

Safety, Efficacy and In-Use Tolerability Study of Turmeric Containing Test Product



Background: Turmeric (*Curcuma longa*), a commonly used spice throughout the world, has been shown to exhibit anti-inflammatory, antimicrobial, antioxidant, and anti-neoplastic properties. Growing evidence shows that an active component of turmeric, curcumin, may be used medically to treat a variety of dermatologic diseases. The test product contains turmeric that inhibit the activity of tyrosinase an enzyme necessary for black colour production.

Aims/Objective: To Evaluate Safety, Efficacy and In-Use Tolerability Study of Test Product in Healthy Adult Human Subjects in Reduction in Facial Dark Spots.

Materials/Methods: This was an open-label, single-arm, single-centre, efficacy, safety, and skin compatibility clinical study. A total of 42 subjects aged 18 to 55 years were enrolled, and 39 subjects completed the study. The duration of the study was 4 weeks with total of 5 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: In this study, the L^* parameter is associated with the skin tone. The more the value, the brighter the skin. The test product demonstrated a statistically significant reduction by 10.72% and 8.95% in dark spots with p -value < 0.01 was seen at Day 07 and Day 14 respectively as compared to baseline. The percent reduction in dark spot over 28 days was significant compared with baseline ($p < 0.01$). Instrumental measurements of erythema level on the skin shows a reduction in skin erythema by 4.32% and 5.92% at day 07 and day 14 with $p < 0.01$. The test product was found to be significantly effective in reducing wrinkles at the crow's feet area by 22.02% at Day 07 and 24.64% at Day 14 with p value < 0.01 . It was seen that the fine lines were also reduced significantly by 31.03% at Day 07 and 35.84% at Day 14 with p -value < 0.01 . The test product was found effective in reducing the skin roughness by 50.02%, and 44.16% with p -value < 0.01 at Day 07 and Day 14. In this study, significant improvement in skin elasticity, skin hydration, and skin gloss, reduction in trans epidermal water loss and maintained sebum level was observed after test product usage. There was an improvement seen in physician global assessment using Griffith scale for skin appearance and glogau skin age.

Conclusion: As per the Investigator and Dermatologist, the test product was found to be efficacious and safe in healthy human adult subjects (18 – 55 years) with 100% well-being. The test product which contains turmeric after 4 weeks of continuous usage has effectively reduces dark spots, improves skin glow, uneven skin tone, skin elasticity, skin hydration, skin barrier function, skin smoothness.