

**PHARMACEUTICAL AND CLINICAL STUDY OF KUMKUMADI  
CREAM PREPARED USING KWATH AS WATER PHASE AND OIL  
AS MODERN PHASE ON THE DISEASE 'VYANGA'**

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**ABSTRACT**

Beauty is a subject of Socio-medical importance. From the ancient Indian and Egyptian to present, through all cultures and through the span of centuries, mankind has been pre-occupied with youth and physical appearance. Beauty has been admired since time immemorial. The importance of Beauty and Personality is increasing now-a-days as it is a competitive era. The increased demand of beautification is evident by number of Beauty contests, Beauty centers, various cosmetic items like creams, lotions, powder etc. Along with increased demand of beautification, the problems are also increasing which cause damage to Beauty or Personality due to changed life style and polluted atmosphere. Among the Personality damaging disorder or disbeautifying conditions, Vyanga is such a condition which affects the

beauty as well as personality. Vyanga is a 'Kshudra Roga' which affects the skin. In Ayurvedic texts, so many remedies are described as internal medicine and external application for skin disorders. Local application is more useful in skin disorders as it directly

act on lesion. In the context of Vyanga, Kumkumadi Taila has been strongly suggested in Ayurvedic classics. Kumkumadi Taila is one such preparation which is attracting a lot of attention now-a-days. It is an effective Taila Kalpana and now being utilized by cosmetic companies. But it is quite difficult to apply oil on the face. So considering this point, in the present study the efficacy of Kumkumadi Cream (Kwatha as water phase + Modern base as oil phase) is being tested for its *Vyangahara* effect.

## INTRODUCTION

Sneha kalpana is an important pharmaceutical process of Bhaishajya kalpana which is used to extract the fat and water soluble active principles of raw material and also to enhance and hasten the absorption of drugs. Cream preparation is formulated as emulsion because of consumer acceptance, compatibility of ingredients, physical characteristics, better feasibility and economic benefits. Creams available these days are more of chemical ingredient stuffed. Hence there is immense need of herbal cosmetics made using least possible modern chemical.

In Ayurvedic texts, there is no description available regarding cream preparation. But, the Acharyas scientifically described preparations of lepa which were as per with modern cream preparation. Bases used were also herbo-mineral. There were many references in which the final product was in an emulsion form.

An Emulsion can be defined as a thermodynamically unstable mixture of two or more essentially immiscible liquids.<sup>[1]</sup> Creams are those emulsions which are either oil in-water or water-in-oil type.<sup>[2]</sup>

Vanishing creams are oil-in-water emulsions chiefly consisting of pearly Stearic acid.<sup>[3]</sup> On application it spreads on the surface of the skin, as very thin, oil-less film which is not obvious or visible to the viewer.

## MATERIAL AND METHODS

### Aims and Objectives

To explore the effect of Kumkumadi cream on the disease Vyanga along with the Pharmaceutical and Chemical analysis of the cream.

**Plan of Study****Conceptual Study**

The work consisted of thorough study of all the related Ayurvedic and Modern literatures related to the preparation and the administration of the Cream and its complete Pharmaceutical and Chemical Study.

**Clinical Study**

The subjects were selected from the OPD of Rishikul State Ayurvedic College and Hospital, Haridwar.

**Inclusion Criteria**

Volunteers were taken from the premise of the institute. Healthy volunteers willing to participate in trial, without any skin disease were selected. The volunteers were selected irrespective of their age, sex, religion, occupation etc.

**Exclusion Criteria**

The individuals excluded from the trial were

1. Volunteer above 60 years and below 16 years of age
2. With past and present history of any skin disease e.g. Psoriasis, Dermatitis, Vitiligo etc.
3. Person suffering from any bacterial or fungal infection or any skin infestation or are under medication with antibiotics and antifungal drugs.
4. Person having viral infection e.g. Herpes.
5. Pregnant or lactating women.
6. Immuno-deficient state.
7. Any history of allergy or hypersensitivity to creams or lotions.
8. Person with endocrinal disorders like Cushing's or Addison's disease, Acne etc.
9. Person with big or dark scars on face.

**Drug****Preparation of Kumkumadi Cream**

The Kumkumadi Cream prepared was with Kwatha as water phase and Modern base as oil phase. The main contents of the Kumkumadi cream are listed in Table 1.

**Table No. 1 Main contents of Kumkumadi Cream**

S.No.	Sanskrit Name	Latin Name	Quantity
1.	Manjishta	<i>Rubia cordifolia</i>	200 gms
2.	Yashtimadhu	<i>Glycirhiza glabra</i>	200 gms
3.	RaktaChandana	<i>Pterocarpus santalinus</i>	200 gms
4.	Laksha	<i>Tachardia lacca</i>	200 gms

All the contents are collected, dried and then separately converted into coarse powder<sup>[4]</sup> using a pulverizer. Then, all the contents are soaked in about the amount of water which just soaks the coarse powder and left overnight. The other day, the soaked powder is added to 4 times of water and boiled on Madhyamagni (mild heat) till it is reduced to 1/4th part of total quantity of water.<sup>[5]</sup> After that Kwatha Drava is filtered through a clean cloth.

**Table No. 2 Contents of Modern Base for Kumkumadi Cream**

Sr. No.	Content	Quantity
1.	Stearic acid	74 gms
2.	Cetyl Alcohol	11 gms
3.	Olive Oil	10 gms
4.	Potassium hydroxide	6 gms
5.	Tankana	9 gms
6.	Methyl paraben	1 gms
7.	Rose perfume	1gms

The main content Kumkum is triturated in 10 ml of Kwatha to convert it into paste form with the help of mortar and pestle. Kwatha is then taken in a beaker. Kumkum paste is added to it and mixed well. Olive oil, Tankana, KOH, and Methyl Paraben are added to it. All these are heated on water bath not exceeding 70°C. In another beaker Stearic acid and Cetyl Alcohol are heated through water bath upto 70°C. Then both the beakers were taken off the heat. Stearic acid and Cetyl Alcohol were then agitated while adding Kwatha contents little by little in it. Agitation should be continuous and in clockwise direction. Perfume is added when temperature reaches 30°C. Then cooled cream is filled in airtight boxes.

### Posology

50 Gms Kumkumadi cream was given to the individual and were asked to apply the cream after washing their face with clean water and mild cleanser at night. They were directed to massage it on face until it is absorbed with upward and outwards strokes.

*Duration of therapy:* 30 days.

**Assessment Criteria**

The improvement provided by the therapy was assessed on the basis of classical signs & Symptoms. All the signs & Symptoms were assigned score depending upon their severity to assess the effect of the drugs objectively. The detail of which is as shown below.

<b>1. Colour</b>	<b>Score</b>
❖ Light Brown	1
❖ Brown	2
❖ Dark brown	3
❖ Black	4
❖ Dark black	5

<b>2. Size</b>	<b>Score</b>
❖ 0-1 cm	1
❖ 1-3 cm	2
❖ 3-6 cm	3
❖ >6 cm	4

When lesions or patches are multiple, the size of the largest lesion is taken into consideration.

<b>3. Dry Skin (Rukshata/Kharata/Parushata)</b>	<b>Score</b>
❖ Normal	0
❖ Mild (Not seen but felt by touch)	1
❖ Moderate (Stretching of the skin that person feels)	2
❖ Severe (Visible dryness Chapping & hardness of the skin)	3

<b>4. Oily Skin (Snigdhata)</b>	<b>Score</b>
❖ Normal	0
❖ Mild (Not seen but felt by touch) No need to wash face frequently (only 1-2 times a day)	1
❖ Moderate (Oiliness is visible on skin) Need to wash face frequently (3-4 times a day)	2
❖ Severe (Excessive Oiliness) Formation of Acne Need to wash face more frequently (>4 times a day)	3

5. <b>Kandu</b> (Itching)	Score
❖ No Itching	0
❖ Mild (Occasional itching but doesn't disturb routine activity)	1
❖ Moderate (frequent itching, disturbs routine activity) Does not disturb sleep	2
❖ Severe (Frequent itching that disturbs routine activity) Disturbs sleep	3

6. <b>Daha</b> (Burning sensation)	Score
❖ No Burning sensation	0
❖ Mild Burning sensation (Occasional burning sensation) Mostly when patient undergoes to Sun exposure	1
❖ Moderate Burning sensation (Frequent burning sensation) This increases when patient undergoes to Sun exposure	2
❖ Severe Burning sensation (Continuous burning sensation) With or without sun exposure	3

## CLINICAL TRIALS

Total 14 volunteers were selected on a random basis and were administered the Kumkumadi Cream for 30 days. Among these, 11 continued the full course of the treatment whereas 3 left before the completion of the assigned duration.

## OBSERVATION AND RESULTS

Among the total no of the subjects 63.63% registered were in the age group 23-30. Also, the female preponderance was of 91.91%. The percentage of unmarried volunteers exceeded those married by 63.6%. 72.72% volunteers were of middle class whereas upper class shared just 9% of all and the lower class contributed 18.27% of the volunteers. 64% individuals were of working class compared to students and housewives. Most of the individuals were vegetarian, i.e. 73% and 54.54% individuals had Krura Koshtha with Visham type of Agni in 45% individuals. 45% individuals were of Kapha-pitta prakriti. 54% had dry skin, 27% dry to normal and only 9% and 10% volunteers had normal and normal to oily skin and none had oily skin. 73% individuals had continuous sun exposure during working hours. The disease manifested gradually in 64% cases, the manifestation was sudden in 27% and insidious in the rest of the subjects. 65% individuals had black colored lesions, 27% had dark black whereas 9% individuals were found with brown and dark brown lesions each. Hyper pigmentation is

chief complaint of the disease Vyanga and it was present in 78.57% volunteers. While associated complaints were not present in all the volunteers, Photosensitivity was present in 35.71%, Daha and Kandu was present in 7.14% subjects each.

At the end of the duration of therapy, the color of the lesion faded up to 37.50%, size of the lesion reduced by 11.50%, moisture of the skin was gained by 76.16%. only one subject with the complaint of Daha had complete relief (i.e., 100%) after just one week of the treatment. Same was the effect on Kandu which was also present in just one of the subjects.

**Table No. 3 The Effect of Therapy on Various Assessment Criteria of the Disease Vyanga**

Symptom	N	Mean		Diff.	% of Diff.	SD	SE	T	P
		BT	AT						
<b>Color of the Lesion</b>	11	4.8	03.00	1.8	37.50	0.51	0.13	3.06	<0.01
<b>Size of the Lesion</b>	11	2.46	01.01	1.45	11.50	0.13	0.10	2.06	<0.01
<b>Dryness of the Skin</b>	11	1.12	0.267	0.853	76.16	0.370	0.13	4.56	<0.01
<b>Daha (Burning Sensation)</b>	01	1.00	0.00	1	100	00	-	-	-
<b>Kandu (Itching)</b>	01	1.00	0.00	1	100	00	-	-	-

## DISCUSSION

The first and foremost parameter for the further successful results of a skin/cosmetic preparation is to be safe and not producing any side effects like burning after application. The formulation Kumkumadi Cream was not only found safe rather much compliant with respect to the correction of the disease chosen i.e., Vyanga. The positive results showed highly significant improvements in three conditions of the subjects, viz., Dryness of the skin, Burning Sensation (Daha) and Itching (Kandu). It also showed significant improvement in the depigmentation of the lesion. The main content of the cream is Kumkum (*Crocus Sativus*) which has monoterpenoids, crocin, quercetin, Kaempferol and other phenolic compounds which exhibit antioxidant activity. These compounds reduce the tyrosinase activity and thus reduce the hyperpigmentation or melanin aggravation.<sup>[6]</sup> Also, Crocin,  $\beta$ -carotene and safranal inhibit the expression of markers of inflammation, Tumor Necrosing Factor (TNF) and Interleukin (IL).<sup>[7]</sup> Hence, helps relieve the Burning and Itching sensations on the lesions. Another content of the formulation, Manjishtha (*Rubia Cordifolia*) on topical application was found to stimulate keratinocyte differentiation in mouse models<sup>[8]</sup> and thus, helps repair the damaged skin reducing the size of the lesions. As per ayurvedic texts *Yashtimadhu* is *Varnya*<sup>[9]</sup> (enhancing skin color) and it destroys all skin diseases. All the actions of the cream

are a combined effect of the herbal ingredients which are known to have special properties that are beneficial to skin. Thus, there is significant improvement in the symptoms.

## CONCLUSION

Kumkum is the main content of the cream. As facial cream it is useful in improving complexion. Other ingredients were depigmenting Agents, Emollients and for enhancing beauty Therapy. The cream used here clearly shows significant effect on 'Vyanga'. Though understanding of any concept and observing the facts in volunteers comprise the main part of any presentation, the critical analysis and interpretation of the clinical data available with the textual references is also important. So the data available can be reutilized for further studies, and to arrive at some definite conclusions. This can lead a vast path in the world of Cosmetology as the carrier of Herbal Cosmetic products.

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