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"Efficacy of a novel anti-acne serum in reducing acne lesions and post-inflammatory hyperpigmentation management in polluted environments"

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1. Introduction

Acne vulgaris or acne is a common dermatological problem of people across the globe irrespective of their races and ethnics (Elbuluk et al., 2021). This inflammatory disease involving the pilosebaceous unit is characterized by increased keratin synthesis of hair follicles, hyperproduction of sebum, bacterial colonization and inflammation. Since *C. acnes* thrives in sebum-rich environment, individuals with oily or combination skin types are particularly susceptible for acne formation (Heng & Chew, 2020).

Environmental pollution has emerged as a significant contributing factor for acne formation (El Haddad et al., 2021). Pollutants, such as sulphur dioxide, nitrogen dioxide, carbon monoxide, particulate matters and heavy metals, generate oxidative stress to exposed skin, leading to increased ATP and oxidized protein synthesis (Araviiskaia et al., 2019). These processes cause excessive proliferation of keratinocytes, trigger release of inflammatory cytokines and disrupt normal cellular functions (Krutmann et al., 2017), thereby affecting the overall skin health. Additionally, inflammation associated with acne often stimulates melanin and its deposition, resulting in post-inflammatory hyperpigmentation (PIH), particularly in individuals with darker skin tone (Fitzpatrick III–VI) (Elbuluk et al., 2021). Sometimes, PIH can persist even after lesions dry, which negatively impacts self-esteem and quality of life of affected individuals (Akinboro et al., 2018; Darji et al., 2017).

Because skin blocks the entry of harmful environmental elements into the internal body, people having acne prone skin is suggested to protect their skin’s barrier function with the application of emollients and creams (Krutmann et al., 2017). Although conventional topical substances like azelaic acid and retinoids are widely used for acne treatment and PIH management (Adebusoye & Srivastava, 2025; Callender et al., 2022), they may not adequately protect against pollution-induced skin damage. There is a critical need for acne treatments that

address both intrinsic and extrinsic aggravating factors. To address this issue, this study investigates the efficacy of a novel anti-acne Formula A composition that contains Glycolic acid, Salicylic acid, Lactic acid, 3-O-Ethyl ascorbic acid, and Niacinamide, in reducing overall acne lesions and managing PIH in pollution-exposed skin. It also assesses the ability of Formula A in preserving skin's protective barrier functions in polluted environments and its effectiveness on improving skin appearance in terms of hydration, oiliness, pore, redness around acne, shine and sebum production.

Literature Review

Formation of acne is influenced by several intrinsic and extrinsic factors. Among the latter, studies highlight the significant role of environmental pollutants in exacerbating acne and its sequelae, including PIH (Yang et al., 2020). While investigating the relationship between air pollution and acne formation in Lebanese adults, El Haddad et al. (2021) identified a clear association between inflammatory acne and high ambient levels of nitrogen dioxide, carbon monoxide, sulphur dioxide and particulate matter. These findings support the hypothesis that air pollution contributes to acne development, encouraging the formulation of skincare regimens tailored for polluted environments.

Beyond pathophysiology, the psychosocial burden of acne, particularly when accompanied by facial hyperpigmentation, is documented. Akinboro et al. (2018) found negative impact of acne and hyperpigmentation on mental health of Nigerian undergraduates. They not only remained anxious and emotionally distressed but also avoided social life, leading to poorer quality of life. This highlights the need for treatments that target both acne and its pigmentary aftermath.

Several recent clinical studies have evaluated topical interventions with combined anti-acne and depigmenting properties. Alexis et al. (2024) demonstrated the efficacy of trifarotene 50 µg/g cream in reducing acne lesions from baseline at week 12 and post-AV hyperpigmentation index (PAHPI) score at week 24. The treatment, when used alongside a skincare regimen, not only improved clinical outcomes but also reduced irritation, promoting better patient adherence. Shucheng et al. (2024) explored the effects of 15% azelaic acid (AzA) gel in managing acne-induced PIH and post-inflammatory erythema (PIE). After application twice daily, patients showed significant reductions in PIH lesion count at weeks 8 and 12 from baseline ($P < 0.05$). It also reduced melanin levels significantly at week 12 ($P < 0.05$), with concurrent improvements in skin barrier function and quality of life. Similarly, Li et al. (2023) conducted a randomized controlled trial in Shanghai assessing a facial serum and mask containing salicylic acid and lipohydroxy acid. After 8 weeks, participants exhibited improvements in acne severity, PIH, pore density, and sebum regulation, suggesting a multifaceted effect on acne-prone skin.

Despite the availability of literature on topical agents for acne treatment, none of the reviewed research offers a dermatological solution that can effectively reduce acne, manage PIH and protect skin barrier in pollution-exposed skin. This highlights a significant research gap and underscores the importance of evaluating novel formulations with anti-oxidant, depigmenting, anti-microbial and barrier-preserving properties while maintaining its efficacy in acne reduction and PIH management under polluted environments.

2. Materials and Methods

The present study conducted both in vitro and in vivo tests for evaluating the efficacy of the anti-acne Formula A composition that contains Glycolic acid, Salicylic acid, Lactic acid, 3-O-Ethyl ascorbic acid, and Niacinamide, and Formula B composition that contains salicylic acid, Lipohydroxy acid (LHA), Niacinamide a well-known market product for Acne.

In vitro assessment

For in vitro assessment, the anti-acne Formula A and Formula B were used. The ability of these products to maintain the skin's protective barrier was evaluated in vitro through Transepidermal Water Loss (TEWL), Differential Scanning Calorimetry (DSC), and a Zein test. TEWL measures the water flux across the skin barrier, DSC measures lipid perturbation in the skin's stratus corneum based on changes in transition temperature whereas Zein score measures protein denaturation.

The anti-microbial activity of both the products against *Cutibacterium acnes* (*C. acne*) was examined by determining their ability to reduce the growth of the bacteria over a period of time. The antioxidant power of the active ingredients was assessed using the HORAC (Hydroxyl Radical Antioxidant Capacity) method.

In vivo study

A 12-weeks mono-centre, parallel, blinded, randomized clinical study was conducted on 131 female subjects with acne-prone skin aged 18 to 35 years.

For analysis of inflammatory acne lesion count, PHI spot size, isolated pigmentary spot size and skin oiliness, pore and redness around acne, products tested were Formula A and Formula B. The study randomly assigned 67 subjects to Formula A and 64 subjects to Formula B groups. Subjects who had mild (grade 2) to moderate acne (grade 3) acne severity based on the Investigator's Global Assessment (IGA) scale (0 - 4), sebum casual level on the forehead >100 µg/cm² (mean), ≥ 10 to ≤ 25 inflammatory acne lesions on the whole face, 25 to ≤100 non-inflammatory acne lesions on the whole face, maximum of 2 nodules (<1 cm in size) and with post-inflammatory hyperpigmentation (PIH) spots measuring 3 mm or more were included in the study. The tested formulas were applied to the face at a dosage of 600 mg. Each subject applied 600mg of the respective product twice daily at home following standardized self-application training and monitoring through video recordings to ensure proper application technique.

The evaluation of shine and sebum was performed using Formula A. A total of 19 healthy Indian female subjects with oily skin type were selected for testing each of the formula. Each subject had 300 mg of the respective applied to half of their face. Effects of these products were assessed at different time points – immediately after application (T0), 1hour (T1), 2 hours (T2) and 4 hours (T4) after application. Shine was assessed specifically in minizones on the subjects' forehead using LightCam, whereas sebum level was measured in forehead using a Sebumeter. Assessment was done under laboratory conditions with 21± 1 °C temperature and 45 ± 5% relative humidity to minimize external variability.

3. Results

3.1 In vitro assessment

3.1.1 Effectiveness on Skin Barrier integrity

In the present study, the effectiveness of the anti-acne formula A on maintaining skin's protective barrier in polluted environments was evaluated through Transepidermal Water Loss (TEWL), Differential Scanning Calorimetry (DSC) for lipid perturbation and Zein test for protein denaturation. Findings revealed that skin treated with Formula A had a 13.3% change in water flux, whereas the Formula B demonstrated 52% increase in water flux (Table 1). In terms of mildness, unlike the Formula B, Formula A showed TEWL values within the threshold value, indicating its ability to preserve skin barrier integrity by preventing water loss. In DSC analysis, Formula A exhibited lipid perturbation of -0.3°C whereas revealed that Formula B revealed a marked shift in lipid melting temperature of -5.9°C (Table 1). This data indicates that Formula A has the ability to maintain lipid bilayer structure even in polluted conditions.

Findings are supported by the scatter plot (Figure 1) which indicates good barrier preservation of Formula A in terms of low water loss and minimum lipid disorganization as Formula A is plotted in the left quadrant (bottom). Conversely, Formula B was placed in the right (top) quadrant, which means it is ineffective in protecting skin barrier due to increased water loss and lipid disruption.

In terms of Zein score, both formulations remained within the mildness range (<50%). However, score was lower for Formula A (21.7%) than Formula A (37%) (Table 1). In the colour map, Formula A appears green, confirming low protein denaturation and mildness whereas Formula B one showed yellow-orange, indicating its higher protein denaturation and potential irritation as compared to Formula A (Figure 1).

Table 1: Effectiveness of Formula A and B on skin's protective barrier function

Sample Details	pPIE (%)	Water Flux	pDSC Lipid Perturbation (°C)	Zein Score (%)
Formula A	13.3	-0.3		21.7
Formula B	52	-5.9		37.0
Mildness Ranges	+/- 20%	+/- 2°C		< 50%

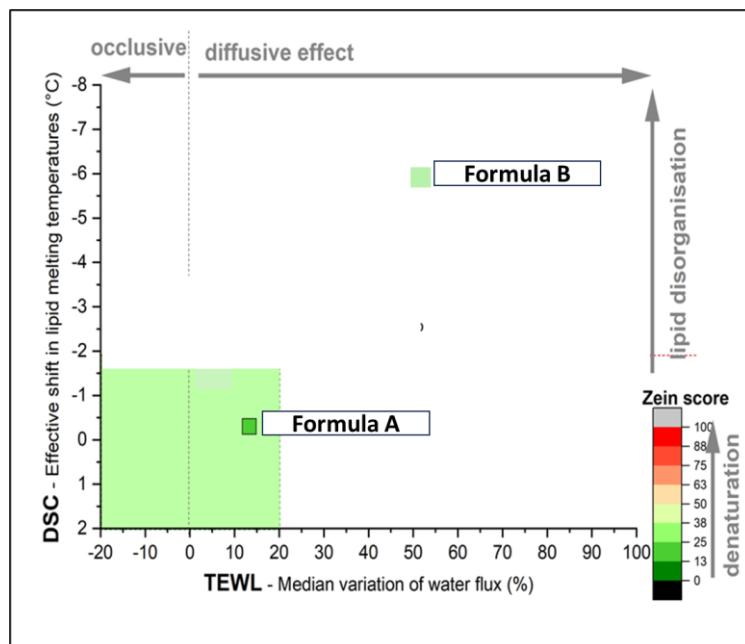


Figure 1: Mapping TEWL vs DSC vs ZEIN score

3.1.2 Evaluation of anti-microbial activity

Reduction of the viable *C. acnes* was observed with Formula A after 2 hr with complete reduction at 24 hr (3.66 log reduction) indicating its antimicrobial activity.

3.1.3 Evaluation of anti-oxidant property

The antioxidant activity of the active ingredients was assessed using the HORAC method. The H-ORAC assay is a method that can measure the titer of a hydrophilic antioxidant, and so was used to evaluate the antioxidative properties of in this study. Table 2 showed that 3-O-Ethyl Ascorbic Acid has antioxidant activity.

Table 2: HORAC test for anti-oxidant property

Raw Materials	Activity (U eq. µmol Gallic acid/ g)
NIACINAMIDE	172
3-O-ETHYL ASCORBIC ACID	672

3.2 In vivo Assessment

3.2.1 Effectiveness on non-inflammatory lesion count

The percentage decrease in non-inflammatory lesions among women treated with Formula A and Formula B were analysed at various timepoints compared to baseline. Both products showed significant ($p \leq 0.05$) reductions in non-inflammatory lesions in a progressive

manner. However, compared to Formula B, Formula A showed greater reduction at each timepoint of active phase, with maximum % reduction seen at D84 (Figure 2). Even after stopping the cream (during relapse phase), Formula A was able to maintain such reduction (42.3%) compared to the Formula B (37.7%).

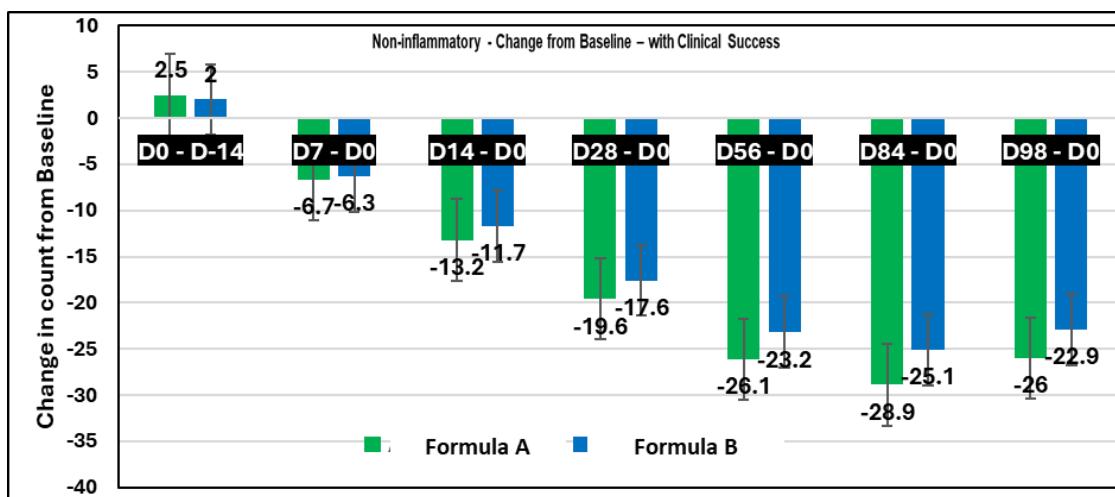


Figure 2: Change in non-inflammatory lesion from baseline at various timepoints

3.2.2 Effectiveness on Inflammatory lesion count

The percentage decrease in inflammatory lesions among women treated with Formula A and Formula B at various timepoints were compared to baseline. Both products showed significant ($p \leq 0.05$) reductions in inflammatory lesions during the active phase. However, compared to Formula B, Formula A showed greater reduction at each timepoint of active phase, with maximum % reduction seen at D56 (Figure 3). Even after stopping the cream (during relapse phase), Formula A was able to maintain such reduction (38.9%) compared to the Formula B (33.2%).

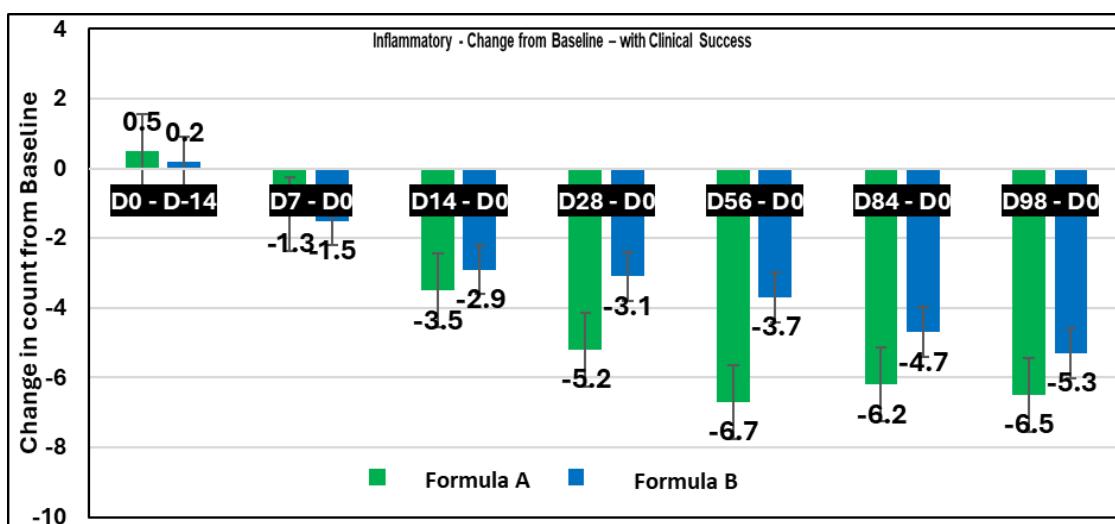


Figure 3: Change in inflammatory lesion from baseline at various timepoints

3.2.3 Effectiveness on the intensity of PIH spot lightness (L^*)

The improvement of post-inflammatory hyperpigmentation (PIH) spot lightness among women treated with Formula A and Formula B at various timepoints were compared to baseline. From D7 onwards, both Formula A and Formula B significantly ($p \leq 0.05$) improved hyperpigmentation as observed from high L^* values (Figure 5). However, compared to Formula B, Formula A performed better in making lighter skin at every timepoints with maximum improvement at D98, indicating its superiority in pigmentation correction.

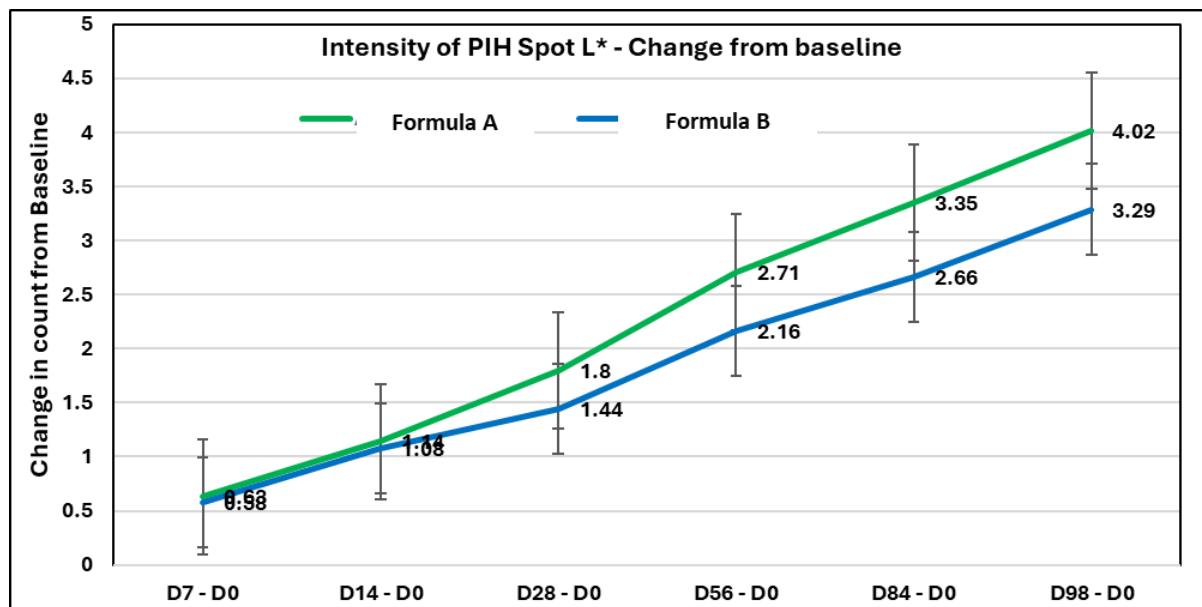


Figure 5: Change in intensity of PIH spot lightness at various timepoints

3.2.4 Effectiveness of isolated pigmentary spot size

The reduction of the size of PIH spot ($\geq 3\text{mm}$) using Formula A and Formula B were tested. Both the products significantly reduced pigmentary spot size ($p \leq 0.05$) compared to the baseline throughout the active phase (from D7 to D84). However, compared to Formula B, Formula A performed better in decreasing the size at every time point, with maximum improvement at D84 (Figure 7). Even during relapse phase, Formula A showed superiority in spot reduction (-56.7%) than the Formula B (-35.4%).

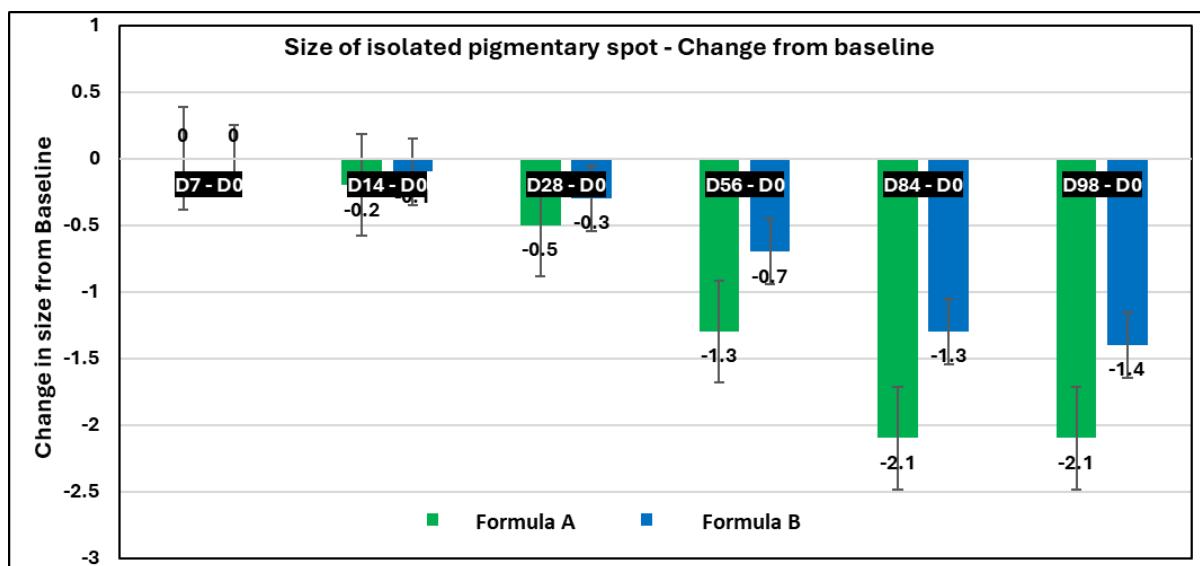


Figure 7: Changes in PIH spot size from baseline

3.2.5 Effectiveness on Sebum level

Formula A demonstrated a significant increase in shine immediately after application and the shiny effect was maintained up to four hours. In contrast, all products showed a significant decrease in sebum level on immediate application. One hour after application (T1), Formula A show a significant sebum reduction.

4. Discussion

The present study evaluated the efficacy of a novel anti-acne Formula A in preserving skin barrier functions, reducing acne lesions, managing PIH and improving various skin parameters, especially in pollution-exposed conditions. Skin barrier integrity was assessed using TEWL, DSC and Zein tests. By measuring amount of water diffused across the skin surface, TEWL serves as an objective marker for stratum corneum function (Alexander et al., 2018). DSC enables detection of lipid bilayer integrity of a sample by analysing heat flow during phase transitions (Schubring, 2009), whereas the Zein test assesses the potential for irritation of a substance via protein denaturation (Paye et al., 2006). In the present study, Formula A significantly prevented water loss, maintained lipid bilayer structure and reduced protein denaturation, indicating its effectiveness in protecting barrier function of pollution-exposed skin. Additionally, the product's antioxidant activity, measured by HORAC method, confirmed its potential to reduce oxidative stress due to presence of 3-O-Ethyl Ascorbic Acid and Niacinamide. Further, the product demonstrated antimicrobial activity against *C. acnes*, a key contributor to acne pathogenesis. This aligns with Wongtada et al. (2023) who reported reduced acne lesions upon using topical agents like benzoyl peroxide and retinoic acid through microbiota modulation.

In vivo clinical assessments supported these in vitro findings. The participants in the present study who used Formula A daily had reduced acne lesions, pigmentary spot, redness and pore visibility over a period of 12 weeks. These results are consistent with previous findings that highlight the effectiveness of topical treatments on inflammation, PIH, oiliness, pores and lesion count (Inui et al., 2014; Tan et al., 2021; Tanghetti et al., 2023). In addition, the present

study also showed the positive role of the anti-acne cream in enhancing the skin hydration while decreasing the sebum level. Earlier studies also mentioned that niacinamide (Permatasari & Tan, 2024), ceramides (Spada et al., 2018), and guarana extract (Leite & Maia Campos, 2020) help balance moisture and oil production. Overall, Formula A offers a comprehensive dermatological solution for acne-prone, pollution-exposed skin.

5. Conclusion

Pollution-induced barrier disruption activates oxidative stress, triggering inflammation, sebum overproduction, promoting *C. acne* proliferation and inflammatory acne lesions, ultimately leading to post-inflammatory hyperpigmentation (PIH) and emotional distress. The proposed anti-acne Formula A is found to be effective in preserving skin barrier, regulating sebum level, inhibiting *C. acne* proliferation, reducing acne lesions and managing PIH spot. This study suggests this anti acne formula as a promising solution for women and men with acne-prone skin as it can address pollution-related skin concerns and improve their overall quality of life.

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