



УДК 615.014.2:615.451.3.322:616.594.12

PHARMACEUTICAL DEVELOPMENT OF A SCALP LOTION BASED ON CAPSICUM

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Abstract. Excessive hair loss (alopecia) is a common aesthetic and medical defect in both men and women. It can be caused by various etiological factors: stress, hormonal abnormalities, improper nutrition or hair care. One of the well-known components in various remedies for baldness is capsicum (*Capsicum annuum*), which contains capsaicin as an active ingredient - a stimulator of the capillary bed of the scalp, which additionally strengthens the bulbs of hair follicles and promotes hair growth. An adult healthy person has about 80-150 thousand hairs on their head, which are in the growth phase or in a state of rest or loss. Normally, we lose dozens of hairs every day, while the volume of our hairstyle does not change. An increase in the number of hairs that fall out can lead to bald spots, which indicates alopecia. According to statistics, more than 60% of the population at different periods of life are faced with this pathology. The features of the skin barrier require careful selection of the composition of the prescription components and often the inclusion of special enhancers (penetrants) in their formula, which temporarily modify the properties of the stratum corneum to ensure effective penetration of active substances (Fig. 1).

Excessive hair loss (alopecia) is a very common problem, both aesthetic and medical, which often occurs in both men and women. It can manifest itself due to various etiological factors: - nervous (emotional) stress; - hormonal abnormalities; - inadequate nutrition; - increased body temperature, which causes excessive sweat and sebum secretion (this creates favorable conditions for the reproduction of bacteria); - negative influence of certain medications; - smoking and excessive alcohol consumption; - imbalance of skin microflora; - genetic disorders or improper hair care are shown in (Fig. 2)

Keywords: Alopecia, capsaicin, hair loss, capsicum, microcirculation, hair follicles, pharmaceutical development, lotion.

Possible ways of penetration of active substances through the layers of the epidermis

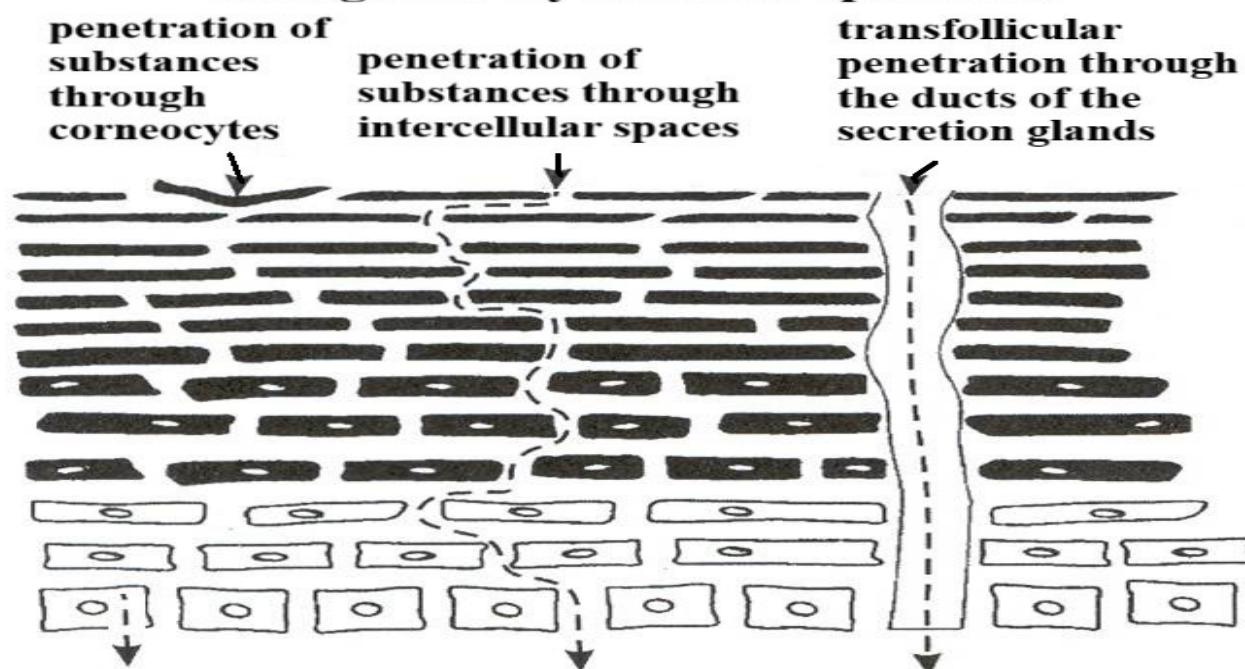


Figure 1. Possible pathways for active substances to penetrate through the layers of the epidermis.

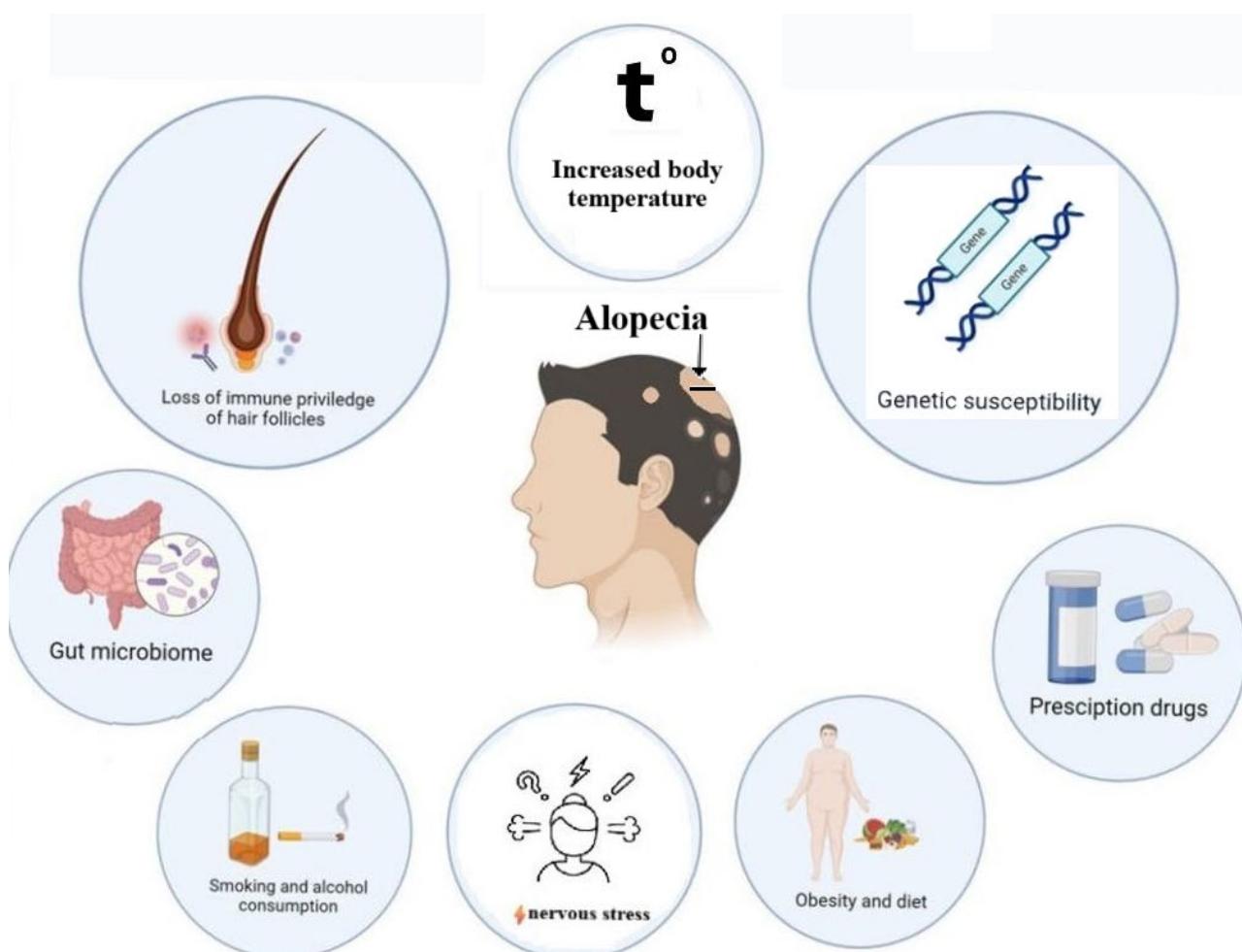


Figure 2 - Factors that may influence the development of alopecia.



Introduction.

Alopecia is a pathological condition that manifests itself in excessive hair loss or complete hair loss. It is not life-threatening, but it negatively affects the psychological state. [3]

According to statistics, about 40% of the world's population suffers from alopecia, and with age its manifestations are observed in 90% of people. In men, the first symptoms appear at the age of 30, in women - after 50 years.[2]

Classification of alopecia 1. Androgenic – the most common form, caused by heredity and hormonal disorders. In men, it is formed according to the male pattern (baldness on the forehead and crown), in women – according to the female pattern (uniform hair loss in the parietal zone). 2. Cicatricial – occurs as a result of injuries, burns, inflammatory processes or autoimmune diseases. The follicles are damaged and hair growth cannot be restored. 3. Focal (nest) – hair loss in limited areas, sometimes with loss of eyebrows and eyelashes; has an autoimmune nature. 4. Seborrheic – associated with seborrheic dermatitis, accompanied by dandruff, itching and inflammation of the scalp. 5. Traumatic – the result of mechanical or chemical damage to the hair, thermal burns, tight hairstyles or mental disorders (trichotillomania). 6. Telogen – the transition of a large part of the follicles into the resting phase under the influence of stress, vitamin deficiency, illness or after childbirth. 7. Anagen – sharp hair loss in the growth phase, usually after chemotherapy; growth is restored after treatment. 8. Involutional – age-related thinning of hair due to the natural transition of follicles into a resting state. [3]

Today, the pharmaceutical and cosmetic industries offer the following remedies for alopecia (Fig. 3).

Today, the current trend is the search for safe and effective means for the prevention and treatment of hair loss. One of the well-known components in various means for baldness is capsicum (*Capsicum ann.*), which contains capsaicin as an active component - a stimulator of the capillary bed of the scalp, which additionally strengthens the bulbs of hair follicles and promotes hair growth (Fig. 4).[4]



Зовнішні засоби проти алопеції (лосьйони, ампули)

Назва препарату / засобу	Виробник	Активна речовина / комплексы	Особливості застосування
Regaine / Rogaine / Alopexy	Johnson & Johnson / Pierre Fabre	Міноксидил 2% або 5%	Єдиний доказаний засіб; наноситься 1–2 рази на день, триває використання.
Kirkland Minoxidil	Kirkland Signature (Costco, США)	Міноксидил 5%	Аналог Regaine, більш доступний; у вигляді розчину та піни.
Dercos Aminexil Clinical 5	Vichy (L'Oréal)	Амінексил + вітамін В, аргінін	Ампули; зміцнює волосся, зменшує фіброз навколо фолікулу.
Kérastase Densifique	Kérastase (L'Oréal)	Stemoxydine	Ампули-лосьйони; «пробуджує» сплячі фолікули.
Neogenic	Vichy (L'Oréal)	Stemoxydine	Аналогічно до Kérastase; курсом 3 місяці.
Triphasic Reactional/Progressiv	René Furterer (Pierre Fabre)	Екстракти рослин, пептиди, вітаміни	Ампули; зміцнення та стимуліація росту.
Phytolium 4	Phyto (Франція)	Рослинні екстракти + пептиди	Ампули-лосьйони, курсова терапія.
Alpecin Liquid	Dr. Wolff (Німеччина)	Кофеїн, ніацинамід, ментол	Лосьйон-«стопік»; стимулює мікроциркуляцію.
Реп'яхова олія з перцем	(різні виробники, аптечні/косметичні)	Рослинні олії + екстракт перцю	Народний та косметичний догляд, допоміжний засіб.

Figure 3 - External remedies for alopecia on the global market. [2]



Figure 4 - Local application of capsicum

In order to improve the method of treating a disease such as alopecia, we have carried out a pharmaceutical development of a liquid product in the form of a lotion, which should be used externally - by applying and then (lightly) rubbing into the scalp in areas of hair loss. Thus, the composition of the lotion includes: [9],[10].

Rp: Capsicum tincture (70%) 5 ml

Caffeine sodium benzoate 0.5

Propylene glycol 10 ml

Glycerine 5 ml



Sol. Nicotinic acid (1%) 1 ml

Aloe oil extract 5 ml

Menthol 0.1

Triclosan 0.3

Ethanole 70% 6.5 ml

Methylcellulose (2%)

Water ~51–55 ml [9]

Justification of the components of the prescription. Selection of active components included in the lotion: As an active substance, a component known in cosmetology and dermatology practice was used - alcoholic tincture of capsicum. The main active element in the composition of capsicum tincture is capsaicin. Which: Activates TRPV1 receptors (transient potential receptors, subtype vanilloid1) of the skin, leading to the release of CHRP (Chromatin Remodeling Protein - a protein associated with the regulation of calcium metabolism), which stimulates the increase in IGD-1 (Insulin-like Growth Factor - insulin-like growth factor-1) in hair follicles, activates the hair growth phase. Improves blood circulation, dilates capillaries, thus enhancing the nutrition of hair follicles. Stimulates blood circulation, activates proliferation processes. A minor drawback of Capsaicin (which can be regulated by the composition of the prescription) is that this substance can cause excessive irritation, burning and dryness on the surface of the skin. Thus, capsaicin requires a combination with substances that reduce its excessive local activity, for example by adding emollients such as: panthenol, menthol, oils, etc. The next active component in the prescription is - Caffeine sodium benzoate, the mechanism of action of which is to block 5-alpha-reductase - an enzyme that converts testosterone into dihydrotestosterone, which causes androgenic alopecia. Improves microcirculation, ensures the supply of oxygen and nutrients to hair follicles. Extends the hair growth phase (anagen), reducing hair loss. And also provides a high level of penetration of all components of the prescription and prolongation of the growth phase at the cellular level, directly affects the hair follicles, activates energy processes.

Inhibits the action of dihydrotestosterone (DHT), prolongs the anagen phase.[7]



The combination of capsaicin and caffeine - causes a synergistic effect, as a result of which the growth of new hair is accelerated. As auxiliary and corrective components of the lotion composition, the following substances are also included: Nicotinic acid (Vit. B3) which dilates capillaries, improves blood supply to follicles, strengthens hair, reduces hair loss, has a vasodilating effect. Niacin in the composition of Vitamin B3 - improves circulation and nutrition, while not having hormonal side effects. In combination with capsaicin, both components stimulate blood circulation, but act through different mechanisms (capsaicin - through a neurogenic irritant effect, and nicotinic acid - through direct vasodilation). Together they provide a prolonged and uniform effect of improving microcirculation.

Menthol is included in the lotion because this substance interacts with ion channels in the nerve endings of the skin, causing a feeling of coolness. This leads to reflex vasodilation (vasodilation) after a short-term spasm, which stimulates local blood circulation. By affecting sensory neurons, menthol reduces the skin's sensitivity to stimuli. It is used as a light local anesthetic, which reduces discomfort after exposure to stimuli. It has a tonic effect. Provides a cooling effect and reduces the excessively irritating effect of capsicum.

Panthenol (Vit B5). Panthenol easily penetrates the stratum corneum of the epidermis and binds to hair keratin. In tissues, it is oxidized to pantothenic acid - an essential coenzyme that participates in cellular metabolism. It has hygroscopic properties, retains moisture inside the hair and scalp (moisturizer). Makes hair more elastic, reduces brittleness, promotes shine. Regenerates the skin, reduces redness, itching and peeling. Used for dermatitis and local skin irritations. As a component of the coenzyme, it participates in the synthesis of fatty acids and acetylation, which is important for the restoration of skin cells and follicles. Has a regenerating and anti-inflammatory effect.

Hyaluronic acid in the lotion – maintains scalp moisture, improves hair follicle condition, reduces irritation and inflammation. Due to its ability to retain moisture and improve skin structure, hyaluronic acid promotes better absorption of other lotion components. Lavender essential oil – strengthens hair follicles, has an antiseptic effect,



promotes hair growth and prevents hair loss. Fights dandruff and dryness on the skin surface, regulates sebum production, locally reduces irritation, stimulates hair nutrition and growth. The following excipients are included in the lotion: castor oil – stimulates hair growth, has antiseptic properties, moisturizer; glycerin – moisturizer, solubilizer, keratolytic; ethanol at a concentration of 10-15% – preservative, enhancer of the action of capsicum and superficial tanning. Sodium carboxymethylcellulose: as a rheological properties co-agent and surface softener. Purified water is the solvent. [7],[9],[10].

Lotion Technology The pharmaceutical development of alopecia lotion involved step-by-step manufacturing. (Table 1)

Table 1 - Step-by-step manufacturing of alopecia lotion. [6],[7].

Raw materials, intermediate products and materials	Manufacturing stages (follow)	Temperature and process control
Purified water + methylcellulose (2%)	Stage 1. Preparation of methylcellulose gel	Room temperature (20-25°C). Swelling time – until complete gelation
Glycerin + propylene glycol	Stage 2. Preparation of water-glycerin solution	20-25°C, control of complete dissolution
Methylcellulose gel + water-glycerol solution	Stage 3. Mixing the base (substances from stages 1 and 2)	Visual control of homogeneity
Dissolution of caffeine-sodium benzoate	Stage 4. Dissolution of caffeine in a water-alcohol mixture with stirring	60-70°C – complete dissolution without sediment.
Dissolution of nicotinic acid (1% solution)	Stage 5. Adding nicotinic acid to the mixture after cooling	35-40°C – to preserve biological activity
Panthenol + hyaluronic acid	Stage 6. Introduction of water-soluble substances. Panthenol + hyaluronic acid + cooled base.	35-40°C - so as not to destroy the structure.
Capsicum tincture (70%)	Stage 7. Introduction of capsicum alcohol tincture	35-40°C, uniformity control
Menthol + lavender essential oil + castor oil	Stage 8. Introduction of fat-soluble substances	35-40°C, control of complete dissolution Control of odor and uniformity
Triclosan	Stage 9. Dissolution in the alcohol part	20-30°C, uniformity control
Preparation of the final solution	Stage 10. Sequentially combine: gel base + caffeine sodium benzoate + nicotinic acid + panthenol, hyaluronic acid + pepper tincture + menthol, lavender essential oil, castor oil + triclosan + alcohol + water to adjust the volume.	Homogenization 15-20 minutes, control pH (5.0-6.0) transparency, odor, alcohol content
Finished product	Stage 11. Packaging, labeling	Storage stability, microbiological purity. Release quality control



At the beginning of the production process: a water-glycerol solution is made, a sodium carboxymethylcellulose gel is made, which after swelling of the gelling agent is mixed together, and to which d-panthenol, nicotinic and hyaluronic acids, caffeine sodium benzoate are added. To this mixture of water-soluble components, with the mixer running at low speed, an alcoholic tincture of capsicum is added, as well as fat-soluble components lavender essential oil, castor oil, menthol. Homogenization is carried out for 15–20 minutes.[9]

Next, the resulting solution is checked for compliance with quality characteristics - quality control: • Organoleptic control - transparency, color, smell. • Physico-chemical indicators - pH (optimally 5.0–6.0), alcohol content, storage stability. • Microbiological purity - compliance with the requirements of the State Sanitary Rules and Norms (DSanPiN) for cosmetic and preventive products. (Table 2)

Table 2 Microbiological safety indicators of products.[8]

Name of the microbiological strain indicator	Unit of measurement	Allowed Norm
The number of mesophilic aerobic and facultative anaerobic microorganisms is not more than	CFU / cm ³	100 no more
Bacteria of the family Enterobacteriaceae	1 cm ³	environment
Bacteria of the family Staphylococcus aureus	1 cm ³	environment
Bacteria of the family Pseudomonas aeruginosa	1 cm ³	environment
The amount of yeast and mold fungi, no more	CFU / cm ³	100 no more

* CFU/cm³ - Colony forming units (of microorganisms) /cm³

The next important stage is filtering, filling, packaging: • The finished lotion is filtered through a membrane filter (0.45 microns) to remove mechanical impurities. • Pour into dark glass bottles with a dropper or dispenser with a volume of 50-100 ml. • Cap and label with storage conditions (“Store in a cool, dark place at a temperature of 15-25 ° C”). Storage conditions and shelf life are necessarily indicated on the packaging with the following indications: • “In tightly closed dark glass bottles”. • “At room temperature”. • “Expiration date – 6 months”.

Conclusion

The paper substantiates the relevance of creating a remedy against hair loss



(alopecia), which is a common problem among men and women. The pharmaceutical development is based on a tincture of capsicum containing capsaicin, a microcirculation activator and hair growth stimulator. To enhance the therapeutic effect and reduce skin irritation, capsaicin is combined with caffeine, nicotinic acid, menthol, panthenol, hyaluronic acid, aloe extract and excipients. A technology for step-by-step production of a lotion with temperature, homogeneity, pH and microbiological purity control is proposed. The complex action of the components contributes to: • strengthening hair follicles; • improving blood supply to the scalp; • stimulating hair growth; • reducing irritation and dryness.

Conclusions. As a result of pharmaceutical development, a trial batch of lotion was produced - for application to the scalp in case of alopecia (partial hair loss). A solution for external, local application to the skin surface - can be considered a promising tool for the prevention and treatment of alopecia. The lotion optimally combines the effectiveness of known active ingredients in cosmetology and dermatology. And the excipients in its composition not only enhance the effect of the active components of the prescription, enhancing the emollient properties and a high level of penetration through the layers of the skin. And in addition - due to the content of methylcellulose, a prolonged effect is provided, and also the convenience of use increases. After all, a solution that is thicker in terms of rheological properties will stay better on the skin surface.[4],[5]

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