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RESEARCH ARTICLE

STANDARDIZATION OF AN AYURVEDIC HERBAL EYE DROPS FOR ALLERGIC CONJUNCTIVITIS

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Abstract

Ayurvedic literatures recount potential ophthalmic drugs for the management of allergic conditions of eye. The drugs such as *Zingiber officinale,Cedrus deodara,Cyperus Rotundus, Jasminum officinale* are described by *Sushruta Samita* in *Khaphaja Abhisyanda*, an etymologically and clinically similar entity to allergic conjunctivitis, attributed with potential anti-inflammatory, anti-allergic and wound healing activities based on scientific evidences. With this rationale background, an *Ayurvedic* eye drops was developed for allergic conjunctivitis systematically following contemporary methods and parameters right from quality assurance of ingredients, formulation of standard operation procedures and also complying with the quality and safety standards of finished product for ophthalmic preparation as specified in Indian Pharmacopeia. The pre-clinical ocular toxicity studies also revealed safety of this formulation on topical use.

INTRODUCTION

Ocular allergy manifests as a number of distinct disease entities, ranging from allergic conjunctivitis, a relatively mild condition, to keratoconjunctivitis, a sight-threatening condition affecting the cornea. Underlying immune mechanism responsible have not yet been fully understood, but it is known that IgE related mast cell and eosinophil mediated inflammation leads to the release of mast cell mediators and toxic eosinophil granule protein and enzymes.[1] Ocular allergy affects approximately 15% of world population and its incidence in increasing in industrialized countries.[2] Patients suffering from ocular allergy might experience such symptoms as redness, itching, burning, swelling or dryness in eyes in differing degrees of severity and duration.

Some people might only be affected for a few weeks, while others may experience symptoms continuously throughout the year. Thus, ocular allergy potentially affects patients, in their daily life activities, there by impacting their health related quality of life[3]. Allergic conjunctivitis can be treated with a variety of medication, including topical antihistamines, mast cell stabilizers, NSAIDS drugs and corticosteroid. Surgical intervention may be indicated in severe case of VKC and AKC. All these drugs do not have any effect on basic pathophysiology, they provide only symptomatic relief and having so many side effects like delayed wound healing, secondary infection, elevated IOP and formation of cataract. So there is need to search a potent, safe and cost-effective *Ayurvedic* herbal eye drop for allergic conjunctivitis.

BASIS FOR FORMULATION HERBAL EYE DROPS

Owing to limitations of different conventional agents it is at this juncture that the need for safe and effective drugs that could effectively tackle allergic conjunctivitis. A vast number of Indigenous drugs coupled with innumerable claims of their varied uses in alleviating wide range of ophthalmic affections calls for scientific validation for their safety and efficacy. *Ayurvedic* literatures record more than fifty ophthalmic plant drugs and more than forty metals minerals having diversified pharmacological actions on visual system and Adnexa of the eye. [4, 5, 6]

Shunti (*Zingiber officinale*), Devdaru(*Cedrus deodara*), Mustak (*Cyperus rotundus*) and Jati mukul (*Jasminum officinale*) and *Saindhava Lavana* are some of such medicinal plant sources having potential leads in the management of ocular allergic conditions such as conjunctivitis, supported by textual references from Ayurvedic literatures(Sushruta samhita uttar tantra 11/18) backed by experimental and clinical studies. A study intervention comprising of internal use of *Zingiber officinale* has shown potent anti-inflammatory property[7]. Similarly *Cyperus rotundus*[8] *Cedrus deodara*[9] and *Jasminum officinale*[10] have shown notable anti-inflammatory action by inhibiting prostaglandin synthesis. In spite of this Cedrus also possess mast cell stabilizing[11] activity and Cyperus rotundus[12] and jasmine[13] have potent wound healing activity. The eye drops is formulated with these two plant ingredients and developed as per Indian Pharmacopeia (IP, 1996) complying quality standards and other parameters such as isotonic to lacrimal fluid, particulate matter, pH, Sodium chloride content, sterility test besides permissible preservatives and packing specifications etc.[14,15]

METHODOLOGY AND OBSERVATIONS

Raw drug identification and quality assurance: Raw ingredients viz. rhizome of Shunti and mustak, bark of Devdaru and Jati mukul procured from authentic market sources **(fig-1).**

The identity was confirmed with compliance of microscopic, macroscopic parameters of Ayurvedic pharmacopoeia of India (API) through pharmacognosy studies**.**[16] 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. India [17]and compliant with parameters of Ayurvedic pharmacopoeia of India(API***).***

Fig.1-Samples of ingredients of Herbal Eye Drops

Jati Mukul *(Jasminum officinale)*

Shunti Rhizome *(Zingiber officinale)*

Devdaru Bark *(Cedrus deodara)*

Mustak Rhizome *(Cyperus rotundus)*

Table-1.Physio-chemical Studies of *Shunti (Zingiber officinale)*

Serial no.	Parameter	Results
1	Total ash	6%
2	Water soluble extract	10%
3	Alcohol soluble extract	4.5%
4	Acid insoluble ash	2%

Table-2.Physio-chemical Studies of *Mustak (Cyperus rotundus)*

Serial no	Parameter (%w/w)	Results
1	Total ash	12.87
2	Acid insoluble ash	4.56
3	Water soluble ash	6.4
4	Sulphated ash	10.22

Table-3 Physio-chemical Studies of Devdaru (*Cedrus deodara)*

Serial No.	Parameter (%w/w)	Results
1	Total ash	1.51
2	Acid insoluble ash	0.43
3	Water soluble ash	0.83
4	Alcohol soluble extract	4.95

Table-4 Physio-chemical Studies of Jati (*Jasminum officinale)*

Serial No.	Parameter	Results
1	Total ash	10.89
2	Acid insoluble ash	1.29
3	Water soluble ash	2.92
4	Loss on drying	4.25

Standard Operative Procedures (SoPs) for eye drops development and analytical

Specifications: The step wise development of eye drops encompass the preparation of distillate, making of the distillate isotonic to lacrimal fluid and adjustment of pH, addition of preservative and packing under sterile conditions. 50g powder (particles passed through 40- mesh) of each of rhizome of Shunti(*Zingiber officinale*), rhizome of Mustak (*Cyperus rotundus*), bark of Devdaru (*Cedrus deodara*) and Jati-mukul (*Jasminum officinale*) of pharmacopeia quality was soaked in 3.2 liters of distilled water for overnight in an air tight container. The material was transferred to a distillation unit. Distillate was obtained by adjusting the temperature to 40oC for 15 minutes and raising the temperature slowly to 80o C. The first 450 ml. of distillate was collected at the rate of 20 drops per minutes in anairtight container. The distillate was made isotonic to lacrimal fluid by adding 0.9% NaCl to distillate and dissolving properly and adding isotonic phosphate buffer viz. 0.16 g. of monobasic Sodium phosphate and 0.76g of dibasic Sodium phosphate. Finally the pH of the eye drops was adjusted to 6.9-7.30. Benzalkonium chloride in a ratio of 1:10000, was added as preservative and pH was again checked and found within the specified range of the ophthalmic drops (pH 6.9-7.30). Test for sterility performed after addition of preservative the preparation was observed for 48 hours, and found sterile. The packing was made in autoclaved sterilized amber glass containers of 10 ml Capacity**.** The finished product tested for quality assurance and safety and the analytical specifications complied specified parameters of Indian pharmacopeia for ophthalmic preparations (**Table-5).**

Table-5 Analytical Specifications of Herbal eye drops

Descriptions	Colorless clear solution with mild characteristic odor
Particulate matter	Passes as per Indian Pharmacopeia, 1996. (when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by unaided eye.)

Identification	Passes *Liberman Burchard* test Extract 10 ml. eye drops in vol. of extract to one ml. add one drop of acetic anhydride and keep it for a drop of conc. Sulphuric acid from the side of test tube a violet color ring appears at the junction of two liquids which disappear gradually
pH	6.9- 7.3
Sodium chloride Content (%)	0.85-0.95% w/v

Preclinical Safety studies: Acute Eye Irritation tests revealed that the eye drops did not cause irritation to ocular mucous membrane of eyes of rats such as opacity and ulceration of cornea; congestion, swelling, hyperemia; hemorrhage of conjunctiva and sclera, any destruction of iris; chemosis of lids etc .and no evident signs of toxicity were observed. Further, no clinical signs of mortality and change in body weight were noticed during the observation period of 72 hours of post application, was found to be practically nonirritant to the eyes of rats.

CONCLUSION

In spite of great technological advances in the field of ophthalmic medicine and surgery, conservative therapy still continues to be mainstay for reversible ailments. Researchers are relentlessly in quest to identify plants metals and minerals with medicinal properties. Often they are successful, proverbially, in turning over a new leaf. At the same time, there are numerous challenging problems, existing before modern ophthalmologists that require special attention to develop unexplored fields of medical knowledge hidden in ancient medical texts. A contemporary management strategy of Allergic conjunctivitis though clinically effective poses certain challenges and limitations. Considering this, it is pivotal to translate some potential leads for management of allergic conjunctivitis as detailed in Ayurvedic texts into user friendly safe, effective and quality assured dosage forms to improve patient's compliance. The herbal eye drops developed certainly contribute significantly in the management of allergic conjunctivitis.

REFERENCES

1. Bhargava A, Jackson WB "Ocular allergy disease", Drugs Today 1998, 34 : 957-971.
2. Wood B. "New treatment to relieve ocular allergies", Rev. Optom 1999, 136 : 124-135
3. Walt J, Jojcik A, Buccholz P, "Initial development and validation of the eye allergy patient impact questionnaire (EAPIQ)". In poster presented at the annual meeting of the International society for Quality of life research Oct. 30- Nov. 2 USA 2002.
4. N Srikanth, The Actions and uses of Indigenous Ophthalmic Drugs, chaukhambha Sanskrit Prakation, Delhi, 2000.
5. N. Srikanth, A.K. Mangal and G.S.Lavekar, An Insight on Indigenous Ophthalmic Medicinal Flora: An Ayurvedic Pharmacological Basis; Bulletin of Medico- Ethno-Botanical Research.. 2005; Vol .XXVI: No.3-4, 65-74.
6. N. Srikanth, A.K.Mangal and G.S.Lavekar, "Scientific Exposition on Medicinal plants indicated in Painful ophthalmic conditions: An Ayurvedic pharmacological perspective", Journal of Drug Research in Ayurveda and Siddha, 2007; Vol .XXVIII: No-3-4, 26-42.
7. Rajiv, Udoh US, Oluwdara OO, Ades hogy K, "Anti-inflammatory and analgesic properties of rhizome extract of *Zingiber officinale*", Afr J Biomed Res. 2002, 5,121-124
8. Gupta MB, Singh N, Bhargava KP, "Anti-inflammatory activity of active constituents of *Cyperus rotundus"* Indian J Med Res 1970; 2: 23-26
9. U.A.Shinde et al, "Studies on anti-inflammatory and analgesic activity of *C.deodara* woodoil" Journal of Ethno pharmacology 65(1999) 21-27
10. Fulzele SV, Sattkrwar PM. Joshi SB, Dorle AK, "Studies on anti- inflammatory activity of poly herbal formulation *Jatyadi Ghrita*" Indian Durgs 2002; 39(1): 42-44

11. U.A Shinde, "Membrane stabilizing, a possible mechanism of action for anti-inflammatory activity of *C.deodara* woodoil", Fitoterapia, 70, 1999:251-257

12. Puratchikody A, Devi Nithya C, Nagalakshmi G. "Wound healing activity of *Cyperus rotundus*" linn. Indian journal of pharmaceutical sciences 2006; 68: 97-101

13. Nayak BS, Krishna M. Influence of ethanolic extract of *Jasminum officinale* Linn. Flower on wound healing activity in rats. Indian J Physio Pharmacol 2007; 51 (2): 189–194

14. N. Srikanth, Ancient Ocular Therapeutics- an integrated approach, Ayur Medline, 1999; 1: 93-103.

15. N. Srikanth, R.M. Anand and K.D. Sharma, Standardization and Development of New Ayurvedic ophthalmic Drugs (with special reference to ocular pharmacology) – An Urgent Need Bulletin of Medico- Ethano- Botanical Research, July-Dec 2000; Vol.XXI, No.3-4: 81-89.

16. Anonymous Ayurvedic Pharmacopoeia of India, Department of AYUSH, Ministry of Health and Family Welfare, Government of India, Part-I, Vol-I, First Edition, 1986; 168-169.

17. Lohar and Ravindra Singh, Protocol For Testing of ASU Drugs, Pharmacopeia Laboratory for Indian Medicine, Department of AYUSH, Govt. India, 2008.

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