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Research Article

STANDARDIZATION OF KATAKADI EYE DROP: AN OPHTHALMIC PREPARATION

Gargi Verma[1]*, Shuchi Mitra[2], Usha Sharma[2], Khem Chand Sharma[3]

*[1]PG Scholar, [2]Associate Professor, [3]Professor and HOD, PG Department of Rasa Shastra and Bhaishajya Kalpana, Rishikul Campus, Uttarakhand Ayurved University, Rishikul Campus Haridwar, Uttarakhand, India.

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ABSTRACT

Ayurveda is science in which we study about not only *Atura Chikitsa* but also *Swasthasya Swasthya Rakshana*. In this study an eye drop which comes under *Arka Kalpana* of *Bhaishajya Kalpana*. This eye drop not only treats allergic conjunctivitis but also prevent healthy eye from allergy. Main symptoms present in allergic conjunctivitis are redness, itching, burning sensation etc. In Ayurveda we correlate cataract with *Vataja Abhishyanda*. This eye drop is made up of *Kataka, Karpura* and *Madhu* mentioned in *Sharangdhar Samhita Uttarkhand* as *Netraprasadana* has a great potential to prevent and treat conjunctivitis. Also in this study light towards the pharmaceutical preparation of *Katakadi* Eye Drop. Standard operating procedures to quality assurance of ingredients, and also adhering to Indian Pharmacopeia's specifications for the final product's safety and quality for ophthalmic preparation. Pre-clinical ocular toxicity investigations have demonstrated this formulation's safety for topical use.

INTRODUCTION

Ocular allergy can present as a variety of different disease entities, from the relatively benign allergic conjunctivitis to the potentially blinding keratoconjunctivitis that affects the cornea. The underlying immunological mechanisms are still unclear, although it is known that inflammation mediated by mast cells and eosinophils, which are associated with IgE, triggers the release of toxic eosinophil granule protein and enzymes as well as mast cell mediators.[1] Statistically 15% of people worldwide suffer from ocular allergies, and the prevalence of these conditions is rising in developed nations.[2] Ocular allergy sufferers may perceive symptoms in varying degrees of severity and duration, such as burning, itching, redness, swelling, or dryness in the eyes.

Evidently are some who may only have symptoms for a few weeks, and others who may have them all year long. Accordingly, patients' quality of life in relation to their health may be impacted by ocular allergies in their day-to-day activities.[3]

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A variety of drugs, such as topical antihistamines, mast cell stabilizers, NSAIDS, and corticosteroids, can be used to treat allergic conjunctivitis. In cases of severe VKC and AKC, surgery can be necessary. All of these medications just relieve symptoms; they have several adverse effects, including delayed wound healing, additional infections, higher IOP, and cataract formation. They also have no effect on underlying pathophysiology. Therefore, it's necessary to look for an effective, secure, and reasonably priced Ayurvedic herbal eye drop to treat allergic conjunctivitis.

Basis for Formulation Herbal Eye Drops

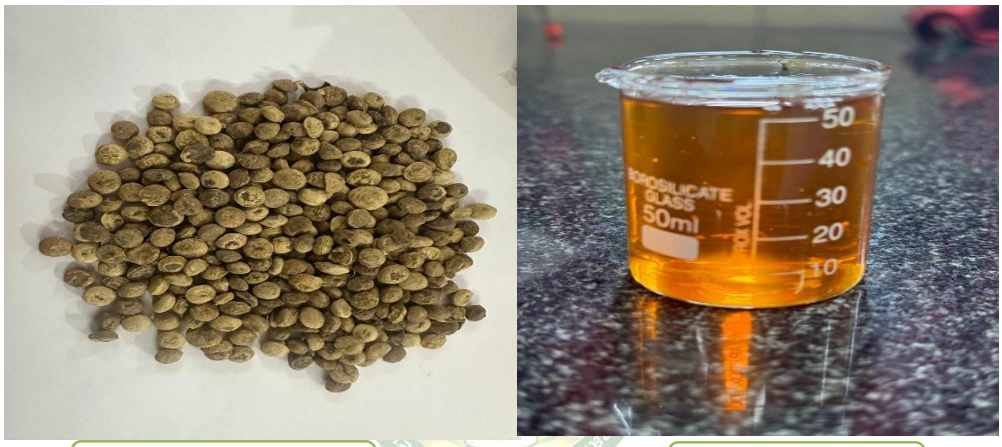
Additionally, there is currently a demand for safe and efficient medications that can treat allergic conjunctivitis due to the shortcomings of many existing treatments. Scientific verification of the safety and effectiveness of a large number of indigenous medications is necessary, as there are numerous claims of their diverse use in treating a wide variety of ocular ailments. Over fifty plant-based ophthalmic medicines and over forty metals and minerals with a variety of pharmacological effects on the visual system and the adnexa of the eye are documented in Ayurvedic literatures. [4-6]

Kataka (Strychnos potatorum Linn), *Madhu* (Apis indica), *Karpura* (Cinnamomum Camphora), include of a few of these medicinal plant sources that may be useful in treating ocular allergy diseases like conjunctivitis. These claims are substantiated by textual references from Ayurvedic literatures (Sharangdhar, Uttar Khand 13/104), as well as by experimental and clinical research. A study intervention comprising of use of *Strychnos potatorum*[7] *& Cinnamomum Camphora*[8] exhibits anti-inflammatory properties whereas Apis *melifera*[9] have shown notable analgesic and anti-inflammatory action by inhibiting prostaglandin synthesis and wound healing properties[10] ingredients are used to formulate the eye drops, which are developed in accordance with Indian Pharmacopeia (IP, 1996), meeting quality standards and other requirements like particulate matter, pH, sterility test, isotonic to lacrimal fluid, permissible preservatives.[11-12]

METHODOLOGY AND OBSERVATIONS

Raw drug identification and quality assurance: Raw ingredients viz., seeds of *Kataka* and *Madhu* procured from authentic market sources. Camphor is extract through clevenger apparatus by using hydro distillation process. (fig 1) The identity was confirmed with compliance of microscopic, macroscopic parameters of Ayurvedic Pharmacopoeia of India (API) through pharmacognosy studies.[13] The purity and strength were also confirmed through physico-chemical studies done as per "Protocol For Testing of ASU Drugs (2008')", Pharmacopeia Laboratory for Indian Medicine, Ministry of AYUSH, Govt. of India and compliant with parameters of Ayurvedic Pharmacopoeia of India (API).[14]

Figure 1: Samples of Ingredients of Eye Drop



Kataka **Honey**

Karpura

Table 1: Pharmacognosy of *Kataka*

S.No	Test	Results
1.	**Morphology**	Green colour fine powder with characteristics odour and taste.

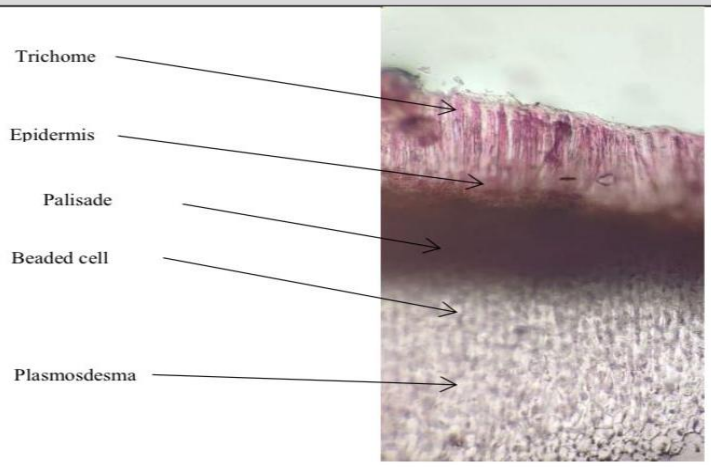
Figure 2: Showing Pharmacognosy of *Kataka*

MORPHOLOGY

Green color fibrous powder with characteristic odor and taste.

Kataka (*Strychnos potatoru*) Seed

MICROSCOPY STUDY



T. S. of Kataka (Strychnos potatoru) Seed

Table 2: Gas Chromatography of Camphor

S.No	Test	Results
1.	Purity	95.88%

Table 3: Identification Test of Honey

S.No	Test	Results
1.	Fiehe's Test	Negative
2.	Hydroxy Methyl Furfural	Negative

Standard Operating Procedure for Eye Drop

Development & Analytical

Firstly make the decoction of *Kataka* by adding 16 times of water and reduced to 1/8th than add honey to it. Following that, the weighed amount of camphor was placed in a glass tube together with honey and an aqueous extract of *Kataka*. Polysorbate 80 was then added, and the tube was placed on the vortex shaker to completely dissolve the camphor. Filter the solution with Whatman filter paper number, measured the solution's pH and viscosity, which came out to be 6.2 and 20.70 cps, respectively. To evaluate for any changes in any of the parameters, the solution was moved to a conical flask, sealed with a lid, and left for seven days. The solution's pH was 3.96 after seven days, and its viscosity stayed the same. After that, 800mg of monobasic sodium phosphate and 947mg of disodium phosphate were dissolved in 100 milliliters of deionized water with 0.52g of sodium chloride to maintain the appropriate tonicity. From the buffer made in Pt. no. 7, 90 milliliters of monobasic sodium phosphate and 10 milliliters of disodium phosphate were collected for a pH of 5.9. The pH of the buffer solution reaches six after adding 10ml. A preservative called benzoalkonium chloride was added. The entire mixture was put into a conical flask, which had a lid tightened on it. Eye drop solution and empty LDPE containers were placed in an autoclavable disposable bag and autoclaved for 15 minutes at 121°C. To prevent contamination, transfer the solution using 10ml syringes and a laminar flow to a micro-filter (0.02µm) before filling low-density polyethylene

containers. The solution was then set away for a month to observe changes in viscosity and pH in order to evaluate how well the preservative was functioning. There's no need to top up or switch out the preservative if the physio-chemical properties remain the same. After one-month pH of the solution remains the same, but viscosity decreases to 13.

Table 4: Analytical Test of Eye Drop

S.No	Physio-chemical analysis	Results
1.	Appearance	Yellow colour clear liquid
2.	Odour	Aromatic
3.	PH	6.00
4.	Specific Gravity	1.077
5.	Viscosity	13cps
6.	Clarity Test	Clear
7.	Sterility Test	PASS
Heavy Metal Analysis		
8.	Lead	Not detected
9.	Cadmium	Not detected
10.	Mercury	Not detected
11.	Arsenic	Not detected
Microbial Contamination		
12.	Total Microbial Plate Count (TPC)	< 10 cfu/g
13.	Total Yeast & Mould Count (TYMC)	Absent
Test For Specific Pathogen		
14.	*Staphylococcus aureus*	Absent
15.	*Salmonella sp.*	Absent
16.	*Pseudomonas aeruginosa*	Absent
17.	*Escherichia coli*	Absent

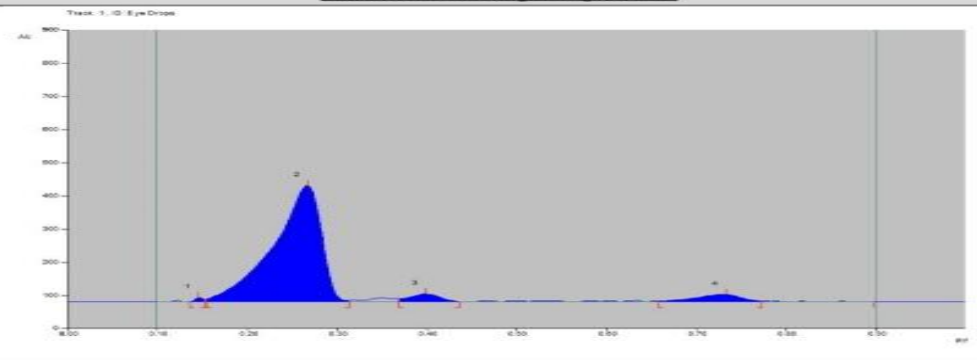
Table 5: Sterility Test of Eye Drop

Name of Media	Observations: (D: 14/03/24 to D: 29/03/24)													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Control (FTGM)	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Control (SCDM)	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Sample (FTGM)	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Sample (SCDM)	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Table 6: HPTLC Fingerprinting of Eye drops

Track	Observation under UV Radiation					
	254 nm		366 nm		540 nm	
	No. of spots	Rf value	No. of spots	Rf value	No. of spots	Rf value
Eye Drop	04	1. 0.15 2. 0.27 3. 0.40 4. 0.73	1	1. ND	2	1. 0.27 2. 0.73

HPTLC Chromatogram @ 254 nm



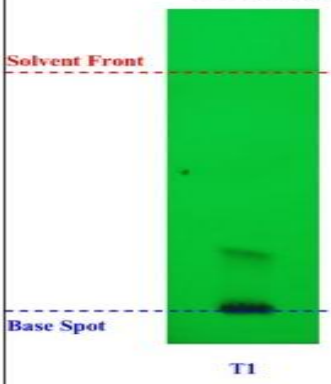
2D Chromatogram

R_f value

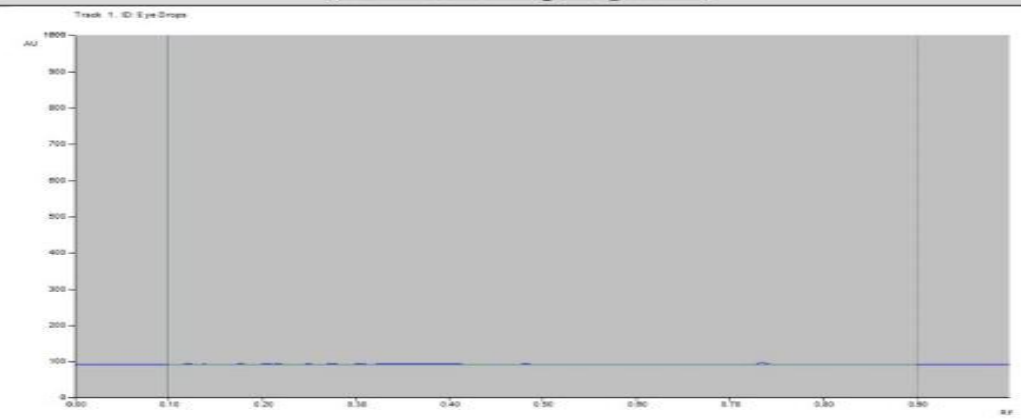
Spot No.	Track T1
1	0.15
2	0.27
3	0.40
4	0.73

Track T1 : Eye Drops

HPTLC Plate



HPTLC Chromatogram @ 366 nm



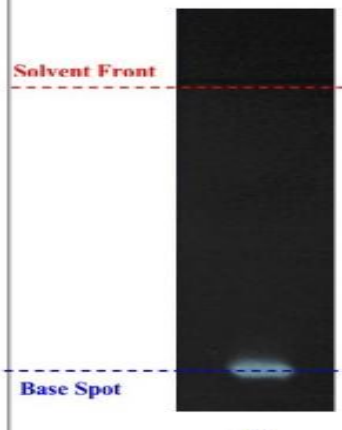
2D Chromatogram

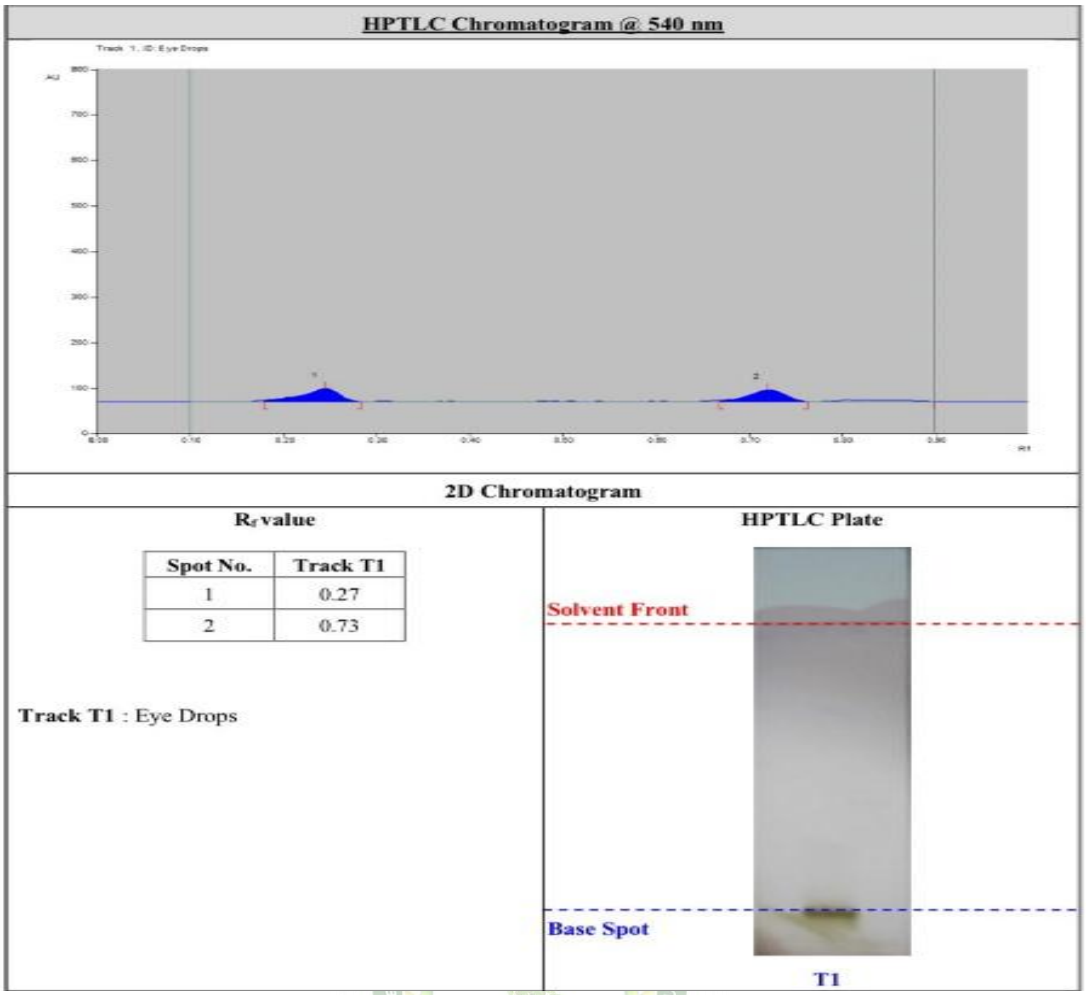
R_f value

Spot No.	Track T1
1	ND

Track T1 : Eye Drops

HPTLC Plate





Pre-Clinical Studies: Acute eye irritation tests showed that the eye drops did not irritate the albino rabbit's eyes' ocular mucous membranes, causing no obvious signs of toxicity or causing opacity and ulceration of the cornea, congestion, swelling, or hyperemia, or causing hemorrhage of the conjunctiva and sclera, destruction of the iris, or chemosis of the lids. Furthermore, it was discovered to be essentially non-irritating to the rats' eyes during the three-week observation period following application, with no clinical indicators of mortality or changes in body weight seen.

CONCLUSION

Despite significant technological advancements in ophthalmic medicine and surgery, conservative treatment remains the cornerstone for treatable conditions. Researchers are always searching for plants, metals, and minerals with medicinal properties, and often they are successful in turning over a new leaf. However, there are a number of difficult issues that existed before modern ophthalmologists that need special attention to develop uncharted medical knowledge hidden in ancient medical texts. Although clinically effective, a modern approach to treating allergic conjunctivitis presents certain difficulties and limitations. Taking these factors into account, it is crucial to translate some potential leads for managing allergic conjunctivitis as detailed in Ayurvedic texts into user-friendly, safe, and quality assured dosage forms to improve treatment.

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***Address for correspondence**
Dr. Gargi Verma
PG Scholar
PG Department of Rasa Shastra and Bhaishajya Kalpana,
Uttarakhand Ayurved University,
Rishikul Campus, Haridwar,
Uttarakhand.
Email: svssssverma8@gmail.com