

## Evaluation of the Irritation Potential of Three Topical Formulations of Minoxidil 5% + Finasteride 0.1% Using Patch Test

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**Abstract :** Topical formulation containing minoxidil and finasteride helps hair growth in the treatment of male androgenetic alopecia. The objective of this study is to compare the irritation potential of three conventional formulations of minoxidil 5% + finasteride 0.1% topical solution of in human patch test. The study was a single centre, double blind, non-randomized controlled study in 53 healthy adult Indian subjects. Occlusive patch test for 24 hours was performed with three formulations of minoxidil 5% + finasteride 0.1% topical solution. Products tested included aqueous based minoxidil 5% + finasteride 0.1% (AnasureTM-F, Sun Pharma, India - Brand A), lipid based minoxidil 5% + finasteride 0.1% (Brand B) and aqueous based minoxidil 5% + finasteride 0.1% (Brand C). Isotonic saline 0.9% and 1% w/w sodium lauryl sulphate were included as negative control and positive control respectively. Patches were applied and removed after 24 hours. The skin reaction was assessed and clinically scored 24 hours after the removal of the patches under constant artificial daylight source using the Draize scale (0-4 points scale for erythema/dryness/wrinkles and for oedema). Follow-up was scheduled after one week to confirm recovery for any reaction. A combined mean score up to 2.0/8.0 indicates a product is "non-irritant" and a score between 2.0/8.0 and 4.0/8.0 indicates "mildly irritant" and a score above 4.0/8.0 indicates "irritant". The procedure of the patch test followed the principles outlined by the Bureau of Indian Standards (BIS) (IS 4011:2018; Methods of Test for safety evaluation of Cosmetics-3rd revision). Fifty three subjects with mean age 31.9 years (25 males and 28 females) participated in the study. The combined mean score  $\pm$  standard deviation were: 0.06  $\pm$  0.23 (Brand A), 0.81  $\pm$  0.59 (Brand B), 0.38  $\pm$  0.49 (Brand C), 2.92  $\pm$  0.47 (positive control) and 0.0  $\pm$  0.0 (Negative control). This means the score of Brand A (Sun Pharma product) was significantly lower than that of Brand B ( $p=0.001$ ) and that of Brand C ( $p=0.001$ ). The combined mean erythema score  $\pm$  standard deviation were: 0.06  $\pm$  0.23 (Brand A), 0.81  $\pm$  0.59 (Brand B), 0.38  $\pm$  0.49 (Brand C), 2.09  $\pm$  0.4 (Positive control) and 0.0  $\pm$  0.0 (Negative control). The mean erythema score of Brand A was significantly lower than Brand B ( $p=0.001$ ) and that of Brand C ( $p=0.001$ ). Any reaction observed at 24hours after patch removal subsided in a week. All the three topical formulations of minoxidil 5% + finasteride 0.1% were non-irritant. Brand A of minoxidil 5% + finasteride 0.1% (Sun Pharma) was found to be the least irritant than Brand B and Brand C based on the combined mean score and mean erythema score in the human patch test as per the BIS, IS 4011:2018

**Keywords :** erythema, finasteride, irritation, minoxidil, patch test

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