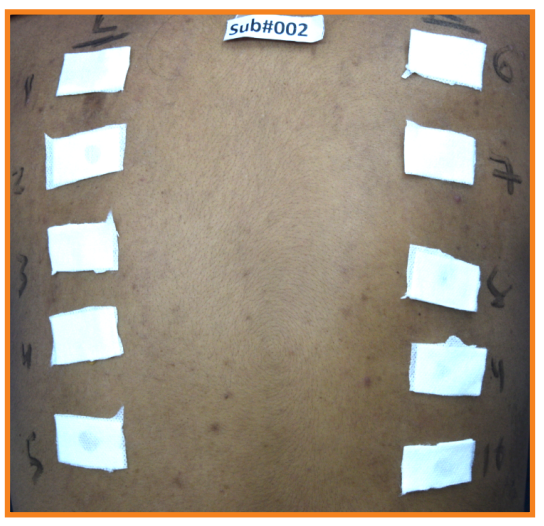
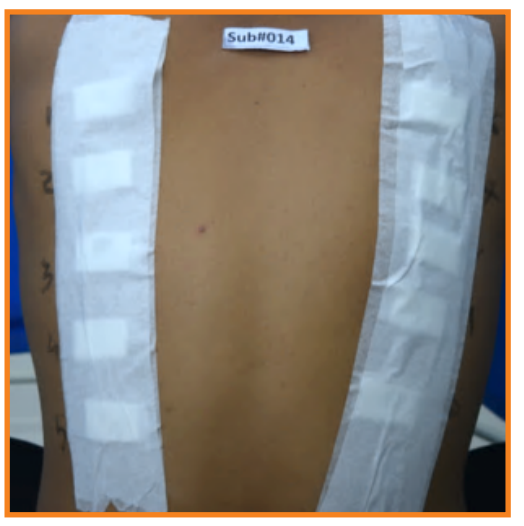
Assessment of Comedogenic Potential of the Test Products in Healthy Adult Men and Women: A Randomized, Evaluator-Blinded Study Utilizing Cyanoacrylate Skin Follicular Biopsy Method

NovoBliss® Research

In this study spanning 29 days, 14 visits were conducted. Subjects underwent screening within 15 days prior to enrolment (Visit 01). Enrolment, randomization, and the first application occurred on Day 01 (Visit 02). From Day 03 to Day 25 (Visits 03 to 13), patches were applied, removed, and skin irritation was scored. Visit 14 marked the end of the study on Day 29.

Test sites, consisting of 2*2 cm squares, received various test products up to five on each side of the upper back. Patches loaded with test products were applied three times a week for four weeks, with removal after 48 or 72 hours of application.

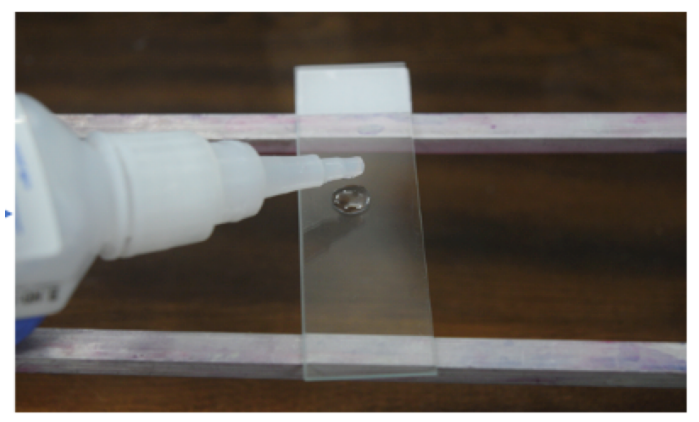


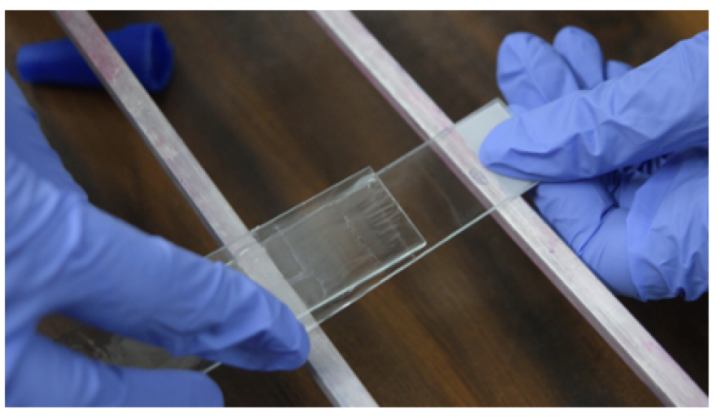


Patch Application

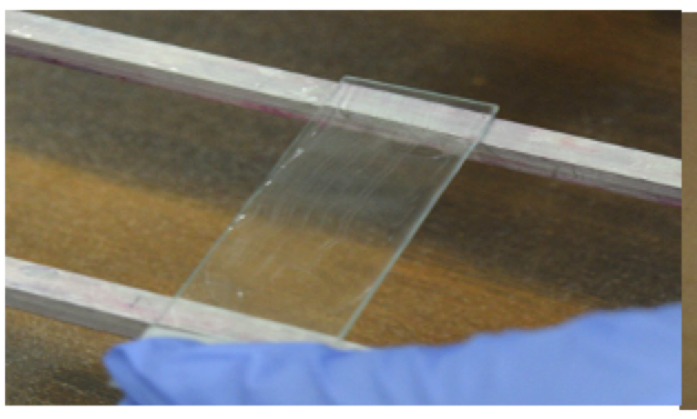
Irritation scoring using the Berger and Bowman scale (Used by USFDA guidelines for Irritation scoring) was conducted by a dermatologist within 30 minutes of patch removal. Subjects' patches were replaced within 24 hours if detached prematurely.

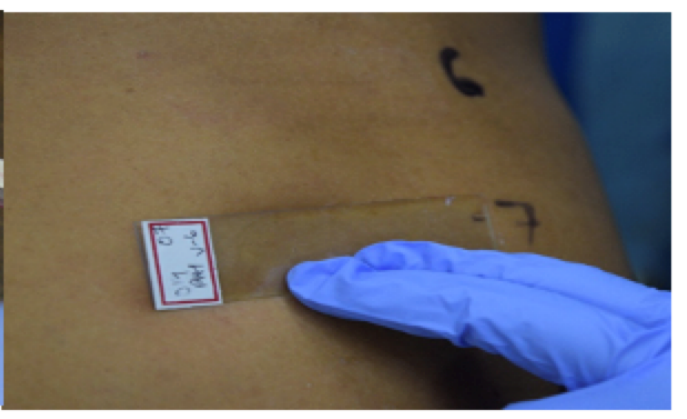
Skin follicular biopsies were performed to assess follicle and microcomedone formation before and after product exposure. Safety was monitored throughout the study, with clinical observations of skin responses and adverse events reported.



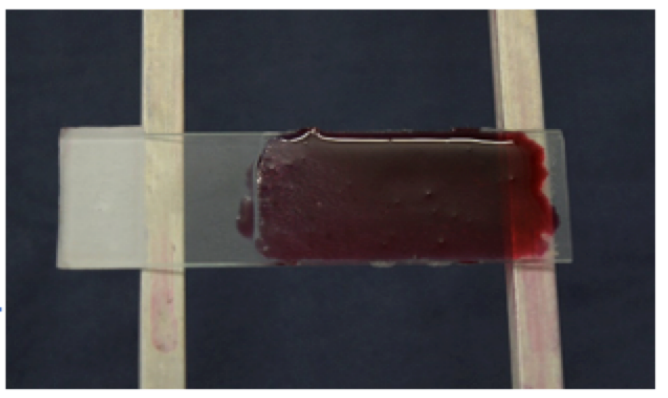


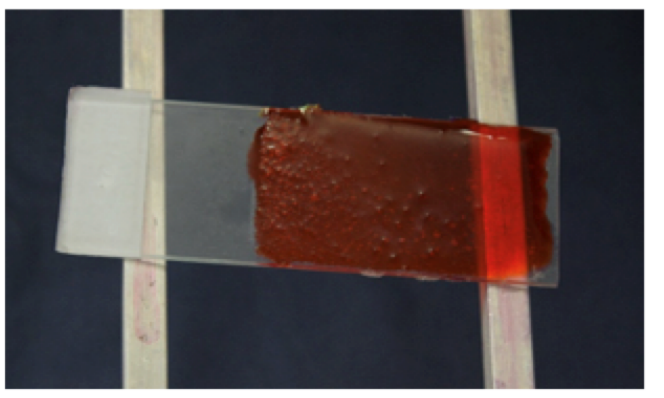
Cyanoacrylate glue (Super Glue or Krazy Glue) application



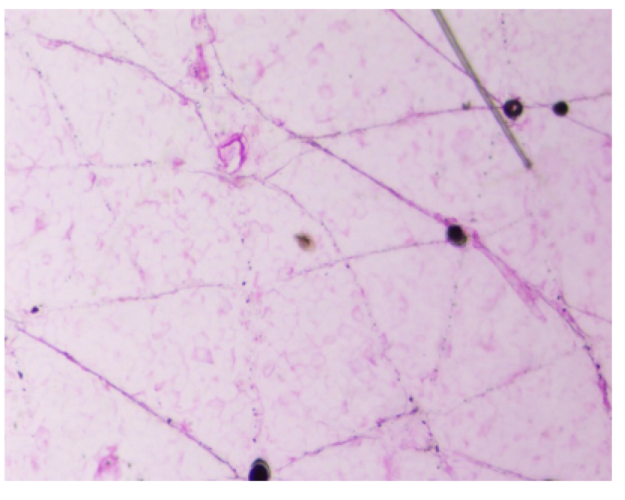


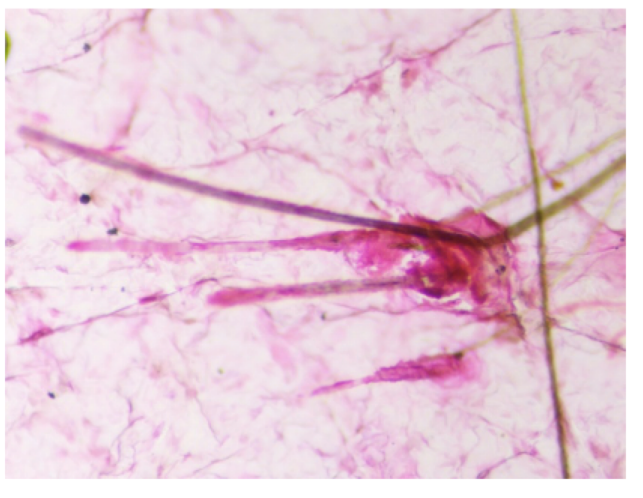
Follicular biopsy sample





H&E Stain





The study assessed the comedogenicity of test products and determined the degree of microcomedone formation as a percentage change from baseline to Visit 14. No serious adverse events or undesirable effects were reported or observed during the study.

+91 99090 13286 | info@novobliss.in