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RESEARCH ARTICLE

KAJAL: COSMECEUTICAL

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ABSTRACT

Cosmeceuticals are cosmetic products that are claimed, primarily by those within the cosmetic industry, to have drug like benefits. Designing medicated kajal as a cosmeceutical product to combat eye infections was thought of as a novel and an innovative technique. The main advantages of this product are more patient compliance, water resistant property, stability, economical to formulate etc. The objective of the present work was to develop ocular cosmeceutical of Sulfacetamide and evaluate their potential for sustained ocular delivery. Four formulations were developed, which differed in the constitution and characterized by in vitro drug release studies using dissolution test apparatus that simulated the eye conditions. The method was found to be linear (r^2=0.9824) in the range of µcg/ml for sodium sulphacetamide at 7.4 P^H at 255 nm. All formulations were found to have about 90 to 96 % w/w of sodium sulphacetamide. On the basis of in vitro drug release studies, it can be concluded that this kajal cosmetic with three times a day application can combat with the eye infections and at the same time will give the aesthetic appeal.

Keywords: *Cosmeceutical, Kajal, Sodium Sulphacetamide, Medicated Kajal.*

INTRODUCTION

Traditionally, Kajal is used for centuries by women for the enhancement and its medicinal properties. It is believed to cure the eye of ailment. It is thick black ointment, it is a mixture of soot and other ingredients used predominantly by Middle Eastern, North African, Sub-Saharan African, and South Asian women, and to a lesser extent by men, to darken the eyelids and as mascara for the eyelashes. Mothers apply kajal to their infants' eyes soon after birth to "strengthen the child's eyes," and also to prevent the child from being cursed by an "evil eye".

Medical opinion is against kajal and therefore its popularity is going down day by day[1]. The product under study can be a drug, a cosmetic or a combination of both included under cosmeceuticals. In modern times, eye makeup is an essential item of facial makeup. Since eye is a very sensitive organ cosmeceutical products for use in eye areas should be made from pure, safe, non toxic and non-irritating materials[2].

All the ingredients used in Traditional Ayurvedic and Siddha kajal preparation are believed to have medicinal properties and they are still used in Indian therapies. Now reputed manufacturers do use amorphous carbon or organic charcoal instead of lead. Plant oils and the soot from various nuts, seeds and gum resins are often added to the carbon powder. Though kajal is one of the most important in eye makeup, but still the medicinal use of kajal is bit limited. Thus, formulating medicated kajal as a cosmeceutical product to combat eye infections was thought of an innovative approach.

MATERIAL AND METHOD

Sodium sulphacetamide was added to the formulation which is widely prescribed sulphonamide for eye infections. It is used mainly in the treatment of acute conjunctivitis and in prophylaxis of ocular infections[3,4].

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Preparation of lamp black by conventional method[1]:
Dipped a clean, white, thin muslin cloth in the sandalwood paste then dried in shade. This dip and dry process is done all over the day. After sunset, made a wick out of the cloth and used it to light a mud lamp filled with castor oil. A vessel was kept over the lamp, leaving a little gap enough for the oxygen to aid the burning of the lamp. This was left burning overnight. Next day the soot was collected and it is then stored in a clean, dry clear glass bottle. The ointment base[1] was prepared (Table No. 1) and stored in a clean, dry clear glass bottle. The carbon black and ointment base were then sterilized[2] in autoclave at 120^0C and 150^0C respectively at 15psi for 5 mins. Marketed eye ointment contain up to 10% sodium sulfacetamide[5], so four kajal formulations were developed with 10% strength of the drug and sterilized (Table No. 2) K_1 (with Propyl paraben and camphor), K_2 (with Camphor), K_3 (with Propyl paraben), and K_4 (without Propyl paraben and Camphor).

All the formulations were examined visually for the clarity, presence of particulate matter. Formulation P^H was determined using a Systronic digital P^H meter. *In vitro* drug release studies and assays were carried out by using USP Type 1 dissolution apparatus and Shimadzu UV 161A Spectrophotometer.

The prepared ophthalmic formulations were subjected to the following tests before and after terminal sterilization.

1. Appearance: formulation was examined visually for the clarity, presence of particulate matter.
2. P^H: Formulation P^H was determined using a digital P^H meter
3. Assay[6]: To 99 ml of the saline phosphate buffer solution P^H 7.4 (PBS), 1 ml of the formulation was added under stirring and the dispersion was sonicated for 15 mins. The solution was filtered using Whatmann filter paper no. 1. The filtrate was diluted suitably and the absorbance was read at 255 nm using Shimadzu UV 161A spectrophotometer. The method of assay was previously validated for specificity and linearity.
4. *In vitro* Drug Release studies[6]:

The study was done using modified USP Type 1 dissolution apparatus where baskets were replaced with the open glass cylinders of same dimensions. One end of the cylinder was tied with cellophane membrane previously soaked in PBS and dried. On inner surface of this membrane, 1ml of the formulation in the gel form was spread uniformly. Then the other end of the cylinder was fixed to the shaft of the dissolution apparatus. The cylinder acted as the donor compartment and the semipermeable cellophane membrane as corneal epithelium. The outer surface of the membrane was in contact with the receptor compartment consisting of 50 ml PBS maintained at 37^0C. The study was carried out in six replicated at 50 RPM, aliquots were withdrawn at 10, 25, 40, 60, 90, 120,160, 180 mins and were directed read for the absorbance at 255 nm using spectrophotometer. Release profile was fitted to the zero order, 1st order and Higuchi's equation to determine the kinetics and mechanism of release of drug from the formulation.

RESULT AND DISSCUSSION

All the four formulations were clear, free from particles (Table. 3). The drug content of the formulation was found to be 90 to 96 % w/w of sodium sulphacetamide (Table. 4). Physicochemical properties of the kajal formulations did not show significant difference upon sterilization, which confirmed that the autoclaving was a suitable method of sterilization.

Formulations when subjected to *in vitro* drug release studies, exhibited about 90% of the drug release in the period of 3 hr. (Graph. 1).The release profile showed a good fit to Higuchi's equation. The method was found to be linear (r^2=0.9824) in the range of µcg/ml for sodium sulphacetamide at 7.0 P^H at 255 nm. On the basis of *in vitro* drug release studies, it can be concluded that this kajal cosmetic with three times a day application can combat with the eye infections and at the same time will give the aesthetic appeal. These formulations have longer contact time, patient compliance, water resistance; precautions during application and storage are minimized, easy for pediatric use and cost effective.

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Table No. 1: Formula for base

Ingredients	Qty taken
Liquid paraffin	05%
Yellow soft paraffin	60%
Hard paraffin	25%
Soft paraffin	10%

Table No. 2: Formula for Kajal formulations:

Ingredients	Quantity taken			
	K_1	K_2	K_3	K_4
Camphor	2%	2%	---	---
Lamp black	1%	1%	1%	1%
Propyl paraben	0.01%	---	0.01%	---
Ointment base q.s. to	100%	100%	100%	100%
Sodium sulphacetamide	10% (pH 7)	10% (pH 7)	10% (pH 7)	10% (pH 7)

Table No. 3: Evaluation of Formulations: Before and After Terminal Sterilization by Autoclaving)

Physicochemical Properties	Before Sterilization	After Sterilization
Visual Appearance	Clear, free from particulate matter	Clear, free from particulate matter
pH	7.00	6.98

Table No. 4: Assay

Sample	Concentration (in 1g Kajal)	% Content
K1	0.096 g	96
K2	0.095 g	95
K3	0.091 g	91
K4	0.090 g	90

Table No. 5: Drug release studies RUG RELEASE STUDIES:

SAMPLE	T10 (mins)	T50 (mins)	T90 (mins)
K1	05	40	125
K2	09	60	145
K3	05	58	145
K4	04	40	149

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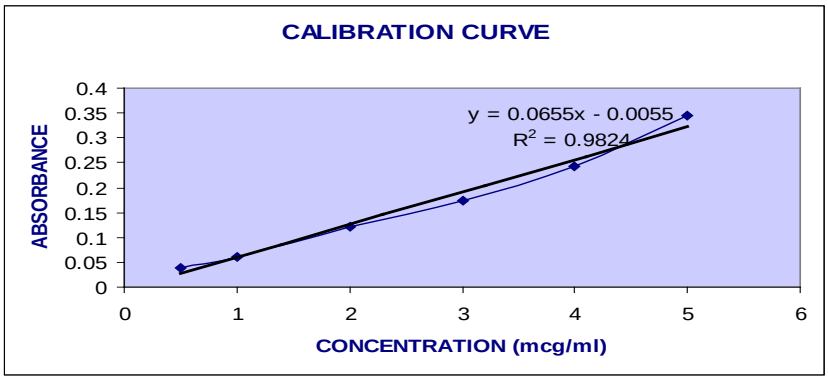
Graph: 1: a: Calibration curve b, c, d, e: *In vitro* drug release profile of the formulations



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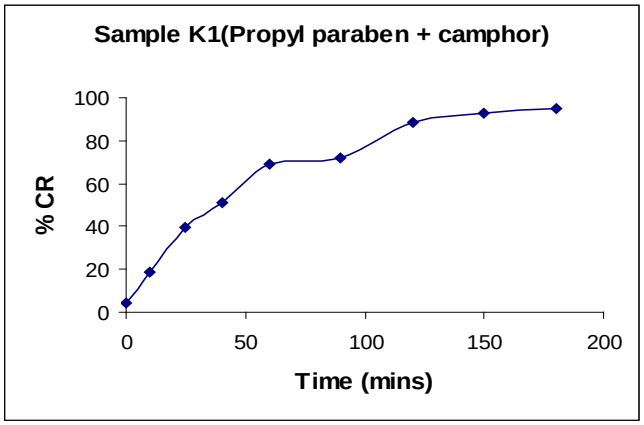

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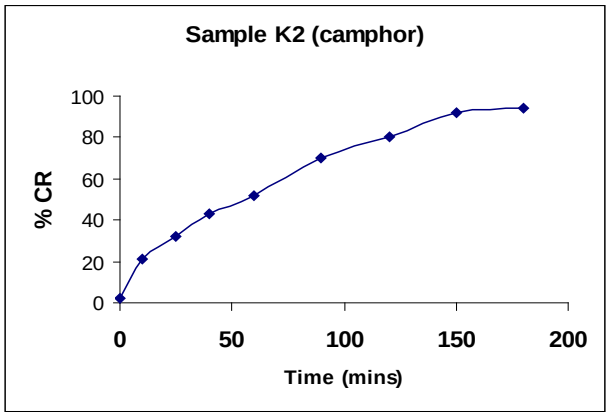

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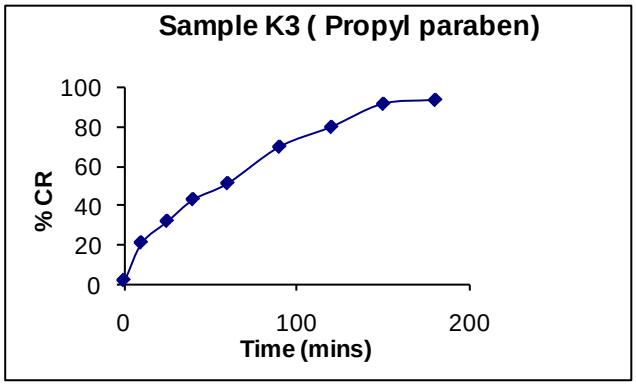

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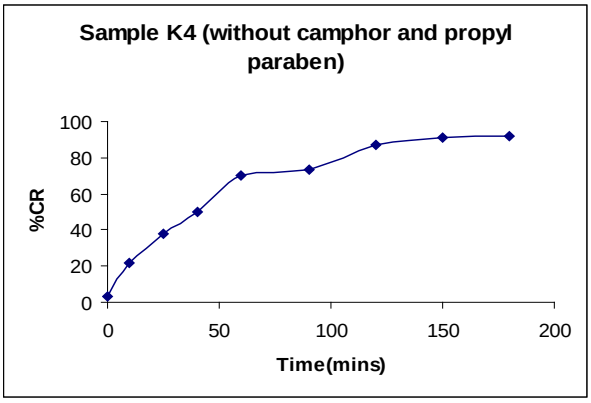

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