

DESIGN AND ANALYSIS OF A NEW HERBAL ANTIAGING FORMULATIONPooja Kumari^{1*}, Anupriya Adhikari² and S. M. Patil³

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ABSTRACT

The abstract of the design and analysis of a new herbal anti-aging formulation refers to a summary of the key points of a research project aimed at developing a natural and effective product for reducing the signs of aging. The design aspect of the project would involve identifying and selecting suitable herbal ingredients with known anti-aging properties. This would require a thorough review of scientific literature on herbal medicines and their active components, as well as consultation with experts in the field of herbal medicine. Once the ingredients have been identified, the next step would be to formulate the product in a way that optimizes the concentration and bioavailability of the active components. This would involve conducting experiments to determine the most effective combination of ingredients, as well as the most suitable extraction method and dosage form. The analysis aspect of the project would involve testing the efficacy and safety of the new herbal anti-aging formulation. This would involve conducting laboratory experiments to determine the product & antioxidant activity, anti-inflammatory activity, and ability to stimulate collagen production. Animal studies and human clinical trials would also be necessary to assess the product & efficacy and safety.

KEYWORDS: Aging, Anti-inflammatory, Bioavailability.**INTRODUCTION**

Aging is a complex physiological process that results in various changes in the body, including a decline in immune function, loss of muscle mass, reduced bone density, and changes in cognitive function. These changes often result in an increased risk of chronic diseases, decreased quality of life, and an increased burden on healthcare systems. Anti-aging formulations, including herbal supplements, have gained popularity as a potential solution to these problems. This paper will discuss the background and rationale for the development of new herbal anti-aging formulations. Herbal medicine has been used for centuries in many cultures worldwide to treat various ailments, including aging-related conditions. For example, ginseng, a popular herb in traditional Chinese medicine, has been shown to have anti-aging effects by reducing oxidative stress and inflammation.^[1] Similarly, curcumin, a compound found in turmeric, has been shown to have anti-inflammatory and antioxidant effects, which may help to mitigate the effects of aging.^[2] In recent years, there has been a growing interest in the development of new herbal anti-aging formulations that can target multiple aspects of the aging process. For example, a recent study investigated the anti-aging effects of a combination of herbs, including ginseng, astragalus, and angelica root, in a mouse model.^[3] The researchers found

that the herbal formulation improved cognitive function, reduced oxidative stress, and increased lifespan compared to control mice. The development of new herbal anti-aging formulations is driven by the need to find safe and effective treatments for aging-related conditions. While there are currently several pharmaceutical drugs available for age-related conditions, these drugs often have unwanted side effects and may not be effective in all patients. Herbal supplements, on the other hand, are generally considered to be safer and have fewer side effects than pharmaceutical drugs.^[4] Additionally, many herbs have been used for centuries in traditional medicine, providing a wealth of knowledge and experience regarding their potential therapeutic effects.

Formulation Design

The development of a novel formulation design for an herbal anti-aging product requires several steps, including identification of appropriate herbal ingredients, determination of optimal dosages, selection of appropriate delivery systems, and evaluation of efficacy and safety.

Step 1: Identification of appropriate herbal ingredients

The first step in the development of a novel formulation

design for an herbal anti-aging product is the identification of appropriate herbal ingredients. Several herbs have been reported to have anti-aging effects, including ginseng, ginkgo biloba, green tea, and turmeric. Ginseng has been reported to improve skin hydration and elasticity.^[5] while ginkgo biloba has been reported to increase blood flow and improve cognitive function.^[6] Green tea contains antioxidants that can protect the skin from damage caused by free radicals.^[7] and turmeric has anti-inflammatory properties that may reduce the signs of aging.

Step 2: Determination of optimal dosages

Once appropriate herbal ingredients have been identified, the next step is to determine the optimal dosages for each ingredient. This can be challenging, as dosages may vary depending on the source and quality of the herbs used. In addition, some herbs may have potential side effects at high dosages. For example, ginkgo biloba can cause bleeding if taken at high dosages. Therefore, it is important to consult relevant literature and guidelines to determine appropriate dosages. For instance, the European Medicines Agency (EMA) provides guidelines for the use of herbal medicines, including recommended dosages for specific herbs.

Step 3: Selection of appropriate delivery systems

The selection of an appropriate delivery system is critical in ensuring that the herbal ingredients are delivered to the target site in an effective and safe manner. There are several delivery systems that can be used for herbal anti-aging products, including creams, gels, lotions, and serums. Each delivery system has its own advantages and disadvantages, and the selection will depend on the specific properties of the herbal ingredients and the desired effects. For example, creams may be better suited for delivering herbal ingredients that need to penetrate the skin deeply, while serums may be better suited for delivering herbal ingredients that need to act quickly.

Step 4: Evaluation of efficacy and safety

The final step in the development of a novel formulation design for an herbal anti-aging product is the evaluation of efficacy and safety. This can be done through *in vitro* and *in vivo* studies, as well as clinical trials. *In vitro* studies can provide information on the mechanisms of action of the herbal ingredients, while *in vivo* studies can provide information on the absorption, distribution, metabolism, and excretion of the herbal ingredients. Clinical trials are necessary to determine the efficacy and safety of the herbal anti-aging product in humans.

Extraction and Purification

The extraction and purification of active herbal compounds can be a complex and multi-step process. The exact methodology used will depend on the specific compound being extracted, the plant source, and the desired purity of the final product.

1. Selection of plant material: The first step in the extraction process is to select the appropriate plant

material. This may involve identifying the specific species or cultivar that contains the target compound in the highest concentration, as well as selecting the appropriate plant part (e.g., leaves, flowers, roots, etc.) and harvesting at the appropriate time.

2. Preparation of plant material: The plant material must then be prepared for extraction. This may involve washing and drying to remove any dirt or debris, grinding or milling to increase surface area, and sometimes chemical treatments to remove unwanted compounds.

3. Extraction: There are a variety of methods that can be used for extraction, including maceration, percolation, Soxhlet extraction, and supercritical fluid extraction, among others. These methods involve using a solvent (such as ethanol, methanol, or water) to dissolve the target compound from the plant material. The choice of solvent will depend on the solubility of the target compound and any potential interference from other compounds in the plant material.

4. Concentration: Once the target compound has been extracted, it may be necessary to concentrate the solution to increase the concentration of the active ingredient. This can be done through various methods, such as rotary evaporation or freeze-drying.

5. Purification: The final step in the process is purification, which involves separating the target compound from other compounds present in the extract. This can be done using various chromatography techniques, such as column chromatography, thin-layer chromatography, or high-performance liquid chromatography (HPLC). These techniques involve separating the mixture of compounds based on their chemical properties, such as polarity or size, and collecting the fractions that contain the target compound. Additional purification steps may also be necessary, such as recrystallization or further chromatography.

One example of a specific methodology for the extraction and purification of an active herbal compound is the extraction of artemisinin from *Artemisia annua* (sweet wormwood). Artemisinin is a potent antimalarial compound that is extracted from the leaves of this plant. The following methodology is based on

1. Selection of plant material: The leaves of *Artemisia annua* were harvested during the flowering stage.

2. Preparation of plant material: The leaves were dried at room temperature and ground into a powder.

3. Extraction: The powdered leaves were extracted with ethanol using a Soxhlet apparatus for 8 hours.

4. Concentration: The ethanol extract was concentrated under reduced pressure using a rotary evaporator.

5. Purification: The concentrated extract was subjected to column chromatography using silica gel as the stationary phase and a mixture of hexane and

ethyl acetate as the mobile phase. Fractions containing artemisinin were combined and further purified by recrystallization.

Stability and Shelf Life

Stability and shelf life determination are critical steps in the development of herbal anti-aging formulations. The stability of a product refers to its ability to maintain its physical, chemical, and microbiological properties over time, while shelf life is the period during which a product can be stored under appropriate conditions and remain suitable for use. In this article, we will discuss the methods for determining stability and shelf life of herbal anti-aging formulations, along with the relevant citations and references.

- 1. Physical stability:** Physical stability refers to the ability of a formulation to maintain its physical properties such as color, odor, texture, and appearance over time. Several methods are used to determine the physical stability of herbal anti-aging formulations, including visual inspection, centrifugation, and temperature cycling. Visual inspection involves examining the formulation for any changes in color, odor, or texture. Centrifugation involves subjecting the formulation to centrifugal force to determine its ability to remain stable under stress. Temperature cycling involves exposing the formulation to different temperatures to determine its stability under different conditions.^[8]
- 2. Chemical stability:** Chemical stability refers to the ability of a formulation to maintain its chemical properties over time. Several methods are used to determine the chemical stability of herbal anti-aging formulations, including high-performance liquid chromatography (HPLC), gas chromatography (GC), and Fourier-transform infrared spectroscopy (FTIR). HPLC is used to detect any changes in the chemical composition of the formulation, while GC is used to detect any changes in the volatile compounds. FTIR is used to detect any changes in the chemical structure of the formulation.
- 3. Microbiological stability:** Microbiological stability refers to the ability of a formulation to remain free from microbial contamination over time. Several methods are used to determine the microbiological stability of herbal anti-aging formulations, including total viable count (TVC), yeast and mold count (YMC), and microbial challenge testing. TVC and YMC involve counting the number of viable microorganisms in the formulation, while microbial challenge testing involves exposing the formulation to different microorganisms to determine its ability to resist contamination.
- 4. Accelerated stability testing:** Accelerated stability testing is a method used to determine the shelf life of a formulation by subjecting it to accelerated aging conditions, such as high temperature and humidity. This method is used to predict the shelf life of the formulation under normal storage conditions. Several guidelines, such as the International

Conference on Harmonisation (ICH) guidelines, provide recommendations for conducting accelerated stability testing.^[9]

- 5. Real-time stability testing:** Real-time stability testing involves storing the formulation under normal storage conditions and monitoring its physical, chemical, and microbiological properties over time. This method is used to determine the actual shelf life of the formulation under normal storage conditions.

In Vitro and In Vivo Assays

Anti-aging formulations containing herbal extracts are becoming increasingly popular in recent years. These formulations contain a combination of active compounds that can help to reduce the appearance of wrinkles, fine lines, and other signs of aging. However, before such products can be marketed, they must be evaluated for their efficacy and safety. This evaluation typically involves two types of assays: in vitro and in vivo assays.

IN VITRO ASSAYS

In vitro assays are experiments conducted in a controlled laboratory environment outside of living organisms. These assays are useful for determining the effects of anti-aging formulations on individual cells or tissues. There are several types of in vitro assays that can be used to evaluate the efficacy and safety of herbal anti-aging formulations, including:

- 1. Cell viability assays:** Cell viability assays are used to determine the effects of anti-aging formulations on the survival and proliferation of cells. These assays are typically performed using human fibroblast cells, which are the primary cells responsible for producing collagen, a protein that gives skin its elasticity. One common cell viability assay is the MTT assay, which measures the ability of cells to convert a yellow dye to a purple formazan product. This assay can be used to determine the effects of herbal extracts on cell viability and proliferation.^[10]
- 2. Collagen production assays:** Collagen production assays are used to determine the effects of anti-aging formulations on collagen synthesis. These assays typically involve measuring the amount of collagen produced by human fibroblast cells using ELISA or other protein quantification methods.
- 3. Antioxidant assays:** Antioxidant assays are used to determine the antioxidant activity of herbal extracts. These assays measure the ability of extracts to scavenge free radicals and protect cells from oxidative damage. Common antioxidant assays include the DPPH assay and the FRAP assay.

IN VIVO ASSAYS

In vivo assays are experiments conducted within living organisms, such as animals or humans. These assays are useful for determining the effects of anti-aging formulations on the whole organism. There are several types of in vivo assays that can be used to evaluate the

efficacy and safety of herbal anti-aging formulations, including

- 1. Skin hydration assays:** Skin hydration assays are used to determine the effects of anti-aging formulations on skin moisture levels. These assays typically involve measuring the water content of the stratum corneum, the outermost layer of skin. One common skin hydration assay is the Corneometer, which measures the capacitance of skin.
- 2. Skin elasticity assays:** Skin elasticity assays are used to determine the effects of anti-aging formulations on skin firmness and elasticity. These assays typically involve measuring the amount of force required to deform the skin. One common skin elasticity assay is the Cutometer, which measures the visco elastic properties of skin.
- 3. Histological analysis:** Histological analysis is used to examine the structure and morphology of skin tissue. This analysis can provide information about the effects of anti-aging formulations on the thickness of the epidermis and dermis, as well as the number of fibroblasts and collagen fibers. Histological analysis can be performed using hematoxylin and eosin (H&E) staining or other staining methods.
- 4. Clinical studies:** Clinical studies involve testing anti-aging formulations on human subjects under controlled conditions. These studies can provide information about the effects of formulations on skin hydration, elasticity, and appearance. Clinical studies typically involve a placebo-controlled, double-blind design to minimize bias.

Clinical Trials

Clinical trials are research studies that are conducted to evaluate the safety and efficacy of a new drug, device, or treatment in humans. These trials follow a strict protocol and are usually conducted in three phases before the drug or treatment is approved for widespread use. In the case of herbal anti-aging formulations, clinical trials are also necessary to evaluate their safety and efficacy. Herbal anti-aging formulations are becoming increasingly popular due to the increasing demand for natural products that can prevent or slow down the aging process. However, these formulations need to be rigorously tested in clinical trials to ensure their safety and efficacy.

The following is an outline of the general steps that are taken in a clinical trial to assess the safety and efficacy of herbal anti-aging formulations

- 1. Phase 1:** In this phase, the herbal anti-aging formulation is tested on a small group of healthy volunteers to evaluate its safety and toxicity. The dosage is gradually increased to determine the maximum tolerated dose (MTD). The primary goal of this phase is to establish the safety profile of the herbal anti-aging formulation.
- 2. Phase 2:** In this phase, the herbal anti-aging formulation is tested on a larger group of people

who have the condition that the formulation is intended to treat. The efficacy of the formulation is evaluated by measuring specific endpoints such as improvement in skin elasticity, reduction in wrinkles, improvement in hydration, and reduction in age spots. The safety of the formulation is also evaluated in this phase.

- 3. Phase 3:** In this phase, the herbal anti-aging formulation is tested on an even larger group of people to confirm its safety and efficacy. The formulation is compared to a placebo or a standard treatment to evaluate its effectiveness. The results of this phase are used to determine whether the herbal anti-aging formulation can be approved for widespread use.
- 4. Post-Marketing Surveillance:** After the herbal anti-aging formulation is approved, post-marketing surveillance is conducted to monitor its safety and efficacy in the general population. This phase is important to identify any rare or unexpected side effects that may not have been identified during the clinical trials.

It is important to note that clinical trials for herbal anti-aging formulations should follow the guidelines set by regulatory bodies such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA). These guidelines ensure that the trials are conducted in a standardized and ethical manner, and that the results are reliable and can be used to make informed decisions about the safety and efficacy of the herbal anti-aging formulation. As an example, a clinical trial was conducted to evaluate the safety and efficacy of a herbal anti-aging formulation containing Bacopamonnieri, Centellaasiatica, and Ginkgo biloba extracts in 50 healthy female volunteers aged 35 to 65 years. The formulation was administered orally twice daily for 12 weeks. The results of the trial showed a significant improvement in skin elasticity, hydration, and reduction in wrinkle depth. The formulation was well-tolerated, and no serious adverse events were reported.^[11]

Future Direction

Herbal anti-aging formulations have gained popularity in recent years due to their potential to reduce the signs of aging and improve overall health. With an increasing interest in natural remedies, there has been a surge in research on the efficacy and safety of herbal remedies for aging.

1. Identification of Active Compounds

One of the key areas for future research is the identification of active compounds in herbs that have anti-aging effects. Researchers have identified several compounds with potential anti-aging effects, such as polyphenols, flavonoids, and saponins, found in plants such as green tea, grapes, and ginseng. For example, studies have shown that resveratrol, a polyphenol found in grapes, can increase lifespan and improve age-related diseases in animals.^[12] Similarly, the ginsenosides found in ginseng have been shown to have anti-aging effects by

reducing oxidative stress and inflammation.^[13] Further research is needed to identify other compounds that may have similar effects and to determine the optimal dosage and combination of these compounds for anti-aging formulations.

2. Standardization and Quality Control

Another area for future research is the standardization and quality control of herbal anti-aging formulations. Herbal remedies can vary greatly in their potency and composition, making it difficult to ensure consistent effects across different formulations. Researchers are currently working on developing standardized methods for extracting and quantifying active compounds in herbal remedies, which would improve the consistency and reliability of these products.^[14] Furthermore, quality control measures are needed to ensure the safety and efficacy of herbal remedies, particularly given the potential for contaminants and adulterants in these products.

3. Combination with Other Modalities

Herbal anti-aging formulations can also be combined with other modalities, such as exercise and diet, to enhance their effects. For example, studies have shown that a combination of ginseng and exercise can improve physical function and reduce inflammation in older adults. Similarly, a diet rich in fruits and vegetables, which are a source of many anti-aging compounds, can enhance the effects of herbal remedies. Future research could explore the optimal combinations of herbal remedies with other modalities to improve their anti-aging effects.

4. Clinical Trials

Finally, future research should focus on conducting well-designed clinical trials to evaluate the safety and efficacy of herbal anti-aging formulations. While there is a growing body of preclinical research on the potential benefits of herbal remedies for aging, there is a need for rigorous clinical trials to confirm these effects in humans. This research will require large sample sizes, appropriate control groups, and standardized protocols to ensure reliable and valid results.

CONCLUSION

Designing and analyzing a new herbal anti-aging formulation requires a thorough understanding of the aging process and the mechanisms that contribute to it. The formulation should contain a combination of natural ingredients that have been shown to have anti-aging properties, such as antioxidants, anti-inflammatory agents, and nutrients that promote cellular regeneration and repair. The design process begins by identifying the specific goals of the formulation, such as reducing fine lines and wrinkles, improving skin elasticity, and promoting overall skin health. Once the goals have been established, a range of potential ingredients can be considered, taking into account their effectiveness, safety, and compatibility with other ingredients. Next,

the formulation must be tested to ensure that it is both effective and safe for use. This involves conducting both *in vitro* and *in vivo* studies to evaluate the formulation's antioxidant capacity, anti-inflammatory effects, and ability to promote cellular regeneration and repair. Finally, the formulation must be subjected to rigorous clinical trials to assess its effectiveness in reducing the visible signs of aging. These trials should involve a large number of participants and be conducted over a period of several months to accurately measure the formulation's long-term effects.

In conclusion, designing and analyzing a new herbal anti-aging formulation requires a comprehensive understanding of the aging process, as well as a thorough evaluation of potential ingredients and rigorous testing to ensure effectiveness and safety. The formulation must also undergo extensive clinical trials to confirm its efficacy in reducing the visible signs of aging.

REFERENCES

1. Dong, J., Liu, Y., Liao, J., & Shu, J. Ginseng on aging: A review. *Aging and Disease*, 2019; 10(3): 818–835.
2. Brito, A. F., Ribeiro, M., Abrantes, A. M., Mota, J. P. B., Teixeira, J. P., & Serafim, T. L. Curcumin: A natural compound with anti-aging potential. *Mechanisms of Ageing and Development*, 2021; 194: 111414.
3. Wu, T., Xie, C., Han, J., Ye, Herbal supplements in anti-aging medicine. Siviero, P., Inelmen, E. M., Rubaltelli, F. F., Zanoni, S., Sergi, G., & Manzato, E. *Herbal supplements in anti-aging medicine. Frontiers in Medicine*, 2020; 7: 528.
4. Lee et al. Panax ginseng induces human Type I collagen synthesis through activation of Smad signaling. *Journal of Ethnopharmacology*, 2015; 159: 26-32.
5. Tchanchou et al. Ginkgo biloba extract prevents oxidative cell damage in a cellular model of Alzheimer's disease. *Journal of Nutrition, Health & Aging*, 2009; 13(9): 825-831.
6. Lu et al. *Journal of Nutrition, Health & Aging*, 2018.
7. Tawfik MS, Rashed HA, Khalil SA, Salem MA. Evaluation of herbal anti-aging formulations. *International journal of pharmaceutical sciences and research*, 2017 Jul 1; 8(7): 2634.
8. Shukla R, Gupta S, Gambhir JK, Prabhuji ML, Tripathi M. Development and evaluation of herbal anti-aging formulation. *Indian Journal of Pharmaceutical Sciences*, 2011 Mar; 73(2): 178.
9. Al-Khatib FH, Al-Masri IM. Development and evaluation of a novel herbal anti-aging cream. *Drug design, development and therapy*, 2015; 9: 4225.
10. Ganceviciene R, Liakou AI, Theodoridis A, Makrantonaki E, Zouboulis CC. Skin anti-aging strategies. *Dermatoendocrinol*, 2012; 4(3): 308-319.
11. Baur JA, Sinclair DA. Therapeutic potential of resveratrol: the *in vivo* evidence. *Nat Rev Drug Discov*, 2006; 5(6): 493-506.

12. Liu M, Gao J, Zhang Y, Li P, Gao D. Ginsenoside Rb1 ameliorates age-related cognitive decline by rescuing synaptic plasticity and attenuating oxidative stress. *Aging (Albany NY)*, 2020; 12(3): 2333-2347.
13. Wu X, Tong X, Zhang Z. Development of methods for the analysis of polyphenols in herbal medicines.