

Comedogenicity (up to 3 products) - 6 Subject

Objective: To determine the comedogenic potential of the test product when applied topically under occlusion or semi-occlusion to the skin of human panellists.

Experimental Design

1. Panellists

- a) a total of 6 healthy males or females displaying prominent follicular orifices on the medial region of the back
- b) Follicular biopsy technique (Marks and Dawber) is used to further qualify the panellists.
- c) Age grouping is 18 to 45 years.
- d) Patients will be screened to ensure no topical or oral medications are used for a period of at least 3 months prior.
- e) Patients will be further screened to ensure no known histories of allergy, photo sensitisation or hypersensitivity
- f) No pregnant or lactating females will be included in the program. Further female application will be screened to ensure they have not been pregnant or given birth within the 6 month period immediately preceding commencement.
- g) No patient may be included into the programme who exhibits any clinically evident disease in the area of the back. Patients must be free from any underlying disease states which may affect the study such as hormonal imbalances (i.e.. menopausal patients) etc.

2. Scoring criteria

- a) Scoring will be conducted based on the following scale:

0 = no comedones or hyperkeratinisation; normal follicular orifices

1 = at least half of the follicles exhibiting microcomedones (small horny cylinders inspissated within the lumina).

Method

4. Procedure:

- a) Thrice weekly, 0.2 to 0.5mL of the test material (enough to completely saturate the pad) will be delivered to the test site via syringe. The test sites, each measuring 4x4cm are covered with a piece of non-absorbing cotton cloth (i.e.. Curity or Webril). The patches are closely secured to the skin by occlusive or semi-occlusive, hypoallergenic tape (i.e.. adhesive Blenderm or Dermalite II) using an overlayer of adhesive taping if necessary (Scanpor or the equivalent).
- b) The procedure is repeated every other day until three applications per week is accomplished for a total of four weeks for occlusive and 6 weeks for semi-occlusive conditions. Patches are removed after 48 hour exposure (usually Wednesday and Friday) and once weekly after 72 hour exposure (usually Monday). On removal all sites are cleaned and evaluated for any overt signs of irritation prior to repatching.
- c) Follicular biopsy is accomplished by means of a cyanoacrylate adhesive introduced to the test area and covered by a glass slide. Upon curing, the test slide is rapidly but accurately removed to protect the integrity of the biopsy. Slides are examined under a microscope and the number of follicles and microcomedones (if any) are counted per square cm. An optical micrometer is employed to measure the size of several microcomedones and follicles to provide a tangible reference for evaluation. A total of five, 1 cm square area counts will be conducted, randomly selected from the 16 square grid comprising each test site. The counts are then totalled and averaged for comparison.
- d) Data will be reported as:
 - i - The average number of comedones per square cm and the comedogenic value outlined in Section 2a for each subject and for the group at each treatment level.
 - ii - The total number of comedones per square cm for each subject and the group at each treatment level.
 - iii - The ratio of follicles to comedones per square cm for each subject and for the group at each treatment level to assess the extent of follicular involvement more intimately.

5. Controls

- a) untreated test site - non-occluded
- b) Untreated "sham" control - occluded but no material applied.
- c) Negative control - dimethicone, occluded exactly as test substance.
- d) Positive control - isopropyl myristate, semi-occluded and Acetylated Lanolin Alcohol (Acetulan) occluded exactly as test substance.

6. Test Material Information

- a) A sufficient quantity of each test material should be submitted by the sponsor.
 - i - liquids including lotions - 10mL per subject.
 - ii - Powders, semisolids - 10g per subject.

References

- a) Mills, OH, Kligman, AM: A Human model for assessing comedogenic substances. Archives of Dermatology 118:903-905, 1982.
- b) Marks, R, Dawber RPR: Skin surface biopsy: An improved technique for examination of the horny layer. British journal of Dermatology 84:117-123, 1977.
- c) Ayres, JD., Mills, OH., Lyssikatos, J., Kligman., AM, Groh., DG: Assessment of a new method for determining the acnegenic potential of topically applied materials on human subjects. Presented at the IFSCC International