

HAIR GROWTH COMPOSITION

TECHNICAL FIELD OF THE INVENTION:

The present invention relates to an improved pharmaceutical and dermatological hair growth composition and to the process for preparation thereof.

BACKGROUND AND PRIOR ART:

Hair loss or Alopecia is one of the major causes of concern for people all around the world. It not only affects the mental well-being of individuals but also decreases their self-confidence. There are many factors that can contribute to hair loss. It can affect just the scalp or the whole body. It can either be temporary or permanent.

The reasons for hair loss could be heredity, medical conditions, hormonal changes, diet related or a normal part of aging. Certain medications including chemotherapy, HIV/AIDS, hypothyroidism, and malnutrition including iron deficiency cause hair loss.

The common types of hair loss include male- or female-pattern hair loss, Alopecia Areata, and a thinning of hair known as Telogen Effluvium.

There are two types of Alopecia (hair loss): non-scarring alopecia and scarring alopecia.

Non-scarring alopecia occurs due to the following reasons:

- Genetics and advanced age (i.e. androgenetic alopecia, female pattern hair loss)
- High fevers, severe infections, thyroid disease
- Childbirth, taking birth control pills
- Inadequate proteins or iron in diet
- Patients on drugs like blood thinners, treatments for gout, arthritis, depression, hypertension, chemotherapy

- Alopecia areata
- Physical or emotional stress
- Topical use of chemical treatments, such as hair dyes, permanent wave solutions, etc.
- Diseases, such as leprosy or syphilis
- Allergy

Scarring alopecia may occur as a result of burns (accidental or post-surgical from cryosurgery or laser surgery) or trauma, which often causes destruction of hair follicles.

There are various types of hair including terminal hair, vellus hair, and modified terminal hair such as in the eyebrows and eyelashes. Terminal hairs are coarse, pigmented, long hairs in which the bulb of the hair follicle is situated deep in the dermis. Vellus hairs, on the other hand, are fine, thin, non-pigmented short hairs in which the hair bulb is located superficially in the dermis. As alopecia progresses, a transition takes place in the area of approaching baldness wherein the hairs themselves are changing from the terminal to the vellus type. The size of the hair follicles is known to decrease.

Another factor that contributes to the end result is a change in the cycle of hair growth. In humans, each hair follicle undergoes repeated cyclical periods of growth. These cycles include anagen, an active growth stage, which can last for ~2 to 6 years; Catagen, a transition phase, which lasts for only ~1-2 weeks; and Telogen, a resting period which lasts ~3-4 months after which the hair is shed and a new hair is grown as the cycle repeats itself. In the normal human scalp, which contains approximately 100,000 hair follicles, 86% of the hair follicles are in Anagen, 1% is in Catagen, and 13% are in Telogen. Thus, under normal conditions, upto approximately 50-100 hairs may shed from the scalp each day. With the onset of male pattern baldness, a successively greater proportion of hairs

are in the Telogen phase with correspondingly fewer in the active growth Anagen phase.

While a good deal is known about the results of male pattern baldness, very little is known about the cause. The cause is generally believed to be genetic and hormonal in origin. The known prior arts attempt to control it through hormone adjustment, but this has been singularly unsuccessful. Alopecia is associated with severe diminution of hair follicles. A bald human subject will have an average of only 306 follicles per square centimeter, whereas, a non-bald subject in the same age group will have an average of 460 follicles per square centimeter. This amounts to a one-third reduction in hair follicles which, when added to the increased proportion of vellus hair follicles and the increased number of hair follicles in the Telogen phase, is both significant and noticeable. Approximately, 50% of hair follicles must be shed to produce visible thinning of scalp hair. It is thus a combination of these factors: transition of hairs from terminal to vellus, increased number of Telogen hairs- some of which have been shed, and loss of hair follicles that produce 'baldness'.

Treatments for alopecia include the medications minoxidil (or finasteride) and hair transplant surgery. Alopecia areata may be treated by steroid injections in the affected area, but these need to be frequently repeated to be effective.

Surgical techniques:

- Self-grafting or transplants - Hair bulbs are drawn from the posterior scalp that is hair-bearing and redistributed in a balding area.
- Flap surgery – A large horse shoe-shaped piece of scalp is partially detached from the donor fringe area and the free end is positioned over the bald spot where a corresponding patch of hair less scalp has been removed.
- Scalp reductions - A section of bald scalp is removed and the sides of scalp are lifted and sutured together, thereby reducing the overall surface area of the scalp.

- Scalp expansion and extension -Silicon bags are inserted beneath an area of hairy scalp and gradually inflated with saline water over a 6 week period. This causes the hair- bearing skin to stretch, thus increasing the amount of hair-bearing scalp. After removing the bags, expanded hair- bearing skin is lifted and moved to an adjacent bald area where similar sized patch of scalp has been excised.

Even though the use of laser and particular non-cicatrizing substances has reduced many chances of cicatrization, the surgical methods are costly, traumatic, painful and produce undesired side effects.

Non- surgical techniques:

These include additions of hair- bearing devices that can consist of human hair, synthetic fibre or a combination of both. These additions are attached by a variety of techniques, either the existing hair or skin being possible anchoring sites.

Medicinal treatments:

Medicinal treatments include topical application of vasodilators like minoxidil, diazoxide etc. which cause the reactivation of cutaneous blood flow, thus producing the influx of oxygen and nutrients necessary for regeneration of tissues. One of the medications uses minoxidil as its active ingredient and is sold under the trade name Rogaine (a trademark of Pharmacia and Upjohn Company). Rogaine has shown to reduce hair loss and stimulate hair growth in upto 10% of men with male pattern baldness. Treatment with it though has to be exhaustively and regularly maintained. It is also very expensive. The topical application of substances used so far makes the ability of cutaneous absorption limited and superficial: that is unavoidable, given that, if the vasodilators should be absorbed in a massive manner, undesired systemic effects would arise.

Certain antiandrogens like Spironolactone, Aldactone, Cimetidine, or 5-alpha reductase inhibitors like oral Finasteride are known to avoid the transformation of

testosterone to DHT which is responsible for hair loss. Finasteride is an active ingredient in Propecia (a trademark of Merck and Co.inc.) in pill form and has to be taken regularly. A drawback of antiandrogen therapy is that it is hard to restrict androgen blockage to the scalp only, thus causing undesired effects especially in men (decreased libido, impotence, gynaecomastia, etc.)

Thus, with regard to hair loss, the results obtained until now are not entirely satisfactory.

Androgens (steroid hormones such as estrogen and testosterone) are the most obvious regulators of human hair growth in both sexes. Interestingly, androgens have contrasting effects on hair follicles depending on the hair follicle's location in the body. Androgens stimulate hair growth in many locations (i.e., beard, axilla) while inhibiting scalp hair growth in genetically predisposed individuals. Androgens act on the hair follicles via the dermal papilla, presumably by altering the production of regulatory factors (growth factors, peptides etc.) that influence the dermal papilla cells. Cultured dermal papilla cells secrete factors which are mitogenic for other dermal papilla cells, outer root sheath cells, epidermal keratinocytes and endothelial cells. Androgen-sensitive cells from beard or balding scalp reflect their in vivo androgenetic responses by responding to testosterone by either increasing (i.e., beard) or decreasing (i.e., balding) their mitogenic ability.

Many growth factors have been implicated in controlling different signals in the cycle of hair growth, with some playing major and some playing minor roles.

Noggin is a protein that is involved in the development of many body tissues, including nerve tissue, muscles, and bones. It is an inhibitor of several bone morphogenetic proteins like BMP2, BMP4, BMP5, BMP6, BMP7, BMP13, and BMP14.

Administration of noggin protein induces new hair growth phase in postnatal telogen skin in vivo. In contrast, BMP4 induces selective arrest of anagen development in the secondary hair follicle. Sonic hedgehog (Shh) is a factor controlling both hair follicle development and telogen-anagen transition. As a hair growth inducer, Noggin increases Shh mRNA in the hair follicle whereas BMP4 down-regulates Shh. Thus the neutralization of the inhibitory activity of BMP2/4 by the BMP antagonist noggin is essential for hair follicle induction. This suggests that modulation of BMP4 signalling by noggin is essential for hair growth phase induction in postnatal skin and that the hair growth-inducing effect of noggin is mediated, at least in part, by Shh. (Botchkarev, V. A., et.al published in FASEB J. 15, 2205–2214 (2001)).

Till date these elixirs to hair growth have been identified and introduced independently in hair growth serums like Anagain (Noggin). Noggin, individually despite being potent hair growth factors have shown complications like allergic skin rashes, itching, muscle pains, headache, vaginal bleeding, pain in the injected area; headache, heaviness of head, swelling, redness, infection, allergic reaction-urticarial rash, temporary skin discoloration, bruising etc.

Peptides essentially have been proven to rejuvenate the hair follicles, stimulate new hair growth and keep that growth healthy and strong. Decapeptide-10 (CG-Keramin2) provides nourishment to scalp and hair root for a healthier and thicker hair shaft through the stimulus of angioedema. Octapeptide-2 (Prohairin-β4) promotes hair growth by activating the stem cells in hair follicles.

While the combination of these ingredients are found in over the counter hair serums commonly available like the DR.CYJ Hair Filler, Derma heal hair concentrating serum, Renokin Hair Growth Serum and Traya Hair Serum to name a few, these serums exclusively either only work through the action of peptides and/or accompanied with side effects like transient short duration pain following wounded scalp introduction, redness, swelling, oedema, hematomas, itching and

slight pain at the injection area following treatment and allergy to any of the ingredients and unwanted hair growth in case of accidental application in other areas.

KR101772574B1 relates a composition comprising a stable basic Fibroblast Growth Factor (stable bFGF), an Insulin-like Growth Factor (IGF-1), Vascular Endothelial Growth Factor (VEGF), Keratinocyte Growth Factor (KGF-2), Stem Cell Factor (SCF), and noggin peptide as an active ingredient.

An article titled “A Randomized Study of Biomimetic Peptides Efficacy and Impact on the Growth Factors Expression in the Hair Follicles of Patients with Telogen Effluvium” by Kubanov et.al. published on April, 2018 discloses a study to determine the effect of a lotion based on biomimetic peptides containing Decapeptide 18, Oligopeptide-54, Decapeptide-10, Octapeptide-2, Decapeptide-19, Oligopeptide-71, and Decapeptide-28 on the expression of growth factors in the hair follicles of patients with telogen effluvium. The application of biomimetic peptides to the scalp of patients with telogen effluvium resulted in a decrease in hair loss due to stimulation and prolongation of the anagen phase and, consequently, reduction of the telogen phase.

EP2383283(A2) discloses a peptide exhibiting a growth factor activity, comprising an amino acid sequence represented by the general formula(1)- Glu-Leu-Ile-Glu-His-linker-Arg-Pro-Ala-Asp. The amino acid sequence represented by the general formula (1), noggin-derived sequences at N- and C-termini are linked by a linker. It further provides a composition for promoting hair growth containing the peptide exhibiting a growth factor activity as an active ingredient.

The existing treatments are very expensive and show unsatisfactory results. The results are not long lasting and there is risk of unwanted side effects. Therefore, there remains an unmet need in the art to provide a hair growth composition capable of preventing hair loss and stimulating hair growth, which is economical,

safe to apply with no after effects even in medically compromised individuals and shows no post treatment hair fall.

IN310925 relates to an intradermal pharmaceutical composition comprising plurality of growth factors and biomimetic peptides for preventing hair loss and promoting hair growth of mammalian hair. The growth factors include vascular endothelial growth factor, Basic fibroblast growth factor, Insulin like growth factor, Keratinocyte growth factor, Thymosin β 4, Copper tripeptide 1.

IN310925 discloses an intradermal pharmaceutical composition comprising vascular endothelial growth factor, Basic fibroblast growth factor, Insulin like growth factor, Keratinocyte growth factor, Thymosin β 4, Copper tripeptide 1 along with vitamins, minerals, amino acids, nucleic acids for preventing hair loss and promoting hair growth.

The present inventors observed that the results obtained after using the composition of IN310925 were not satisfactory and felt a need to improve the formulation to increase the Hair density and Shaft diameter of the hair.

OBJECT OF INVENTION

It is therefore an object of the present invention to provide an improved hair growth composition for effective treatment and prevention of hair loss and for stimulation of hair regrowth which is potently organic, non-toxic, biocompatible and hence favors its prolonged use with minimal to no side effects.

The other objective is to provide the hair growth composition that can serve both as a cosmetic composition as well as dermatological composition with no adverse side effects and to the process for preparation thereof.

SUMMARY OF THE INVENTION:

In accordance with the above, the present invention provides a pharmaceutical and dermatological hair growth composition comprising;

- a) Growth factors analogous to recombinant human peptides including their biomimetic polypeptide variants in an amount of 0.005mg/L to 500mg/L;
- b) Noggin in an amount of 9-11mg/L,
- c) Decapeptide-10 (CG-Keramin2) in an amount of 8.0-10.05mg/L;
- d) Octapeptide-2 (Prohairin-β4) in an amount of 0.0025 to 0.005mg/L;
- e) Vitamins, minerals, nucleic acids and amino acids in appropriate concentration;

along with pharmaceutically and dermatologically acceptable excipients;

wherein said hair growth composition may comprise the ingredients selected from other peptides and botulinum toxin of type A.

The Growth factors in said hair growth composition include but is not limited to Vascular Endothelial Growth Factor (Human oligopeptide-11) including its biomimetic analogue Sh-Polypeptide-9, Basic Fibroblast Growth Factor (Human oligopeptide-3) including its biomimetic analogue Sh-Polypeptide-1, Insulin-like Growth Factor 1 (Human oligopeptide-2) including its biomimetic analogue Sh-Oligopeptide-2, Copper Tripeptide 1, Keratinocyte Growth Factor including its biomimetic analogue Sh-Polypeptide-3, Thymosin-β4 including its biomimetic analogue Sh-Oligopeptide-4 and the like.

The other peptides in said pharmaceutical and dermatological hair growth composition are selected from ; Elastin scalp peptide (Tetrapeptide 32) in the concentration of 15-25 ppm; Elastin Hair Peptide (Hexapeptide-12) in the concentration of 15-25 ppm; Acetyl Tetrapeptide-3 in the concentration of 50-100 ppm; Octapeptide-11 in the concentration of 15-25 ppm; Octapeptide-20 in the concentration of 10-20 ppm; Palmitoyl pentapeptide -3 in the concentration of 50-

100; Oligopeptide-74 (CG-Grotene) in the concentration of 15-25 ppm and the like.

The Botulinum Toxin Type A in said pharmaceutical and dermatological hair growth composition is in the concentration of 50 -100U/ml.

The pharmaceutically and dermatologically acceptable excipients include but are not limited to diluents, carriers, buffering agents, colorants and the like in appropriate amount.

In a preferred aspect, the present invention provides a hair growth composition comprising;

- a) Vascular endothelial growth factor (Human oligopeptide-11) including its biomimetic analogue Sh-Polypeptide-9 in an amount of 0.01mg/L – 100mg/L;
- b) Basic fibroblast growth factor (Human oligopeptide-3) including its biomimetic analogue Sh-Polypeptide-1 in an amount of 0.01mg/L – 100 mg/L;
- c) Insulin like growth factor (Human oligopeptide-2) including its biomimetic analogue Sh-Oligopeptide-2 in an amount of 0.01mg/L – 100mg/L;
- d) Copper tripeptide 1 in an amount of 0.1mg/L – 500 mg/L;
- e) Keratinocyte growth factor including its biomimetic analogue Sh-Polypeptide-3 in an amount of 0.01mg/L – 100 mg/L;
- f) Thymosin β 4 including its biomimetic analogue Sh-Oligopeptide-4 in an amount of 0.005mg/L – 100 mg/L;
- g) Noggin in an amount of 9-11 mg/l;
- h) Decapeptide-10 (CG-Keramin2) in an amount of 8.5-10.5 mg/l;
- i) Octapeptide-2 (Prohairin- β 4) in an amount of 0.0025 to 0.005 mg/l;

- j) Vitamins, minerals, nucleic acids and amino acids in appropriate concentration;
along with pharmaceutically and dermatologically acceptable excipients;
wherein said hair growth composition may comprise the ingredients selected from other peptides and botulinum toxin of type A.

The other peptides in said pharmaceutical and dermatological hair growth composition are selected from ; Elastin scalp peptide (Tetrapeptide 32) in the concentration of about 20ppm; Elastin Hair Peptide (Hexapeptide-12) in the concentration of about 20ppm; Acetyl Tetrapeptide-3 in appropriate concentration; Octapeptide-11 in appropriate concentration; Octapeptide-20 in appropriate concentration; Palmitoyl pentapeptide -3 in appropriate concentration; and Oligopeptide-74 (CG-Grotene) in appropriate concentration and the like.

The Botulinum Toxin Type A in said pharmaceutical and dermatological hair growth composition is in the concentration of about 100U/ml.

The vitamins are selected from the group consisting of Vitamin A in an amount of 0.01 – 0.50 mg/L, Vitamin B1 in an amount of 0.01 – 0.50 mg/L, Vitamin B2 in an amount of 0.01 – 0.50 mg/L, Vitamin B3 in an amount of 1.0 - 50 mg/L, Vitamin B5 in an amount of 0.001 – 0.050 mg/L, Vitamin B6 in an amount of 0.01 – 0.10 mg/L, Vitamin B7 in an amount of 0.001 – 0.050 mg/L, Vitamin B12 in an amount of 0.01 – 0.50 mg/L, Vitamin C in an amount of 10 – 80 mg/L, Vitamin E in an amount of 0.001 – 0.050 mg/L, Vitamin K in an amount of 0.001 – 0.050 mg/L and the like; minerals and mineral salts selected from the group consisting of Calcium salt in an amount of 100 - 300 mg/L, Sodium salt in an amount of 5000 – 7000 mg/L, Potassium salt in an amount of 200 – 600 mg/L, Magnesium salt in an amount of 10 - 200 mg/L and the like, nucleic acids selected from the group consisting of Adenosine, Cytosine, Guanine and Thymine and essential and non-essential amino acids selected from the group consisting of

Taurine, Hydroxyproline, Methionine, Proline, Ornithine, Asparagine, Glutamic acid, Aspartic acid, Cystine, Serine, Glycine, Tyrosine, Phenylalanine, Isoleucine, Tryptophan, Threonine, Leucine, Histidine, Valine, Arginine, Lysine, Alanine and Glutamine. The nucleic acids each are in the range of 1-50 mg/L, essential and non-essential amino acid in the range of 2-150 mg/L.

The pharmaceutically and dermatologically acceptable excipients include but are not limited to diluents, carriers, buffering agents, colorants and the like in appropriate amount.

In a further aspect, present invention provides a process for the preparation of the hair growth composition comprising ;

- a) Adding the Growth factors analogous to recombinant human peptides including their biomimetic polypeptide variants in an amount of 0.005mg/L to 500mg/L, Noggin in an amount of 9 to 11mg/L; Decapeptide-10 (CG-Keramin2) in an amount of 8.0 to 10.05mg/L; Octapeptide-2 (Prohairin-β4) in an amount of 0.0025 to 0.005mg/L; Vitamins, minerals, nucleic acids and amino acids in appropriate concentration; along with pharmaceutically and dermatologically acceptable excipients to distilled water at ambient temperature in the disperser set at 750-1000rpm;
- b) Adjusting the pH and filtering the final product followed by filling the vials.

The ingredients selected from other peptides and botulinum toxin of type A may be added in step a) of the above process. The other peptides are selected from Elastin scalp peptide (Tetrapetide 32) in the concentration of about 20ppm; Elastin Hair Peptide (Hexapeptide-12) in the concentration of about 20ppm; Acetyl Tetrapetide-3 in appropriate concentration; Octapeptide-11 in appropriate concentration; Octapeptide-20 in appropriate concentration; Palmitoyl pentapeptide -3 in appropriate concentration; Oligopeptide-74 (CG-Grotene) in

appropriate concentration and the like and the Botulinum Toxin Type A is in the concentration of about 100U/ml.

In another aspect, the present hair growth composition may be formulated for intradermal, dermaroller or topical administration. The formulation may be available as vials, prefilled syringes and hair fillers.

The composition of the present invention is effective to treat or prevent hair loss by stimulating hair follicles and promoting hair growth, where such hair growth improves the bodily appearance of said person.

In yet another aspect, the present invention provides a method for treating alopecia, for treating or preventing hair loss by stimulating hair follicles and promoting hair growth and improving the bodily appearance of a person comprising administering the pharmaceutical and dermatological hair growth composition in an effective amount to a person in need.

In another aspect, the pharmaceutical and dermatological hair growth composition may be administered intradermally or applied topically.

In yet another aspect, the pharmaceutical and dermatological hair growth composition may be administered through micro-needling techniques such as the nappage technique, through dermaroller, or hair filler inserts.

The hair growth composition of the present invention may be co-administered with one or more hair growth promoting compounds selected from the group consisting of minoxidil, minoxidil analogues, minoxidil derivatives, anti-androgens and 5-alpha-reductase inhibitors and such like in appropriate concentration.

In another aspect, the present hair growth composition is used for treating or preventing hair loss and promoting hair growth.

In yet another aspect, the present invention provides a medical device in the form of dermaroller, prefilled syringes, vials or hair filler inserts for administering the hair growth composition of the present invention in an effective amount to the subject.

In another aspect, the present invention provides a kit comprising;

- a) prefilled syringes or vials or a dermaroller comprising said pharmaceutical or dermatological composition or hair filler insert embedded in hyaluronic acid enriched with said composition; and
- b) instruction manual for application.

BRIEF DESCRIPTION OF THE DRAWINGS:

Figure 1: Results of hair pull test

Figure 2: Video microscopic assessment showing percentage improvement in hair density, terminal hair, and shaft diameter

Figure 3: Video microscopic assessment showing percentage improvement in terminal hair count

The novel features which are considered characteristic for the invention are set forth in particular in the appended claims. Other aspects of the invention will become evident upon reference to the following detailed description. The invention itself, however, both as to its construction and its method of operation, together with additional objects and advantages thereof, will be best understood from the following description.

DETAILED DESCRIPTION OF THE INVENTION:

In line with the object of present invention, there is provided a hair growth composition for nourishment of hair follicles for preventing hair loss and stimulating hair regrowth in mammals.

As used herein the term 'effective amount' means an amount which stimulates hair growth associated with hair loss afflictions like male pattern baldness, or insults such as radiation or chemotherapy.

The term 'growth factor' relates to a naturally occurring protein capable of stimulating cellular growth, proliferation and cellular differentiation.

The invention is based on two considerations:

1. Alopecia is a deficiency of terminal hair. In the bald person, there is a noticeable absence of terminal hair; though the skin does contain vellus hair which is the fine colorless hair which may require microscopic examination to determine its presence. This vellus hair is the precursor to terminal hair. Thus, the present invention relates to a method of treating the scalp to reduce hair loss and stimulate hair regrowth on the scalp.
2. Hair loss follows the alteration of microcirculation of the scalp. Its ongoing atrophy causes the loss of functionality of the hair follicle that becomes gradually unable to generate the hair. Like any tissue that slowly gets atrophic, the follicle which is no more supported by the microcirculation, (and thus by oxygen and nutrition) produces at first a fragile hair easy to tear at its root, and in the subsequent step includes spontaneous shedding of hair and the impossibility of its regeneration.

The epidermal hair follicles are regulated by interactions between the dermis and epidermis (the 2 layers of the skin), and undergo stages of growth (anagen), involution (catagen), and silence (telogen). Factors from the hair root which is present in the dermis, act as inducing signals for this cyclic growth of the hair.

There are stem cells in an area of the hair follicle which pick up these signals and form a down growth into the dermis to form the hair shaft. A network of capillaries surrounding the base of the hair follicle delivers the nutrients - amino acids, vitamins, minerals - necessary for proper functioning. Cell division in the hair follicle is extremely fast. This rapid cell proliferation requires a constant supply of nutrients. The inducing signals for the hair follicle growth are the growth factors identified and components of the invention.

Many growth factors have been found to be responsible for the regulation of the hair growth cycle. The factors found to stimulate hair growth are insulin like growth factor 1, Basic fibroblast growth factor, vascular endothelial growth factor, thymosin β 4, keratinocyte growth factor, copper tripeptide 1, Noggin, Decapeptide-10 (CG-Keramin2) and Octapeptide-2 (Prohairin- β 4), follistatin, Wnt proteins, β catenin proteins, stem cell factor, platelet derived growth factors. Analysis of several protein growth factors to find out which actually causes hair growth or the absence of which causes hair loss, and the optimum concentration required to get the desired result, resulted in the development of the present invention.

Accordingly, in an embodiment, the present invention provides a hair growth composition that can stimulate the conversion of vellus hair to terminal hair as well as increase the rate of growth of terminal hair. Further, the hair growth composition of the current invention prevents hair loss and stimulates the natural growth of hair in bald areas by restoring valid microcirculation to the scalp.

In an embodiment, the present invention provides a pharmaceutical and dermatological hair growth composition comprising;

- a) Growth factors analogous to recombinant human peptides including their biomimetic polypeptide variants in an amount of 0.005mg/L to 500mg/L;
- b) Noggin in an amount of 9-11mg/L,
- c) Decapeptide-10 (CG-Keramin2) in an amount of 8.0-10.05mg/L;

- d) Octapeptide-2 (Prohairin- β 4) in an amount of 0.0025 to 0.005mg/L;
 - e) Vitamins, minerals, nucleic acids and amino acids in appropriate concentration;
- along with pharmaceutically and dermatologically acceptable excipients;
- wherein said hair growth composition may comprise the ingredients selected from other peptides and botulinum toxin of type A.

The Growth factors in said pharmaceutical and dermatological hair growth composition include but is not limited to Vascular Endothelial Growth Factor (Human oligopeptide-11) including its biomimetic analogue Sh-Polypeptide-9, Basic Fibroblast Growth Factor (Human oligopeptide-3) including its biomimetic analogue Sh-Polypeptide-1, Insulin-like Growth Factor 1 (Human oligopeptide-2) including its biomimetic analogue Sh-Oligopeptide-2, Copper Tripeptide 1, Keratinocyte Growth Factor including its biomimetic analogue Sh-Polypeptide-3, Thymosin- β 4 including its biomimetic analogue Sh-Oligopeptide-4 and the like.

The other peptides in said pharmaceutical and dermatological hair growth composition are selected from; Elastin scalp peptide (Tetrapeptide 32) in the concentration of 15-25 ppm; Elastin Hair Peptide (Hexapeptide-12) in the concentration of 15-25 ppm; Acetyl Tetrapeptide-3 in the concentration of 50-100 ppm; Octapeptide-11 in the concentration of 15-25 ppm; Octapeptide-20 in the concentration of 10-20 ppm; Palmitoyl pentapeptide -3 in the concentration of 50-100; Oligopeptide-74 (CG-Grotene) in the concentration of 15-25 ppm and the like.

The Botulinum Toxin Type A in said pharmaceutical and dermatological hair growth composition is in the concentration of 50-100U/ml.

The vitamins are selected from the group consisting of Vitamin A in an amount of 0.01 – 0.50 mg/L, Vitamin B1 in an amount of 0.01 – 0.50 mg/L, Vitamin B2 in an amount of 0.01 – 0.50 mg/L, Vitamin B3 in an amount of 1.0 - 50 mg/L,

Vitamin B5 in an amount of 0.001 – 0.050 mg/L, Vitamin B6 in an amount of 0.01 – 0.10 mg/L, Vitamin B7 in an amount of 0.001 – 0.050 mg/L, Vitamin B12 in an amount of 0.01 – 0.50 mg/L, Vitamin C in an amount of 10 – 80 mg/L, Vitamin E in an amount of 0.001 – 0.050 mg/L, Vitamin K in an amount of 0.001 – 0.050 mg/L and the like; minerals and mineral salts selected from the group consisting of Calcium salt in an amount of 100 - 300 mg/L, Sodium salt in an amount of 5000 – 7000 mg/L, Potassium salt in an amount of 200 – 600 mg/L, Magnesium salt in an amount of 10 - 200 mg/L and the like, nucleic acids selected from the group consisting of Adenosine, Cytosine, Guanine and Thymine in an amount of 1 – 50 mg/L and essential and non-essential amino acids selected from the group consisting of Taurine, Hydroxyproline, Methionine, Proline, Ornithine, Asparagine, Glutamic acid, Aspartic acid, Cystine, Serine, Glycine, Tyrosine, Phenylalanine, Isoleucine, Tryptophan, Threonine, Leucine, Histidine, Valine, Arginine, Lysine, Alanine and Glutamine in an amount of 2-150 mg/L.

The pharmaceutically and dermatologically acceptable excipients include but are not limited to diluents, carriers, buffering agents, colorants and the like in appropriate amount.

In an embodiment, the biomimetic analogues are derived from potato.

In a preferred embodiment, the present invention discloses a pharmaceutical and dermatological hair growth composition comprising:

- a) Vascular endothelial growth factor (Human oligopeptide-11) including its biomimetic analogue Sh-Polypeptide-9 in an amount of 0.01mg/L – 100mg/L;
- b) Basic fibroblast growth factor (Human oligopeptide-3) including its biomimetic analogue Sh-Polypeptide-1 in an amount of 0.01mg/L – 100 mg/L;

- c) Insulin like growth factor (Human oligopeptide-2) including its biomimetic analogue Sh-Oligopeptide-2 in an amount of 0.01mg/L – 100mg/L;
- d) Copper tripeptide 1 in an amount of 0.1mg/L – 500 mg/L;
- e) Keratinocyte growth factor including its biomimetic analogue Sh-Polypeptide-3 in an amount of 0.01mg/L – 100 mg/L;
- f) Thymosin β 4 including its biomimetic analogue Sh-Oligopeptide-4 in an amount of 0.005mg/L – 100 mg/L;
- g) Noggin in an amount of 9-11 mg/L;
- h) Decapeptide-10 (CG-Keramin2) in an amount of 8.5-10.5 mg/L;
- i) Octapeptide-2 (Prohairin- β 4) in an amount of 0.0025 to 0.005 mg/L;
- j) Vitamins, minerals, nucleic acids and amino acids in appropriate concentration;

along with pharmaceutically and dermatologically acceptable excipients; wherein said hair growth composition may comprise the ingredients selected from other peptides and botulinum toxin of type A.

In an embodiment, the other peptides in said pharmaceutical and dermatological hair growth composition are selected from; Elastin scalp peptide (Tetrapeptide 32) in the concentration of 15-25 ppm; Elastin Hair Peptide (Hexapeptide-12) in the concentration of 15-25 ppm; Acetyl Tetrapeptide-3 in the concentration of 50-100 ppm; Octapeptide-11 in the concentration of 15-25 ppm; Octapeptide-20 in the concentration of 10-20 ppm; Palmitoyl pentapeptide -3 in the concentration of 50-100; Oligopeptide-74 (CG-Grotene) in the concentration of 15-25 ppm and the like.

In yet another embodiment, the Botulinum Toxin Type A in said pharmaceutical and dermatological hair growth composition is in the concentration of 50-100U/ml.

The vitamins are selected from the group consisting of Vitamin A in an amount of 0.01 – 0.50 mg/L, Vitamin B1 in an amount of 0.01 – 0.50 mg/L, Vitamin B2 in an amount of 0.01 – 0.50 mg/L, Vitamin B3 in an amount of 1.0 - 50 mg/L, Vitamin B5 in an amount of 0.001 – 0.050 mg/L, Vitamin B6 in an amount of 0.01 – 0.10 mg/L, Vitamin B7 in an amount of 0.001 – 0.050 mg/L, Vitamin B12 in an amount of 0.01 – 0.50 mg/L, Vitamin C in an amount of 10 – 80 mg/L, Vitamin E in an amount of 0.001 – 0.050 mg/L, Vitamin K in an amount of 0.001 – 0.050 mg/L and the like; minerals and mineral salts selected from the group consisting of Calcium salt in an amount of 100 - 300 mg/L, Sodium salt in an amount of 5000 – 7000 mg/L, Potassium salt in an amount of 200 – 600 mg/L, Magnesium salt in an amount of 10 - 200 mg/L and the like, nucleic acids selected from the group consisting of Adenosine, Cytosine, Guanine and Thymine in an amount of 1-50 mg/L and essential and non-essential amino acids selected from the group consisting of Taurine, Hydroxyproline, Methionine, Proline, Ornithine, Asparagine, Glutamic acid, Aspartic acid, Cystine, Serine, Glycine, Tyrosine, Phenylalanine, Isoleucine, Tryptophan, Threonine, Leucine, Histidine, Valine, Arginine, Lysine, Alanine and Glutamine in an amount of 2-150 mg/L.

The pharmaceutical and dermatological acceptable excipients include but are not limited to diluents, carriers, buffering agents, colorants and the like in appropriate amount. . Preferably, suitable carriers or diluents include but are not limited to distilled water, physiologic saline, bacteriostatic saline, (saline containing 0.9mg/ml benzyl alcohol).

The present invention further encompasses the compositions involving one or more known growth factors in addition to the composition of invention as mentioned above.

In yet another embodiment, the present invention discloses a pharmaceutical and dermatological hair growth composition, comprising:

- a) Vascular endothelial growth factor (Human oligopeptide-11) including its biomimetic analogue Sh-Polypeptide-9 in an amount of 0.1mg/L – 10mg/L;
 - b) Basic fibroblast growth factor (Human oligopeptide-3) including its biomimetic analogue Sh-Polypeptide-1 in an amount of 0.1mg/L – 5mg/L;
 - c) Insulin like growth factor (Human oligopeptide-2) including its biomimetic analogue Sh-Oligopeptide-2 in an amount of 0.1mg/L – 5mg/L;
 - d) Copper tripeptide 1 in an amount of 1mg/L – 100mg/L;
 - e) Keratinocyte growth factor including its biomimetic analogue Sh-Polypeptide-3 – 0.1mg/L in an amount of 10mg/L;
 - f) Thymosin β 4 including its biomimetic analogue Sh-Oligopeptide-4 in an amount of 0.001mg/L – 1mg/L;
 - g) Noggin in an amount of 5-10 mg/L;
 - h) Decapeptide-10 (CG-Keramin2) in an amount of 8.5-10.5 mg/L;
 - i) Octapeptide-2 (Prohairin- β 4) in an amount of 0.0025 to 0.005 mg/L;
 - j) vitamins, minerals, nucleic acids and amino acids in appropriate concentration;
- along with pharmaceutically and dermatologically acceptable excipients; wherein said hair growth composition may comprise the ingredients selected from other peptides and botulinum toxin of type A.

The other peptides in the above composition are selected from; Elastin scalp peptide (Tetrapeptide 32) in the concentration of about 20ppm; Elastin Hair Peptide (Hexapeptide-12) in the concentration of about 20ppm; Botulinum Toxin Type A in the concentration of about 100U/ml; Acetyl Tetrapeptide-3 in appropriate concentration; Octapeptide-11 in appropriate concentration; Octapeptide-20 in appropriate concentration; Palmitoyl pentapeptide -3 in appropriate concentration; Oligopeptide-74 (CG-Grotene) in appropriate concentration.

The Botulinum Toxin Type A in above pharmaceutical and dermatological hair growth composition is in the concentration of about 100U/ml.

The vitamins in above hair growth composition are selected from the group consisting of Vitamin A in an amount of 0.01 – 0.50 mg/L, Vitamin B1 in an amount of 0.01 – 0.50 mg/L, Vitamin B2 in an amount of 0.01 – 0.50 mg/L, Vitamin B3 in an amount of 1.0 - 50 mg/L, Vitamin B5 in an amount of 0.001 – 0.050 mg/L, Vitamin B6 in an amount of 0.01 – 0.10 mg/L, Vitamin B7 in an amount of 0.001 – 0.050 mg/L, Vitamin B12 in an amount of 0.01 – 0.50 mg/L, Vitamin C in an amount of 10 – 80 mg/L, Vitamin E in an amount of 0.001 – 0.050 mg/L, Vitamin K in an amount of 0.001 – 0.050 mg/L and the like; minerals and mineral salts selected from the group consisting of Calcium salt in an amount of 100 - 300 mg/L, Sodium salt in an amount of 5000 – 7000 mg/L, Potassium salt in an amount of 200 – 600 mg/L, Magnesium salt in an amount of 10 - 200 mg/L and the like, nucleic acids selected from the group consisting of Adenosine, Cytosine, Guanine and Thymine in an amount of 1-50 mg/L and essential and non-essential amino acids selected from the group consisting of Taurine, Hydroxyproline, Methionine, Proline, Ornithine, Asparagine, Glutamic acid, Aspartic acid, Cystine, Serine, Glycine, Tyrosine, Phenylalanine, Isoleucine, Tryptophan, Threonine, Leucine, Histidine, Valine, Arginine, Lysine, Alanine and Glutamine in an amount of 2-150 mg/L.

The pharmaceutical and dermatological acceptable excipients include but are not limited to diluents, carriers, buffering agents, colorants and the like in appropriate amount. . Preferably, suitable carriers or diluents include but are not limited to distilled water, physiologic saline, bacteriostatic saline, (saline containing 0.9mg/ml benzyl alcohol).

In one of the preferred embodiments, the hair growth composition of the present invention comprises:

- a) Vascular endothelial growth factor including its biomimetic analogue Sh-Polypeptide-9 in an amount of 5 mg/L;
- b) Basic fibroblast growth factor including its biomimetic analogue Sh-Polypeptide-1 in an amount of 2 mg/L;
- c) Insulin like growth factor including its biomimetic analogue Sh-Oligopeptide-2 in an amount of 2 mg/L;
- d) Copper tripeptide 1 in an amount of 10mg/L;
- e) Keratinocyte growth factor including its biomimetic analogue Sh-Polypeptide-3 in an amount of 1mg/L;
- f) Thymosin β 4 including its biomimetic analogue Sh-Oligopeptide -4 in an amount of 0.01mg/L;
- g) Noggin in an amount of 5-10 mg/L;
- h) Decapeptide-10 (CG-Keramin2) in an amount of 8.5-10.5 mg/L;
- i) Octapeptide-2 (Prohairin- β 4) in an amount of 0.0025 to 0.005 mg/L;
- j) vitamins, minerals, nucleic acids and amino acids in appropriate concentration;
along with pharmaceutically and dermatologically acceptable excipients;
wherein said hair growth composition may comprise the ingredients selected from other peptides and botulinum toxin of type A.

The other peptides in the above composition are selected from; Elastin scalp peptide (Tetrapeptide 32) in the concentration of about 20ppm; Elastin Hair Peptide (Hexapeptide-12) in the concentration of about 20ppm; Acetyl Tetrapeptide-3 in appropriate concentration; Octapeptide-11 in appropriate concentration; Octapeptide-20 in appropriate concentration; Palmitoyl pentapeptide -3 in appropriate concentration; Oligopeptide-74 (CG-Grotene) in appropriate concentration.

The Botulinum Toxin Type A in above pharmaceutical and dermatological hair growth composition is in the concentration of about 100U/ml.

The vitamins in above hair growth composition are selected from the group consisting of Vitamin A in an amount of 0.01 – 0.50 mg/L, Vitamin B1 in an amount of 0.01 – 0.50 mg/L, Vitamin B2 in an amount of 0.01 – 0.50 mg/L, Vitamin B3 in an amount of 1.0 - 50 mg/L, Vitamin B5 in an amount of 0.001 – 0.050 mg/L, Vitamin B6 in an amount of 0.01 – 0.10 mg/L, Vitamin B7 in an amount of 0.001 – 0.050 mg/L, Vitamin B12 in an amount of 0.01 – 0.50 mg/L, Vitamin C in an amount of 10 – 80 mg/L, Vitamin E in an amount of 0.001 – 0.050 mg/L, Vitamin K in an amount of 0.001 – 0.050 mg/L and the like; minerals and mineral salts selected from the group consisting of Calcium salt in an amount of 100 - 300 mg/L, Sodium salt in an amount of 5000 – 7000 mg/L, Potassium salt in an amount of 200 – 600 mg/L, Magnesium salt in an amount of 10 - 200 mg/L and the like, nucleic acids selected from the group consisting of Adenosine, Cytosine, Guanine and Thymine in an amount of 1-50 mg/L and essential and non-essential amino acids selected from the group consisting of Taurine, Hydroxyproline, Methionine, Proline, Ornithine, Asparagine, Glutamic acid, Aspartic acid, Cystine, Serine, Glycine, Tyrosine, Phenylalanine, Isoleucine, Tryptophan, Threonine, Leucine, Histidine, Valine, Arginine, Lysine, Alanine and Glutamine in an amount of 2-150 mg/L.

The pharmaceutically and dermatologically acceptable excipients include but are not limited to diluents, carriers, buffering agents, colorants and the like in appropriate amount. . Preferably, suitable carriers or diluents include but are not limited to distilled water, physiologic saline, bacteriostatic saline, (saline containing 0.9mg/ml benzyl alcohol).

The physical properties and the functions of the components in the composition of present invention are detailed below:

- i. Vascular endothelial growth factor (VEGF), also called as Human Oligopeptide-11

Source: E.coli

Appearance: White milky solution
Purity: 95±1 % (SDS-PAGE)
Amino acid: 165 amino acids
Molecular Weight: 19.2 kDa
pH: 6.5±1.00
Shape: Nanosome
Preservative: Phenoxyethanol 0.2%
Biomimetic Variant: Sh-Polypeptide-9

ii. bFGF (basic fibroblast growth factor) also called Human Oligopeptide-3,

Source: E.coli
Appearance: White Milky Solution
Purity: >95 ±1% (SDS-PAGE)
Amino acid: 155 a.a
Molecular Weight: 17.3 kDa
pH: 6.5± 1.00
Shape: Nanosome
Preservative: Phenoxyethanol 0.2%
Biomimetic variant: Sh-Polypeptide-1

iii. Insulin-like Growth Factor (IGF-1) also called Human oligopeptide-2.

Source: E.coli
Appearance: White Milky Solution
Purity: >95 ±1% (SDS-PAGE)
Amino acid: 70 a.a
Molecular Weight: 7.6 kDa
pH: 6.5± 1.00
Shape: Nanosome
Preservative: Phenoxyethanol 0.2%
Biomimetic variant: Sh-Oligopeptide-2

Recombinant Human IGF-I produced in *E.Coli* is a single, non-glycosylated, polypeptide chain containing 70 amino acids and having a molecular mass of 7655 Dalton. Dermal papilla cells are known to produce IGF1.

iv. Copper tripeptide-1

Source:	Chemical synthesis
Appearance:	Transparent Solution
Purity:	>90% (HPLC)
Amino acid:	3 a.a
Molecular Weight:	404 Da
pH:	6.5±1.00
Preservative:	Phenoxyethanol 0.2%

v. Keratinocyte Growth Factor (KGF) also called Human Oligopeptide 5.

Source:	<i>E.coli</i>
Appearance:	White Milky Solution
Purity:	>95 ±1% (SDS-PAGE)
Amino acid:	163 a.a
Molecular Weight:	18.9 kDa
pH:	6.5± 1.00
Shape:	Nanosome
Preservative:	Phenoxyethanol 0.2%
Biomimetic variant:	Sh-Polypeptide-3

KGF is a member of the family of fibroblast growth factors, it is secreted in large amounts by fibroblast- like stromal cells in epithelial tissues.

vi. Thymosin β4

Source:	<i>E.coli</i>
Appearance:	Milky White Solution
Purity:	95± 1% (SDS-PAGE)
Amino acid:	43 a.a

Molecular Weight: 4.9 kDa
pH: 6.5 ± 1.00
Shape: Nanosome
Preservative: Phenoxyethanol 0.2%
Biomimetic variant: Sh-Oligopeptide-4

vi. Noggin

Source: E.coli
Appearance: Sterile filtered white powder
Purity: Greater than 95% as determined by SDS-PAGE
Amino acid: 206 amino acids
Molecular Weight: 46 kDA

viii. Decapeptide-10

Source: Synthetic
Appearance: white to pale yellow powder
Purity: 95%
Amino acid: 10
Molecular Weight:
pH: 6 to 7.5
Preservative: they are stable at room temperature for 3 months, should be stored dessicated below -18 degree Celsius. Upon reconstitution of the peptide it should be stored at 4 degree Celsius between 2-21 days.

ix. Octapeptide-2

Source: Synthetic
Appearance: white powder
Purity: 95 to 98%
Amino acid: 8
Molecular Weight: 975.14
pH: 6 to 7

x. Tetrapetide 32 (Elastin scalp peptide)

Source: Synthetic

Appearance: white powder

Purity: 95%

pH: 6

xi. Hexapeptide-12 (Elastin Hair Peptide)

Source: Synthetic

Appearance: white powder

Purity: 95%

Amino acid: 6

xii. Acetyl Tetrapetide-3

Source: Synthetic

Appearance: White powder

Purity: 95%

Amino acid: 5

Molecular Weight: 509.6

pH: 7.2

xiii. Octapeptide-11

Source: Synthetic

Appearance: White powder

Purity: 95%

xiv. Octapeptide-20

Source: Synthetic

Appearance: White powder

Purity: 95%

xv. Palmitoyl pentapeptide -3

Source: Synthetic

Appearance: White powder

Purity: 95%

xvi. Oligopeptide-74 (CG-Grotene)

Source: Synthetic

Appearance: White powder

Purity: 95%

Amino acids: 11

In another embodiment, the present hair growth composition may be formulated for intradermal or topical administration. The formulation may be available as vials, prefilled syringes.

In an embodiment, the present invention disclose a medical device in the form of dermaroller, prefilled syringes, vials or hair filler inserts for administering the hair growth composition of the present invention in an effective amount to the subject.

The present hair growth composition as described herein above is an enhanced drug delivery system by incorporating the key ingredients of the composition in a targeted Lecithin-Derived Liposomal encapsulation through metered high concentrations (100 nm~) of liposomes. It is formulated using sonication and Micro-fluidizer technology. Lipoencapsulation/ Liposomal derivatives are Lecithin-Derived Liposomes. High concentrations (100 nm~) of liposomes are formulated using sonication and Microfluidizer technology.

In yet another embodiment, the hair growth composition of the present invention is prepared by a process comprising:

- a) Adding the Growth factors analogous to recombinant human peptides including their biomimetic polypeptide variants in an amount of

0.005mg/L to 500mg/L, Noggin in an amount of 9 to 11mg/L; Decapeptide-10 (CG-Keramin2) in an amount of 8.0 to 10.05mg/L; Octapeptide-2 (Prohairin-β4) in an amount of 0.0025 to 0.005mg/L; Vitamins, minerals, nucleic acids and amino acids in appropriate concentration; along with pharmaceutically and dermatologically acceptable excipients to distilled water at ambient temperature in the disperser set at 750-1000rpm;

- b) Adjusting the pH and filtering the final product followed by filling the vials.

In another embodiment, the ingredients selected from other peptides and botulinum toxin of type A in the above process may be added in step a) of the above process.

The other peptides in the above process are selected from Elastin scalp peptide (Tetrapeptide 32) in the concentration of about 20ppm; Elastin Hair Peptide (Hexapeptide-12) in the concentration of about 20ppm; Acetyl Tetrapeptide-3 in appropriate concentration; Octapeptide-11 in appropriate concentration; Octapeptide-20 in appropriate concentration; Palmitoyl pentapeptide -3 in appropriate concentration; Oligopeptide-74 (CG-Grotene) in appropriate concentration and the like. The Botulinum Toxin Type A in the above process is in the concentration of about 100U/ml.

The pharmaceutical and dermatological hair growth composition of the present invention is used to treat alopecia, treat or to prevent hair loss by stimulating hair follicles and promoting hair growth and improving the bodily appearance of a person.

The composition of the present invention is stable and can be stored at room temperature (below 25°C). The composition of the present invention may also be packaged as prefilled syringes and as a hair filler.

The prefilled syringe containing the composition is a 1mL syringe with a needle of 31 gauge. The barrel of the syringe is marked with graduations, each syringe consisting of 40 such graduations and each graduation corresponding to one unit. One unit is equivalent to 0.025mL of the formulation.

The present invention disclose a hair filler insert embedded in hyaluronic acid enriched with present composition for enhanced delivery at the site of action.

The hair growth composition of the present invention may be administered to a subject in a manner which will result in an effective delivery of the amount or dose of the ingredients to the area where hair growth is desired.

In another embodiment, the present invention discloses a method of treating alopecia, treating or to preventing hair loss by stimulating hair follicles and promoting hair growth and improving the bodily appearance of a person comprising administering the pharmaceutical and dermatological hair growth composition in an effective amount to a person in need.

Accordingly, the method of treating/administration of said pharmaceutical and dermatological hair growth composition to a subject comprises:

- a. cleaning the scalp of the subject with alcohol swab or surgical spirit;
- b. treating the affected area of the scalp with pharmaceutical and dermatological composition of the present invention in an effective stimulatory amount to treat or prevent alopecia.

The hair growth composition of the present invention may be administered intradermally or applied topically.

The composition is administered into the hair loss affected scalp through standard micro-needling techniques such as the nappage technique, through dermaroller application, hair filler inserts or topical application.

In another embodiment, the present invention discloses a device for administering the pharmaceutical and dermatological composition comprising a dermaroller, prefilled syringes, vials or hair filler inserts.

In yet another embodiment, the present invention discloses a kit comprising;

- a) prefilled syringes or vials or a dermaroller comprising the pharmaceutical or dermatological composition or hair filler insert embedded in hyaluronic acid enriched with the present composition; and
- b) instruction manual for application.

In another embodiment, the hair growth composition can be co-administered with one or more hair growth promoting compounds selected from the group consisting of minoxidil, minoxidil analogs, minoxidil derivatives, anti-androgens and 5 alpha-reductase inhibitors. The one or more hair growth promoting compounds mentioned above may be co-administered in the form of oral, liquid or topical administration.

In another embodiment, the hair growth promoting compounds which is selected from the group consisting of minoxidil, minoxidil analogues, minoxidil derivatives, anti-androgens and 5-alpha- reductase inhibitors may be co-prescribed with the pharmaceutical composition.

In an embodiment, the pharmaceutical and dermatological hair growth composition of the present invention may be formulated as intradermal, dermaroller and topical application.

In another embodiment, the present invention relates to a method of treating alopecia and improving the bodily appearance of a person comprising administering to the scalp of subject a hair growth composition comprising plurality of growth factors including their biomimetic analogues, Copper tripeptide 1, Noggin, Decapeptide-10 (CG-Keramin2), Octapeptide-2 (Prohairin- β 4) and nourishing complex of vitamins, minerals, amino acids, nucleic acids together with other peptides and botulinum toxin of type A and one or more pharmaceutically and dermatologically acceptable excipients in an amount effective to treat or to prevent hair loss by stimulating hair follicles and promoting hair growth.

The alopecia that may be treated includes androgenetic alopecia, alopecia areata, female pattern baldness and secondary alopecia.

The method of treating alopecia and improving the bodily appearance of a person includes the step of introducing or applying an effective amount of hair growth composition into a subject once in 2 to 6 weeks, preferably about once in 3 weeks.

The pharmaceutical and dermatological hair growth composition of the present invention increases superficial cutaneous circulation in the subject thereby inhibiting the action of 5- α -reductase enzyme and thereby preventing hair loss by stimulating hair follicles and promoting hair growth.

In an embodiment, the hair growth composition of the present invention may be co-administered with one or more hair growth promoting compounds selected from the group consisting of minoxidil, minoxidil analogs, minoxidil derivatives and anti-androgens.

The hair growth composition of this invention may be used to stimulate hair growth in humans afflicted with androgenetic alopecia. Humans afflicted with this condition are usually male, and the condition results in loss of scalp hair with age,

usually called male pattern baldness. Thus, these molecules may be administered in order to stimulate hair growth, thereby eliminating or reducing the severity of hair loss and/or the speed at which alopecia progresses. Other hair loss afflictions which can be treated include androgenetic alopecia, alopecia areata, female pattern baldness and secondary alopecia, and hair loss secondary to chemotherapy, radiation, post-COVID19 hair loss etc. (secondary alopecia). In the case of secondary alopecia, these may be used in advance of the hair loss insults such as chemotherapy or radiation regimens, to stimulate hair growth prior to the insults, thereby resulting in reduced amount of hair loss resulting therefrom. The pharmaceutical and dermatological composition increases superficial cutaneous circulation in the subject, inhibits action of 5- α -reductase enzyme and thereby prevents hair loss by stimulating hair follicles and promoting hair growth.

The invention can be better understood by the following non-limiting examples. The examples given are mere an illustration of the instant invention and should not be construed as limiting the scope of the present invention in any manner.

Examples:**Example 1**

Preparation of the hair growth composition:

- 1) The solvent i.e. water at a temperature of 25°C is added with the conditioning ingredients of the composition to the disperser;
- 2) The disperser is set at 800 rpm for 30 minutes.
- 3) pH is adjusted and a 500 MESH micron filter system is used to filter the final product.
- 4) This is followed by filling, closing and labeling of the vials.

Example 2:

5mg of Vascular endothelial growth factor, 2mg of Basic fibroblast growth factor, 2mg of Insulin like growth factor, 10mg of Copper tripeptide 1, 1mg of Keratinocyte growth factor and 0.01mg of Thymosin β 4, 10mg of Noggin, 10 mg

of Decapeptide-10 (CG-Keramin2), 5 mg of Octapeptide-2 (Prohairin-β4) additionally with additives, pharmaceutically/ cosmetically acceptable and appropriate dose of vitamins, minerals, amino acids and nucleic acids is added to 1 liter of distilled water. The composition is then biologically sterilized and bottled into vials of 5 milliliter each.

Table 1: Hair growth composition

Growth factors / peptides	Concentration
Vascular endothelial growth factor (Human oligopeptide-11) or its biomimetic analogue Sh-Polypeptide-9	5mg/L
Basic fibroblast growth factor (Human oligopeptide-3) or its biomimetic analogue Sh-Polypeptide-1	2mg/L
Insulin like growth factor (Human oligopeptide-2) or its biomimetic analogue Sh-Oligopeptide-2	2mg/L
Copper tripeptide 1	10mg/L
Keratinocyte growth factor or its biomimetic analogue Sh-Polypeptide-3	1mg/L
Thymosin β4 or its biomimetic analogue Sh-Oligopeptide-4	0.01mg/L
Noggin	10mg/L
Decapeptide 10	10mg/L
Octapeptide 2	0.005 mg/L
Tetrapeptide 32	20 mg/L
Hexapeptide-12	20 mg/L
Acetyl Tetrapeptide-3	50 mg/L

Octapeptide-11	20 mg/L
Octapeptide-20	15 mg/L
Palmitoyl pentapeptide -3	50 mg/L
Oligopeptide-74	20 mg/L
Vitamins	q.s.
Minerals	q.s.
amino acids	q.s.
nucleic acids	q.s.
carriers or diluents	q.s.

Example 3: Assessment to determine improvement in hair loss

A sample size of 50 patients was taken and assessment was done on the following parameters:

Hair pull test

Assessment to determine improvement in hair loss was done before every session with the Hair pull test. Before treatment, the average number of hairs pulled out was 10. After eight sessions, the average number of hairs pulled out was less than 3 (which is a negative pull test) in almost 87% of patients and the pull test remained negative henceforth, suggesting a reduction in hair fall, which is apparent around the eight sessions.

Video-microscopic pictures

Video-microscopic photographs were taken with a pro-scope digital handheld camera, at fixed positions on the central scalp, 15 and 20 cm posterior to the glabella. At each fixed position, images were taken through both $\frac{1}{4}$ and $\frac{1}{2}$ cm windows to calculate hair counts per cm². All video-microscopic images were analyzed for changes in vellus hair count, terminal hair count, and hair shaft diameter.

Hair density

The hair density showed an improvement of around 24.6% with the baseline value being $176.5 \pm 2.3 \text{ cm}^2$ and a drastic improvement post treatment with the final value of $199.7 \pm 2.0 \text{ cm}^2$

Vellus hair counts

Overall improvement was seen in congruence to a decrease in the number of vellus hairs from $38.54 \pm 3.1 \text{ cm}^2$ at baseline to $20.43 \pm 2.5 \text{ cm}^2$ at the final length.

Terminal hair counts

Terminal hair counts for each patient were taken at 15 cm from the glabella. An improvement of 26.5 % was seen with patients showing an increase in length from an average of $65.42 \pm 1.7 \text{ cm}^2$ at the beginning of the treatment to $82.50 \pm 2.9 \text{ cm}^2$ at the end of the treatment.

Hair shaft diameter

The average hair shaft diameter for each patient was taken at 15 cm from the glabella which showed a statistically significant change of 38% with an increase from $30.21 \pm 2.0 \text{ }\mu\text{m}$ to $44.31 \pm 2.6 \text{ }\mu\text{m}$.

Subjective evaluation of clinical photographs was provided by three blinded reviewers. All images were randomized prior to grading, so the reviewers did not know which was before or after. There was a decreased score for 3.6% of the patients, and no change in score for 0% of the patients. A mean global assessment score was provided by the reviewers on a scale of 0 to +10, where 0 represented no growth and 10 indicated full thick hair growth which improved from 5 initially to 8 after 6 months of treatment and 8.5 at the end of 1 year.

Finally, an overall opinion of the patients was assessed. Patients completed a validated questionnaire at the end of study comprising 2 sections. First section had 5 questions related to the efficacy of the treatment which were to be rated on a scale of 0-5, with 0 being strongly disagree and 5 being strongly agree. The 2nd section had 4 options regarding the adverse effects due to the treatment and

patients were asked to tick the appropriate response (multiple ticks were allowed). In section A, 5 questions were asked to assess the efficacy of the treatment and patients were advised to rate it on a scale of 0-5. Higher agreement score was given for the improvement in bald spots (mean = 4.6). Other factors like improvement in appearance (mean=5.3), improvement in growth of hair (mean=4.7), overall effectiveness of the treatment (mean=4.2), and satisfaction with the treatment (mean=4.7) were also higher than its original counterpart.

Safety assessment

Tolerable pain was experienced by 23% of the patients while the injections were administered. There were no deaths or serious drug-related adverse experiences and no drug-related adverse experiences that resulted in discontinuation of the study medication during the study. Diabetics, hypertensives, and hypercholesterolaemic patients included in the study had been monitored, and there was no significant change in the biochemical values due to the injections. The findings of this study suggest that the beneficial clinical effects of this therapy are similar in men and women, across different age groups, and in patients irrespective of the presence of metabolic disorders like diabetes, hypertension, hypercholesterolemia, etc. Moreover, results indicate that therapy was also effective in controlling hair loss in 14 post-hair transplant patients. There was a negative correlation between the duration and stage of hair loss, and the degree of improvement.

Example 4: Comparison between intradermal injection, dermaroller application and topical application of present invention:

S.NO	Criteria	Intradermal Injection	1.5mm Dermaroller Application	Topical Application
1	Video-microscopic assessment	Hair density (cm ²) %	Hair density (cm ²) % improvement- Mean +/- SD	Hair density (cm ²) % improvement- Mean +/- SD

		improvement - Mean +/- SD Baseline: 176.5 ± 2.3 Final: 199.7 ± 2.0 Terminal hair (cm2) % improvement - Mean +/- SD Baseline: 65.42 ± 1.7 Final: 82.50 ± 2.9 Vellus hair (cm2) % REDUCTIO N- Mean +/- SD Baseline:	Baseline: 175.2 ± 1.6 Final: 182.5 ± 2.2 Terminal hair (cm2) % improvement- Mean +/- SD Baseline: 66.23 ± 1.9 Final: 73.44 ± 2.6 Vellus hair (cm2) % REDUCTION- Mean +/- SD Baseline: 37.43 ± 2.8 Final: 28.19 ± 3.2 Shaft diameter(µm) % improvement- Mean +/- SD Baseline: 29.70 ± 3.1 Final: 24.0 ± 1.5	Baseline: 173.1 ± 1.5 Final: 179.5 ± 2.1 Terminal hair(cm2) % improvement- Mean +/- SD Baseline: 65.13 ± 1.9 Final: 68.44 ± 2.6 Vellus hair(cm2) % REDUCTION- Mean +/- SD Baseline: 36.43 ± 2.7 Final: 24.19 ± 3.2 Shaft diameter(µm) % improvement- Mean +/- SD Baseline: 28.70 ± 3.1 Final: 31.0 ± 1.5
--	--	--	--	--

		38.54 ± 3.1 Final: 20.43 ± 2.5 Shaft diameter(μm) % improvement - Mean $\pm$ SD Baseline: 30.21 ± 2.0 Final: 44.31 ± 2.6		
2	Subjective analysis via Global photographic assessment	Mean global assessment score: Baseline=4 6 months=7 1 year=8.8 No. of Patients showing no Improvement = 0 No. of Patients	Mean global assessment score: Baseline=4 6 months=5.5 1 year=6.7 No. of Patients showing no Improvement= 2 No. of Patients showing worsening=0	Mean global assessment score: Baseline=6.5 6 months= 7.2 1 year= 7.2 No. of Patients showing no Improvement= 0 No. of Patients showing worsening=0

		showing worsening=0		
3	Patient self-assessments	Patient self-assessment Score (mean): Improvement in bald spots = 4.6 Improvement in appearance = 5.3 Improvement in growth of hair = 4.7 Overall effectiveness of the treatment = 4.7 Satisfaction with the treatment = 4.7	Patient self-assessment Score (mean): Improvement in bald spots = 2 Improvement in appearance = 2.5 Improvement in growth of hair = 3 Overall effectiveness of the treatment = 3 Satisfaction with the treatment = 3	Patient self-assessment Score (mean): Improvement in bald spots = 2 Improvement in appearance = 2 Improvement in growth of hair = 2.5 Overall effectiveness of the treatment = 2.5 Satisfaction with the treatment = 3
4	Safety assessments	13% patients = Tolerable pain was experienced by most patients while the injections	20% patients = Tolerable pain was experienced by most patients while the injections were administered.	No pain was experienced by the patients while the composition was administered. There were no deaths or serious drug-related adverse experiences The

		were administered.		diabetics, hypertensives, and hypercholesteraemic patients included in the study showed no significant change in the biochemical values due to the injections.
5	Hair pull test	Average no. of hair pulled out: Pre-treatment: = 10 After 8 sessions= 87% negative pull test (Less than 3 hair strands)	Average no. of hair pulled out: Pre-treatment: = 10 After 8 sessions= 81 %negative pull test (Less than 3 hair strands)	Average no. of hair pulled out: Pre-treatment: = 10 After 8 sessions= 78% negative pull test

We Claim;

1. A pharmaceutical and dermatological hair growth composition comprising;
 - a) Growth factors analogous to recombinant human peptides including their biomimetic polypeptide variants in an amount of 0.005mg/L to 500mg/L;
 - b) Noggin in an amount of 9 to 11mg/L;
 - c) Decapeptide-10 (CG-Keramin2) in an amount of 8.0 to 10.05mg/L;
 - d) Octapeptide-2 (Prohairin- β 4) in an amount of 0.0025 to 0.005mg/L;
 - e) Vitamins, minerals, nucleic acids and amino acids in appropriate concentration;along with pharmaceutically and dermatologically acceptable excipients;
wherein said hair growth composition may comprise the ingredients selected from other peptides and botulinum toxin of type A.
2. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, wherein the growth factors are selected from Vascular Endothelial Growth Factor (Human oligopeptide-11) including its biomimetic analogue Sh-Polypeptide-9, Basic Fibroblast Growth Factor (Human oligopeptide-3) including its biomimetic analogue Sh-Polypeptide-1, Insulin-like Growth Factor 1 (Human oligopeptide-2) including its biomimetic analogue Sh-Oligopeptide-2, Copper Tripeptide 1, Keratinocyte Growth Factor including its biomimetic analogue Sh-Polypeptide-3, Thymosin- β 4 including its biomimetic analogue Sh-Oligopeptide-4 and the like .
3. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, wherein the other peptides are selected from Elastin

scalp peptide (Tetrapetide 32) in the concentration of about 20ppm; Elastin Hair Peptide (Hexapeptide-12) in the concentration of about 20ppm; Acetyl Tetrapetide-3 in appropriate concentration; Octapeptide-11 in appropriate concentration; Octapeptide-20 in appropriate concentration; Palmitoyl pentapeptide -3 in appropriate concentration; Oligopeptide-74 (CG-Grotene) in appropriate concentration and the like.

4. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, wherein the Botulinum Toxin Type A is in the concentration of 50-100U/ml.
5. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, wherein the vitamins are selected from the group consisting of Vitamin A in an amount of 0.01 to 0.50 mg/L, Vitamin B1 in an amount of 0.01 to 0.50 mg/L, Vitamin B2 in an amount of 0.01 to 0.50 mg/L, Vitamin B3 in an amount of 1.0 to 50 mg/L, Vitamin B5 in an amount of 0.001 to 0.050 mg/L, Vitamin B6 in an amount of 0.01 to 0.10 mg/L, Vitamin B7 in an amount of 0.001 to 0.050 mg/L, Vitamin B12 in an amount of 0.01 to 0.50 mg/L, Vitamin C in an amount of 10 to 80 mg/L, Vitamin E in an amount of 0.001 to 0.050 mg/L, Vitamin K in an amount of 0.001 to 0.050 mg/L and the like.
6. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, wherein the minerals and mineral salts are selected from Calcium salt in an amount of 100 to 300 mg/L, Sodium salt in an amount of 5000 to 7000 mg/L, Potassium salt in an amount of 200 to 600 mg/L, Magnesium salt in an amount of 10 to 200 mg/L and the like.
7. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, wherein the nucleic acids are selected from the group consisting of Adenosine, Cytosine, Guanine and Thymine in an amount of

1-50 mg/L; the essential and non-essential amino acids selected from the group consisting of Taurine, Hydroxyproline, Methionine, Proline, Ornithine, Asparagine, Glutamic acid, Aspartic acid, Cystine, Serine, Glycine, Tyrosine, Phenylalanine, Isoleucine, Tryptophan, Threonine, Leucine, Histidine, Valine, Arginine, Lysine, Alanine and Glutamine in an amount of 2-150 mg/L.

8. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, wherein the composition may comprise the known growth factors selected from the group consisting of follistatin, Wnt proteins, β catenin proteins, stem cell factor, and platelet derived growth factors in appropriate concentration.
9. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, wherein compounds selected from the group consisting of minoxidil, minoxidil analogues, minoxidil derivatives, anti-androgens and 5-alpha- reductase inhibitors may be co-prescribed with said composition.
10. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, wherein said composition may be formulated as intradermal or topical composition.
11. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, comprising;
 - a) Vascular endothelial growth factor (Human oligopeptide-11) including its biomimetic analogue Sh-Polypeptide-9 in an amount of 0.01mg/L to 100mg/L;
 - b) Basic fibroblast growth factor (Human oligopeptide-3) including its biomimetic analogue Sh-Polypeptide-1 in an amount of 0.01mg/L to 100 mg/L;

- c) Insulin like growth factor (Human oligopeptide-2) including its biomimetic analogue Sh-Oligopeptide-2 in an amount of 0.01mg/L to 100mg/L;
- d) Copper tripeptide 1 in an amount of 0.1mg/L to 500 mg/L;
- e) Keratinocyte growth factor including its biomimetic analogue Sh-Polypeptide-3 in an amount of 0.01mg/L to 100 mg/L;
- f) Thymosin β 4 including its biomimetic analogue Sh-Oligopeptide-4 in an amount of 0.005mg/L to 100 mg/L;
- g) Noggin in an amount of 9 to 11 mg/L;
- h) Decapeptide-10 (CG-Keramin2) in an amount of 8.5 to 10.5 mg/L;
- i) Octapeptide-2 (Prohairin- β 4) in an amount of 0.0025 to 0.005 mg/L;
- j) Vitamins, minerals, nucleic acids and amino acids in appropriate concentration;
along with pharmaceutically and dermatologically acceptable excipients;
wherein said hair growth composition may comprise the ingredients selected from other peptides and botulinum toxin of type A.

12. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, comprising;

- a) Vascular endothelial growth factor (Human oligopeptide-11) including its biomimetic analogue Sh-Polypeptide-9 in an amount of 0.01mg/L to 100mg/L;
- b) Basic fibroblast growth factor (Human oligopeptide-3) including its biomimetic analogue Sh-Polypeptide-1 in an amount of 0.1mg/L to 5mg/L;
- c) Insulin like growth factor (Human oligopeptide-2) including its biomimetic analogue Sh-Oligopeptide-2 in an amount of 0.1mg/L to 5mg/L;

- d) Copper tripeptide 1 in an amount of 1mg/L to 100mg/L;
- e) Keratinocyte growth factor including its biomimetic analogue Sh-Polypeptide-3 in an amount of 0.1mg/L to 10mg/L;
- f) Thymosin β 4 including its biomimetic analogue Sh-Oligopeptide-4 in an amount of 0.001mg/L to 1mg/L;
- g) Noggin in an amount of 5 to 10 mg/L;
- h) Decapeptide-10 (CG-Keramin2) in an amount of 8.5 to 10.5 mg/L;
- i) Octapeptide-2 (Prohairin- β 4) in an amount of 0.0025 to 0.005 mg/L;
- j) vitamins, minerals, nucleic acids and amino acids in appropriate concentration;
along with pharmaceutically and dermatologically acceptable excipients;

wherein said hair growth composition may comprise the ingredients selected from other peptides and botulinum toxin of type A.

13. The pharmaceutical and dermatological hair growth composition as claimed in claim 1, comprising;

- a) Vascular endothelial growth factor including its biomimetic analogue Sh-Polypeptide-9 in an amount of 5 mg/L;
- b) Basic fibroblast growth factor including its biomimetic analogue Sh-Polypeptide-1 in an amount of 2 mg/L;
- c) Insulin like growth factor including its biomimetic analogue Sh-Oligopeptide-2 in an amount of 2 mg/L;
- d) Copper tripeptide 1 in an amount of 10mg/L;
- e) Keratinocyte growth factor including its biomimetic analogue Sh-Polypeptide-3 in an amount of 1mg/L;
- f) Thymosin β 4 including its biomimetic analogue Sh-Oligopeptide-4 in an amount of 0.01mg/L;
- g) Noggin in an amount of 10 mg/L;

h) Decapeptide-10 (CG-Keramin2) in an amount of 10 mg/L;
i) Octapeptide-2 (Prohairin-β4) in an amount of 0.005 mg/L;
j) vitamins, minerals, nucleic acids and amino acids in appropriate concentration;
along with pharmaceutically and dermatologically acceptable excipients;
wherein said hair growth composition may comprise the ingredients selected from other peptides and botulinum toxin of type A.

14. The pharmaceutical and dermatological hair growth composition as claimed in any one of the claims 11 to 13, wherein the other peptides are selected from Elastin scalp peptide (Tetrapeptide 32) in the concentration of about 20ppm; Elastin Hair Peptide (Hexapeptide-12) in the concentration of about 20ppm; Acetyl Tetrapeptide-3 in appropriate concentration; Octapeptide-11 in appropriate concentration; Octapeptide-20 in appropriate concentration; Palmitoyl pentapeptide -3 in appropriate concentration; Oligopeptide-74 (CG-Grotene) in appropriate concentration and the like.
15. The pharmaceutical and dermatological hair growth composition as claimed in any one of the claims 11 to 13, wherein the Botulinum Toxin Type A is in the concentration of 50-100U/ml.
16. The pharmaceutical and dermatological hair growth composition as claimed in any one of the claims 11 to 13, wherein the vitamins are selected from the group consisting of Vitamin A in an amount of 0.01 to 0.50 mg/L, Vitamin B1 in an amount of 0.01 to 0.50 mg/L, Vitamin B2 in an amount of 0.01 to 0.50 mg/L, Vitamin B3 in an amount of 1.0 to 50 mg/L, Vitamin B5 in an amount of 0.001 to 0.050 mg/L, Vitamin B6 in an amount of 0.01 to 0.10 mg/L, Vitamin B7 in an amount of 0.001 to 0.050

mg/L, Vitamin B12 in an amount of 0.01 to 0.50 mg/L, Vitamin C in an amount of 10 to 80 mg/L, Vitamin E in an amount of 0.001 to 0.050 mg/L, Vitamin K in an amount of 0.001 to 0.050 mg/L and the like.

17. The pharmaceutical and dermatological hair growth composition as claimed in any one of the claims 11 to 13, wherein the minerals and mineral salts are selected from Calcium salt in an amount of 100 to 300 mg/L, Sodium salt in an amount of 5000 to 7000 mg/L, Potassium salt in an amount of 200 to 600 mg/L, Magnesium salt in an amount of 10 to 200 mg/L and the like.
18. The pharmaceutical and dermatological hair growth composition as claimed in any one of the claims 11 to 13, wherein the nucleic acids are selected from the group consisting of Adenosine, Cytosine, Guanine and Thymine in an amount of 1-50 mg/L; the essential and non-essential amino acids selected from the group consisting of Taurine, Hydroxyproline, Methionine, Proline, Ornithine, Asparagine, Glutamic acid, Aspartic acid, Cystine, Serine, Glycine, Tyrosine, Phenylalanine, Isoleucine, Tryptophan, Threonine, Leucine, Histidine, Valine, Arginine, Lysine, Alanine and Glutamine in an amount of 2-150 mg/L.
19. The pharmaceutical and dermatological hair growth composition as claimed in any one of the claims 11 to 13, wherein the composition may comprise the known growth factors selected from the group consisting of follistatin, Wnt proteins, β catenin proteins, stem cell factor, and platelet derived growth factors in appropriate concentration.
20. A pharmaceutical and dermatological hair growth composition prepared by the process comprising;
 - a) Adding the Growth factors analogous to recombinant human peptides including their biomimetic polypeptide variants in an

amount of 0.005mg/L to 500mg/L, Noggin in an amount of 9 to 11mg/L; Decapeptide-10 (CG-Keramin2) in an amount of 8.0 to 10.05mg/L; Octapeptide-2 (Prohairin-β4) in an amount of 0.0025 to 0.005mg/L; Vitamins, minerals, nucleic acids and amino acids in appropriate concentration; along with pharmaceutically and dermatologically acceptable excipients to distilled water at ambient temperature in the disperser set at 750-1000rpm;

- b) Adjusting the pH and filtering the final product followed by filling the vials.

- 21. The pharmaceutical and dermatological hair growth composition as claimed in claim 20, wherein the ingredients selected from other peptides and botulinum toxin of type A may be added in step a) of the process.
- 22. The pharmaceutical and dermatological hair growth composition as claimed in claim 20, wherein the other peptides are selected from Elastin scalp peptide (Tetrapeptide 32) in the concentration of about 20ppm; Elastin Hair Peptide (Hexapeptide-12) in the concentration of about 20ppm; Acetyl Tetrapeptide-3 in appropriate concentration; Octapeptide-11 in appropriate concentration; Octapeptide-20 in appropriate concentration; Palmitoyl pentapeptide -3 in appropriate concentration; Oligopeptide-74 (CG-Grotene) in appropriate concentration and the like.
- 23. The pharmaceutical and dermatological hair growth composition as claimed in claim 20, wherein the Botulinum Toxin Type A is in the concentration of 50-100U/ml.
- 24. The pharmaceutical and dermatological hair growth composition as claimed in any one of the claims 1 to 23, wherein said composition is used to treat alopecia, treat or to prevent hair loss by stimulating hair follicles

and promoting hair growth and improving the bodily appearance of a person.

25. A method of treating alopecia, treating or for preventing hair loss by stimulating hair follicles and promoting hair growth and improving the bodily appearance of a person comprising administering the pharmaceutical and dermatological hair growth composition as claimed in any one of the claims 1 to 23 in an effective amount to a person in need.
26. The method as claimed in claim 25, wherein said composition may be administered intradermally or applied topically.
27. The method as claimed in claim 25, wherein said composition may be administered through micro-needling techniques such as the nappage technique, through dermaroller, or hair filler inserts.
28. The method as claimed in claim 25, wherein one or more hair growth promoting compounds selected from the group consisting of minoxidil, minoxidil analogs, minoxidil derivatives, anti-androgens and 5-alpha-reductase inhibitors and such like may be co-administered with said hair growth composition.
29. The method as claimed in any one of the claims 25 to 28 comprising;
 - a) cleaning the scalp of the subject with alcohol swab or surgical spirit;
 - b) treating the affected area of the scalp with pharmaceutical and dermatological composition in an effective stimulatory amount.
30. A device for administering the pharmaceutical and dermatological composition comprising a dermaroller, prefilled syringes, vials or hair filler inserts.

31. A kit comprising;

- a) prefilled syringes or vials or a dermaroller comprising the pharmaceutical or dermatological composition as claimed in claim 1 or hair filler insert embedded in hyaluronic acid enriched with composition of claim 1; and
- b) instruction manual for application.