

Safety, Efficacy and In-Use Tolerability Study of Test Product in Healthy Human Females.



Background: There is a long tradition of rose water being used in medicine, including in Iran and other parts of the Middle East, as far back as the 7th century. The antioxidants in test product protect the cells in the skin against damage. The test product acts as an inhibitor against elastase and collagenase, hence can help soothe the skin and reduce redness, as well as act as an anti-aging product by reducing the appearance of lines and wrinkles.

Aims/Objective: To determine the skin safety and effectiveness of hair removal cream in Healthy Human Females.

Materials/Methods: This was a two-arm, two-test products, randomized, evaluator-blinded, safety, efficacy, and in-use tolerability clinical study. A total of 35 female subjects ages 18 to 55 years were enrolled, and 30 female subjects completed the study. The duration of the study was 28 Days from enrolment with total of 05 visits. The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and are consistent with ICH/GCP guidelines. The study was approved by Ethics Committee and registered at Clinical Trial Registry of India.

Results: The effectiveness of the test product was evaluated for change in skin color, skin tone, skin hydration/moisturization, skin texture- smoothness, roughness, and hair re-growth, from baseline and also compare with another test product usage arm. There was a significant change in skin color with 9% and 20% at visit 01 (T0 hour) post application and Day 28 as compared to the control arm. There was a 2X improvement in skin color observed in the forearm post-application with test product usage as compared to the forearm on which the comparator was used. There was a statistically significant improvement observed in skin hydration as measured by MoisturemeterEpiD with 68% (p-value <0.01) and 69% (p-value < 0.01) in the arm on which test product was used as compared to 11% and 29% in the arm on which comparator was used at Visit 01 and Visit 05 respectively. The subject's application sites were visually evaluated for signs of redness, irritation, itchiness, dryness, scaliness, burning sensation, skin cuts, etc. 100% of the subjects reported no such signs as compared to the arm on which comparator was used. The efficacy of the test product was evaluated in terms of sensorial parameters assessed by a dermatologist-trained evaluator and consumer perception about test products was provided by the subjects.

Conclusion: As per the Investigator, the test product was found to be efficacious and safe in healthy human adult subjects (18 – 55 years) with 100% well-being in comparison to the comparator. The test product offers 2X times improvement in skin color, 3X times improvement in skin tone, 7X times improvement in hydration, and 9X times improvement in smoothness, less visible hair growth after application with no cuts, nicks, pain, no malodor, no double hair from one follicle or ingrown hair, major itching, irritation or redness.