Supportable Claims
- Reduction in Severity
- Acne Treatment
- Non-comedogenic Claim

Subjects
Panels of subjects, male and female, professionally assessed as exhibiting acne conditions. Parental consent of minors is obtained. Prior to initiation of a test, each subject will complete a medical history form.

Subjects are asked to apply the product on affected area as per sponsor supplied directions. Visual counts and classifications of lesions will be done, typically at day 0 (pre-treatment), 2 & 4 weeks.

Percent difference (reduction) in separate types (comedones, papules & pustules) and total count of lesions are calculated. The skin condition is evaluated in terms of adverse reactions, such as erythema, itching, burning, scaling, and irritation. The overall improvement in skin condition is graded using evaluation indices. The grading of efficacy is expressed as 0 = excellent, >66% improvement; 1 = very good, 33% to 66% improvement; 2 = good, <33% improvement; and 3 = no change. The weighted mean will be calculated by dividing the sum of all individual patient indices by the total number of test subjects. The initial index in all cases will be 3.

Comedogenicity Test
Thrice weekly, 0.2 to 0.5mL of the test material is delivered to the test site via syringe. The test sites, each measuring 4x4cm are covered with a piece of non-absorbing cotton cloth. The patches are closely secured to the skin by occlusive or semi-occlusive, hypoallergenic tape using an over-layer of adhesive taping if necessary. 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 and once weekly after 72 hour exposure. On removal all sites are cleaned and evaluated for any overt signs of irritation prior to re-patching. sum of all patients’ degree of reaction.

References
Acne Gradings
0 = Normal, clear skin with no evidence of acne vulgaris
1 = Skin is almost clear: rare non-inflammatory lesions present, with rare non-inflamed papules (papules must be resolving and may be hyperpigmented, though not pink red)
2 = Some non-inflammatory lesions are present, with few inflammatory lesions (papules/pustules only; no nodulo-cystic lesions)
3 = Non-inflammatory lesions predominate, with multiple inflammatory lesions evident: several to many comedones and papules/pustules, and there may or may not be one small nodulo-cystic lesion
4 = Inflammatory lesions are more apparent: many comedones and papules/pustules, there may or may not be a few nodulo-cystic lesions
5 = Highly inflammatory lesions predominate: variable number of comedones, many papules/pustules nodulo-cystic lesions

Palpules / Pustules - inflammed
Nodulocystic Lesions
Non-inflammatory lesions:
* Open comedones (blackheads)
* Closed comedones (whiteheads)
* Uninflamed nodules (sometimes called cysts)
Inflammatory lesions:
* Papules (small red bumps)
* Pustules (white or yellow ‘squeezable’ spots)
* Inflamed nodules (large red lumps)
Secondary lesions:
* Excoriations (picked or scratched spots)
* Erythematous macules (red marks from recently healed spots, mostly in fair skin)
* Pigmented macules (dark marks from old spots, mostly in dark skin)
* Scars

Proposed areas for measurement and photography.
Cheek Neck Forehead