

# A Proof-of-Concept, Efficacy Study of Test Products for Long Lasting Effect in Healthy Human Female Subjects

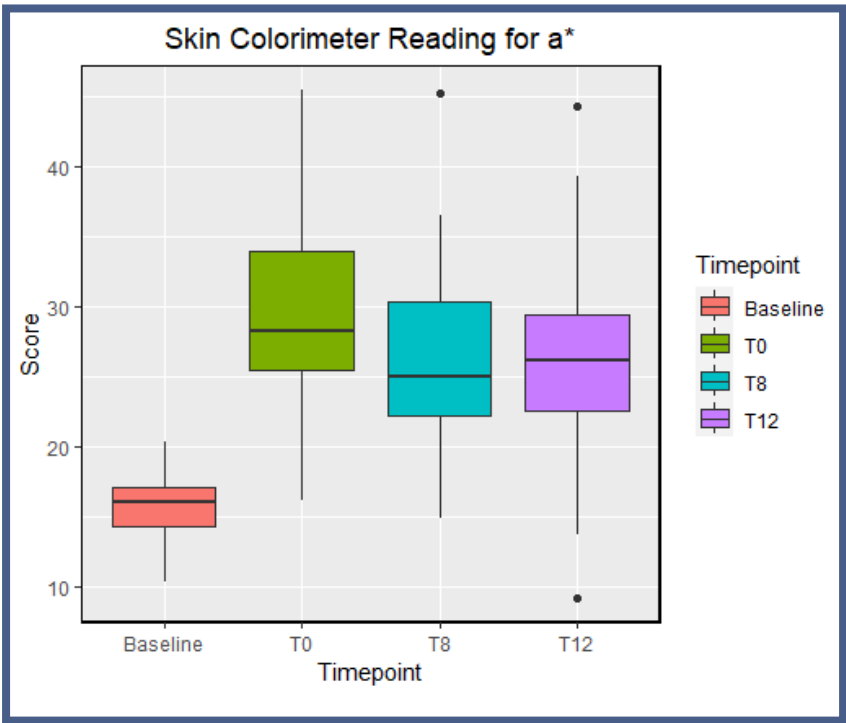
### Experimental Design

It was an open-label, a single-arm, single-center, proof-of-concept, and efficacy, clinical study. The objective of this study was to evaluate the determine the efficacy of test products for Long Lasting Effect in Healthy Human Females Subjects. A total of 32 female subjects ages 18 to 47 years were enrolled, and 32 subjects have completed the study. This clinical trial has been registered at CTRI [Clinical Trial Registry of India] with the Trial Registered number is CTRI/2022/12/048122 [Registered on: 14/12/2022].

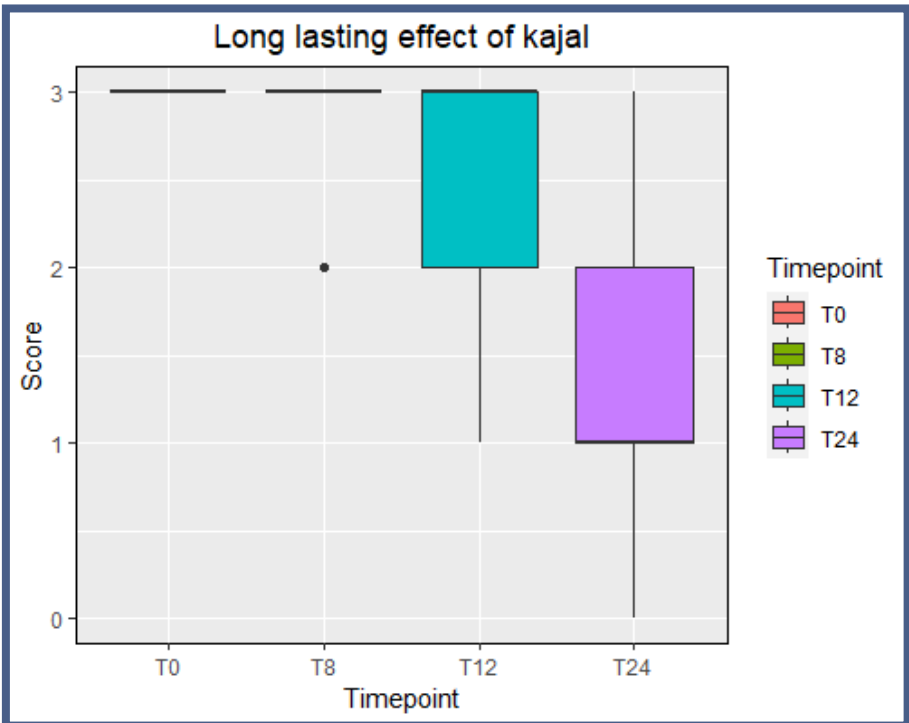
### Methodology

Subjects with good general health as determined from recent medical history determined by the Investigator. The subjects were instructed to apply test product starting from the centre of the upper lip, move towards the corner of the lip. Repeat the same with your bottom lip and press them together for a full coverage. They were also instructed to apply another test product starting with the inner corner of the eye and gently move outwards on the upper lid. Repeat on the lower lid. The application of the test products was started in the morning. The subjects were in-house at the facility from pre-application to 12 hours post application of the test product. The test products were taken back from the subject post application. The test products were kept in separate zip lock bags numbered as per subject number in a secured area. The test product was distributed to the subjects after the completion of the study.

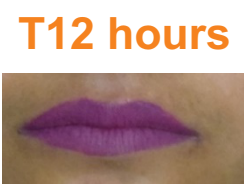
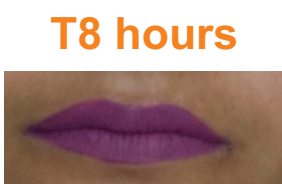
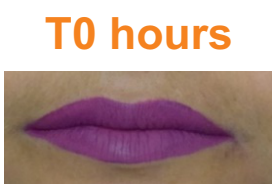
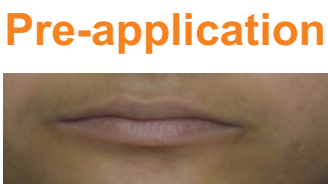
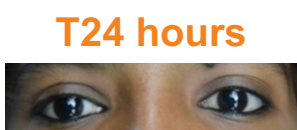
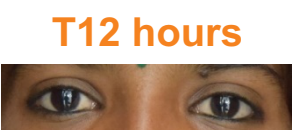
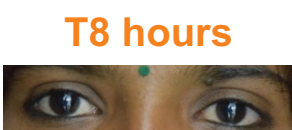
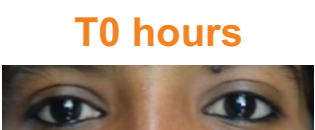
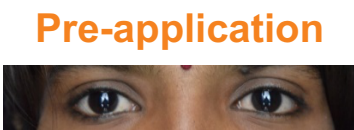
Assessment of efficacy parameters was done before application of the test product, after product application at T0 hour (within 15 min of application), T8 hour and T12 hour for both the test product. The additional timepoint for one of the test product was T24 hour post application. One of the test product was evaluated for its long- lasting effect, matte finish & non-cakey, hydration, non-transfer feature whereas another test product was evaluated for long-lasting effect, smudge-free feature, and safety. Upon completion of the Clinical Phase of the study, all raw data were reviewed, and an excel spreadsheet with raw data was shared with Biostatistician. Statistical analysis was performed by Biostatistician Team. There were no adverse events reported by the subjects/parents, nor by the Investigator throughout the study period.



In the clinical trial, T0 (within 15 min), T8 hours, and T12 hours of test product application, the a\* values show no significant reduction with  $P<0.01$  concluding the long-lasting effect of the test product for up to 12 hours.



There was a statistical difference observed during visual assessment for the long-lasting effect of test product at T24 hours with  $P<0.01$  from baseline. This shows the test product had a long-lasting effect for up to 24 hours.



### Overall Conclusion

As per the Investigator and study evaluator, the test products were found to be efficacious in healthy human adult subjects (18 – 50 years) with 100% well-being. Wearing makeup can give individuals a confidence boost by making them feel more physically attractive, increasing feelings of self-esteem, attitude, and personality. The test products can be an integral part of any make-up. The test product was long-lasting for up to 24 hours, smudge-proof, and safe on eyes with no inflammation of bulbar conjunctiva, inflammation of palpebral conjunctiva, lacrimation, and any eye discomfort. The another test product lasts long up to 12 hours, was transfer-proof, had matte-finish, not producing fine line and cakey lips for up to 12 hours and has increased the appearance of study population.