Original Research Paper

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EVALUATION OF THE OCULAR SAFETY AND THERAPEUTIC EFFECT OF YASHTI-SARIVA EYE DROPS IN ANIMAL STUDY (RABBITS).

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ABSTRACT **Background:** Yashtimadhu(Glycyrrhiza glabra) and Sariva (Hemidesmus indicus) are described in Ayurveda as Chakshushya, Rasayana, Pitta-Raktahara and Vranaropaka drugs. Their phytochemicals (glycyrrhizin, liquiritin, hemidesmin, saponins, flavonoids) possess antioxidant and anti-inflammatory activity, making them promising candidates for ophthalmic formulations. However, any new eye drop requires preclinical ocular safety and efficacy evaluation in animals before human trials. **Materials and Methods:** In this animal study 3 rabbits were studied . Management: the eyes of the rabbits carefully observed for 7 days. **Results:** the animal study shows no irritations. **Conclusion:.** This Animal study is the major milestone for human trials.

KEYWORDS : Dry eye, Eye drops, Animal study.

INTRODUCTION

Dry eye occurs when there is inadequate tear volume or function resulting in An unstable tear film and ocular surface disease.

Yashtimadhu being a best Chakshushya dravya locally and Sariva is the Best drug to be effective in corneal layers healing .Both plant drugs are attributed best with potential anti-inflammatory, anti-allergic and wound healing activities backed by scientific evidences. Any new drop requires preclinical ocular safety and efficacy evaluation in animals before human trials .

AIM: To evaluate the ocular safety and therapeutic efficacy of Yashti–Sariva eye drops in an experimental rabbit model.

Animal Study Details W.r.t Dry Eye.

1.1Objective

The objective of this study is to evaluate the acute eye irritation potential and ocular toxicityof Yashti-Sariva eye drop in Rabbits.

1.2 To study the anti-inflammatory effect in induced conjunctival congestion.

2.0 MATERIALS

2.1 Test Item Details

Name	:	Yashti-Sariva eye drop
Physical Appearance	:	Transparent Liquid
pH	:	6.9
Storage conditions	:	Room Temperature
Handling Precautions	:	Standard Laboratory Precautions

3.0 Experimental Procedures

3.1 Animal Welfare

All procedures of the this study were in accordance with the protocol set forth and approved by IAEC Committee under the Project Proposal No.: SC/IAEC/2024/036and the guidelines provided by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) as published in The Gazette of India, December 15, 1998. Prior approval of the Institutional Animal Ethics Committee (IAEC) is in place IAEC-17-015.

Species	:	New Zealand White Rabbit (Oryctolagus cuniculus)
Sex	:	Male
Age	:	3-4 months
Initial Body Weight	:	1.7-2.0 kg
Environmental Conditions	:	Room temperature maintained between 21+3ºC; Relative humidity 50±5 and illumination cycle set to 12 hours light and 12 hours dark.
Accommodation	:	1 Rabbit per cage was housed in a single stainless-steel cage with facilities for food and water bottle.
Diet	:	Standard Pelleted feed (Maintenance Diet).
Water	:	RO Water

3.2 Preparation of the Dose Formulation

Test substance was in the form of ready to use eye drop. Therefore, it was used as it is.

3.3 Experimental Design

Three New Zealand White Rabbits were used to evaluate the eye irritation potential of formulation. 60 minutes before application of test sample, systemic anaesthetic (Buprenorphine 0.01 mg/kg by SC route) was administered. 0.5% Proparacaine hydrochloride was used to ocular region five minutes prior to application of test substance. Eight hours after application of test substance, Buprenorphine 0.01 mg/kg and Meloxicam 0.5mg/Kg injected by subcutaneous route.

A volume of 0.10 ml of the test material was applied to the one conjunctiva sac of one New Zealand White Rabbits for determination of severity and reversibility before proceeding to a confirmatory test in a next animal. The other site was served as Control. The experiment was conducted in similar manner in other two animals as there was no irritation observed in first animal till 72 hr after instillation of test item.

3.4 Clinical Observations and grading of eye reactions

The eyes of the rabbits were carefully examined and observed at 1 hr, 24 hr, 48 hr and 72 hr post application and the observations extended to determine the reversibility or irreversibility till the end of the observation period of minimum 7 days.

3.5 Evaluation of Results

Based on clinical observations and grading of ocular lesions as per **Table *I*** observations were recorded.

Table 1 Grading of Ocular Lesions

CORNEA	Grade
Opacity: degree of density (readings of most dense area)	
No Ulceration or Opacity	0
Scattered or diffuse areas of opacity (other than slight dulling of normal lustre), details of iris clearly visible	1
Easily discernible translucent area; details of iris slightly obscured	2
Nacreous area, no details of iris visible; size of pupil barely discernible	3
Opaque cornea; iris not discernible through the opacity	4
Maximum possible: 4	
IRIS	Grade
Normal	0
Markedly deepened reggae, congestion, swelling, moderate circumcorneal hyperaemia; or injection; iris reactive to light (a sluggish reaction is considered to be an effect)	1
Haemorrhage, gross destruction, or no reaction to light	2
Maximum possible: 2	
CONJUNCTIVAE	Grade
Redness (Refers to palpebral and bulbar conjunctivae; excluding cornea and iris)	

Normal	0
Some blood vessels hyperaemic (injected)	1
Diffuse, crimson colour; individual vessels not easily discernible	2
Diffuse beefy red	3
Maximum possible: 3	
CHEMOSIS	Grade
Swelling (refers to lids and/or nictating membranes)	
Normal	0
Some swelling above normal	1
Obvious swelling, with partial eversion of lids	2
Swelling, with lids about half closed	3
Swelling, with lids more than half closed	4
Maximum possible: 4	

- The reaction was evaluated in terms of Maximum Mean Total Score as per following formula,
- Maximum Mean Total Score = (Score of Cornea X 5) + (Score of Iris X 5) + Score of Conjunctive (Chemosis + Redness) X 2
- The test item is classified as per GHS classification as indicated in Table 2.

Table 2 Classification of Eye Irritation Scores from the Draize Eye Irritation Test

MMTS	Irritation Classification
0.0-0.5	Non-irritative
0.6-2.5	Practically non-irritative
2.6-15.0	Minimally irritative
15.1-25.0	Mildly irritative
25.1-50.0	Moderately irritative
50.1-80.0	Severely irritative
80.1-100.0	Extremely irritative
100.1-110	Maximally irritative

*MMTS: Maximum Mean Total Score

4.0 RESULTS

4.1 Change in Body Weight

Body weights of each animal were recorded prior to the test item administration (Day 0) and on Day 3 and Day 7 of the experiment. Body weights changes are indicated below.

Table 3 Body Weight

Animal	Sex	Body Weight (Kg)		
		Day 0	Day 3	Day 7
1	Male	1.910	2.060	2.190
2		1.890	2.030	2.140
3		1.865	1.995	2.115
Mean		1.888	1.888	2.028
±SD		0.023	0.023	0.033

4.2 Observations for Ocular Lesion

All the animals were carefully observed for Ocular lesions and their observations were recorded as shown below.

Table 4 Grading of ocular lesions: Cornea

Animal	1 hr		24 hr		48 hr		72 hr	
	T	C	T	C	T	C	T	C
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
Total Score	0	0	0	0	0	0	0	0

Table 5 Grading of ocular lesions: Iris

Animal	1 hr		24 hr		48 hr		72 hr	
	T	C	T	C	T	C	T	C
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
Total Score	0	0	0	0	0	0	0	0

Table 6 Grading of ocular lesions: Conjunctivae

Animal	1 hr		24 hr		48 hr		72 hr	
	T	C	T	C	T	C	T	C
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
Total Score	0	0	0	0	0	0	0	0

Table 7 Grading of ocular lesions: Chemosis

Animal	1 hr		24 hr		48 hr		72 hr	
	T	C	T	C	T	C	T	C
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
Total Score	0	0	0	0	0	0	0	0

Table 8 Maximum Mean Total Score

Animal	1 hr		24 hr		48 hr		72 hr	
	T	C	T	C	T	C	T	C
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
Total Score	0	0	0	0	0	0	0	0

Based on the above Table 8Scores, the test material "Yashti-Sariva eye drop" has shown Maximum Mean Total Score of 0.0 indicating non-irritative category.

4.3 Clinical Observations

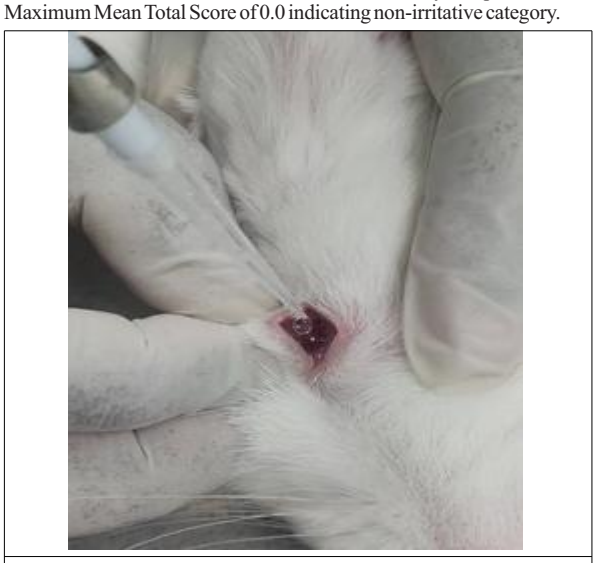
During the study animals were evaluated for cage side observations and clinical observations. The changes in clinical observations are indicated in terms of AG: Abnormal Gait; AP: Abnormal Posture; AI: Any other signs of illness; HL: Hair Loss; LC: Lacrimation; LM: Lameness; LT: Lethargy; ND: Nasal discharge; PD: Physical deformities; SL: Salivation; TR: Tremors/convulsions; UR: Urination; NC: No clinical changes observed; and D: Dead. The summary of clinical observation is given in Table 9.

Table 9 Clinical Observations

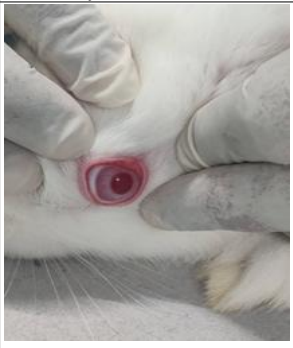
	Animal	Hr					Days						
		0 hr	1/2 hr	1 hr	2 hr	4 hr	1	2	3	4	5	6	7
Step -1	1	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
	2	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
	3	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC

4.4 Evaluation of Results

Based on the scores, the test material "Yashti-Sariva eye drop" has shown Maximum Mean Total Score of 0.0 indicating non-irritative category.



Test Item Application Eye	Control Eye



DISCUSSION:

Rabbits are the most commonly recommended species for ophthalmic toxicity testing because of their large ocular surface and standardized ocular examination methods.

CONCLUSION

A well-designed rabbit study can establish the ocular safety of Yashti–Sariva eye drops, providing the necessary preclinical evidence before clinical evaluation in humans. Current ophthalmic toxicology literature supports rabbits as the preferred species for ophthalmic local eye drop studies .This study ensures the major gateway towards ocular therapeutics.

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