banyan tree or Vata or Vada tree in Ayurveda. There are more than 800 species and 2000 varieties of Ficus species, most of which are native to the old World tropics. *Ficus benghalensis* a remarkable tree of India sends down its branches and great number of shoots, which take root and become new trunk. This tree is considered to be sacred in many places in India. It is used in Ayurveda for the treatment of Diarrhea, Dysentery and piles, teeth disorders, Rheumatism, skin disorders like sores, to boost immune system, as a hypoglycemic. The extracts of *Ficus benghalensis* were also reported to inhibit insulinase activity from liver

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and kidney. Fruit extracts exhibited antitumor activity in the potato disc bioassay (Mukherjee *et al*., 1998; Shrotri and Aiman, 1960; Augusti *et al*., 1994; Mousa *et al*., 1994). The aqueous and ethanolic extract of *Ficus benghalensis* has been evaluated for its wound healing activity (Murti *et al*., 2011).

Ficus racemosa Linn (Moraceae) is an evergreen, moderate to large sized spreading, lactiferous, deciduous tree, without much prominent aerial roots found throughout greater part of India in moist localities and is often cultivated in villages for its edible fruit. The astringent nature of the bark has been employed as a mouth wash in spongy gum and also internally in dysentery, menorrhagia and haemoptysis. All parts of this plant (leaves, fruits, bark, latex and sap of the root) are medicinally important in the traditional system of medicine in India. The leaves powdered and mixed with honey is given in bilious infections.

The main aim was to formulate the two different ointment formulations (formulation A and B) with same active bases. Both the Formulation code A and B contains hard paraffin 1.5% w/w, microcrystalline 2.5% w/w, light liquid paraffin 26% w/w and Cetostearyl alcohol 15% w/w. Acceptability and clinical efficacy of such preparations required them to pass optimal mechanical properties (ease of removal from the container, spreadability on the substrate), rheological properties (viscosity, elasticity, thixotropy, flowability) and other properties such as bioadhesion, desired drug release and absorption (Opaswong, 2001).

2. MATERIALS AND METHODS

Boric acid, zinc oxide, menthol, cetostearyl alcohol, hard paraffin, white soft paraffin, microcrystalline wax, light liquid, methyl paraben, propyl paraben, triethanolamine, propylene, demineralized water were provided by Vidyabharti Trust College of Pharmacy, Umrakh, India.

The composition for Formulation A and B are depicted in **Table 1**.

2.1. Procedure for Formulation Code A and B

Water phase was prepared by heating Zinc oxide, boric oxide sodium lauryl sulphate, methyl paraben and triethanolamine in a vessel till temperature attains 750-800°C. Oil phase was prepared by heating soft paraffin, hard paraffin, microcrystalline wax, cetostearyl alcohol; light liquid paraffin in a stainless steel vessel till temperature of oil phase attains 750-800°C. Both water phase and oil phase were mixed by passing them through 40 and 150# double cone sandwitch stainless steel filter respectively into ointment manufacturing vessel under vaccum. The mass was stirred and cooled for 1.5 h. Active ingredients like propylene glycol, menthol were made into homogenous slurry by stirring it for 30 min. The slurry was transferred to ointment manufacturing vessel and homogenization was continued for 1.5 h. Then it was cooled and again stirred till ointment is obtained. Temperature was maintained to 35-37°C.

2.2. Evaluation of Ointment

2.2.1. Uniformity of Weight

Ten tubes were filled randomly and weighed. Ointment was removed from each tube and each empty tube was washed with methanol. The empty tubes were dried and their weight was taken. The difference between two weights was calculated as net weight of the ointment of tube. The average of net weight of ointment of ten tubes was noted.

2.3. Globule Diameter

The average globule diameter was calculated with help of microscope.

2.4. pH

The pH of ointment solution was measured with the help pH meter.

2.5. Loss on Drying

Loss on drying was determined by placing ointment in petridish on water bath and dried for 105°C:

$$\text{Percentage loss on drying} = \frac{100 \times (\text{Wt} - \text{MW})}{\text{Wt}}$$

2.6. Spreadability

Spreadability of the formulation was determined by an apparatus suggested by Muttimer (1999) it consist of a wooden block having a pulley at one end with fixed glass slide on block. An excess of ointment (3 gm) placed on ground plate. The ointment was sandwiched between this plate and another glass plate having the dimension of fixed ground plate and provided with the hook. A 1kg weight was placed on the top of the two plates for 5 min to expel air and to provide a uniform film of the ointment between the plates. Excess of ointment was scrapped off from the edges. The top plate was then subjected to pull of 240 gms. With the help of string attached to the hook and time required by the top plate to cover a distance of 10cm. was noted. A shorter interval indicates better spreadability (Kostenbauder and Martin, 1954). Spreadability is measured as $S = m \times l / t$.

Table 1. Formula for both formulations A & B

	Formulation code	
Name of Ingredient	A (*Ficus racemosa* Aq. Extract)	B (*Ficus benghalensis* Aq. Extract)
Boric acid	1.0 gm	1.0 gm
Zinc oxide	3.0 gm	3.0 gm
Menthol	1.0 gm	1.0 gm
Hard Paraffin	1.5 gm	1.5 gm
Microcrystalline Wax	2.5 gm	2.5 gm
Light Liquid Paraffin	26 gm	26 gm
White soft Paraffin	25 gm	25 gm
Cetostearyl Alcohol	20 gm	20 gm
Sodium laurlyl sulphate	1.0 gm	1.0 gm
Methyl Paraben	0.1 gm	0.1 gm
Propyl Paraben	0.1 gm	0.1 gm
Triethanolamine	0.5 gm	0.5 gm
Propylene glycol	10 gm	10 gm
Purified water	q.s.	q.s.

2.7. Consistency or Hardness of Ointment

It was measured by Penetrometer. Three containers were filled carefully and completely, without forming air bubbles and stored at 25+0.5°C for 24 h. Three samples were stored at 25+0.5°C and with shear for 5 min. Three samples were melted and carefully and completely filled three containers, without forming air bubbles stored at 25+0.5°C for 24 h. Test samples were placed on Penetrometer. Temperature of penetrating object was adjusted at 25+0.5°C and position was also adjusted such that its tip just touches the surface of sample. Penetrating object was released for 5sec. Depth of penetration was measured. Same was repeated with remaining containers.

2.8. Viscosity of Ointment

The viscosity was determined by CAP-2000 Brookfield viscometer. Test sample was taken in a clean and dry 250 mL beaker and the viscosity of the test sample was determined by standard operating procedure of Viscometer by using spindle nos. 1-4. Each spindle was used for finding the viscosity of the sample at speeds of 0.3, 0.6, 1.5, 3, 6, 12, 30 and 60r.p.m. respectively. Their rheological characteristics were also tested at 25°C using Brookfield viscometer (Wood *et al*., 1963).

2.9. Stability Studies

The International Conference on Harmonization (ICH) harmonized tripartite guidelines on stability testing of new drug substance and product was issued on 27, 1993. The formulated ointment (A and B) were filled in the collapsible tubes and stored at different temperature condition viz. 25°C+20°C/60% RH+5%RH, 30°C+20°C/65% RH+5%RH, 40°C+20°C/75% RH+5%RH for a period of three months and studied for appearance, pH, extrudability, viscosity, spreadability and assay of the drug (ICHG, 2003).

3. RESULTS

The formulation code A and B were found to be in light brown in colour and mentholated odor. All the parameters like uniformity of weight, pH, globule diameter, loss on drying, drug content were found to comply with standard. The results are shown in **Table 2**.

The consistency of formulation code B was better (205 mm) than formulation code A (154 mm). The formulation code A was found to be more viscous (209cps) than formulation B (185 cps). Because of this, the formulation code B has good spreadability character (6.8 cm gm/sec) than formulation code A (5.3 cm gm/sec).

The developed ointment formulations were subjected to stability study as per ICH guidelines for the period of 3 weeks i.e., 25°C/60%RH, 30°C/65%RH and 40°C/75% RH. The results are discussed in **Table 3**.

Table 2. Evaluation of different parameters of A and B ointment Formulations

Evaluation parameters	Formulation Code A	Formulation Code B
Physical Properties	Color Light Brown, Mentholated Odor	Color Light Brown, Mentholated odor, soft semisolid
Uniformity of Weight	Comply with Standard	Comply with Standard
Globule Diameter	4.28 mm	4.56 mm
pH (W/V Solution)	5.6	6.8
Loss on drying	37 w/w	40 w/w
Hardness or Consistency	154 mm	205 mm
Viscosity	209 cps	185 cps
Spreadability	5.3 cm gm/sec	6.8cm gm/sec

Table 3. Stability parameters

(After 3RD Week)	Formulation A			Formulatiuon B		
Parameters	25°C	30°	40°	25°	30°	40°
pH	5.70	5.70	5.50	6.60	6.50	6.40
Spreadability	5.30	5.80	6.70	6.40	6.70	7.60
Consistency	156.00	154.00	151.00	204.00	203.00	201.00
Globule Diameter (mm)	4.24	4.22	4.15	4.39	4.36	4.26

4. DISCUSSION

From the data it is clearly evident all the physicochemical characteristics of both the formulation were found satisfactory and there were no significance changes in evaluation parameters. The formulation code B containing hard paraffin, microcrystalline wax, cetostearyl alcohol, light liquid paraffin was found to be more satisfactory than formulation code A. From all above results it is concluded that the formulation code B exhibited stable and good physical properties like consistency and viscosity.

5. CONCLUSION

In this study, ointment (A and B) was formulated with different bases like white soft paraffin, cetostearyl alcohol hard paraffin, light liquid paraffin and microcrystalline wax. From the study, it can be concluded that formulation B (Aq. Extract of *Ficus benghalensis*) was better than formulation A (Aq. extract of *Ficus racemosa*. By combining these drugs with appropriate ointment bases a better therapy and patient compliance can be attained.

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