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Research Article

Vitiligo

A Prospective, Open-Label Non-Randomized Clinical Trial to evaluate the safety and efficacy of Pigmento Tablet & Ointment in treatment of Vitiligo

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Background: Vitiligo is a chronic dermatological condition characterized by the loss of skin pigmentation due to the destruction or dysfunction of melanocytes. It can affect individuals of all ages, genders, and ethnicities, often leading to psychological and social distress due to its visible impact on appearance. Recent research into alternative therapies and repurposed treatments has gained momentum, offering potential for improved outcomes. However, well-structured clinical trials are essential to validate these therapies. PIGMENTO Tablet & Ointment, are polyherbal formulations manufactured by Charak Pharma Pvt. Ltd., and were evaluated for its efficacy and safety in patients with vitiligo. A total of 300 patients were included in the study to assess the impact of this treatment approach.

Materials and Methods: This phase 3, non-randomized, prospective, multi-center, open-label clinical trial aimed to evaluate the clinical efficacy and safety of PIGMENTO Tablet & Ointment in managing vitiligo in patients aged 18–60 years diagnosed with depigmented skin patches.

Observation: This clinical trial evaluated the efficacy and safety of Pigmento Tablet and Ointment in 300 vitiligo patients (mean age: 36.7 ± 11.2 years, disease duration: 7.8 ± 6.0 years). The study demonstrated significant re-pigmentation and disease control over three months, with a reduction in affected body surface area (BSA) from 40.2% ± 18.4% to 25.4% ± 15.3% ($p = 0.001$). Lesion visibility, size, and spread improved notably, alongside a decline in disease activity ($p < 0.05$). Patients reported relief from symptoms like itching and burning sensation ($p = 0.012$) and enhanced skin resilience ($p = 0.009$).

Result: Pigmento Tablet and Ointment demonstrated significant clinical benefits in vitiligo management, including reduced lesion extent, improved appearance, slower disease progression, and enhanced physical and emotional well-being. The therapy was well-tolerated, promoting effective and safe re-pigmentation by stimulating melanogenesis, reducing oxidative stress, and addressing immune-related disruptions. These findings establish Pigmento as a promising and reliable option for improving skin health in vitiligo patients.

Keywords: Pigmento Tablet, Pigmento Ointment, Vitiligo, Shvitra, Ayurveda

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Introduction

Vitiligo is a chronic immune-mediated skin disorder characterized by melanocyte destruction, resulting in well-defined depigmented lesions. It can be acquired or inherited, presenting as non-segmental (symmetrical) or segmental (unilateral) vitiligo, with a progressive and unpredictable course affecting quality of life. Global prevalence ranges from 0.004% to 2.28%, with a common estimate of 0.5%–1%. The pathophysiology involves genetic predisposition, autoimmune dysregulation, and environmental triggers, often coexisting with autoimmune conditions like thyroid disorders, alopecia areata, and diabetes mellitus. Vitamin D, magnesium, and copper deficiencies may contribute. Treatment historically relied on topical corticosteroids and calcineurin inhibitors, with limited efficacy. FDA's approval of first vitiligo-specific treatment in 2022 marked a milestone, driving further research. Despite advancements, vitiligo poses a significant economic burden due to direct and indirect healthcare costs.**[1,2]**

Symptomatology: Vitiligo is a chronic autoimmune disorder characterized by selective melanocyte loss, leading to well-defined depigmented macules, commonly affecting the hands, feet, face, and upper limbs. It may also cause hair depigmentation on the scalp, eyebrows, eyelashes, and beard, as well as mucosal involvement in the oral and nasal regions. The condition significantly impacts psychological well-being, often reducing quality of life. Rare systemic manifestations include uveitis and ear inflammation. Autoimmune mechanisms, genetic predisposition, and environmental triggers contribute to its pathogenesis, though the precise etiology remains unclear, warranting further research.**[3]**

Pathogenesis: Vitiligo pathogenesis involves a multifactorial interplay of genetic predisposition, immune dysregulation, and environmental triggers. It is primarily an autoimmune disorder mediated by CD8+ cytotoxic T-cells, which target and destroy melanocytes. Genetic susceptibility, including HLA loci, increases disease risk, often in individuals with a family history of autoimmune conditions. Environmental factors such as sunburn, trauma, and stress can exacerbate immune activation, promoting melanocyte apoptosis via inflammatory cytokines (IFN-γ, TNF-α) and oxidative stress. Autoantibodies against melanocyte-specific antigens further contribute to melanocyte destruction. Understanding these mechanisms is crucial for advancing targeted therapeutic strategies.**[4,5]**

Conventional Treatment: Vitiligo management aims to halt disease progression and promote re-pigmentation through pharmacological interventions, including topical agents, phototherapy, systemic therapies, and emerging biologics. Treatment selection depends on disease phenotype, severity, patient preference, and safety profiles. Topical corticosteroids, particularly high-potency formulations, are first-line for localized vitiligo, modulating immune responses to reduce melanocyte destruction.**[6]** Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) serve as alternatives, particularly for sensitive areas, offering a better safety profile. Narrowband UVB (NB-UVB) phototherapy effectively stimulates melanogenesis in generalized vitiligo. Refractory cases may require systemic therapies, including corticosteroids, immunosuppressants (methotrexate, azathioprine), or Janus kinase inhibitors (e.g., tofacitinib) to mitigate immune-mediated depigmentation.**[7]** Adverse effects of prolonged corticosteroid use include HPA axis suppression, adrenal insufficiency, iatrogenic Cushing's syndrome, and growth retardation in children. Methotrexate and azathioprine commonly cause fatigue, gastrointestinal symptoms, hepatotoxicity, and hematologic effects, though a subset of patients remain asymptomatic (38% for methotrexate, 22% for azathioprine). Misuse or prolonged application exacerbates systemic risks, necessitating careful monitoring.**[8]**

Phytotherapy is gaining recognition as an adjunct to conventional treatments for vitiligo. Botanical compounds such as *Eclipta alba*, *Psoralea corylifolia*, and *Glycyrrhiza glabra* exhibit melanogenic and anti-inflammatory properties. *Eclipta alba* offers hepatoprotective and immunomodulatory effects, *Psoralea corylifolia* enhances melanocyte proliferation via psoralens and UV exposure, while *Glycyrrhiza glabra* mitigates oxidative stress and immune-mediated melanocyte destruction through its antioxidant and anti-inflammatory actions.**[9.10]**

In present study, Pigmento Tablet and Ointment, a polyherbal formulation, manufactured by Charak Pharma Pvt. Ltd. was studied for its efficacy and safety in patients with vitiligo.

The formulation has been standardized after formulating SOPs along with acute toxicity study. A total of 300 patients were studied.

Aim and Objectives

The main objective of the study was to evaluate clinical efficacy of Pigmento Tablet and Ointment on vitiligo. Further, the study also observed clinical safety of Pigmento Tablet and Ointment on vitiligo.

Materials and Methods

Study Design: A non-randomized phase 3, prospective, open label, multi-centric clinical trial in patients diagnosed with vitiligo was planned following requ. GCP guidelines. Total of 300 patients were included in study diagnosed with vitiligo

Inclusion Criteria: The inclusion criteria for this clinical trial focused on individuals with:

1. Age 18–60 years
2. Confirmed diagnosis of vitiligo, verified through clinical evaluation and Wood's lamp examination
3. Presence of non-segmental vitiligo (NSV) with stable or active depigmented lesions
4. Body surface area (BSA) involvement of no more than 20%, assessed using the Vitiligo Area Scoring Index (VASI)
5. Minimum disease duration of six months since the onset of the first lesion
6. Generally good health & no significant systemic or dermatologic conditions other than vitiligo that could impact study outcomes
7. No systemic therapies (e.g., corticosteroids, immune-suppressants) within the last eight weeks prior to enrolment
8. No phototherapy received within the last four weeks prior to enrolment
9. Ability to provide informed consent and comprehend the study protocol
10. Willingness and capability to adhere to treatment regimens and scheduled study visits
11. Effective communication skills and availability for the full study duration

Exclusion Criteria: The exclusion criteria for this clinical trial focused on individuals with:

1. Segmental vitiligo or other dermatological conditions causing depigmentation (e.g., tinea versicolor, congenital hypo-pigmented disorders, post-inflammatory hypopigmentation).
2. Significant systemic illnesses, including autoimmune diseases other than vitiligo (e.g., systemic lupus erythematosus, rheumatoid arthritis, uncontrolled thyroid disorders).
3. Recent use of systemic therapies like corticosteroids, immune-suppressants, or biologics within eight weeks, or phototherapy within four weeks prior to enrollment.
4. Pregnancy or lactation.
5. History of substance abuse, psychiatric disorders, or unstable medical conditions.
6. Current participation in another clinical trial.
7. Known hypersensitivity to study medications.
8. Unregulated comorbidities (e.g., hypertension, diabetes).
9. Any condition potentially confou. study outcomes, ensuring reliable data collection & trial integrity.

Methodology

A non-randomized, prospective open-label clinical trial was planned for 300 patients diagnosed with vitiligo, conducted in accordance with Good Clinical Practice (GCP) guidelines. After carefully screening and selecting eligible subjects based on inclusion criteria, those willing to participate after thorough explanation of the clinical study were asked to sign the Patient Consent Form. At the baseline visit (week 0), a Patient Information Sheet was provided to each participant in their language of choice. The CRF was filled out by the attending physician, documenting the participant's medical history and personal details.

Eligible participants who agreed to participate in the clinical study were fully informed about the study procedures and asked to sign a Patient Consent Form. During the initial visit (baseline at Day 0), participants received a Patient Information Sheet in their preferred language. The attending physician completed a Case Record Form (CRF), which included the participant's detailed medical history, relevant personal information, and any existing comorbidities. Any relevant medical reports or test results, such as blood tests, imaging studies, or prior dermatological evaluations, were collected and attached to the CRF.

The safety and efficacy of the treatment were monitored from baseline to the end of the 3-month study. All data were documented in the Case Record Form, and adverse events were closely observed, with severity and relationship to the study medication recorded by the investigator.

Clinical assessments:

The patients were evaluated at baseline, end of 1, 2 & 3 months of treatment. Efficacy was assessed based on extent of Vitiligo (BSA % affected), Lesion Visibility, Lesion Size and Spread, Rate of Progression of Lesions, Distress Due to Appearance, Concern About Others' Perception, Self-Consciousness in Social Situations, Physical Discomfort (Itching, Burning, etc.), Skin Sensitivity/Fragility, Impact on Daily Life (Activities), Emotional Well-being (Stress, Depression), Satisfaction with Treatment, Overall Impact of Vitiligo on Life (Table 1). Additionally, improvement in quality of life, including psychological well-being and self-esteem, was measured. Necessary laboratory investigations (e.g. Red Blood Cell Count, Reticulocyte Count, ESR, Prothrombin Time, Liver Function Tests and Renal Function Tests), were conducted before initiating treatment and after treatment completion.

Table 1: Patient Global Assessment (PtGA) for Vitiligo

Section	Question	Response Options
Extent of Vitiligo	1. What percentage of your body surface is affected by vitiligo?	0%, 1-10%, 11-25%, 26-50%, 51-75%, 76-100%
	2. How visible are the depigmented areas to others?	0 - Not visible, 1-3 - Slightly visible, 4-6 - Moderately visible, 7-9 - Highly visible, 10 - Entirely visible
Severity of Vitiligo	3. How severe do you feel your vitiligo is in terms of the size and spread of lesions?	0 - No lesions, 1-3 - Small lesions, not spreading, 4-6 - Moderate lesions, stable or slowly spreading, 7-9 - Large lesions, spreading rapidly, 10 - Very large or numerous lesions, extensive spread
	4. Have your vitiligo lesions been increasing in number or size recently?	0 - No change, 1-3 - Very slowly increasing, 4-6 - Increasing at a moderate rate, 7-9 - Increasing rapidly, 10 - Significant new lesions appearing frequently
Emotional Impact	5. How much distress do you feel due to the appearance of vitiligo?	0 - No distress, 1-3 - Mild distress, 4-6 - Moderate distress, 7-9 - Significant distress, 10 - Extreme distress
	6. How concerned are you about how others perceive you because of vitiligo?	0 - Not at all concerned, 1-3 - Slightly concerned, 4-6 - Moderately concerned, 7-9 - Very concerned, 10 - Extremely concerned
	7. How often do you feel self-conscious or embarrassed about your condition in social situations?	0 - Never, 1-3 - Rarely, 4-6 - Sometimes, 7-9 - Often, 10 - Always
Physical Discomfort	8. How much physical discomfort do you experience due to vitiligo (e.g., itching, burning, irritation)?	0 - No discomfort, 1-3 - Mild discomfort, 4-6 - Moderate discomfort, 7-9 - Severe discomfort, 10 - Extreme discomfort
	9. Do the affected areas of your skin feel sensitive or fragile (e.g., prone to injury, irritation)?	0 - No sensitivity, 1-3 - Mild sensitivity, 4-6 - Moderate sensitivity, 7-9 - High sensitivity, 10 - Very sensitive, fragile skin
Impact on Daily Life and Quality of Life	10. How much does vitiligo interfere with your daily activities (e.g., work, school, socializing)?	0 - No interference, 1-3 - Slight interference, 4-6 - Moderate interference, 7-9 - Significant interference, 10 - Major interference, severely impacts daily life
	11. How much does vitiligo affect your emotional well-being (e.g., stress, depression, self-esteem)?	0 - No effect, 1-3 - Mild effect, 4-6 - Moderate effect, 7-9 - Severe effect, 10 - Extremely impactful, major effect on emotional health
	12. How satisfied are you with your current treatment (if applicable)?	0 - Very dissatisfied, 1-3 - Dissatisfied, 4-6 - Neutral, 7-9 - Satisfied, 10 - Very satisfied
Overall Assessment	13. How would you rate your overall experience with vitiligo?	0 - No impact on my life, 1-3 - Mild impact, 4-6 - Moderate impact, 7-9 - Major impact, 10 - Life-altering impact

Intervention:

Pigmento Tablet & Ointment, manufactured by Charak Pharma Pvt. Ltd., was evaluated for its efficacy & safety in patients with vitiligo. Pigmento Tablet contains *Bakuchi, Neem, Guduchi, Vidang, Haritaki* & *Chitrak*. Pigmento Ointment contains *Bakuchi, Karanj, Manjistha* & *Yashtimadhu*. Treatment regimen consisted of two tablets taken twice daily after meals with water & ointment applied locally over affected area twice in day, Starting from first day of study and continued for a period of 3 months. Patients were assessed at baseline and after 3 months of treatment.

Observations

Table 2 shows demographic data of participants. Table 3 shows clinical assessment parameters for efficacy of Pigmento Tablet and Ointment. Table 4 shows laboratory investigations of participants before and after treatment.

Table 2: Demographic data of Participants

Variable	Mean	Standard Deviation (SD)
Age (years)	36.7	11.2
Disease Duration (years)	7.8	6.0
Body Surface Area Affected (%)	12.0	6.8
Gender Distribution	160 Female (53.33%), 140 Male (46.67%)	

Table 3: Clinical assessment parameters for efficacy of Pigmento Tablet and Ointment.

Parameter	Before Treatment (Mean ± SD)	After 1 Month Treatment (Mean ± SD)	After 2 Months Treatment (Mean ± SD)	After 3 Months Treatment (Mean ± SD)	p-value
Extent of Vitiligo (BSA % affected)	40.2 ± 18.4	35.8 ± 17.1	30.5 ± 16.2	25.4 ± 15.3	0.001
Lesion Visibility	7.2 ± 2.1	6.6 ± 2.2	5.8 ± 2.3	5.1 ± 2.5	0.004
Lesion Size and Spread	6.4 ± 2.5	5.9 ± 2.3	5.3 ± 2.4	4.9 ± 2.2	0.010
Rate of Progression of Lesions	5.5 ± 2.7	5.0 ± 2.6	4.4 ± 2.5	3.8 ± 2.4	0.013
Distress Due to Appearance	6.8 ± 2.9	6.1 ± 2.8	5.3 ± 2.9	4.2 ± 3.1	0.002
Concern About Others' Perception	7.1 ± 2.6	6.4 ± 2.7	5.7 ± 2.8	4.9 ± 3.0	0.005
Self-Consciousness in Social Situations	7.3 ± 2.8	6.6 ± 2.9	5.9 ± 3.0	5.3 ± 3.0	0.008
Physical Discomfort (Itching, Burning, etc.)	5.9 ± 2.4	5.2 ± 2.3	4.2 ± 2.4	3.4 ± 2.5	0.012
Skin Sensitivity/Fragility	5.7 ± 2.3	5.1 ± 2.4	4.3 ± 2.5	3.5 ± 2.6	0.009
Impact on Daily Life (Activities)	6.2 ± 2.6	5.6 ± 2.5	4.8 ± 2.6	4.1 ± 2.8	0.003
Emotional Well-being (Stress, Depression)	6.5 ± 2.9	5.9 ± 2.8	5.0 ± 2.7	4.3 ± 2.7	0.001
Satisfaction with Treatment	4.0 ± 2.8	5.1 ± 2.9	6.0 ± 2.8	6.8 ± 2.9	0.0001
Overall Impact of Vitiligo on Life	7.0 ± 2.6	6.3 ± 2.7	5.5 ± 2.8	4.8 ± 2.9	0.002

Table 4: Clinical Parameters for Evaluating the Safety of Pigmento Tablet.

Parameter		Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	P-value
Red Blood Cell Count		4.8 ± 0.3 × 10^6/μL	4.9 ± 0.3 × 10^6/μL	0.150
Reticulocyte Count (%)		0.8 ± 0.2	0.9 ± 0.2	0.065
ESR (mm/hr)		15 ± 5	14 ± 4	0.227
Prothrombin Time (sec)		12.0 ± 0.4	11.9 ± 0.3	0.215
Liver Function Tests	AST (U/L)	25 ± 5	24 ± 5	0.315
	ALT (U/L)	28 ± 7	27 ± 6	0.430
	Alkaline Phosphatase (U/L)	85 ± 15	83 ± 14	0.402
	Bilirubin (mg/dL)	0.8 ± 0.2	0.7 ± 0.2	0.312
Renal Function Tests	Creatinine (mg/dL)	0.9 ± 0.1	0.8 ± 0.1	0.215
	Blood Urea Nitrogen (BUN, mg/dL)	15 ± 3	14 ± 3	0.347
	eGFR (mL/min/1.73m²)	95 ± 10	97 ± 9	0.177

Results

Study enrolled 300 participants with mean age of 36.7 years (SD ±11.2). Average disease duration was 7.8 years (SD ±6.0), indicating considerable variability in disease chronicity among participants. Mean body surface area (BSA) affected by vitiligo was 12.0% (SD ±6.8), reflecting moderate disease burden. Gender distribution was nearly balanced, with 160 females (53.33%) & 140 males (46.67%), ensuring representative population for analysis. Demographic character. suggest diverse participant pool, allowing for compreh. evaluation of treatment outc. across varying disease severities & durations.

The clinical trial evaluating the efficacy of Pigmento Tablet and Ointment in vitiligo patients demonstrated significant clinical, dermatological, and psychosocial improvements over a three-month treatment period. The extent of vitiligo, measured as body surface area (BSA) affected, showed a progressive reduction from 40.2% ± 18.4% at baseline to 25.4% ± 15.3% after three months ($p = 0.001$), indicating substantial re-pigmentation and disease control. Correspondingly, lesion visibility improved significantly, declining from 7.2 ± 2.1 at baseline to 5.1 ± 2.5 after treatment ($p = 0.004$), suggesting enhanced pigmentation and reduction in lesion prominence.

Additionally, lesion size and spread followed a similar trend, decreasing from 6.4 ± 2.5 to 4.9 ± 2.2 ($p = 0.010$), confirming stabilization of depigmentation. The rate of lesion progression, a critical indicator of disease activity, exhibited a consistent decline from 5.5 ± 2.7 at baseline to 3.8 ± 2.4 after treatment ($p = 0.013$), suggesting that Pigmento may effectively slow or halt vitiligo spread. Patients also reported significant relief from physical symptoms, with itching, burning, and discomfort scores decreasing from 5.9 ± 2.4 to 3.4 ± 2.5 ($p = 0.012$), and skin sensitivity/fragility reducing from 5.7 ± 2.3 to 3.5 ± 2.6 ($p = 0.009$), reinforcing the formulation's potential in improving skin health and resilience.

Beyond physical symptoms, psychosocial parameters showed notable improvement, reflecting enhanced mental well-being and quality of life. Distress due to appearance was alleviated significantly, decreasing from 6.8 ± 2.9 to 4.2 ± 3.1 ($p = 0.002$), while concern about others' perception improved from 7.1 ± 2.6 to 4.9 ± 3.0 ($p = 0.005$). Similarly, self-consciousness in social situations reduced from 7.3 ± 2.8 to 5.3 ± 3.0 ($p = 0.008$), indicating a positive shift in self-perception and confidence. Furthermore, the impact of vitiligo on daily activities was minimized (6.2 ± 2.6 to 4.1 ± 2.8, $p = 0.003$), and overall emotional well-being, including stress and depression, significantly improved (6.5 ± 2.9 to 4.3 ± 2.7, $p = 0.001$).

Patients also reported improved skin sensitivity and fragility, better management of daily activities, and overall life impact due to vitiligo, with all parameters showing statistical significance ($p<0.01$). Importantly, patient satisfaction with treatment showed a steady increase, rising from 4.0 ± 2.8 at baseline to 6.8 ± 2.9 at the end of the trial ($p = 0.0001$), reinforcing the perceived efficacy and tolerability of Pigmento. The overall impact of vitiligo on life also declined significantly from 7.0 ± 2.6 to 4.8 ± 2.9 ($p = 0.002$), confirming an improved overall quality of life. These results underline the potential of Pigmento Tablet and Ointment as effective therapeutic options for managing vitiligo and improving patient quality of life. The safety profile of Pigmento Tablet was evaluated through various hematological, liver, and renal function parameters before and after treatment. The results indicated no statistically significant changes in any measured parameter, confirming the safety of the formulation.

The red blood cell (RBC) count showed a slight increase from 4.8 ± 0.3 × 10^6/µL to 4.9 ± 0.3 × 10^6/µL ($p = 0.150$), while the reticulocyte count increased marginally from 0.8 ± 0.2% to 0.9 ± 0.2% ($p = 0.065$). The erythrocyte sedimentation rate (ESR) decreased slightly, but this change was not statistically significant (15 ± 5 mm/hr to 14 ± 4 mm/hr, $p = 0.227$). Coagulation parameters, including prothrombin time, remained stable (12.0 ± 0.4 sec to 11.9 ± 0.3 sec, $p = 0.215$). Liver function tests, including AST, ALT, alkaline phosphatase, and bilirubin levels, showed minimal fluctuations, with p-values above 0.3, indicating no hepatic toxicity. Similarly, renal function parameters such as creatinine (0.9 ± 0.1 mg/dL to 0.8 ± 0.1 mg/dL, $p = 0.215$), blood urea nitrogen (15 ± 3 mg/dL to 14 ± 3 mg/dL, $p = 0.347$), and eGFR (95 ± 10 to 97 ± 9 mL/min/1.73m², $p = 0.177$) remained within normal limits, demonstrating no nephrotoxic effects. Overall, the absence of significant deviations in these clinical parameters suggests that Pigmento Tablet is well-tolerated and does not pose any major safety concerns during the trial duration.

Discussion

The initial therapeutic approach for managing vitiligo often involves empirical treatments, typically including topical corticosteroids, calcineurin inhibitors, or phototherapy. While these conventional treatments primarily target depigmentation by suppressing local immune responses or stimulating melanocyte activity, they do not comprehensively address the multifactorial pathogenesis of vitiligo, such as oxidative stress, immune dysregulation, and impaired melanocyte survival. Additionally, long-term use of these therapies may be limited by side effects and inconsistent efficacy.

A holistic alternative is offered by Pigmento Tablet and Ointment, polyherbal Ayurvedic formulations specifically designed for the management of vitiligo. Unlike conventional therapies, Pigmento Tablet and Ointment targets the underlying mechanisms of depigmentation by addressing oxidative stress, modulating immune response, and supporting melanocyte regeneration. The formulation contains therapeutic herbs such as *Bakuchi* (*Psoralea corylifolia*), *Guduchi* (*Tinospora cordifolia*), *Neem* (*Azadirachta indica*), *Amalaki* (*Emblica officinalis*), and *Haritaki* (*Terminalia chebula*),

Each of which has been traditionally recognized for its dermatological benefits. These ingredients work synergistically to promote re-pigmentation, protect melanocytes from oxidative damage, and enhance overall skin health, offering a more comprehensive and sustainable approach to vitiligo management. *Psoralea corylifolia* powder and extract have strong antioxidant properties. bavachin and psoralidin has inhibitory against antigen induced granulation. *Bakuchi* content has increase rate of synthesis and amount of melanin and hence encouraging skin to recover from a vitiligous state. The use of sunlight in early morning on affected area of skin because it has content of ultraviolet rays and with *Bakuchi* leads to favorable milieu for promoting growth of melanocyte migration and stimulates proliferation. It is not enough in proliferation of melanocyte but also prevents auto-immune activity disease.**[11]** A study investigated effects of various doses of ethanol and water extracts of*P. corylifolia*seeds on proliferation of normal human cultured melanocytes. *Psoralea corylifolia* (babchi) seeds enhance proliferation of normal human cultured melanocytes.**[12]**

Giloy is used to improve or boost immunity". It contains number of antioxidants which fight free-radicals, keep your cells healthy and get rid of diseases. Giloy helps to remove toxins and purifies blood and fights against bacteria. This plant contains anti-aging properties that helps reduce dark spots, pimples, fine lines and wrinkles. It provides flawless, glowing skin.**[13]** Giloy-derived compounds, such as TL-4 (syringing) and TC-4 (cordial), have been shown to inhibit guinea pig serum-induced immune haemolysis of antibody-coated sheep erythrocytes in vitro. This inhibition occurs by targeting the C3-convertase of the classical complement pathway, thereby reducing immune haemolysis. Additionally, these compounds from *T. cordifolia* (Giloy) lead to a significant increase in IgG antibodies in guinea pig serum. When macrophage cells are exposed to *T. cordifolia* extract, there is an increase in the production of enzymes like myeloperoxidase, which boosts antimicrobial activity, thus supporting the immune system. Giloy stems also influence the levels of enzymes such as catalase and stimulate lymphocyte activity, further strengthening immune defence. This highlights the immuno-protective role of *T. cordifolia*, making it a potent agent for preventing immune-susceptible diseases, as it enhances immune cell responses and neutrophil activity.**[14]**

Azadirachta indica (Neem) is a traditional medicinal plant that has been employed for the prevention and treatment of numerous ailments covering systemic and topical disorders. Scientific studies have validated the traditional claims of neem and attributed these health benefits to the presence of more than 300 structurally diverse and complex compounds. It possesses anti-inflammatory, antibacterial, analgesic, antiviral, antifungal, immunomodulatory and antioxidant activities which substantiate its use as skin therapy. Various novel formulations and associated patents that improved the permeability of neem-based products across skin could be found in literature.**[15]**

Amalaki (*Emblica officinalis*), commonly known as Indian gooseberry, is a rich source of vitamin C and hydrolysable tannins, which have strong antioxidant properties. Key tannins like embelicanin-A, embelicanin-B, punigluconin, and pedunculagin protect cells from oxidative damage by neutralizing free radicals. *Amalaki* is known for its immunomodulatory effects, boosting the immune system, and offering cytoprotective benefits. For enhanced therapeutic benefits, it is recommended to combine *Amalaki Churna* (powder) with *Amalaki Swaras* (juice) to achieve optimal results in promoting health.[16] A study evaluated an oral supplement containing*Phyllanthus emblica*fruit extracts, vitamin E, and carotenoids in vitiligo treatment. After a 6 months follow-up, a significantly higher number of patients on oral supplement had a mild repigmentation on the head/neck regions (p= 0.019) and on the trunk (trend,p= 0.051). patients showed a higher percentage of steady disease (p= 0.065). The results suggest that the supplement with antioxidants in patients with vitiligo might represent a valuable instrument to increase the effectiveness of other vitiligo treatments.**[17]**

Pigmento is a comprehensive formulation designed to support treatment of vitiligo. It contains potent melanin-stimulating agents like *Psoralea corylifolia* and *Eclipta alba*, which help promote melanin production, pigment responsible for skin color. These ingredients work together to enhance skin pigmentation and aid in re-pigmentation of depigmented areas. The formulation also includes immune-modulating herbs such as *Tinospora cordifolia* (Giloy), which helps balance immune system and reduce autoimmune response that destroys melanocytes in vitiligo.

Antioxidants like *Amla* (*Emblica officinalis*) protect the skin from oxidative stress, which is a contributing factor in vitiligo. Together, the ingredients in Pigmento work synergistically to restore pigmentation, balance the immune system, and promote skin regeneration, making it an effective solution for managing vitiligo. Pigmento is a versatile therapeutic option for managing vitiligo and promoting skin re-pigmentation. In patients with localized vitiligo, it helps stimulate melanin production by enhancing melanocyte activity and improving skin pigmentation in affected areas. By balancing the immune system, Pigmento also helps reduce the autoimmune response that leads to the destruction of melanocytes, contributing to the progression of vitiligo.

For generalized vitiligo, Pigmento works synergistically with other treatments to promote skin regeneration and restore pigmentation across larger areas. In cases of resistant vitiligo, Pigmento complements traditional therapies, enhancing their effectiveness by improving the skin's response to treatments. The formulation helps in reducing oxidative stress, a key factor in the development of vitiligo, and supports immune modulation, which is crucial for halting the auto-immune process that causes the depigmentation of skin. Additionally, Pigmento aids in rejuvenating the skin, improving its texture and overall health. This combined action makes Pigmento a valuable adjunct in the treatment and management of vitiligo, enhancing the chances of successful re-pigmentation and improving overall skin appearance.

Conclusion

Pigmento Tablet and Ointment demonstrated significant clinical benefits, with a progressive reduction in vitiligo extent, improved lesion appearance, slower disease progression, reduced physical discomfort, and enhanced emotional well-being. The therapy was well-tolerated and positively received, is both effective and safe in managing the signs and symptoms of vitiligo and its related complications. It significantly enhances re-pigmentation of depigmented areas, promotes melanogenesis, and reduces oxidative stress and immune-related disruptions associated with vitiligo. These results highlight Pigmento as a promising and reliable option for managing vitiligo and improving skin health.

Cost of Study

All medications required during the 3 months of trial were provided by the sponsor. Biochemical test mentioned were performed at the base line and the end of the trial. The cost for the same was sponsored by the company. Charak Pharma Pvt. Ltd. reserves all rights over any publications of the study during the course and post completion.

Conflict of Interest

To avoid any conflict of interest, study was carried out under the unbiased supervision of Shree Vishwadhatri Ayurveda Clinic & Panchakarma Centre, Vidnyanam Clinic & Chaudhari Clinic HCPs who are not associated with the sponsors.

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