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Research article

FORMULATION AND EVALUATION OF SOME HERBAL PREPARATION FOR THE TREATMENT OF ECZEMA

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ABSTRACT:
Eczema which is also termed as **atopic dermatitis** or **atopic eczema** which is the most common form of the eczema. It is a chronic skin condition in which the skin becomes itchy, spotted, splintered and dry. Effective therapeutic agents are limited in number, and may have long-term toxic side effects. The present study was conducted in order to formulate a polyherbal ointment consisting of various plant extracts in order to check their potential in order to treat the Eczema. Stability studies and the antimicrobial potential of the formulation was also carried out to estimate the efficacy of the formulations in comparison to the base (control) and to the marketed formulation i.e. Nixoderm® cream. The result concluded that the formulation F15 and F19 showed the better inhibition of the microorganism during the *ex vivo* Studies and based on the other in vitro studies it has been concluded that the formulation F is best for the treatment of Eczema.

Keywords: Eczema, Atopic Dermatitis, Herbal remedies, Well diffusion Study.

INTRODUCTION

Eczema is a chronic skin condition in which the skin becomes itchy, spotted, splintered and dry. The eczema word has been derived from the Greek word *ekzein* meaning "to boil out"; the Greek word *ek* means "out", while the Greek word *zema* means boiling. Mainly the eczema affects the children but it may continue in the later stages of life or it may start in the later stage of life. Approximately 30% of all skin-related patients who visits medical practitioner in Western Europe result in a diagnosis of atopic eczema. It affects both males and females equally, as well as people from different ethnic backgrounds.[1] Most primary health care physicians in Western Europe, North America and Australia declare that the number of people diagnosed each year with eczema is has been rising in recent years. Approximately 80% of atopic eczema cases start before the age of 5, and a sizeable number develops it during their first year of life. [2] 60% of children with atopic eczema have one parent with the same condition. The study also revealed that the children have an 80% risk for developing eczema if both of their parents have the condition. The studies done on the topic recently reveal a picture that early life style habits that reduce the risk of developing eczema later on, either during early childhood or later in the life. A Swedish study concluded that the infant diet which includes fish before the age of 9 months curbs the risk of developing the eczema. [3]

Generally the disease being with the formation of the patches that may occur in any part of the skin, usually they tend to appear on the hands, feet, arms, behind the knees, ankles, wrists, face, neck, and upper chest. Some patients also develop the symptoms around the eyes, including the eyelids. The Scratching around the eyes may ultimately lead to noticeable loss of eyebrow and eyelash hairs. In the case of babies the symptoms usually develops on the face. The Experts in this field says that people with eczema are born with it – that means it is a genetically inherited condition. It can worsened with the exposure to external or environmental factors such as pollen or, and internal factors such as hormones level and stress. [4]

A study was carried out in the University of Edinburgh in which they estimated that a particular gene known as filaggrin gene which shows a linked in considerably developing an amplified risk of allergic disorders like eczema, rhinitis and many more. [5]

In the case of atopic eczema patients the immune system of atopic eczema releases a chemical under the skin surface which generally causes inflammation. There is no any official declaration why this happens. They only claim that it is an immune overreaction. [6]

Herbal Medicine which is also called as the Botanical medicine or Phytomedicine generally refers of the method of using a plant seeds, leaves, berries, bark, root, or flower for the treatment of certain diseases or for any other medicinal purpose. From a long period of time Herbalism is being used outside the conventional system of medicine it has now being used in the mainstream as the improvements in the analysis and the quality control along with the advancement in the clinical research revealed the value of the herbal medicine in the treatment and prevention of the disease. It has been concluded that the one-third of the Americans uses the herbs for the treatment of many disease. In the present study herbal formulation was prepared in order to limit or inhibit the various side effects that is associated with the normally used medicine in the treatment of Eczema which mainly includes corticosteroids and antihistaminics. [7]

The main problem associated with the therapy of corticosteroids is that it leads to thin and fragile skin and it cannot be applied on the face and other delicate skin and if used in eye leads to glaucoma. To relief from the itches antihistaminics is used which only provide temporary relief from the itches. [8]

Ointment is a viscous semisolid preparation which is intended to be used topically on a variety of body surfaces which include the skin and the mucous membrane of the eye, anus, vagina and the nose also. [9]

Generally the ointments are classified into two classes:-

1. Medicated Ointment.
2. Non medicated ointment.

Medicated ointment contains a medicament dissolved, suspended or emulsified in the base.

Ointments are used topically as protectants, antitussives, emollients, antipruitic, keratiolytics and astringents.
In the present study a Hydrophillic ointment (o/w emulsion Base) was prepared the reason behind preparing the ointment was

1. Composition: Oleagionous base + water (>45% w/w) + o/w surfactant (HLB value>9).
2. Water content: Hydrous.
3. Affinity for water: Hydrophillic.
4. Spreadibillity: Easy
5. Washabillity: Washable.
6. Stabillity: Unsatable esp. in alkali soaps and natural colloids; non ionics better.
7. Drug release potential: Fair to good.
8. Drug incorporation Potential: solids & aqueous solution (Small amounts).
9. Occulusiveness: No. [10]

MATERIALS AND METHOD:

Materials

The extract of *Andrographis paniculata* (Kalmegh), *Azadirachta indica* (Neem), *Ocimum sanctum* (Tulsi), *Pongemia pinnata* (Karanj), *Tinospora cordifolia* (Guduchi), *Allium sativum* (Garlic), *Psoralea cordifolia* (Buguchi) herbal drug has been procured from the **Amsar Labs. Pvt. Ltd., Indore** with a certificate of analysis as a gift sample. All the other chemicals that have been used in the study are of Analytical grade.

Method of preparation of Polyherbal ointment

The polyherbal ointment was formulated by melting the stearyl alchoal and white petrolactum on a hot plate to 70°C. dissolving the remaining ingredients in water and heat the solution to 70°C. Add the oleaginous phase slowly to the aqueous phase, stirring constantly. Remove from heat and stir the mixture until it congeals. Finally adding the citronella oil during the cooling time. [9]

Characterisation:

Physicochemical Evaluations:

The preliminary evaluations on the prepared formulations were carried out for

- Colour
- Odour

Determination of PH:

The PH of various formulations was determined by using digital PH meter (DPH-115PM) Eutech- Instrument. One gram of the formulation was dissolved in 100ml of distilled water and then stored for two hours. The measurement of the PH was done in triplicate and the average values were taken. [11]

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Determination of Homogenicity:
The prepared formulations was tested for the homogeneity by Visual inspection and tested for the presence of lumps.

Determination of loss of drying:
The prepared ointment was tested for loss on drying by placing the formulation on the petridish in water bath and dried for 105°C. [12]

Determination of spreadabillity.
Spreadability is a term which is applied for expressing the extent of area to which the ointments easily and readily spreads upon application to the skin or the affected area. The spreadibillity was expressed in the terms of the times in seconds taken by the two slides to slip off from the ointment and in between the slides the ointment were placed under the direction of certain load.[13]
Lesser the time being taken for the sepration of the two slides better is the spreadibillity. It is generally calculated by the formulae:

$$\text{Spreadibillity, } S = \frac{M.L}{T}$$

Where, S= spreadibillity,
M= weight tied to the upper slide,
T= time taken to seprate the slides.

Determination of Extrudabillity:
For determination of extrudibillity a simple method was employed. In this method the formulations were filled in the collapsible tube after the ointment were set in the container. The extrudibillity of the different ointment were determined in terms of weight in grams which is required to extrude a 0.5 cm of ribbon of ointment in 10 seconds. [14]

Determination of viscosity:
100mg of each formulation was weighed and transferred to a beaker containing 100 ml of distilled water and the viscosity was determined using Brookfield viscometer (Model no. LVDV-I+) using spindle no. 06 at rpm 1. [15]

Ex-vivo studies/ Evaluation of Antimicrobial activity:
Microorganism
Staphyloccocus aureus, Bacillus subtillis.
Standard used
Nixoderm Cream.
Sample preparation
About 10mg of the ointments were weighed and dissolved in the 6.8 saline Buffer and used for activity studies.
Preparation of medium and nutrient broth

Antimicrobial activity of the ointment was determined by using agar well diffusion method. The entire test microorganism was inoculated in Nutrient Broth.
Agar surface was bored by using sterilized gel borer to make wells (7mm in diameter). 100µl of the test ointment, standard and the vehicle were poured in to the separate wells. Plates were incubated at 37°C for 24 hours.

Determination of relative percentage inhibition
The relative percentage inhibition of the test extract with respect to positive control was calculated by using the following formula.
Relative percentage inhibition of the test extract=

$$\frac{100\times (x-y)}{(z-y)}$$

Where,

x: total area of inhibition of the test extract.
Y: total area of inhibition of the solvent
z: total area of inhibition of the standard drug.

The total area of inhibition was calculated by using area = πr^2 where, r= radius of zone of inhibition. [16]

Stability studies:
The stability studies were carried out for the prepared formulations at different conditions (4°C, 25°C and 75°C) for 2 months. [17]

RESULT AND DISCUSSION:
The polyherbal formulation meant for treating Eczema was prepared and then at first it was evaluated for various *in vitro* parameters in which the pH of all the formulations was found to be in the range of 6.5to7.4 and the ideally the pH of the formulation to be applied on the skin should be 6.8. Among the formulation no lumps were seen in the formulation except for the formulation F19 in which the lumps appeared after two months. The determination of Spreadibillity was carried out in which the formulation F2, F4, F15 and the formulation F15 show a spreadibillity of 9.20,9.12,9.23,8.38gcm/sec respectively. Extrudabillity of the formulation for F2, F4, and F15and F19 was determined and all the formulation shows extrudabillity in the range of 90-94% only F15 shows a extrudabillity of 81% and it has been concluded that all the formulation are easy to extrude. The viscosity of all the optimised batches was determined using Brookfield Viscometer and it has been found that the viscosity of all the formulations F2, F4, F15, F19 were in the optimum range as mentioned. Finally the antibacterial activity of the formulation was determined and the efficacies of the formulation were also compared against the marketed preparation (Nixoderm® cream). The antibacterial activity of prepared ointments were compared with Nixoderm cream using selected species of microorganism such as *Staphylococcus aureus*, *Bacillus subtillis* and it showed that formulations like F 15 and F19 showed best activity towards the inhibition of the growth of microorganisms. Finally the stability studies were determined on the basis of the

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physical parameters that have been evaluated among the formulations F2, F4, F15, F19 it has been concluded that the F15 is the best formulation so it has been kept for stability studies for a period of two months. The stability studies were carried out and inferred that the formulations showed no signs of instability.

Table 1(a): Formulation code for the preparation of polyherbal ointment.

Ingredients	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Tinospora cordifolia	1%	1%	1%	1%	1%	1%	1%	1%	1%
Pongemia pinnata	1%	1%	1%	1%	1%	1%	1%	1%	1%
Ocimum sanctum	1%	1%	1%	1%	1%	1%	1%	1%	1%
Psorelea cordifolia	1%	1%	1%	1%	1%	1%	1%	1%	1%
Andrographis paniiculata	1%	1%	1%	1%	1%	1%	1%	1%	1%
Azadirachita indica	1%	1%	1%	1%	1%	1%	1%	1%	1%
Allium sativum	1%	1%	1%	1%	1%	1%	1%	1%	1%
Sodium Lauryl Sulphate	1%	2%	0.5%	1%	1%	1%	1%	1%	1%
Polypropylene Glycol	12%	12%	12%	11%	10%	12%	12%	12%	12%
Stearyl Alchol	25%	25%	25%	25%	25%	24%	26%	25%	25%
White Petrolactum	25%	25%	25%	25%	25%	25%	25%	24%	26%
Citronella oil	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Purified water	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

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Table 1(b): Formulation codes cont. for the preparation of polyherbal ointment.

Ingredients	F10	F11	F12	F13	F14	F15	F16	F17	F18	F19
Tinospora cordifolia	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Pongemia pinnata	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Ocimum sanctum	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Psorelea cordifolia	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Andrographis paniiculata	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Azadirachita indica	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Allium sativum	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Sodium Lauryl Sulphate	3%	5%	1%	1%	1%	1%	1%	1%	1%	4%
Polypropylene Glycol	12%	12%	15%	17%	12%	12%	12%	12%	12%	13%
Stearyl Alchol	25%	25%	25%	25%	26%	28%	25%	25%	25%	26%
White Petrolactum	25%	25%	25%	25%	25%	25%	26%	28%	25%	26%
Citronella oil	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Purified water	q.s.	q.s	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

Table 2: Evaluation parameter of the prepared polyherbal ointment.

Formulation code	pH	Homogenicity	LOD (in %w/w)	Speadibillity (in gcm/sec)	Extrudabillity (In %)	Viscosity (in cps)
F2	7.27	No Lumps	39	9.20	81	32598
F4	6.75	No Lumps	48	9.12	90.1	32727
F15	6.79	No Lumps	57	9.23	93.2	30475
F19	7.07	Lumps were seen after two months.	26	8.38	92.4	31976

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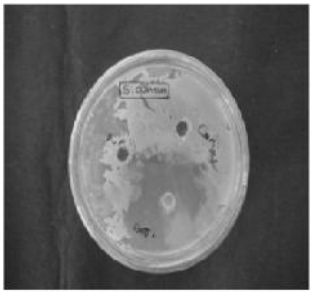
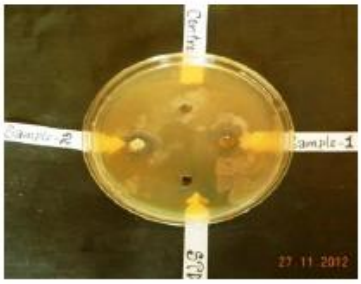
Table 3: Determination of % Zone of inhibition.

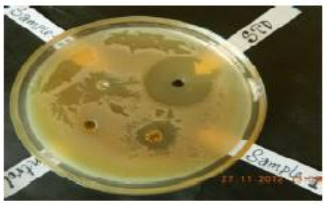
Formulation Codes	Microorganisms	% Zone of Inhibition
F2	*Staphylococcus aureus*	19.02%
	Bacillus subtillis	8.13%
F4	*Staphylococcus aureus*	28.44%
	Bacillus subtillis	18.39%
F15	*Staphylococcus aureus*	76.49%
	Bacillus subtillis	66.01%
F19	*Staphylococcus aureus*	7.41%
	Bacillus subtillis	53.74%



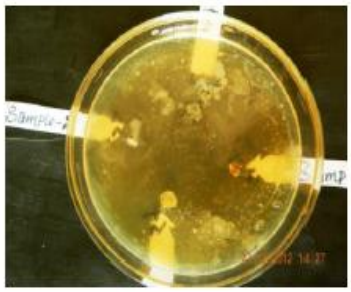
a) F15 formulation *S.aureus*



b)* F19 formulation for *S.aureus



c) F15 formulation *B. Subtillis*



d) F19 formulation *B. subtillis*

Fig. 1: Agar plates showing the growth of various microorganisms

Table 4: Stability studies data

Parameters	Initial days			After 15 days			After 30 days		
	4°C	RT	75°C	4°C	RT	75°C	4°C	RT	75°C
Color	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Feel on application	Smooth	Smooth	Smooth	Smooth	Smooth	Smoth	Smooth	Smooth	Smooth
Spreadibility (in gcm/sec)	9.23	9.23	9.23	8.83	10.27	11.51	8.70	8.08	12.80
pH	6.8	6.8	6.8	6.8	6.92	6.97	6.8	6.91	6.97
Viscosity (in cps)	30475	30475	30475	30447	22832	20831	30414	22832	19183

Parameters	After 45 days			After 60 days		
	4°C	RT	75°C	4°C	RT	75°C
Color	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Feel on application	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth
Spreadibility (in gcm/sec)	8.63	7.65	14.07	8.63	7.65	4.07
pH	6.8	6.94	6.97	6.8	6.94	6.96
Viscosity (in cps)	29615	22814	19108	29614	22164	14316

FUTURE PROSPECTS:

As we all know that the plants have been used as medicines for thousands of years. Recent research indicates that some herbs offer substantial medicinal benefits. Recently the level of awareness in alternative treatment by the general public continues to increase. Medical practicioner needs information about the effects of herbal remedies in order to serve patients in a better way. There is a need for more in vitro and in vivo studies to evaluate and validate the efficacy and safety of these herbs in the present era of evidence-based medicine. It is expected to open new horizon in therapeutic field. Further studies evaluating the effectiveness of this natural system of healing are needed.

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