eurofins | Dermatest

Ophthalmologist Testing 50 Subject

STEPS

1. Product Sample Application

Skin Grading (Eye Area):

0 - no reaction
1+ -Weak (non vesicular) showing erythema, infiltration and possible papules
2+ -Strong reaction with vesicles in addition to erythema and infiltration
3+ =Extreme reaction, bullous or ulcerative
Eye Grading:

0 = no reaction
1+ =conjunctivae (palpebral and bulbar) injected above normal with possible chemosis(swelling);no discharge
2+ =conjunctivae injected above normal; obvious swelling; possible discharge.
3+ =conjunctivae more diffuse, deeper crimson red, individual vessels not easily discernible; excessive swelling and/or discharge.

Only panelists with initial scores of "0" will be admitted to the study.

Objective To evaluate the safety of an eye area use product under exaggerated use conditions.

Products
Designed for areas too distal from surrounding eye involvement will generally be disqualified by the physician, i.e. declotte creams, hair line acne products etc.

Experimental Design
Subject's eyes and eye area, including eye lids, will be checked for irritation, scaling and edema.
1. Demographics Female population n = 60 Age - 14 to 55 years
2. Inclusion Criteria General good health Completed medical history, screening and informed consent document.
Willingness to cooperate with study requirements
3. Exclusion Criteria - Pregnant or lactating
Patients with known allergies or skin and/or eye conditions which would interfere with the study at the discretion of the Study Director.
Patients under the care of a physician Patients currently taking medication
Patients will be instructed to keep a log(Appendix D) noting date and time of each application together with any
subjective comments.

Fifty healthy female subjects willing to use the test product as indicated twice (2X) daily for 28 days, will be recruited. Subject age will range from 14-55 years with approximately 30 or more panelists between the ages of 18 and 30. Approximately 50 % of the population can be contact lens wearers.

Participants will be instructed to use the test product twice daily for 28 days and to return to the lab 7, 14, 21 and 28 days post commencement for evaluation. At 0 time and on day 28 subjects will be examined by an ophthalmologist. On day 7, 14 and 21 a trained technician will conduct the scoring. Graders will score for signs and symptoms of objective irritation and/or sensitization. Patients will also report subjective comments relating to product use and user perceived after feel if any.

Sample Requirements
Individual pack/s for each participant, sufficient to provide 56 applications of the product to the target area.
Typically, this would be 25 to 50 gms of product for each test subject, depending on the area of application.

References
Wilkinson, et al: Terminology of Contact Dermatitis, ACTA Dermatovener (Stockholm) 50:287-292, 1970
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Assoc. Food and Drug Officials of the U.S. Austin, Texas, 1959
References

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