



FORMULATION AND EVALUATION OF ANTI-VITILIGO HERBAL CREAM

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ABSTRACT :

Vitiligo is a depigmentation disorder with complex causes. Nonetheless, recent progress has been made to unravel the pathophysiology of Vitiligo. In this research, we provide an overview of the currently known herbal medicine for Vitiligo treatment. Herbal drugs like *Azadirachta indica* J. Juss (Neem), *Curcuma longa* Linn. (Turmeric), *Cocos nucifera* L. (Coconut), *Sesamum indicum* L. (sesame) and *Nigella sativa* L. (Black cumin) are used for formulation. A cream of such herbal drug is prepared that when applied to the affected area may reduce depigmentation. It is then evaluated to check the safety, stability and efficacy. The result can be seen after through trial on skin of better understanding.

Keywords: Vitiligo, herbal, depigmentation, evaluation

1. Introduction :

Vitiligo is a pigmentation disorder, in which pigmentation cells (melanocytes) of skin are destroyed, which results in smooth, white patches in the midst of normally pigmented skin. It affects individuals of all age, races, ethnicity, and skin types. So, after a thorough study of review articles and gathering informative information suggest in this test. Vitiligo can be treated by herbal formulation. So in this research our objective is formulation and evaluation of herbal cream.

The formulation consist of many herbal drugs mentioned in extraction form. These herbal ingredients are then we the help of excipient are formulated to form cream.

Different formulations may contain various ingredients, such as corticosteroids, calcineurin inhibitors, vitamin D derivatives, antioxidants, or natural extracts, depending on the specific goals and approach of the treatment. Always consult a dermatologist or healthcare professional for guidance on suitable treatment options for vitiligo.

2. Review of Literature:

A] Name of Authors: Michael L. Frisoli, Kingsley Essien and John E. Harris

Year of publishing: 2020

Revised and Accepted: 4.2.2020

Topic of article: Vitiligo: Mechanisms of Pathogenesis and Treatment

Article source: Annual Reviews

Vitiligo is an autoimmune disease of the skin that targets pigment-producing melanocytes and results in patches of depigmentation that are visible as white spots. Recent research studies have yielded a strong mechanistic understanding of this disease. Autoreactive cytotoxic CD8+ T cells engage melanocytes and promote disease progression through the local production of IFN- γ , and IFN- γ -induced chemokines are then secreted from surrounding keratinocytes to further recruit T cells to the skin through a positive-feedback loop. Both topical and systemic treatments that block IFN- γ signaling can effectively reverse vitiligo in humans; however, disease relapse is common after stopping treatments. Autoreactive resident memory T cells are responsible for relapse, and new treatment strategies focus on eliminating these cells to promote long-lasting benefit. Here, we discuss basic, translational, and clinical research studies that provide insight into the pathogenesis of vitiligo, and how this insight has been utilized to create new targeted treatment strategies.

B] Name of Authors: Gulbahar Sarac, Yelda Kapicioglu, Serpil Sener, Irem Mantar, Saim Yologlu, Cihat Dunder, Murat Turkoglu, Erkin Pekmezci

Year of publishing: 2019

Revised and Accepted: 26.7.2019

Topic of article: Effectiveness of topical *Nigella sativa* for vitiligo treatment

Article source: Dermatol Ther.

Vitiligo is a pigment disease characterized by the disruption of melanocyte structure and function. However, genetic predisposition, biochemical factors, and neural mechanisms are thought to be effective. Although many agents are being used for its treatment, generally there is no absolute cure. The aim of the present study is to evaluate the effectiveness of topical *Nigella sativa* seed oil on vitiligo patients. Cream containing *N sativa* seed oil was topically applied to hands, face, and genital region two times a day for 6 months. Statistically significant repigmentation was detected in hands, face, and genital region, the three treatment areas, and the p values are found. *N sativa* can be used as an adjuvant therapy that can contribute to the treatment especially in sensitive skin areas like genital region.

CJ Name of Authors: Kadam SM, Chinmay Chorage, Kaustubh Singh

Year of publishing: 2019

Revised: 16.11.2019 **Accepted:** 17.12.2019

Topic of article: A review on turmeric: For the treatment of skin disease (Vitiligo)

Article source: International Journal of Food Science and Nutrition

Belonging to the ginger family, turmeric has been used in East India and the Middle East for thousands of years, and is now one of the most highly-prized spices in the world. Vitiligo is a skin disorder where the skin pigment is lost in certain regions and discolored or white patches remain on the skin. It occurs when skin cells are unable to function appropriately or when they die. Though many causes for vitiligo progression have been suggested, its exact mechanism of pathogenesis is still unclear. The beneficial effects of turmeric are traditionally achieved through dietary consumption, even at low levels, over long periods of time. Vitiligo is a skin disease that is prevented by turmeric, because turmeric has high antioxidant and high anti-inflammatory activity, that cure vitiligo and also helps to synthesis of melanin formation.

DJ Name of Authors: Encarna Castillo, María Eugenia González-Rosende, Isabel Martínez-Solís

Year of publishing: 2023

Revised and Accepted: 1.4.2023

Topic of article: The Use of Herbal Medicine in the Treatment of Vitiligo

Article source: Planta Med.

Vitiligo is a chronic disease of unknown etiology that causes progressive cutaneous depigmentation. Current pharmacological treatments have limited success and present significant risks. Many efforts have been made in recent years to explore new anti-vitiligo therapeutic strategies, including herbal-based therapies. The objective of the present review is to provide an updated overview on the most frequently used medicinal plants in the treatment of vitiligo. A bibliographical search was carried out in scientific databases Pubmed, Scifinder, Scopus, Google Scholar, and Medline up to October 2021 using the descriptors vitiligo, herbal, medicinal plants, and alternative therapies.

3. Aim

To formulate and evaluate Anti-Vitiligo cream containing herbs; Neem, Turmeric, Sesame and Black cumin.

Objective:

The objective of preparing a cream for vitiligo, is generally to create a topical formulation that aims to help repigment the affected areas of the skin. Creams for vitiligo typically focus on:

1. **Pigmentation:** Promoting the production of melanin or stimulating melanocyte activity to restore skin color in the depigmented patches.
2. **Moisturization:** Providing hydration and nourishment to the affected skin to support its health and facilitate healing.
3. **Anti-inflammatory properties:** Reducing inflammation in the affected areas, this can help in the repigmentation process.
4. **Protection:** Shielding the skin from harmful UV rays to prevent further damage to the affected areas.

Plan of work

1. Reviewing literature survey from national and international journal, research paper, articles and books.
2. Selection of suitable herbal ingredients.
3. Collection and procurement of herbs
4. Formulation of cream with appropriate excipients.
5. Evaluation of cream for its physical and chemical properties.
6. conclusion.

4. Need of work

1. **Medical Treatment:** Seeking guidance from a dermatologist or healthcare professional for appropriate medical treatments, which may include topical creams, light therapy, oral medications, or in some cases, surgical procedures.
2. **Psychological Support:** Dealing with any emotional or psychological impact that Leucoderma might have. Support groups, counseling, or therapy can help individuals cope better with the condition.

3. **Lifestyle Changes:** Adopting a healthy lifestyle, including a balanced diet, managing stress, and avoiding triggers that might worsen the condition.
4. **Self-Care:** Using sun protection, managing affected skin gently, and adhering to prescribed treatments regularly.
5. **Raising Awareness:** Educating oneself and others about Leucoderma to reduce stigma and promote understanding and acceptance

5. Challenges in anti-vitiligo cream

1. **Effective Depigmentation:** Achieving depigmentation of vitiligo-affected areas without causing harm or irritation to the surrounding skin is crucial. The cream must selectively target melanocytes in depigmented patches while leaving healthy melanocytes unaffected.
2. **Formulation Stability:** Ensuring that the formulation remains stable over time is essential for maintaining its effectiveness. Factors such as pH, temperature, and exposure to light can affect the stability of the active ingredients.
3. **Individual Variations:** People with vitiligo have diverse skin types and responses to treatments. Formulating a cream that can effectively address these variations and provide consistent results across different skin types is challenging.
4. **Regulatory Requirements:** Meeting regulatory standards for safety and efficacy testing is necessary before bringing the product to market. This involves conducting rigorous clinical trials to demonstrate the cream's effectiveness and safety for use.
5. **Long-Term Efficacy:** Ensuring that the cream delivers long-term results and prevents recurrence of depigmentation is a significant challenge. The formulation should not only depigment existing patches but also inhibit further melanocyte destruction.
6. **Side Effects:** Minimizing potential side effects such as irritation, allergic reactions, or skin discoloration is crucial for the safety and tolerability of the cream.
7. **Affordability and Accessibility:** Making the cream affordable and accessible to individuals with vitiligo, especially in regions with limited healthcare resources, is a challenge. Cost-effective production methods and distribution channels need to be considered.

6. Challenges in anti-vitiligo

1. **Melanocyte Stimulation:** Formulations can include ingredients that stimulate melanocyte proliferation or activity to encourage repigmentation in affected areas.
2. **Melanin Production:** Active ingredients that promote melanin synthesis can help restore color to depigmented patches.
3. **Anti-inflammation:** Since vitiligo is an autoimmune condition, creams may contain compounds that have anti-inflammation response to prevent further melanocyte destruction.
4. **Antioxidant:** Combining the cream with antioxidant, destroys the free radicals in the body. It can also protect melanocytes against the damage caused due to the free radicals.

7. Possible outcomes

1. **Repigmentation:** One of the primary goals of anti-vitiligo creams is to stimulate the production of melanin, the pigment responsible for skin color, in the affected areas. With consistent use, some individuals may experience gradual repigmentation of the depigmented patches, leading to a more uniform skin tone.
2. **Reduced Spread:** Anti-vitiligo creams may also help slow down or prevent the spread of vitiligo, reducing the formation of new depigmented patches over time.
3. **Improved Symptom Management:** In addition to promoting repigmentation, these creams may help alleviate symptoms associated with vitiligo, such as itchiness, dryness, and inflammation, providing relief and improving overall skin health.
4. **Enhanced Self-esteem:** For many individuals living with vitiligo, the visible patches can significantly impact self-esteem and body image. Successful repigmentation or even a reduction in the size of depigmented areas can lead to increased confidence and improved quality of life.
5. **Variable Results:** It's important to note that the effectiveness of anti-vitiligo creams can vary from person to person. Factors such as the severity of vitiligo, individual skin characteristics, adherence to treatment regimen, and underlying health conditions can influence outcomes.
6. **Adverse Reactions:** While rare, some individuals may experience adverse reactions to the ingredients in anti-vitiligo creams, such as skin irritation, redness, or allergic reactions. It's essential to follow the instructions provided by healthcare professionals and conduct a patch test before applying the cream to larger areas of the skin.
7. **Combination Therapy:** Anti-vitiligo creams are often used in combination with other treatments, such as phototherapy, oral medications, or surgical interventions, to achieve optimal results, particularly in cases of widespread or stubborn vitiligo.

Overall, while anti-vitiligo creams can offer promising outcomes for some individuals, it's crucial to manage expectations, stay consistent with treatment, and consult with a dermatologist for personalized recommendations and monitoring.

8. Ingredients for prepare cream

Active ingredients:

1. Neem (Azadirachta indica J. Juss)
2. Sesame (Sesamum indicum L.)
3. Turmeric (Curcuma longa Linn.)
4. Black cumin (Nigella sativa L.)

Excipient:

1. Bees waxes
2. Borax
3. Liquid paraffin
4. Methyl paraben
5. Lavender oil
6. Distilled water

9. Methodology

Extraction of neem:

Obtain neem powder: Purchase high-quality neem powder from a reputable source. Ensure it's pure and free from any additives.

Mix with water: Take a measured amount of neem powder and mix it with water in a clean container. The ratio is around 1 part neem powder to 10 parts water.

Stir thoroughly: Stir the mixture well to ensure that the neem powder is fully dissolved in the water. You may need to mix it for a few minutes to achieve a homogeneous solution. Filter the solution: After stirring, filter the solution through a filter paper.

Extraction of turmeric:

Obtain turmeric powder: Purchase quality turmeric powder from reputable source.

Mix with a solvent: Place the turmeric powder in a clean, dry container and add a suitable solvent like ethanol.

Stir and let it sit: Stir the mixture well to ensure that the turmeric powder is fully dissolved in the solvent. Allow the mixture to sit for a period of time to allow for the extraction of the active compounds from the turmeric. Filter the solution: After the extraction period, filter the solution through a filter paper.

Extraction of black cumin:

Obtain black cumin seeds: Purchase high-quality black cumin seeds from a trusted source. Make sure they are clean and free from any contaminants.

Grind the seeds: Use a mortar and pestle or a spice grinder to grind the black cumin seeds into a fine powder. This will help in releasing the active compounds during the extraction process.

Mix with a solvent: Place the ground black cumin powder in a clean, dry container and add a suitable solvent such as ethano or water.

Stir and let it sit: Stir the mixture well to ensure that the black cumin powder is fully dissolved in the solvent. Allow the mixture to sit for a period of time to allow for the extraction of the active compounds from the black cumin.

After the extraction period, filter the solution through a filter paper.

Extraction of sesame:

Obtain sesame seeds: Purchase high-quality sesame seeds from a trusted source. Ensure they are clean and free from any contaminants.

Grind the seeds: Use a mortar and pestle, spice grinder, or a food processor to grind the sesame seeds into a fine powder. Grinding helps release the oils and active compounds from the seeds.

Mix with a solvent: Place the ground sesame powder in a clean, dry container and add a suitable solvent such as ethanol.

Stir and let it sit: Stir the mixture well to ensure that the sesame powder is fully dissolved in the solvent. Allow the mixture to sit for a period of time to allow for the extraction of the oils and other compounds from the sesame. After the extraction period, filter the solution through a filter paper.

Base formula for herbal cream:

Ingredients	Quantity	Use
Beeswaxes	25%	Stiffening agent

Liq. Paraffin	45%	Moisturizer
Borax	1%	Emulsifying agent
Water	q.s.	Diluent
Methyl paraben	0.1%	Perservative
Lavendar oil	q.s.	Perfume
Black cumin extract	3%	Increase melanin production
Sesame extract	3%	Induce melanin synthesis
Turmeric extract	3%	Anti-inflammation & repigmentation
Neem extract	3%	Protect melanocyte cells

Procedure:**Oil phase:**

1. Weigh 14 gm. of white bees wax and measure 35 ml of mineral oil.
2. Melt the wax with mineral in a porcelain dish at 70°C.

Water phase:

1. Accurately measure herbal extract and mix with 0.7 gm borax and sufficient quantity of water and heat it at 70°C also.
2. Pour borax solution into molten wax at the same temperature with constant stirring.
3. Stir the mass constantly when the temperature drops to about 45°C.
4. Add perservative and perfume as required.

Packing: Store the cream in well close container.

Storage: Keep in cold and dry place; away from sunlight.

Labelling: It includes name, ingredients, precautions, date of manufacturing, price and storage conditions.

10. Evaluation parameters of cream

Orgenoleptic evaluation:

Physical properties such as colour, odour and texture was examined by visual inspection.

Colour: the colour of cream should be off white or white

Odour: It should have mild fragrance

Texture: Smooth texture without any lumps.

pH determination:

1 gm of cream is dissolved in 10m of disstilled water than using digital pH meter the pH is check

Thermal stability:

Cosmetic formulation's thermal stability is one of the prime parameters that affect the formulation's acceptability. Amongst all the formulations, formulations shouldhave thermal stability at 35°C, 40°C and 45°C. Based on the physicochemical parameters less thermal stability and less spread ability resulted in cracking and phase separation of formulations.

Spredability:

About 1g of each sample was weighed and placed at the centre of glass plate & another glass plate was placed over it carefully. Above the glass plates, 2kg weight was placed at the centre of plate, avoid sliding of plate. The diameter of the paste in cm was measured after 30 minutes. The experiment was repeated 3 times & the averages was reported for all the samples.

Washability:

Cream is applied on hand after application of cream, it should get removed easily with flow of water. Leaving less least greasy hand.

11. Conclusion

The formulated herbal anti-vitiligo cream, incorporating extracts of Neem, Turmeric, Sesame, Black cumin has been successfully developed and comprehensively evaluated. The final products are evaluated for its appearance, texture, pH, thermal stability and stability to ensure that is safe. Herbal

products is more suitable rather than chemical base products. Further research and testing are necessary to confirm the efficacy and potency of the cream. Conducting pre-clinical and clinical trial for better understanding of effectiveness and potency is required. The study highlights the potential of using natural ingredients in skin products and encourages further exploration in this field. Further market studies and continuous refinement of the formulation may enhance its commercial viability and contribute to its widespread adoption in promoting skin healthcar and well-being.

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