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Innovation development and standardization of Novel Herbal Formulation

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Formulation development of patient friendly dosage form for eye drug delivery: Kajal

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Abstract

Traditionally kajal is known as kohl or surma which is used as an eye liner. Designing herbal kajal with medicinal plants as a cosmetic product for beautification was thought of an innovative technique and as a novel. More patient compliance, water resistant property, stability and of course economical to formulate are the main advantages of these cosmetics products. with the help of two medicinal plants viz. *Rosa rubiginosa* and *Triphala* and evaluate their potential for sustained ocular delivery for looking at the present study was carried out with the aim of formulation of herbal kajal. Revealed the values were within the prescribed limits by Standardization of the herbs was performed based on different physiochemical parameters. On the basis of selected parameters and its anti-microbial potential was compare with comparator products the herbal kajal was evaluated.

Keywords: Kohl, kajal, *Rosa rubiginosa*, *Triphala*, herbal kohl

Introduction

Eyes are the important connections between the outer and inner worlds. For the element of fire and light that governs our eyes pitta dosha stands for that in Ayurveda. Hence eyes are very important organ in our body system. For care and beautification of eyes vedic science offers several natural, safe and effective techniques. With the help of science of ayurveda, several herbs and floras were used to make Ayurvedic cosmetics that not only beautified the skin but as well as act as the shield against any kind of external affects for the body. In cosmetics for useful purposes such as moisturizing, whitening, coloring, sunscreen, antioxidant, immunostimulant, cleansing, preservatives, thickeners, etc. plants products are also used. Role of kajal in eye products can't be ignored as it is one of those products [1].

Kajal is worn for many reasons including tradition, beautification, to ward off the "evil eye". It is the widespread belief that kohl is medically beneficial for the eyes, and finally because wearing kohl is encouraged within the sunna, the traditional behavioral guidelines of the Islamic religion [2]. There are number of plants which are used ophthalmic disorders, either single or in compound formulations are present in the Ayurvedic system of medicine, as mentioned in ancient Indian books like *Charak Samhita*, *Sushrut Samhita*, *Bhav prakasha*, *Ras Tarang*, *Nayan Drastam* and *Astanghriday*. Various eye disorders and diseases like *Abhishyand* (Conjunctivitis), *Adhimanth* (Glaucoma), *Timir* (Cataract), etc. have been described in great details¹ in Ayurveda.(Indian system of medicine).Their etiology and treatments have also been described. Use of Various herbal drugs in different dosage forms like extract, *arkas* (aqueous distillate), *kajal* (collerium), and fomentation and washing with different extracts have also been prescribed frequently [3]. Not only the use of animals for laboratory testing but also with the use of materials and ingredients derived from animal sources is the concern in this area. For the standards and quality of drugs and cosmetics manufactured and sold in India the Drugs and Cosmetic act is concerned [1].

Hence, for the "natural" products used in various preparations there is a prime need for regulation. Oflate, the primary concept that can create trust and confidence in the products and

increase market relevance is standardization. The consumer as well as the practitioner now seeks assurance from the manufacturer about quality, safety and efficacy of products. Hence the earlier recommendations related to any cosmetic preparations with herbs for specific condition states may not hold true today unless validated properly [4]. In this study *Rosa rubiginosa* and *Triphala* herbs were selected to formulate Kajal by carried out different extracts. Well known from Ayurveda Triphala is polyherbal formulation. Triphala is a Rasayana Drug used in Indian System of Medicine (ISM) [5]. It is a mixture of three fruits as described in Ayurvedic formulary of India which consist of dried fruits of *Emblia officinalis* Gaertn (Euphorbiaceae), *Terminalia bellerica* Linn (Combretaceae) and *Terminalia chebula* (Combretaceae) with equal proportions of (1:1:1). [6]. The most commonly found polyphenolic compounds in plant extracts are Tannin, Gallic acid, Chebulagic acid, Ellagic acid, Phenols and Glycosides. Phenolic acids, flavonoids and tannins are most commonly found in triphala [7]. Triphala is also widely taken for all eye diseases including the treatment of conjunctivitis, progressive Myopia, the early stages of glaucoma and cataracts as described by the Mahajan *et al.*, protection against delaying the onset and progression of cataract is given by Triphalaghrita at a dose of 1080 mg. antioxidant activity of Gallic acid, ellagic acid and ascorbic acid may also give anticataract effect [8]. For the cure of constipation, inflammation, and swelling and for easing throat infection rose water was used traditionally. However, when used as eye drops it worked in curing eye issues as per observations in study. For preparation of eye drops and used it on patients

suffering from dry eyes, conjunctivitis, and pterygium study used herbal preparation that also included rose extracts. In postoperative cataract patients the drops are also used by them. And a significant improvement in their condition is noticed. Needless to say, for the eyes rose water is good.

Benefits of Rose Water for the Eyes are: It Soothes the Eyes, Helps in Treating Skin Irritation, Prevents Cell Damage, Lightens Dark Circles, Is a Soothing Eye Wash [9].

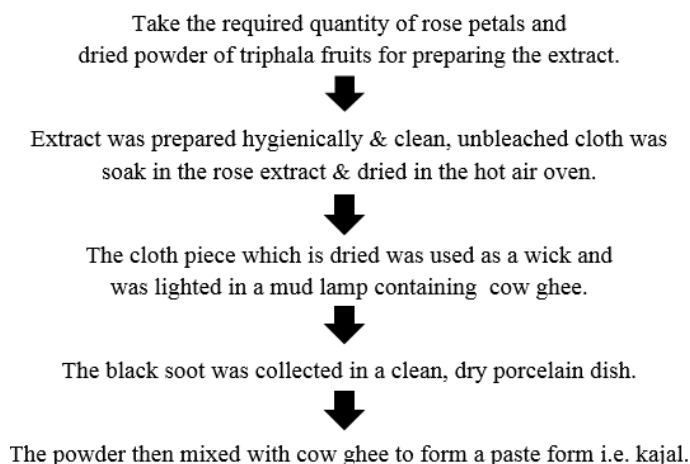
Formulating medicated Kajal as a cosmeceutical product to combat eye infections and beautification was thought of an innovative approach as kajal is most important in eye makeup but still the medicinal use of kajal is limited. Looking at that the present study was aimed to prepare a contemporary formulation from the preliminary Ayurvedic Kajal called soot/Lamp black, prepared by two herbs namely *Rosa rubiginosa* and *Triphala* and standardize in terms of identity, physical evaluation and toxicity study for safety usage.

2. Materials and Methods

2.1. Collection of plant materials & proximal analysis

The fresh fruits of triphala such as amala, baheda, haritaki and flowers of *Rosa rubiginosa* were collected. quantitative standards for the fruits of triphala and petals of flower *Rosa rubiginosa*, in terms of moisture content, total ash, acid insoluble ash, alcohol and water soluble extractive values for both the samples were performed by Preliminary macroscopical identification of both the raw plant materials were carried out as per the method described by the World Health Organization (WHO) guidelines [10]

2.2. Preliminary Ayurvedic formulation of Kajal



2.3. Contemporary formulation of Kajal

Modern Kajal was formulated as the preliminary Ayurvedic Kajal with the ingredient given in below Table 1:

Table 1. Quantitative composition of formulation of Kajal

Ingredients	Quantity Taken
Kajal powder	10 gm
Cow ghee	15 gm
Rose water extract	0.5 ml
Triphala extract	0.5 ml
BHA	12 gm
BHT	12 gm

2.4. Standardization of ingredients, process and products

The standardization of quality of the ingredients used in the product was done by using TLC. Physicochemical characters

that includes Moisture content (using Karl Fischer method), Penetrometer test (the pressure at which the needle penetrates), microbial contamination, TLC, and toxicity study of the product were performed for the Lamp black, plant extracts, and Kajal products of two separate Herb plant.

2.4.1. TLC of extracts

Both the *Rosa rubiginosa* and *Triphala* extracts were to begin with, checked by Thin Layer Chromatography (TLC) on analytical plates over silica gel. The isolation of the principle components that were present in most effective extracts of plant and the final products carried out by using TLC. The different polarities solvents were prepared and for better resolution TLC studies were carried out to select the suitable solvent system [11]. Based on that, 6 g of the product (prepared from *Rosa rubiginosa*) was subjected to Soxhlet extraction

with water as solvent. Further 65 g of whole plant Triphala refluxed with 100 ml of alcohol for one hour and then evaporated with water bath to reduce the volume. Crude extract then diluted to sufficient volume of alcohol.

Finally, the leaf extract of *Rosa rubiginosa*, Lamp black, Kajal products and alcoholic plant extract of Triphala, Lamp black,

Kajal products were performed by TLC using two separate mobile phases viz. Toluene: Acetone: Formic acid (11:6:1) and Toluene: Ethyl acetate (95:5) for *Rosa rubiginosa* and Triphala respectively. Both the samples were visualized at 254 nm and 366 nm and band of similar R_f value was identified.

Table 2. TLC for ingredients (Water extract, Lamp black extract) and product (Water Kajal extract) of *Rosa rubiginosa* at different wavelength.

Visualization	Water extract	Lamp extract	Kajal extract
254 nm	T ₁ : 0.67 (R _f)	T ₂ : 0.67 (R _f)	T ₄ : 0.09 (R _f)
366 nm	T ₁ : 0.67 (R _f)	T ₂ : 0.67 (R _f)	T ₄ : 0.09 (R _f)

• T₁, T₂, T₃ and T₄ are the tracks of respective extracts

Table 3. TLC for ingredients (alcoholic extract, Lamp black extract) and product (alcoholic Kajal extract) of Triphala at different wavelength.

Visualization	Alcoholic extract	Lamp extract	Kajal extract
254 nm	T ₁ : 0.58 (R _f)	T ₂ : 0.60 (R _f)	T ₄ : 0.60 (R _f)
366 nm	T ₁ : 0.58 (R _f)	T ₂ : 0.60 (R _f)	T ₄ : 0.60 (R _f)

• T₁, T₂, T₃ and T₄ are the tracks of respective extracts

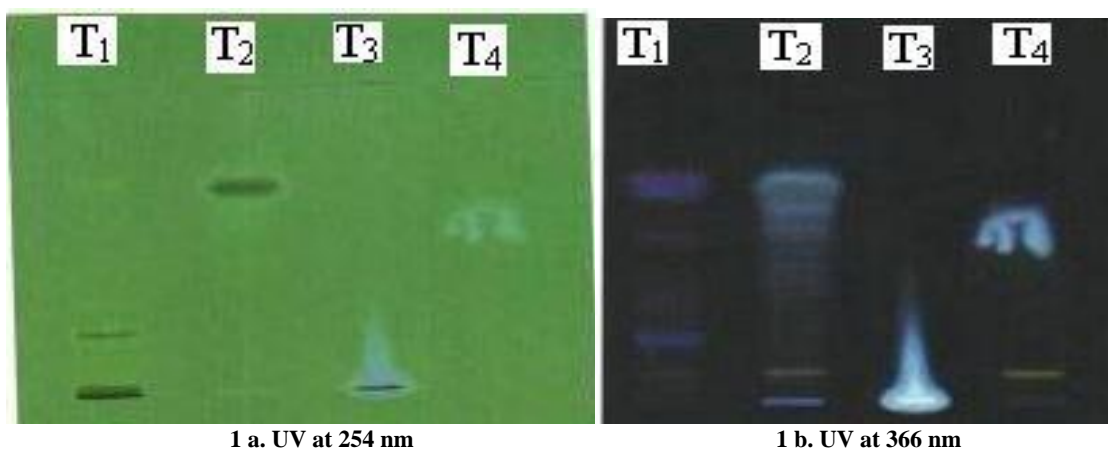


Fig 1: TLC plates at different wavelength for *Rosa rubiginosa* Kajal extracts

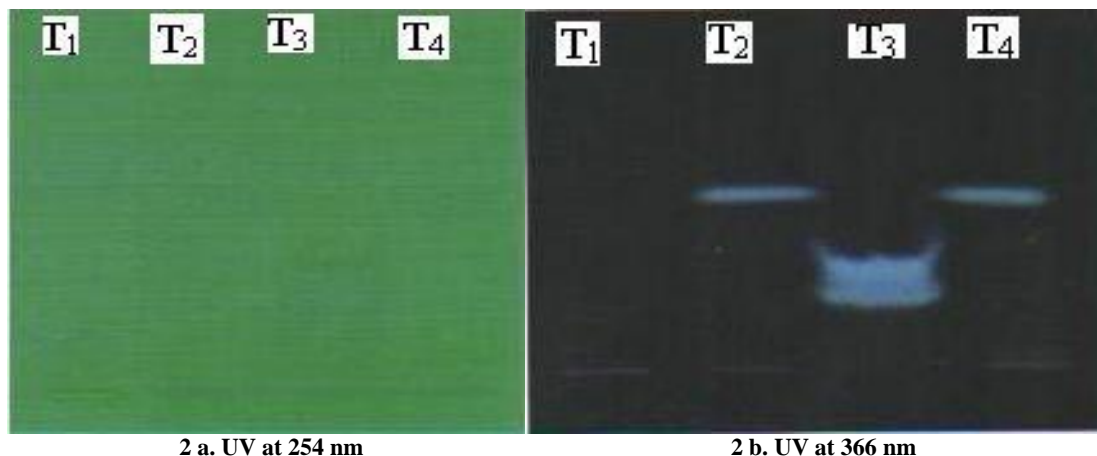


Fig 2: TLC plates at different wavelength for Triphala Kajal extracts.

2. 4. 2. Microbial contamination

The Kajal products were performed to check quality with the microbial test to find out the microbial count, total fungal count and *E. coli* count through cylindrical plate method using nutrient agar (for total bacterial count), MacConkey agar (for total *E. coli* count) and Sabouraud dextrose agar (for fungal and yeast count) method by incubated 37° over night, 43° over night and 25 °C for 4 days respectively. Finally the growth were observed and by colony counter, counted in per volume plated and results expressed as cfu/g (Colony forming unit per gram of the sample).

2. 5. Evaluation of allergenic studies on Kajal products

Physical Evaluation: The formulated product is of a shiny black color, with a characteristic odour. It was non-gritty and smooth in texture with a semisolid consistency.

PH Determination: From Ph meter read as 7.2

Viscosity Determinations: By Using Brookfield Viscometer.

Evaluation of Base: For acid value, Saponification value and ester value Vegetable ghee was evaluated as per I.P. 1996.

Acid Value: Acid Value = $5.61 \times n/w$; where n = no. of ml of 0.1 M KOH required and w = weight in grams of solvent; where n = 0.5 and w = 2.0 Hence Acid value equals to $5.61 \times 0.5/2 = 1.4025$.

Saponification Value: Saponification value equals to $28.05 (b-a) / w$; Where w = weight in grams of substance, b = blank solution reading, a = sample solution reading; b = 21, a = 4.6, w = 2.0 Therefore, Saponification value = $28.05 (21-4.6) / 2 = 230.01$ Ester Value: Ester value = Saponification value – Acid value Hence Ester value = $230.01 - 1.4025 = 228.6075$.

3. Conclusion

Standardization of Triphala and Rosa rubiginosa plants were carried out with respect to organoleptic characters and founded same characters reported for both the drugs in the official Pharmacopoeia. Revealed similarities in the values for both the herbs by carrying out various proximate parameters. Chromatographic profile of extracts of the plants showed that there are compounds present had similar R_f values in the duos when they were identified and separated with different mobile phase. Thereafter microbial tests showed in both the plant products, absence of microbial load which showed safety of the Kajal products. These studies concluded that the formulated herbal Kajal is safe and can be used as one of the herbal cosmetic products.

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