## cliantha° research

## **CASE STUDY:**

## Standardization Plan for Patch Irritation Test

For a company, nothing is as vital as the integrity of their products, which is especially true in case of skincare. The customers want a product that delivers what it promises. Getting the right formula before mass production is a key to success. If it is found that consumers are having major issues with the products after its release, it's difficult to recover from that kind of setback. Also, if the product is poorly rated by consumers, the negative publicity is almost impossible to overcome.

Patch Irritation Test is used to evaluate the potential of a product to cause skin irritation upon contact period of definite duration when used by the consumer. This case study refers to the standardization process for Patch Irritation Test Studies.

Standardization is the process of implementing and developing technical standards based on the consensus of different users, evaluators, performers to ensure compatibility, interoperability, repeatability and quality of a method.

The objectives of this standardization plan was to standardize the methods, procedural steps and evaluations that were performed during the conduct of Patch Irritation Test studies at/by Cliantha Research. By the implementation of this standardization plan, we have optimized our ability of performing Patch Irritation Test studies.

Various methods and procedures for Patch Irritation Test studies were standardized, including,

- Sensitive Skin Test
- Site Wash
- Site Marking
- Patch Application and Removal
- Irritation Scoring (Varied Light Source)
- Light Intensity Measurement
- · Lactic Acid Stinging Test
- Digital Photography

Standardization plan was done in 2 phases of 10 subjects of normal skin types and 25 subjects of varied skin types (normal, oily, sensitive and combination). Successful standardization of the various methods, procedures and Controls i.e. 1% SLS and 3% SLS as positive control and 0.9% normal saline as negative control of conduct of Patch Irritation Test studies were achieved at the end of the study. From this standardization plan,



Materials/Equipment for Standardization Plan and Scoring



Site Marking

Site Numbering

Cliantha has set a benchmark for Patch Irritation Test studies which can produces consistent, compatible, accurate, qualitative and reproducible results.

For more information contact info@cliantha.com