Research Article

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ANTIBLEMISH ACTIVITY OF PROPRIETARY POLYHERBAL OIL- "SANDANYA"

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ABSTRACT

In the modern era, skin and appearance profoundly influence personal confidence, leading people to seek safe and well-tolerated remedies for their skincare concerns. Ayurveda, the traditional science of life, offers numerous solutions for persistent skin imperfections. Sandanya is a polyherbal formulation developed based on the principles and concepts of skin disease–treating oils described in the classical ancient Ayurvedic text Chakradutta. The oil is prepared using the classical Snehakalpana (medicated oil preparation) procedure to manage skin pigmentation commonly known as blemishes. Grapeseed oil was chosen as the base oil because of its light, penetrating, non-greasy texture. The preparation method was adopted to enhance the concentration of active phytoconstituents. The formulation contains *Mesua ferrea, Glycyrrhiza glabra*, and *Symplocos racemosa*, each with documented dermatological activity, especially in skin lightening, anti-inflammatory action, and tissue repair. We conducted a three-month clinical evaluation of Sandanya oil in 18 participants with topical application. The results showed improvement in acne marks, dark spots, blemishes, and participant-reported breakouts. No acneiform eruptions were observed under the study conditions. Participants showed improvements in skin evenness, pigmentation, texture, oiliness, sebum levels, and pore appearance, indicating this formulation as a well-tolerated topical therapy for blemishes and other skin imperfections. At Week 12, key improvements included reduced sebum levels (−43.08%, p=0.0002), skin oiliness (−72.48%, p<0.05), pore index (−48.21%, p<0.0001), global pigmentation (−3.16%, p<0.0005), scaliness (−52.06%), and smoothness index (−28.54%, p≤0.0002), along with improved Spot-L* (+5.66%, p<0.0005) and skin evenness (+19.90%, p<0.05).

Keywords: Blemishes, Snehakalpana, anti-inflammatory, noncomedogenic

INTRODUCTION

Today, maintaining clear, healthy skin is an important part of self-care and wellbeing. Clear skin has gained considerable importance due to increased aesthetic consciousness, social visibility, and growing awareness of skin health. Contemporary market reports indicate that rising consumer interest in skincare, ingredient-led formulations, and dermo cosmetics reflects the growing importance of maintaining clear, healthy skin.[1]

Blemishes, including dark spots, acne marks, and post-inflammatory hyperpigmentation (PIH), are among the most common dermatological concerns and are often persistent and difficult to manage.[2]However, multiple factors such as environmental pollution, stress, hormonal imbalances, and inadequate skincare practices contribute to different skin concerns, particularly blemishes, acne marks, hyperpigmentation, and uneven skin tone, thereby negatively affecting both physical appearance and psychological well-being.[3]

Although conventional dermatological treatments may provide temporary improvement, they often cause undesirable effects such as skin irritation, dryness, and increased sensitivity. These limitations underscore the need for better-tolerated and effective alternatives for long-term results.

In this context, Ayurveda offers a holistic approach to skin care, using polyherbal formulations that address visible symptoms while targeting underlying imbalances. Moreover, acceptance of Ayurvedic and herbal products has increased considerably due to growing consumer awareness of natural ingredients, preventive health care, perceived safety, and a preference for plant-based personal care products.[4]

Sandanya Anti-Blemish Ayurvedic Oil is a polyherbal formulation developed according to classical Ayurvedic principles. The formulation includes ingredients known for their complexion-enhancing (Varnya), anti-inflammatory (Shothahara), antioxidant, and skin-rejuvenating properties, while ensuring safety and tolerability.

Despite the long-standing traditional use of Ayurvedic formulations for skin care, robust scientific evidence supporting their efficacy and safety remains limited. Therefore, this study aims to develop and evaluate Sandanya oil for managing blemishes, acne marks, dark spots, and improving overall skin quality. The evaluation was conducted through dermatological and instrumental assessments to generate comprehensive clinical evidence supporting the formulation.

Aims and objectives

Aim: This study aimed to develop a novel polyherbal Ayurvedic oil with anti-blemish properties and clinically evaluate its effectiveness in improving overall skin quality.

Objectives: To formulate a novel polyherbal oil with potential anti-blemish activity; conduct a clinical evaluation to determine

the oil's efficacy in reducing skin blemishes, including acne marks and post-inflammatory hyperpigmentation; and document changes in overall skin condition with regular use.

MATERIALS and METHODS

Drug review

The main ingredients of Sandanya oil are *Mesua ferrea*, *Glycyrrhiza glabra*, *Symplocos racemosa,* and grapeseed oil as the base (Table 1).

Table 1: Drug review, Ayurvedic properties of ingredients.[5]

Botanical name	Rasa	Guna	Virya	Vipaka	Karma
Mesua ferrea	Kashaya, Tikta	Laghu, Ruksha	Sheeta	Katu	Pacifies, Pitta and Kapha Varnya, Kusthaghna, Raktashodhaka, Shothahara
Glycyrrhiza glabra	Madhura	Guru, Snigdha	Sheeta	Madhura	Pacifies, Vata and Pitta Varnya, Vranaropana, Raktaprasadana, Kusthaghna
Symplocos racemosa	Kashaya	Laghu, Ruksha	Sheeta	Katu	Pacifies Kapha and Pitta Varnya, Shothahara, Raktastambhaka, Kusthaghna
Grapeseed oil (Vitis vinifera)	Madhura, Kashaya	Laghu, Snigdha	Sheeta	N/A	Pacifies Vata and Pitta Twachya, Varnya, Rasayana

Based on these Ayurvedic properties, the herbs in the formulation may work synergistically to reduce inflammation, support traditional Raktashodhana (blood-purifying)-related skin benefits, improve complexion and skin tone, reduce pigmentation, soothe irritated skin, control excess oil, and help reduce blemishes.

Preparation of medicine

Sandanya oil is a Proprietary Ayurvedic Oil prepared according to the traditional Sneha Kalpana method.[6] Sneha Kalpana involves the processing of herbal ingredients with a lipid base in the presence of a liquid medium to extract the active principles of the herbs into oil. Sandanya oil is prepared using herbal paste Kalka (herbal paste), Decoction (Drava Dravya -liquid medium), and grapeseed oil as the base oil (Sneha Dravya (oil medium)).

Preparation of Kalka (Herbal Paste)

The herbal ingredients mentioned above were taken according to the formulation requirements. The raw materials were cleaned and subjected to disintegration followed by pulverization to obtain Kalka (herbal paste) powder. [7]

Preparation of Decoction (Drava Dravya)

The decoction was prepared using *Glycyrrhiza glabra* (licorice). The required quantity of licorice was thoroughly washed and disintegrated into smaller pieces. The disintegrated material was boiled with the required amount of water under controlled heating until a proper decoction was obtained. [8]

Preparation of Medicated Oil (Sneha Dravya)

A clean stainless-steel vessel was used to prepare Sandanya oil. The required quantity of grapeseed oil was first introduced into the vessel according to the batch size. Subsequently, the prepared herbal paste (Kalka (herbal paste)) was added to the oil, followed by the addition of the decoction.

The mixture was thoroughly mixed to achieve uniform dispersion and then subjected to heating using steam. Continuous stirring was maintained during heating to ensure uniform mixing and prevent the herbal paste from adhering to or burning at the base of the vessel.

The heating continued until the herbal paste attained a sand-like consistency, an important indicator of completion of the Sneha Kalpana process. At this stage, heating was stopped. [6]

Filtration

The prepared medicated oil was allowed to cool slightly, then filtered through a clean cloth to remove residual herbal particles. The Sandanya oil was completed by adding black cumin seed oil and rumi mastagi as Prakshepa Dravya (finishing additives) to improve the formulation's sensory properties.

The prepared Sandanya oil was then packed in appropriate containers, transferred for quality evaluation, and then used for clinical testing.

CLINICAL STUDY

Plan of study

The clinical study was designed to evaluate the efficacy of Sandanya oil in reducing various types of facial blemishes, including spots, pigmentation, blackheads, post-inflammatory hyperpigmentation (PIH), acne, unevenness and scars. A total of 20 female subjects were enrolled, of whom 18 completed this three-month study consisting of 6 visits (Table 2).

Table 2: Study Phase / Visit Plan.

Study Phase	Visit	Assessments
Visit 1	Day minus 7 ± 2 days	Initial screening and study briefing Washout period
Visit 2	Day 0	Dermatological screening and inclusion to the study Informed consent obtained under ICH–GCP guidelines Baseline assessment Distribution of Sandanya oil, participant diary, training and usage instructions
Visit 3, 4 and 5	Day 14 (Week 2), Day 28 (Week 4), and Day 56 (Week 8)	Dermatologist clinical evaluation Instrumental measurements in predefined sequence (Figure 1)
Visit 6	Day 84 (Week 12)	Final dermatological and instrumental evaluations Completion of exit form

Eligibility Criteria

Inclusion Criteria

- Female participants aged 18 to 35 years, inclusive.
- In general good health, with facial blemishes (spots, pigmentation, blackheads, PIH, acne, unevenness, or scars).
- Willing and able to provide written informed consent.
- Agreed to comply with all study protocol requirements.
- Confirmed no participation in any similar cosmetic or dermatological study in the previous two weeks.
- Agreed not to use additional skincare products, treatments, or home remedies during the study period that could influence outcomes.

Exclusion Criteria

- History or presence of uncontrolled medical conditions (including diabetes mellitus, hypertension, HIV, thyroid disorders, hepatitis, severe anaemia, major cardiac or respiratory illnesses).
- Known allergy or hypersensitivity to any cosmetic or dermatological product.
- Presence of active dermatological conditions (such as active atopic dermatitis, pigmented contact dermatitis, other significant cutaneous disorders).
- Pregnancy and lactation.
- Receipt of facial procedures or other treatments likely to compromise the study outcomes within the previous four weeks.
- Use of topical or systemic corticosteroids, antifungals, antibiotics, or prolonged NSAIDs or antihistamines within the past two weeks.
- Employees of MSCR or Kama Ayurveda/PUIG.

Method of application

Participants were trained in the standardised application procedure and applied Sandanya at home exactly as instructed, using the required quantity twice daily - morning and night - after washing the face. Participants applied the product as small dots evenly across the face and gently massaged it with their fingertips in an upward motion until it was fully absorbed into the skin.

Study Assessments

Dermatological Assessments

The dermatologist evaluated skin evenness, skin clarity, skin texture, and skin oiliness using the standardised 10-point scale shown in Table 3, with half-point scores permitted when required.

Table 3: Dermatological assessment 10-point scoring scale

Score	Severity descriptor	Operational interpretation
0	Absent/optimal	Lower score indicates a more favourable skin condition.
1	Minimal	Lower score indicates a more favourable skin condition.
2	Very slight	Lower score indicates a more favourable skin condition.
3	Slight	Lower score indicates a more favourable skin condition.
4	Mild	Lower score indicates a more favourable skin condition.
5	Mild to moderate	Lower score indicates a more favourable skin condition.
6	Moderate	Lower score indicates a more favourable skin condition.
7	Moderate to marked	Lower score indicates a more favourable skin condition.
8	Marked	Lower score indicates a more favourable skin condition.
9	Severe	Lower score indicates a more favourable skin condition.
10	Very severe/worst	Highest severity observed.

Assessment Procedure

Participants were acclimatised under standardised environmental conditions before evaluation. The Dermatologist assessed the same predefined facial areas at each visit under consistent illumination. The dermatologist rated skin evenness based on tone uniformity and surface appearance; skin clarity based on visible dullness, spots, and overall translucency; skin texture through visual inspection and gentle tactile assessment of roughness and smoothness; and skin oiliness based on visible shine and a greasy appearance, particularly on the forehead, nose, and cheeks. Each parameter was scored independently from 0 to 10, where 0 represented absence of the concern or the optimal condition and 10 represented the most severe condition. Half-point scores were permitted, and lower follow-up scores indicated improvement.

Instrumental assessments

Table 4: Instrument-based biophysical skin measurements

Instrument	Measurement Site	Assessment Details
Sebumeter	Forehead	Skin sebum level
Spectrophotometer	Forehead, Right or Left cheek	Instrumental assessment of skin colour and imperfections through two independent measurements at dermatologist-identified skin areas using standard colour parameters (L*, a*, b*) and their changes (ΔL*, ΔITA, ΔE)
Visio Scan	Right or Left cheek	Surface evaluation of skin
Antera 3D	Forehead, Right or Left cheek and	
Visia CR	Front, Left or Right profiles	Image acquisition

Statistical Analysis

Data from 18 participants who completed the study were included in the analysis. Normality of baseline measurements was assessed using the Shapiro–Wilk test. Parameters meeting the normality assumption ($p > 0.05$) were evaluated using a paired t-test while non-normal parameters ($p < 0.05$) were analysed using the Wilcoxon signed-rank test. All analyses were two-tailed with a 5% significance level, and 95% confidence intervals were reported.

OBSERVATIONS AND RESULTS

Unless otherwise stated, numerical values reported in the text and Annexure are exact calculated values, whereas values displayed in figures are rounded for presentation purposes and visual clarity.

Oiliness and Sebum Production

Instrumental assessment

Relative to baseline, sebum levels decreased by 13.61% at Day 14 (Week 2), 24.37% at Day 28 (Week 4), 35.22% at Day 56 (Week 8), and 43.08% at Day 84 (Week 12), indicating a steady and substantial improvement in oil control with continued application of Sandanya oil (Figure 1).

Dermatological assessment

Compared with baseline, skin oiliness decreased by 5.50% at Day 14 (Week 2), 30.28% at Day 28 (Week 4), 56.88% at Day 56 (Week 8), and 72.48% at Day 84 (Week 12) (Figure 2). Sandanya oil demonstrated a progressive and substantial reduction in skin oiliness across all evaluation time points.

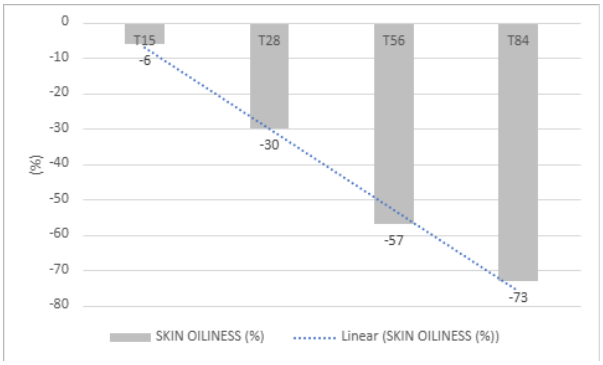
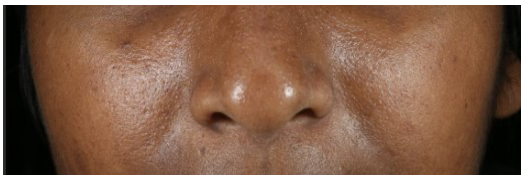


Figure 1: Sebumeter assessment of percent change in sebum levels over time. Lower mean values indicate reduced sebum levels. Time points are reported as Day 14 (Week 2), Day 28 (Week 4), Day 56 (Week 8), and Day 84 (Week 12). All reported results were statistically significant at p=0.0002.



a. Before application; Front view of face

b. After 12 weeks; Front view of face

Images 1a, b. Representative images of Volunteer 14 showing visible changes in skin oiliness from baseline to Week 12 after application of Sandanya oil.

Figure 2: Dermatological assessment of skin oiliness over time. Lower mean values indicate reduced skin oiliness. Time points are reported as Day 14 (Week 2), Day 28 (Week 4), Day 56 (Week 8), and Day 84 (Week 12). All reported results were statistically significant at $p<0.05$.

Pigmentation and Skin Evenness

Instrumental assessment

Spot – Lightening (L*): Compared with baseline, Spot-L* increased by 1.52% at Day 14 (Week 2), 2.76% at Day 28 (Week 4), 4.54% at Day 56 (Week 8), and 5.66% at Day 84 (Week 12), indicating improved spot lightening with continued application (Figure 3).

Global – Pigmentation: Compared with baseline, global pigmentation decreased by 0.79% at Day 14 (Week 2), 1.50% at Day 28 (Week 4), 2.41% at Day 56 (Week 8), and 3.16% at Day 84 (Week 12), indicating a steady reduction in global pigmentation with continued application (Figure 3).

Dermatological assessment

Sandanya oil demonstrated a progressive improvement in skin evenness across the evaluation period. Compared with baseline, the dermatological skin evenness score decreased by 3.48% at Day 14 (Week 2), 13.93% at Day 28 (Week 4), 19.90% at Day 56 (Week 8), and 19.90% at Day 84 (Week 12), indicating improved skin evenness with continued application (Figure 4).

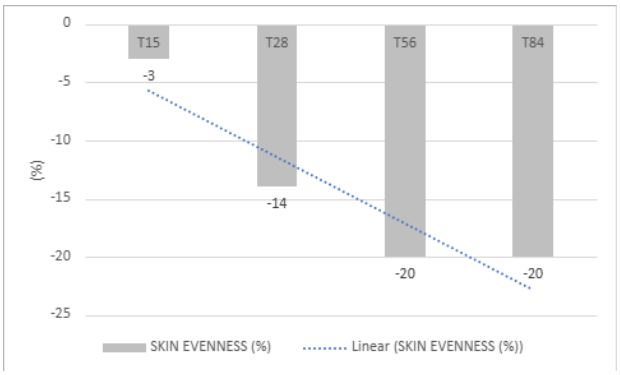
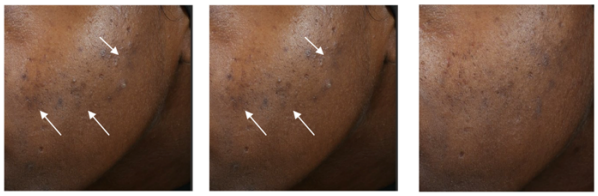


Figure 3: Instrumental measurement of percent change in global pigmentation and Spot-L* over time. Higher Spot-L* values indicate improved spot lightening, whereas lower global pigmentation values indicate reduced pigmentation. Time points are reported as Day 14 (Week 2), Day 28 (Week 4), Day 56 (Week 8), and Day 84 (Week 12). All reported results were statistically significant at $p<0.0005$.



a. Before application b. After 4 weeks c. After 12 weeks

Images 2a–c. Representative images of Volunteer 10 showing visible changes in pigmentation and skin texture from baseline to Week 12 after application of Sandanya oil.

a. Before application; lateral view of face (left). b. After 2 weeks; lateral view of face (left)

c. Before application; lateral view of face (right) d. After 4 weeks: lateral view of face (right)

Images 3a–d. Representative lateral-view images of Volunteer 17 showing visible changes in pigmentation and skin texture during the study period.

Figure 4. Dermatological assessment of skin evenness over time. Lower mean values indicate improved skin evenness. Time points are reported as Day 14 (Week 2), Day 28 (Week 4), Day 56 (Week 8), and Day 84 (Week 12). All reported results were statistically significant at $p<0.05$.

Texture

Instrumental assessment

Scaliness: Compared with baseline, scaliness decreased by 16.64% at Day 14 (Week 2), 31.73% at Day 28 (Week 4), 43.50% at Day 56 (Week 8), and 52.06% at Day 84 (Week 12), indicating a progressive reduction in skin scaliness with continued application (Figure 5).

Smoothness: Compared with baseline, the instrumental smoothness index decreased by 9.54% at Day 14 (Week 2), 17.45% at Day 28 (Week 4), 21.38% at Day 56 (Week 8), and 28.54% at Day 84 (Week 12). Since a lower smoothness index indicates smoother skin in this assessment, these findings indicate improved skin smoothness with continued application (Figure 5).

Dermatological assessment

Visual: when compared with baseline, skin texture showed measurable enhancement of 7.84% at Day 28 (Week 4) and 9.15% at both Day 56 (Week 8) and Day 84 (Week 12).

Tactile: compared with baseline, skin texture improved by 7.19% at Day 28 (Week 4) and by 8.50% at both Day 56 (Week 8) and Day 84 (Week 12).

Sandanya oil demonstrated consistent and sustained enhancement of skin texture with continued application (Figure 6).

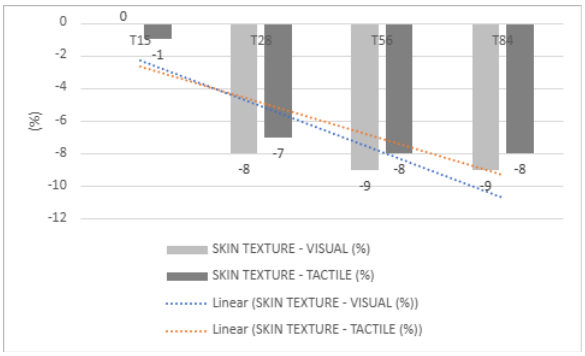


Figure 5: Instrumental assessment of percent improvement in scaliness and smoothness index over time. Lower mean values indicate reduced scaliness and improved skin smoothness. Time points are reported as Day 14 (Week 2), Day 28 (Week 4), Day 56 (Week 8), and Day 84 (Week 12). All reported time points were statistically significant at $p \leq 0.0002$.

a. Before application: Front view of face

b. After 12 weeks; Front view of face

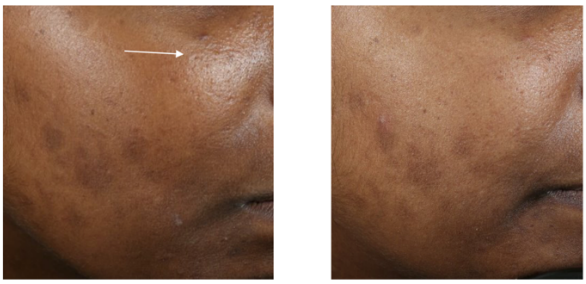
Images 4a, b. Representative images of Volunteer 09 showing visible changes in skin texture from baseline to Week 12 after application of Sandanya oil.

Figure 6: Dermatological assessment of visual and tactile skin texture over time. Lower mean values indicate improved skin texture. Time points are reported as Day 14 (Week 2), Day 28 (Week 4), Day 56 (Week 8), and Day 84 (Week 12). Significant improvements were observed from Day 28 (Week 4) onward.

Pores

Instrumental assessment: (pore index – cheek. Lower mean value indicates reduction in pores)

Compared with baseline, pore visibility decreased by 10.15% at Day 14 (Week 2), 22.31% at Day 28 (Week 4), 32.25% at Day 56 (Week 8), and 48.21% at Day 84 (Week 12), indicating a cumulative refining effect with continued application of Sandanya oil (Figure 7).



a. Before application: lateral view of face (right). b. After 12 weeks: lateral view of face (right).

Images 5a,b. Representative lateral-view images of Volunteer 14 showing visible changes in pore appearance from baseline to Week 12 after application of Sandanya oil.

Figure 7: Instrumental assessment of percent change in cheek pore index over time. Lower mean values indicate reduced pore appearance. Time points are reported as Day 14 (Week 2), Day 28 (Week 4), Day 56 (Week 8), and Day 84 (Week 12). All reported results were statistically significant at $p<0.0001$.

DISCUSSION

Blemishes represent a broad category of visible skin imperfections, including acne lesions, post-inflammatory hyperpigmentation (PIH), dark spots, minor scars/marks, pigmentations and uneven skin tone. These vary in severity and can be caused by multiple contributing factors, including inflammatory, pigmentary, hormonal, and environmental.

In many individuals, the process is initiated by an underlying inflammatory condition, most commonly acne. Inflammatory mediators released during acne can stimulate melanocyte activity, resulting in excess melanin deposition during the healing process. This process often leads to PIH, particularly in susceptible individuals.[9]

Excessive sebum production plays a pivotal role in the development and persistence of blemishes. Increased sebum promotes follicular obstruction and microbial proliferation, particularly by Cutibacterium acnes, thereby creating a pro-inflammatory microenvironment.[11,12] This inflammatory state may delay the natural skin healing process, increasing the risk of post-inflammatory pigmentation and uneven skin tone. Consequently, individuals with oily or combination skin are more prone to persistent blemishes, highlighting the critical role of sebaceous gland activity in pigmentation-related skin imperfections. [13]

In classical Ayurveda literature, including the Charaka Samhita, Sushruta Samhita and Ashtangahridaya Vyanga (facial hyperpigmentation) blemishes are classified under Kshudra roga (skin concerns), primarily affecting the facial region. They are characterised by painless bluish-black or brownish discolouration (Shyava varna mandala). These classical descriptions closely resemble modern dermatological conditions of facial hyperpigmentation, particularly melasma and PIH. The Samprapti (etiopathogenesis) of Vyanga (facial hyperpigmentation) is primarily attributed to vitiation of the Vata and Pitta doshas, with involvement of Rakta dhatu (blood tissue). Pitta, being responsible for skin colour and metabolic activities, plays a central role in the development of discolouration when aggravated. Vata contributes by causing irregular distribution and localisation of the pigmentation over the skin. Vitiation of Rakta dhatu (blood tissue) further aggravates the condition by impairing normal skin complexion and promoting discolouration.

This Ayurvedic conceptual framework aligns with contemporary dermatological understanding, in which inflammation, oxidative stress, and dysregulated melanocyte activity contribute to abnormal melanin deposition and hyperpigmentation. Psychological and environmental factors are emphasised as key causative elements in Vyanga (facial hyperpigmentation). Nidanas (causative factors) (causative factors) such as Krodha (anger), Shoka (grief), and Ratri jagarana (sleep deprivation) are known to aggravate Pitta and Vata, thereby triggering or exacerbating Vyanga (facial hyperpigmentation).[14-16]

Sandanya oil is a polyherbal formulation composed of Varnya (complexion-enhancing) (complexion-enhancing), Vranaropana (wound-healing), Rakta Shodhana (blood-purifying), and Shothahara (anti-inflammatory) (anti-inflammatory) herbs, delivered in a light, penetrating and non-greasy grapeseed oil base[17]. The ingredients were selected through an-in-depth review of classical Ayurvedic formulations, such as Varnakaghritam and Kanakathailam.

The incorporation of these functionally grouped herbs into a modern, cosmetically acceptable base may enhance both the therapeutic potential and user compliance in the integrative management of blemishes.

Instrumental and dermatological assessments conducted over a three-month period demonstrated statistically significant improvements in the parameters reported in the Results and Annexure, including skin evenness, pigmentation, oiliness/sebum production, scaliness, smoothness, texture, and pore appearance. Measurable benefits were observed as early as Day 14 (Week 2) for several instrumental parameters, with progressive improvements at Day 28 (Week 4), Day 56 (Week 8), and Day 84 (Week 12). These findings indicate improved sebaceous regulation, reduction invisible pigmentation-related imperfections, enhanced surface texture, and reduced pore visibility with continued application.

Collectively, these findings suggest that the formulation addresses key aesthetic aspects of blemish-prone skin. The reduction in pigmentation and improvement in skin evenness may be attributed to the synergistic action of Varnya (complexion-enhancing), Rakta Shodhana, and Shothahara (anti-inflammatory) herbal components. Furthermore, the observed reduction in oiliness/sebum levels and pore appearance supports the formulation's role in regulating sebaceous activity, thereby contributing to the management of acne-associated blemishes and subsequent post-inflammatory hyperpigmentation.

Overall, these findings suggest that Sandanya oil offers a comprehensive approach to blemish management by addressing pigmentation, oiliness, visible pores, and skin texture.

CONCLUSION

The results of this clinical evaluation highlight Sandanya oil's beneficial effects in visibly reducing blemishes while improving overall skin tone and quality. The study observed statistically significant improvements in the reported dermatological and instrumental endpoints, including oiliness/sebum production, pigmentation, skin evenness, texture, and pore appearance.

In addition, the formulation demonstrated high user acceptability and good skin tolerance throughout the study period. Taken together, these findings suggest that Sandanya oil is a well-tolerated formulation with potential benefits for the management of blemish-related skin concerns.

Nevertheless, further studies involving larger sample sizes and longer study durations are recommended to confirm the long-term efficacy of the formulation. Comparative clinical trials against standard dermatological treatments may provide additional insights into its relative effectiveness. Furthermore, investigation into the underlying molecular mechanisms of action of the herbal ingredients could help to strengthen the scientific understanding and clinical positioning of the formulation.

ACKNOWLEDGEMENTS

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DECLARATIONS

Ethics approval and consent to participate

The clinical study protocol (SKIN/PUAB/2024-01, Version 1.0 dated 26 September 2024) was reviewed and approved by the ACE Independent Ethics Committee (ACE IEC), Bangalore,

India. The ethics committee reviewed the study and approved the protocol on 07 October 2024. The ethics approval was issued under Protocol Number: SKIN/PUAB/2024-01. All participants provided written informed consent before study enrolment, and informed consent was obtained in accordance with ICH-GCP ethical principles and the Declaration of Helsinki.

Clinical trial registration

The study was prospectively registered with the Clinical Trials Registry–India (CTRI) under registration number CTRI/2024/10/075272 on 15 October 2024. The first participant enrolment was planned to begin on 25 October 2024, confirming prospective registration.

Conflict of interest

Several authors are employees of Puig and/or Kama Ayurveda, and the study evaluated a proprietary test product associated with these organizations. This potential conflict of interest is disclosed. The clinical study was conducted by MS Clinical Research Pvt Ltd, Bangalore, India, and dermatological evaluations were performed under the supervision of an independent dermatologist/principal investigator, Dr. Mukta Sachdev, MD Dermatology, who was not listed as an employee of Puig or Kama Ayurveda in the study report. The dermatologist/principal investigator had no direct financial relationship with the sponsor. Employees of MS Clinical Research Pvt Ltd or the sponsor were excluded from participation as study subjects.

ABBREVIATIONS

PIH – Post-inflammatory hyperpigmentation
ICH–GCP – International Council for Harmonisation–Good Clinical Practice
RandD – Research and Development
SD – Standard deviation
L* – Lightness value in the CIELAB colour space
a* – Red–green chromaticity value in the CIELAB colour space
b* – Yellow–blue chromaticity value in the CIELAB colour space
ΔL* – Change in lightness value
ΔITA – Change in Individual Typology Angle
ΔE – Total colour difference
VISIA CR – VISIA Complexion Analysis System
MSCR – MS Clinical Research
Pvt Ltd – Private Limited
HIV – Human immunodeficiency virus
NSAIDs – Non-steroidal anti-inflammatory drugs
Day 14/28/56/84 – Study assessment days corresponding to Week 2, Week 4, Week 8, and Week 12, respectively
N/A – Not applicable

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