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Clinical insights into Galapep™ infused dark patches corrector: A safe and active approach to manage body hyperpigmentation

Abstract

Introduction: Dark spots, also referred to as hyperpigmentation, are regions of the skin that appear darker than the surrounding areas due to an overproduction of melanin, the pigment responsible for skin color. This study aims to assess the safety and effectiveness of a novel depigmentation treatment. Galapep™ is a proprietary ingredient designed to target hyperpigmentation through a synergistic blend of active ingredients, including lactic acid, gallic acid, niacinamide, tranexamic acid, and retinaldehyde. The cream's formulation targets key pigmentation pathways, providing a comprehensive approach to skin brightening and evening out skin tone in healthy participants.

Methods: The open-label, single-arm, single-center, prospective, interventional clinical study to evaluate the safety, efficacy, and in-use tolerability of the test treatment for depigmentation. Ethical approval was obtained from the Independent Ethics Committee, and all participants provided written consent. The study assessed changes in severity of hyperpigmentation by dermatological assessment using IGA scale, changes in melanin (pigmentation) level, erythema index using instrument Mexameter® MX 18. Evaluations were conducted at baseline, T30 minutes, Day 21, and Day 45 post-usage. Statistical analyses performed by SPSS (Version: 29.0.1.0) and Microsoft® Excel 2019 software, with results reported using p-values and confidence intervals at a 5% significance level.

Results: Based on the clinical, and statistical analysis, the results obtained from the study showed that: Notably, the application of the test treatment provides to a remarkable reduction in melanin pigment levels, with decrease of 16.32% observed immediately post T30 mins of application compared to baseline. This reduction continued to demonstrate efficacy over time, with subsequent reductions of 27.64% and 33.84% after 21 and 45 days of continuous usage respectively, each accompanied by a highly significant p-value of <0.0001. Similarly, reductions in erythema were observed, with a 5.04% decrease compared to baseline post T30 mins of application, and further reductions of 11.50% and 18.12% after 21 and 45 days of usage, also displaying highly significant p-values <0.0001. 100% subjects experienced test treatment effective in lightening the dark patches and 100% subjects experienced test treatment satisfactory after use.

Conclusion: ThriveCo Dark Patches Corrector Cream is a clinically proven solution designed to target dark patches by exfoliating the skin, promoting cell turnover, and inhibiting melanin production. This study demonstrates that the test product, formulated with the advanced Galapep™ complex, is both safe and effective in managing hyperpigmentation. The synergistic action of its active ingredients—lactic acid, gallic acid, niacinamide, tranexamic acid, and retinaldehyde—significantly reduces melanin production, promoting even skin tone. Clinical results further show a marked reduction in erythema levels, with participants experiencing a significant improvement in the severity of dark patches. These findings highlight the potential of Galapep™-based formulations as a reliable solution for safely reducing hyperpigmentation and improving skin clarity.

Keywords: hyperpigmentation, dark spots, dark patches, IGA scoring, melanin, erythema

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Introduction

Hyperpigmentation, commonly known as dark spots, occurs when certain areas of the skin appear darker than the surrounding skin due to an excess of melanin production. Melanin is the pigment responsible for skin color, and its overproduction can lead to aesthetically concerning dark patches, despite them being generally harmless. Dark spots can vary in size and location, but they are most frequently found on sun-exposed areas such as the face, hands, and shoulders. While the condition is widespread, it presents both cosmetic and psychological challenges for many individuals.[1]

Dark spots can be classified into several types, each with distinct underlying causes. Solar lentigines, also known as sunspots, are flat, dark patches caused by prolonged sun exposure and are commonly seen on the face, hands, shoulders, and arms. Melasma is characterized by larger, darker patches on the skin, often triggered by hormonal changes, and typically appears on the face, especially the cheeks, forehead, and upper lip. Post-inflammatory hyperpigmentation (PIH) results from skin injuries or inflammation caused by conditions such as acne, eczema, or cuts, and can appear anywhere on the body where damage has occurred.[2] While not technically classified as hyperpigmentation, freckles are small, concentrated melanin spots, often genetic, that become more pronounced with sun exposure.[3]

Several factors can contribute to the development and severity of dark spots. Genetics play a significant role, as individuals with darker skin tones are more prone to hyperpigmentation due to higher melanin index.[4] Age is another factor, as the skin's natural regenerative abilities decline over time, making it more susceptible to damage and discoloration. Environmental factors, particularly sun exposure, are major contributors to dark spots. Prolonged exposure to UV radiation without proper protection accelerates melanin production, leading to dark spots. Additionally, lifestyle choices, such as smoking and an unhealthy diet, can weaken the skin's ability to repair itself, making it more prone to discoloration.[5,6]

Hyperpigmentation is highly prevalent in India, with conditions like melasma, post-inflammatory hyperpigmentation (PIH). Contributing factors include excessive sun exposure, hormonal changes, genetic predisposition, and the misuse of skin-lightening agents. Melasma affects 8–10% of dermatology patients, predominantly women aged 20–40, while PIH often occurs following acne or eczema. These trends highlight the need for public education on sun protection and the development of effective, tailored treatments.[7]

Given the multifactorial nature of hyperpigmentation, effective treatment requires a comprehensive understanding of its causes and the development of targeted therapeutic strategies. Traditional products for dark spots often include individual ingredients like retinoids, vitamins, tranexamic acid, niacinamide, and alpha hydroxy acids. However, there remains a need for novel formulations that combine these potent ingredients into a single, effective treatment.[8–10]

Common Dark spots products typically includes retinoids, vitamins, tranexamic acid, niacinamide, alpha hydroxy acids etc. However, the test product offers a novel approach by combining several ingredients into a single product. The test product, contains Galapep™ (Lactic Acid, Niacinamide, Gallic acid, Tranexamic Acid, Retinaldehyde) a comprehensive solution for management for hyperpigmentation.

Retinal, a potent form of vitamin A, is effective in dark patches corrector creams as it accelerates skin cell turnover, promotes collagen production, and exfoliates to fade dark spots and even skin tone. It works quickly and is gentle on sensitive skin, making it suitable for treating hyperpigmentation and signs of aging.[11,12] Tranexamic acid, a synthetic lysine derivative, inhibits melanin synthesis, helping to reduce hyperpigmentation and lighten dark spots. It is particularly effective for melasma and post-inflammatory hyperpigmentation, with anti-inflammatory properties that calm the skin, reduce redness, and enhance overall complexion. Topical application of tranexamic acid is safe and effective for addressing pigmentation disorders.[13,14]

Niacinamide, a vitamin B3 form, is often used in dark patches corrector creams to reduce hyperpigmentation and improve skin texture. It inhibits melanin transfer, strengthens the skin barrier, reduces inflammation, minimizes redness, and regulates oil production.[15,16] Lactic acid, an alpha-hydroxy acid, promotes cell turnover, fades dark spots, and hydrates the skin, enhancing skin texture and radiance.[17]

In conclusion, effectively addressing dark spots and hyperpigmentation necessitates not only a deep understanding of their underlying causes but also the development of advanced formulations tailored to these issues. The novel depigmentation cream in this study combines a unique blend of potent ingredients, including Retinal, Tranexamic Acid, Niacinamide, and Lactic Acid, offering a synergistic approach to reducing pigmentation. Retinal accelerates cell turnover and promotes collagen production, while Tranexamic Acid inhibits melanin synthesis and calms inflammation. Niacinamide enhances skin barrier function and reduces redness, and Lactic Acid exfoliates and hydrates the skin for a smoother, more even complexion. This innovative formulation distinguishes itself by delivering both rapid and gentle effects, making it highly effective for reducing dark spots and hyperpigmentation, especially in sensitive skin types. The study aims to validate the cream's ability to provide comprehensive skin tone improvement, marking a significant advancement in depigmentation treatments.

Materials and methods

Ethical conduct of the study

This study was conducted in accordance with the principles outlined in the New Drugs and Clinical Trials Rules 2019, ICH guidance E6 (R2) on 'Good Clinical Practice,' ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, and the Declaration of Helsinki (Brazil, October 2013). Ethical approval for the study plan was obtained from the Ethics Committee prior to the commencement of any study-related activities. All participants provided signed informed consent before enrolment in the study. The consent process included a detailed explanation of the study objectives, procedures, confidentiality measures, and the voluntary nature of participation.

Furthermore, this clinical study was registered with the Clinical Trial Registry of India (CTRI) [CTRI/2023/12/060424]. This comprehensive ethical framework ensures the study's compliance with international and national ethical standards, safeguarding the rights, safety, and well-being of all participating subjects.

Study design

This was an open-label, single-arm, single-center, prospective, interventional clinical study to evaluate the safety, efficacy, and in-use tolerability of the test product. The study was conducted at NovoBliss Research Private Limited, Ahmedabad, India, involving a total of 32 adult subjects both male and female aged 25 to 53 years with dark patches at different body regions (neck, elbows, knees, underarms). The study duration was 45 Days.

The primary objective was to evaluate the effectiveness of the test product in terms of changes in dark spots patches of the skin, hyperpigmentation score. The secondary objective was to evaluate the effectiveness of the test product in terms of changes in product perception of the test product.

Subjects were screened based on predefined inclusion and exclusion criteria to ensure a homogeneous study population. Inclusion criteria included healthy adult male and non-pregnant/ non-lactating females aged 25-53 years. Female of childbearing potential had self-reported negative urine pregnancy test, had good in general health as determined from recent medical history, had hyperpigmentation/ post inflammatory hyperpigmentation/ melasma/ acanthosis nigricans, who willing and able to follow the study directions and participate in the study, agreed to returning for all specified visits, was able to understand and provide written informed consent to participate in the study.

Exclusion criteria included subjects with known allergy or sensitization to product ingredients, had history of alcohol or drug addiction, using other marketed products for dark patches removal/

corrector products during the study period, had skin irritation, open wounds, cuts, abrasions, irritation symptoms or dermatological condition on the reading site that can interfere with the reading, had undergone any laser therapies and chemical peeling, had current or past medication history which may affect skin response, had any concurrent skin disease, had taken any systemic corticosteroids, anti-bacterial, immunosuppressant drugs in the past 30 days, who had engage in activities that involve excessive exposure to sunlight, female who was pregnant or breastfeeding or planning to became pregnant during the study period, who had a medical condition or had been taking or had taken a medication which, in the Investigator's judgment, made the subject ineligible or places the subject at undue risk, had been treated with topical steroids, retinoids or other topical drugs within 2 weeks prior to entry to the study, had participated in other clinical studies simultaneously.

Study procedure

The study was conducted over three visits in total product duration was 45 Days. On Visit 01 participants underwent screening, enrolment and baseline test product evaluations, visit 02 encompassed the evaluations phase, and test product usage period and last Visit 03 involved final product evaluations and end of study.

Details about test product for dark patches management

The ThriveCo Dark Patches Corrector Cream a topical formulation designed for the treatment of hyperpigmentation. Participants had applied the cream to the desired area of the skin and massaged until fully absorbed. The product contains Galapep™ which includes key ingredients such as lactic acid, niacinamide, gallic acid, propanediol, aqua, phenoxyethanol, ethylhexylglycerin, tranexamic acid, retinaldehyde, triethanolamine, sodium metabisulfite, and PEG-40 hydrogenated castor oil. For optimal efficacy, the cream was applied twice daily. The product is produced by Anveya Living Private Limited, India.

Investigator Global Assessment Scale (IGA) was performed to evaluate the hyperpigmentation. Evaluation was performed before and after usage of the test product T30 mins on Day 01, Day 21 and Day 45. The scoring system for grading brown spots or areas of discoloration ranges from 0 to 4. A score of 0, labeled "Clear," indicates no brown spots or areas of discoloration. A score of 1, "Almost clear," signifies the presence of a few very small brown spots that are only slightly darker than the surrounding skin. A score of 2, "Mild," indicates several small brown spots that are slightly darker than the surrounding skin. A score of 3, "Moderate," represents many medium-sized brown spots that are much darker than the surrounding skin. Finally, a score of 4, "Severe," is assigned when there are many large brown spots that are markedly darker than the surrounding skin.

The Mexameter® MX 18 (by Courage + Khazaka Electronic GmbH) utilizes a probe that emits light at three specific wavelengths, with a receiver capturing the light reflected from the skin. This measurement is based on the principles of absorption and reflection. By knowing the emitted light intensity, the device calculates the amount absorbed by the skin. Facial blemishes, including dark spots, are evaluated in a designated area of the subject's face. Evaluation was performed before usage of the test product on Day 01 and after usage of the test product at T30 mins on Day 01, Day 21 and Day 45 (Figure 1 Mexameter® MX 18).

Figure 1 Measurement of the hyperpigmentation by the Mexameter® MX 18.

Study-specific digital photographs were taken before test product usage on Day 01, and after usage of test product at T30mins on Day 01, Day 21 and Day 45 by using Nikon Digital Camera D3300.

Statistical analysis

Continuous variables were described by descriptive statistics (N, Mean, SD, Median, Minimum, and Maximum). Categorical variables were expressed by frequency and percentage along with graphical presentations whenever required.

The statistical analysis was done using SPSS (Version: 29.0.1.0) and Microsoft® Excel 2019 software with a 5% level of significance. Withdrawn subjects were not included in the statistical analysis.

Data handling and analysis

All data were carefully reviewed and cleaned before analysis to ensure accuracy and completeness. Frequency analyses and cross-tabulations were performed to ensure data accuracy and consistency. Missing data were addressed through appropriate imputation methods or excluded from the analysis, depending on the extent and nature of the missingness. The results of the statistical tests, including p-values, were reported with corresponding confidence intervals to provide a measure of precision and reliability.

Sample size determination

The sample size for this study was determined based on insights from a thorough literature review, providing guidance on typical enrollment numbers for similar research. This approach ensured a balance between feasibility and scientific rigor, with a target of 30 completed subjects to account for potential dropouts. A total of 32 participants were enrolled, and 30 successfully completed the study, ensuring data robustness and reliability. The sample size was carefully selected to generate meaningful outcomes while maintaining a 95% confidence interval, reinforcing the validity and reliability of the study's findings.

Results

Demographic and other baseline characteristics

A total of 32 participants, aged between 25 and 53 years, were enrolled in the study, with 30 completing it. Although there were

two dropouts, complete data was obtained for both pre- and post-dark spot assessments, allowing for a thorough analysis. The study demonstrated strong adherence to the intervention and assessment schedules. Figure 2 illustrates the subject disposition. The cohort was well-balanced, comprising 53.13% women (n=17) and 46.88% men (n=15) with mean age of 37.06 ± 7.59 years.

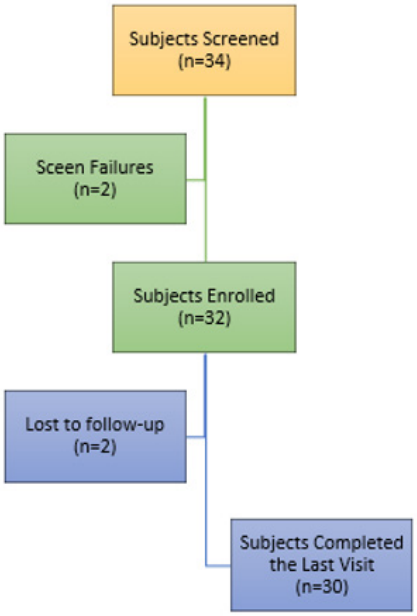

Figure 2 Subject disposition during conduct of the study.

Primary endpoints

Melanin (pigmentation) and Erythema using Mexameter ® MX 18

Skin melanin index, measured using the Mexameter® MX 18, exhibited significant changes following the application of the test product. At baseline, before the product, the melanin index was 768.22 ± 133.98. Thirty minutes after product application (T30), the melanin index decreased to 643.24 ± 146.62, showing a highly significant reduction ($p < 0.0001$). This trend continued, with melanin index further decreasing to 552.73 ± 131.55 on Day 21 ($p < 0.0001$) and reaching 505.91 ± 118.37 by Day 45 ($p < 0.0001$). These results indicate a substantial and statistically significant reduction in melanin index over time with the use of the test product (Figure 3).

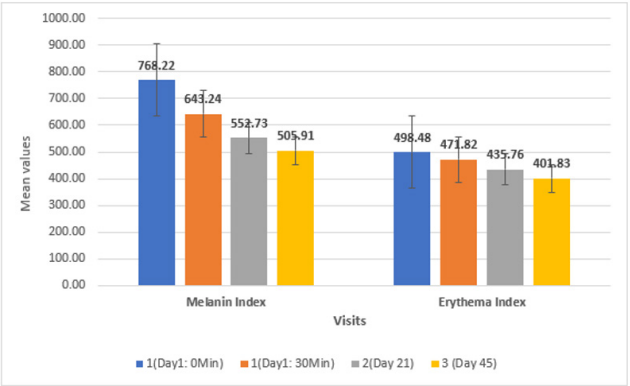

Figure 3 Change in melanin index and erythema index assessed by Mexameter® MX 18- Evaluation of hyperpigmentation.

Skin erythema index, measured using the Mexameter® MX 18, exhibited significant changes following the application of the test product. At baseline, before the product, the erythema index was 498.48 ± 97.90. Thirty minutes after product application (T30), the melanin index decreased to 471.82 ± 81.82, showing a highly significant reduction ($p < 0.0001$). This trend continued, with melanin index further decreasing to 435.76 ± 67.21 on Day 21 ($p < 0.0001$) and reaching 401.83 ± 67.76 by Day 45 ($p < 0.0001$). These results indicate a substantial and statistically significant reduction in erythema index over time with the use of the test product.

Hyperpigmentation using investigator global assessment scale

At baseline, prior to the use of the test product, 43.33% of the subjects had mild hyperpigmentation, and 56.67% had moderate hyperpigmentation. After 30 minutes of product application, there was no change in the distribution of hyperpigmentation severity, with the same percentages of subjects experiencing mild and moderate hyperpigmentation. However, by Day 21, a slight improvement was observed, with 44.83% of subjects showing mild hyperpigmentation and 55.17% showing moderate hyperpigmentation. The most significant changes occurred by Day 45, where 10.00% of subjects had almost clear skin, 66.67% had mild hyperpigmentation, and only 23.33% continued to exhibit moderate hyperpigmentation. These results indicate a progressive improvement in skin hyperpigmentation with the test product, especially by Day 45, where a noticeable shift from moderate to mild or almost clear hyperpigmentation was observed in a significant proportion of subjects (Figure 4).[17]

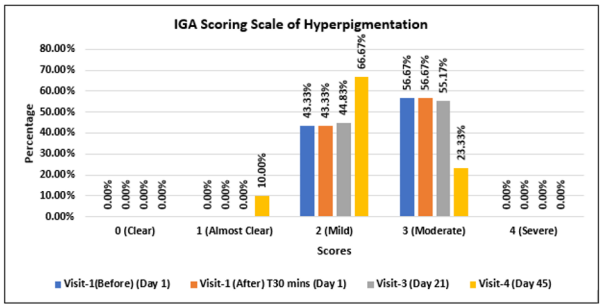

Figure 4 Change in hyperpigmentation assessed by IGA scoring- Evaluation of hyperpigmentation.

Secondary endpoints

In the study, hyperpigmentation was documented using a detailed photographic assessment. High-resolution images of affected skin areas were captured under standardized conditions to ensure consistency across all participants. These images were then documented to assess the extent and severity of hyperpigmentation over time (Figure 5) (Figure 6).

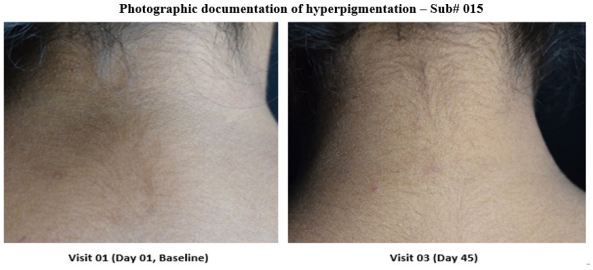

Figure 5 Change in hyperpigmentation.

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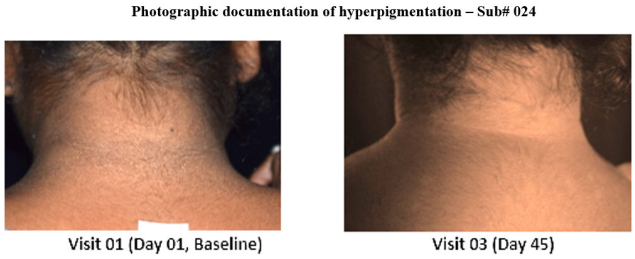
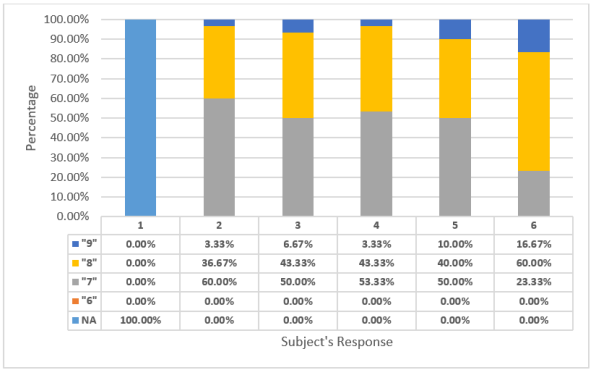


Figure 6 Change in hyperpigmentation.

Change in subject response index using 9-point hedonic scale

This 9-point hedonic scale includes questions assessing the effectiveness of the test product in areas such as reduction in skin itchiness, redness, roughness, scaliness and dryness, reduction in area dark patches, lighten the dark patches, nourishes and soothes the skin without causing inflammation, overall satisfaction. Respondents rate each aspect from 1 to 9, where 1 means "extremely ineffective," 2 means "very much ineffective," 3 means "moderately ineffective," 4 means "slightly ineffective," 5 means "don't know," 6 means "slightly effective," 7 means "moderately effective," 8 means "very much effective," and 9 means "extremely effective."

In the Figure 7 Subject Response Index, the horizontal axis represents different measured outcomes related to the test product's efficacy during the study. Each numbered point along the axis corresponds to the following "1" represents the earlier test product usage. "2" represents the reduction in skin dryness, itchiness, redness, roughness, scaliness and smoothness, "3" represents the reduction in area dark patches, "4" represents the lighten the dark patches, "5" represents the nourishes and soothes the skin without causing inflammation, "6" represents the overall satisfaction after the use of test product at the end of the study.



	1	2	3	4	5	6
"9"	0.00%	3.33%	6.67%	3.33%	10.00%	16.67%
"8"	0.00%	36.67%	43.33%	43.33%	40.00%	60.00%
"7"	0.00%	60.00%	50.00%	53.33%	50.00%	23.33%
"6"	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
NA	100.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Figure 7 Subject response index.

Discussion

Hyperpigmentation, characterized by dark skin patches, arises from increased melanin production, the pigment responsible for skin color. Common triggers include UV exposure, hormonal changes, inflammation, aging, and certain medications. Conditions like melasma, often seen in pregnant women, and post-inflammatory hyperpigmentation (PIH), following acne or injury, are frequent causes. While generally benign, hyperpigmentation may cause cosmetic concerns. Treatments such as topical agents, chemical peels, and laser therapy are commonly used for skin lightening.[18]

This open-label, single-arm, single-center, prospective clinical study evaluated the safety, efficacy, and tolerability of a depigmentation cream in healthy adults with hyperpigmentation. Key parameters assessed included changes in melanin and erythema indices, Investigator Global Assessment (IGA) of hyperpigmentation severity, photographic documentation of dark spots, and participant-reported outcomes. Dermatological assessments were conducted using validated methodologies to ensure consistency and precision.[10]

Niacinamide, a derivative of vitamin B3, has been shown to reduce hyperpigmentation by inhibiting the transfer of melanin from melanocytes to keratinocytes. Clinical studies have demonstrated that niacinamide can significantly decrease hyperpigmentation and improve skin brightness within four weeks of use. Additionally, niacinamide helps to correct uneven skin tone without bleaching the skin or altering the individual's natural pigmentation.[19]

Retinal exerts its effects at the cellular level by activating nuclear receptors, which regulate cell proliferation and differentiation, promoting the emergence of newer, healthier skin. It also inhibits tyrosinase, the enzyme involved in melanin synthesis, thereby reducing the formation of new hyperpigmented lesions.[20]

Tranexamic acid (TXA) is used to treat hyperpigmentation due to its anti-inflammatory and anti-melanogenic properties. It can be administered topically, orally, or via intradermal injection, and is often combined with other skincare agents. TXA inhibits pathways involved in excess melanin production, thereby reducing pigmentation.

Despite promising results, challenges such as variations in skin type, the recurrence of dark spots, and potential side effects often highlight the need for personalized product approaches and further research.

The findings demonstrate that the test product effectively reduces both melanin and erythema indices, suggesting its potential for improving skin pigmentation and reducing inflammation. The significant reduction in the melanin index over time indicates a progressive lightening of hyperpigmentation, with the most notable changes occurring during study. This is further supported by the observed shift in hyperpigmentation severity, with a greater proportion of subjects showing mild or almost clear skin. The product's ability to decrease erythema suggests an additional anti-inflammatory benefit, contributing to improved skin health. Overall, these results support the product's efficacy in addressing hyperpigmentation and inflammation over an extended period.

Numerous studies on hyperpigmentation have explored its etiology, prevalence, and treatments, focusing on conditions like melasma and post-inflammatory hyperpigmentation (PIH). Research highlights the role of genetic, hormonal, and environmental factors, with interventions ranging from topical agents to advanced techniques like chemical peels and lasers. While these treatments show promise, variable responses and side effects emphasize the need for personalized approaches. Preventive strategies, such as sun protection, remain crucial for effective management.

The study has several limitations that should be acknowledged. First, the small sample size and the short duration of 45 days may limit the generalizability and long-term relevance of the findings. Additionally, key factors such as environmental conditions, diet, genetics, and hormonal imbalances were not accounted for, which could have influenced the outcomes. Caution is therefore required when interpreting the results. Long-term studies are necessary to gain a clearer understanding of the sustained benefits of continued use.

Despite these limitations, the test product demonstrated potential as a treatment option for hyperpigmentation. The combination of active ingredients, including Retinal, Tranexamic acid, Niacinamide, and Lactic acid, appeared to effectively reduce pigmentation. Future research should explore the long-term efficacy of the product across diverse populations to expand its clinical applicability.

A further limitation is the single-arm, open-label design, which lacks a control group such as a placebo or comparator. This design makes it difficult to definitively attribute improvements in hyperpigmentation to the test product, as natural skin healing or placebo effects cannot be excluded. The open-label nature could also introduce bias in outcome assessment. Future studies should adopt a randomized controlled trial (RCT) design to strengthen the evidence and minimize bias.

Exploring the test product's long-term safety and efficacy in varied populations and examining its interactions with lifestyle and environmental factors could provide deeper insights into its clinical potential and broaden its application.

Conclusion

The ThriveCo Dark Patches Corrector Cream has been resulted as safe and effective, achieving a 100% well-being rating among all participants in clinical trials. The cream's formulation includes Galapep™ (a blend of lactic acid, niacinamide, gallic acid, tranexamic acid and retinaldehyde), which works synergistically to target dark patches. Lactic acid and retinaldehyde collaborate to exfoliate the skin and boost cell turnover, aiding in the removal of pigmented cells. Niacinamide, tranexamic acid, and gallic acid contribute to skin brightening by inhibiting melanin production.

The efficacy of Galapep™ was particularly notable in reducing dark patches in areas such as the neck, elbows, knees, and underarms, leading to a visible decrease in pigmentation. Clinical trials demonstrated significant reductions in melanin and erythema index, along with a marked decrease in hyperpigmentation.

Incorporating the ThriveCo Dark Patches Corrector Cream into a regular skincare routine may provide substantial benefits in reducing dark patches, resulting in a more radiant and even complexion.

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Conflict of interest

The authors declared that there are no conflicts of interest.

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