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MINISTRY OF HEALTH OF UKRAINE

NATIONAL PHARMACEUTICAL UNIVERSITY

Pharmaceutical faculty

Department pharmaceutical technology of drugs

QUALIFICATION WORK

on the topic "**SCIENTIFIC JUSTIFICATION AND DEVELOPMENT OF THE FORMULATION OF AN EXTEMPORANEOUS CREAM FOR THE TREATMENT OF DERMATITIS IN PATIENTS WITH DIABETES MELLITUS"**

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ANNOTATION

During the study, a comprehensive theoretical search and analysis of scientific literature were carried out concerning the botanical characteristics, chemical composition, and pharmacological properties of oats. Based on the obtained theoretical data, the composition of the cream was substantiated, including the identification of the main active and auxiliary ingredients, and the key technological approaches to its preparation under pharmacy conditions were determined.

The qualification paper is presented on 46 pages of typed text and consists of an introduction, three chapters with conclusions for each chapter, general conclusions, and a list of references. The bibliography includes 39 sources. The work is illustrated with 12 tables and 5 figures.

Key words : oat extract, phytopharmaceuticals, cream, dermatology, diabetes mellitus, plant oils.

ANNOTATION

У процесі виконання роботи здійснено ґрунтовний теоретичний пошук і аналіз наукових літературних джерел, присвячених ботанічним особливостям, хімічному складу та фармакологічним властивостям вівса. На підставі отриманих теоретичних даних обґрунтовано склад крему, визначено основні активні та допоміжні компоненти, а також окреслено ключові технологічні підходи до його виготовлення в умовах аптечного виробництва.

Кваліфікаційна робота викладена на 46 сторінках машинописного тексту та складається зі вступу, трьох розділів із висновками до кожного з них, загальних висновків і списку використаних літературних джерел. Бібліографічний список налічує 39 джерел. Матеріал роботи проілюстровано 12 таблицями та 5 рисунками.

Ключові слова: екстракт вівса, фітопрепарати, крем, дерматологія, цукровий діабет, фітоолії.

CONTENT

Introduction

Relevance of the research problem . Diabetes mellitus is one of the most common chronic non-communicable diseases of our time and is accompanied by the development of numerous complications, among which pathological skin conditions occupy a special place. Disorders of carbohydrate metabolism, microangiopathy, neuropathy and a decrease in the immune response in patients with diabetes mellitus lead to a decrease in the regenerative potential of the skin, its dryness, susceptibility to trauma and the formation of chronic wound defects. Such lesions are often characterized by a long course, susceptibility to infection and a significant decrease in the quality of life of patients.

Modern pharmacotherapy of pathological skin conditions in diabetes requires the use of drugs that combine anti-inflammatory, antimicrobial, regenerative and dermatoprotective effects. However, a significant part of ready-made industrially produced drugs has limitations on the duration of use, possible side effects or insufficient effectiveness in chronic skin lesions. In this regard, the search for alternative approaches to local treatment is relevant, in particular, through the use of extemporaneous dosage forms, which allow individualizing therapy taking into account the patient's condition and the characteristics of the course of the disease.

In this context, phytotherapy attracts special attention as a component of modern evidence-based medicine. Medicinal plants contain a wide range of biologically active compounds that exhibit anti-inflammatory, antioxidant, emollient and reparative properties. Oat extract (Avena sativa) is a promising phytosubstrate for the creation of dermatological medicines due to the presence of flavonoids, saponins, polysaccharides, vitamins and trace elements that contribute to the reduction of inflammation, restoration of the skin barrier function and stimulation of regeneration processes.

In addition, oat extract is characterized by a high safety profile, good tolerability and the possibility of long-term use, which is especially important for patients with diabetes. The use of extemporaneous dosage forms based on phytoraw materials allows to ensure the optimal concentration of active substances, increase

bioavailability and adapt the composition of the drug to the individual needs of the patient.

Thus, the development of the composition and technology of an extemporaneous gel (cream) based on oat extract for the treatment of pathological skin conditions in diabetes mellitus is a scientifically sound and relevant direction of pharmaceutical research that meets the modern requirements of clinical practice and contributes to the expansion of the range of effective and safe topical agents.

Object and subject of the study. The object of the study is the extract of oat (Avena sativa), which is characterized by anti-inflammatory, emollient, antioxidant and reparative activity and is widely used in dermatology and pharmacy. A number of vegetable oils are also used as the object of the study

The subject of the study is the development of the composition and technology of an extemporaneous cream with wound healing and dermatoprotective effects for the treatment of pathological skin conditions in diabetes mellitus.

Purpose and objectives of the study. The purpose of the work is to scientifically substantiate the composition and develop the technology of an extemporaneous topical medicinal product based on oat extract.

To achieve the set goal, the following tasks are planned:

analyze modern literary sources on the topic of research;

to investigate the physicochemical properties of dry oat extract;

to determine the main technological stages and develop extemporaneous technology for a cream with dermatoprotective and wound healing effects.

Research methods. During the experimental studies, visual and organoleptic evaluation methods were used, as well as generally accepted physicochemical and physicotechnological methods regulated by the State Pharmacopoeia of Ukraine and relevant scientific monographs.

Practical significance of the results obtained. Based on the conducted experimental organoleptic and physicochemical studies, the composition of an extemporaneous topical medicinal product was scientifically substantiated, which

can be introduced into the practice of pharmacy manufacturing for the treatment and care of the skin of patients with diabetes mellitus.

Scientific novelty. For the first time, the composition and technology of an extemporaneous medicinal product based on oat extract (Avena sativa) for topical use in pathological skin conditions in patients with diabetes mellitus, taking into account its physicochemical and technological characteristics, have been scientifically substantiated and developed.

Structure and scope of the qualification work. The work consists of the following structural units: introduction, literature review, experimental part, general conclusions, list of used literature sources, appendices. The qualification work is presented on 46 pages of typewritten text and consists of an introduction, three sections with conclusions for each of them, general conclusions and a list of used literature sources. The bibliographic list includes 39 sources. The material of the work is illustrated with 12 tables and 5 figures.

Chapter 1
THE ROLE OF DERMATOLOGICAL PRODUCTS IN THE SYMPTOMATIC TREATMENT OF DIABETES MELLITUS

1.1 Epidemiology of diabetes mellitus

Diabetes mellitus is one of the most common chronic non-communicable diseases and poses a serious threat to public health on a global scale. According to the World Health Organization and the International Diabetes Federation, the number of people with diabetes mellitus in the world is steadily increasing, which allows us to consider this disease as one of the most important medical and social problems of the 21st century. The prevalence of diabetes mellitus is increasing both in developed and developing countries, which is associated with changes in the demographic structure of the population, urbanization and lifestyle transformation.

As of today, there are hundreds of millions of people in the world with diabetes, and the incidence is predicted to continue to increase in the coming decades. Mortality from diabetes is presented in Fig. 1.1 and indicates a constant increase in the dynamics of the disease.

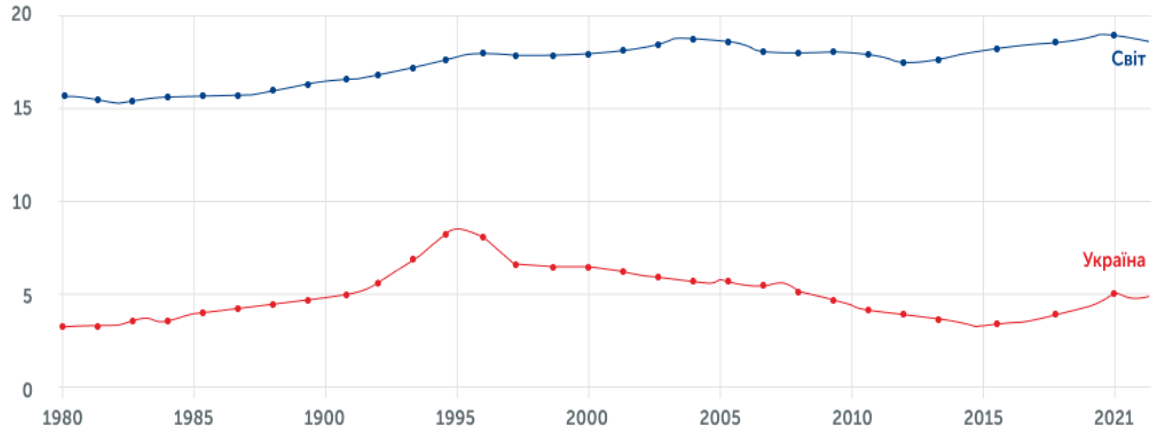

Fig. 1.1. Mortality from diabetes (IHME, Global Burden of Disease (2024)

The vast majority of cases, over 85–90%, are type 2 diabetes, which is directly associated with obesity, metabolic syndrome, and a sedentary lifestyle. Type 1 diabetes is much less common, but has a severe course and requires lifelong insulin therapy.

Age and gender characteristics are important in the epidemiology of diabetes. Type 2 diabetes is more often diagnosed in middle-aged and elderly people, but in recent years there has been a tendency to "rejuvenate" the disease, particularly among adolescents and young adults. This phenomenon is associated with the increase in the prevalence of obesity, eating disorders and a decrease in the level of physical activity among young people. Gender differences are manifested in a slightly higher prevalence of the disease among men of working age, while in older age groups these indicators are leveled.

According to the International Diabetes Federation, the total direct healthcare costs related to the treatment and prevention of diabetes reached a whopping US$966 billion in 2021. Over the past fifteen years, these costs have increased by a significant 316%, clearly demonstrating the global increase in the disease and its financial burden. Interestingly, treatment costs for women were found to be slightly higher than for men, which may be due to biological, social or other factors.

There are significant differences in health care spending between countries, which are represented by three main income groups. In high-income countries, the total cost of diabetes is more than 300 times higher than in low-income countries. When measured on a per capita basis, annual direct costs in high-income countries are 38 times higher than in low-income countries. These figures highlight the magnitude of the gap between developed and developing countries in access to quality health services.

According to the World Health Organization (WHO), the situation in the fight against diabetes continues to cause serious concern. In 2022, it was found that more than half of adults over 30 years of age (59%) with this diagnosis did not receive adequate medical treatment. This problem is especially acute for low- and middle-income countries, where the lack of access to basic health care remains a significant obstacle to effective control of the disease. The result is an increase in future risks, which includes a sharp increase in the cost of treating complications

caused by advanced diabetes. Other tragic consequences include economic losses due to reduced working capacity, disability and premature mortality.

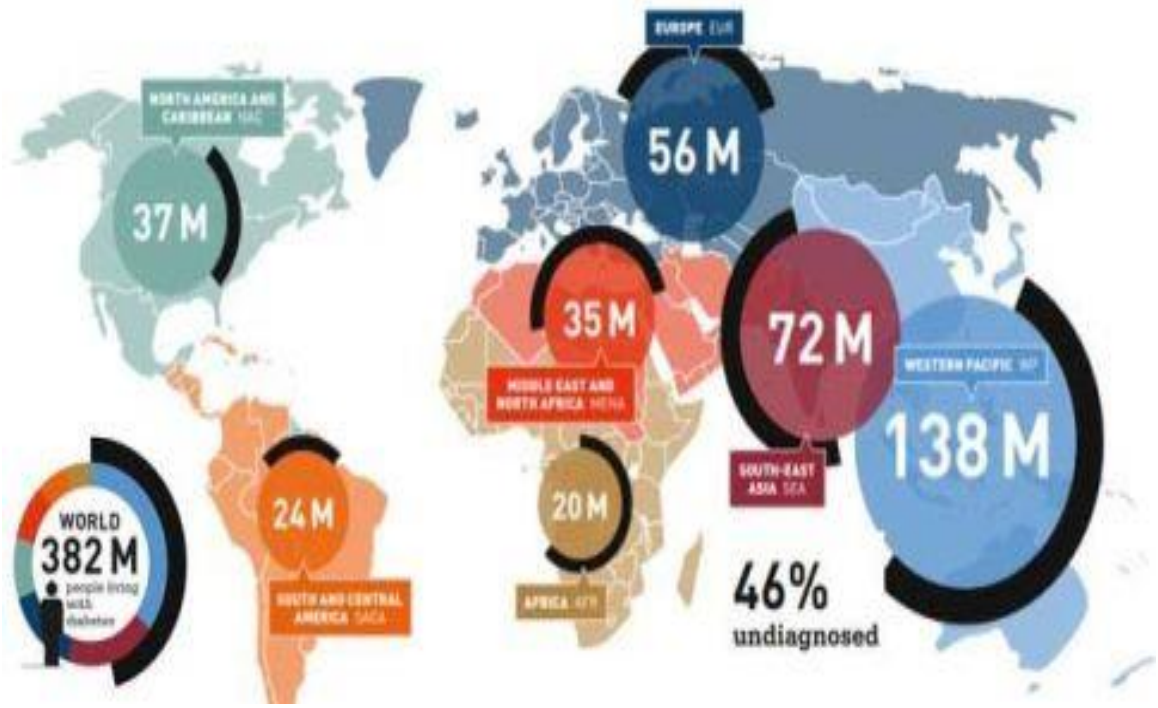

Fig. 1.2. Diabetes mellitus is a global pandemic.

Ukraine is also feeling the economic burden of diabetes. In 2021, direct costs to combat the disease amounted to approximately $1.5 million. This amount is relatively small in a global context, but still a strong indicator of the urgency of addressing the problem for a country with limited healthcare resources.

Regional differences in the incidence of diabetes mellitus are due to socio-economic, cultural and genetic factors. The highest prevalence rates are recorded in the countries of the Middle East, North Africa, Southeast Asia and North America. In European countries, the incidence is somewhat lower, but is steadily increasing. In Ukraine, diabetes mellitus is also a significant problem of the healthcare system, with a significant proportion of cases remaining undiagnosed, which complicates timely treatment and prevention of complications.

Risk factors for diabetes are multifactorial and include hereditary predisposition, excess body weight, obesity, physical inactivity, unhealthy diet with excess of simple carbohydrates and saturated fats, chronic stress, smoking, and comorbidities, including hypertension and dyslipidemia. The combined effect of

these factors significantly increases the risk of developing the disease and its progression.

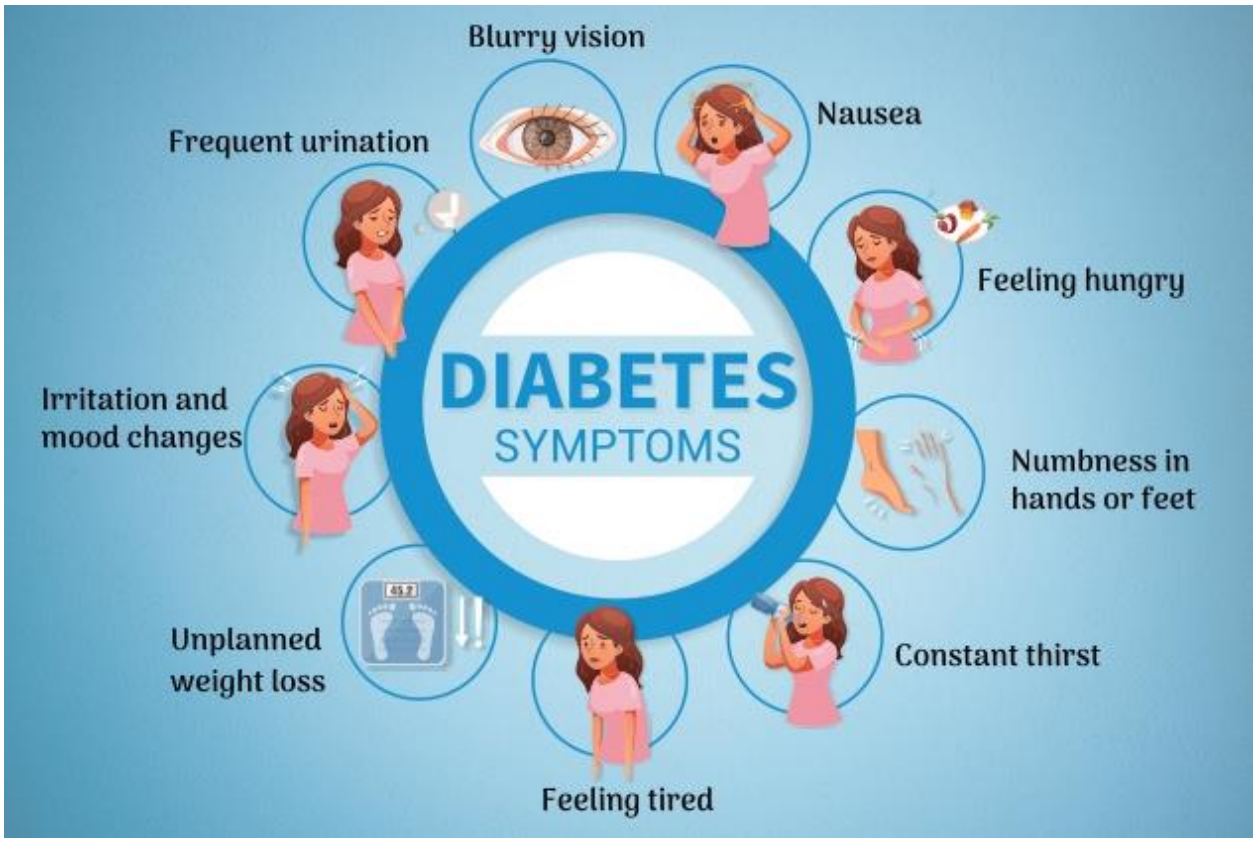

Fig. 1.3 Symptoms of diabetes mellitus

Diabetic retinopathy. Diabetes is one of the leading causes of vision loss among people aged 20 to 74, making it a major medical and social problem. Every year, 12,000 to 24,000 new cases of total blindness are recorded worldwide, caused by diabetic retinopathy, a complication associated with damage to the blood vessels of the retina. However, modern treatments such as laser surgery, combined with continued medical care, can reduce the risk of total vision loss by as much as 90% if the disease is diagnosed and treated early.

Kidney failure

End-stage renal failure is another serious complication of diabetes mellitus. This disease, which requires the use of renal replacement therapy, such as dialysis or kidney transplantation, in most cases becomes a direct consequence of uncontrolled diabetes. About 44% of all new cases of end-stage renal failure are associated with this disease. Such statistics indicate the need for regular monitoring

of kidney function and strict control of blood glucose levels to prevent progression of the pathology.

Neuropathy and vasculopathy

Diabetes mellitus significantly affects the peripheral nervous and vascular systems, which can lead to serious consequences, including lower limb amputations. According to statistics, the probability of non-traumatic amputation in people with diabetes exceeds the corresponding figure in healthy individuals by 15-40 times. This is due to the effect of the disease on small blood vessels and nerves, which leads to impaired blood supply and loss of sensitivity in the extremities. Regular skin care, the right choice of footwear and disease control help minimize such risks.

Cardiovascular diseases

Patients with diabetes mellitus face a significantly higher risk of developing cardiovascular diseases, in particular coronary heart disease. It is known that their probability of developing coronary heart disease increases by 2-4 times compared with individuals without diabetes. In addition, cardiovascular events, such as myocardial infarction and stroke, are the cause of death in approximately two thirds of patients with type 2 diabetes. Interestingly, even a moderate increase in fasting glucose levels (over 5.6 mmol/L) significantly increases the risk of developing these diseases and mortality, regardless of the presence of other favorable factors. This emphasizes the importance of controlling sugar levels and preventing risk factors.

Gestational diabetes

Gestational diabetes is a form of glucose metabolism disorder that first appears during pregnancy and is associated with increased blood sugar levels. Approximately 4% of pregnant women experience this disease, which occurs not due to insulin deficiency, but due to the development of insulin resistance. This condition is caused by excessive production of placental hormones - placental lactogen, estrogens and progesterone, which weaken the effect of other

The socio-economic consequences of diabetes mellitus are extremely significant. The disease is associated with high treatment costs, long-term disability, reduced quality of life of patients and increased mortality. That is why

epidemiological studies of diabetes mellitus are important for the formation of public health policy and the development of effective prevention programs.

1.2. Pathogenesis of diabetes mellitus

The pathogenesis of diabetes mellitus is a complex and multifactorial process that involves impaired insulin secretion, decreased tissue sensitivity to its action, or a combination of both mechanisms. The central pathophysiological feature of the disease is chronic hyperglycemia, which leads to systemic metabolic disorders and the development of complications.

Insulin is a key hormone regulating carbohydrate metabolism and is synthesized by β-cells of the pancreas. Its main function is to ensure the transport of glucose into the cells of insulin-dependent tissues, stimulate the synthesis of glycogen and lipids, and inhibit gluconeogenesis in the liver. Disruption of any of these functions leads to an increase in blood glucose levels.

Type 1 diabetes is an autoimmune disease characterized by progressive destruction of pancreatic β-cells. The pathogenesis is based on immunological dysfunction caused by genetic predisposition, in particular association with certain HLA alleles, and the influence of external factors, among which viral infections are considered the most significant.

As a result of the autoimmune process, the mass of functionally active β-cells gradually decreases, which leads to absolute insulin deficiency. The lack of insulin disrupts the utilization of glucose by cells, stimulates lipolysis and proteolysis, which is accompanied by the accumulation of free fatty acids and ketone bodies. The development of ketonemia and metabolic acidosis can lead to diabetic ketoacidosis - a severe acute complication that poses an immediate threat to the patient's life.

Pathogenesis of type 2 diabetes mellitus

The pathogenesis of type 2 diabetes is much more complex and is characterized by a combination of insulin resistance and relative insulin deficiency. Insulin resistance is a decrease in the biological response of cells to insulin, which leads to impaired glucose transport into muscle and adipose tissue.

Obesity, especially visceral obesity, plays a key role in the formation of insulin resistance. Excess adipose tissue is an active endocrine organ that produces adipokines and pro-inflammatory cytokines that disrupt insulin signaling. Elevated levels of free fatty acids in the blood also contribute to a decrease in tissue sensitivity to insulin and increased gluconeogenesis in the liver.

In the initial stages of the disease, β-cells compensatorily increase insulin secretion, but over time their functional reserves are depleted. Dysfunction of β-cells is accompanied by a decrease in insulin secretion, a violation of the pulsatile nature of its release, and a decrease in the response to glucose load.

An important pathogenetic factor is the dysfunction of the incretin system, in particular, a decrease in the secretion or action of glucagon-like peptide-1. This leads to insufficient inhibition of glucagon secretion and increased glucose production by the liver.

Molecular mechanisms and complications

Chronic hyperglycemia triggers a series of pathobiochemical processes that underlie the development of diabetes complications. These include activation of the polyol pathway of glucose metabolism, formation of advanced glycosylation products, oxidative stress, and endothelial dysfunction. These mechanisms lead to damage to micro- and macrovascular vessels and the development of diabetic retinopathy, nephropathy, neuropathy, and cardiovascular disease.

The epidemiology and pathogenesis of diabetes mellitus demonstrate its extraordinary prevalence and the complexity of its pathophysiological mechanisms. Understanding these processes is a fundamental basis for the development of pharmaceutical sciences, the improvement of pharmacotherapy, and the development of new drugs aimed at reducing the burden of this disease.

Diabetes mellitus — complex , multifaceted and multifaceted a disease whose development is determined by a subtle and multidimensional interaction of genetic, epigenetic, and environmental factors .

At the molecular level , this disease is characterized by a number of key pathological processes, such as impaired insulin signaling, functional dysfunction of

pancreatic β - cells, chronic and inflammatory reactions , manifestation active oxide stress , as well as abnormal changes in the expression of genes that regulate carbohydrate and fat metabolism . Insulin is one of the most important hormones that ensures the normal functioning of the body's metabolism, realizing its biological effects by binding to the insulin receptor . This The receptor belongs to the group of receptors with tyrosine kinase activity and plays a key role in signal transmission within the cell.

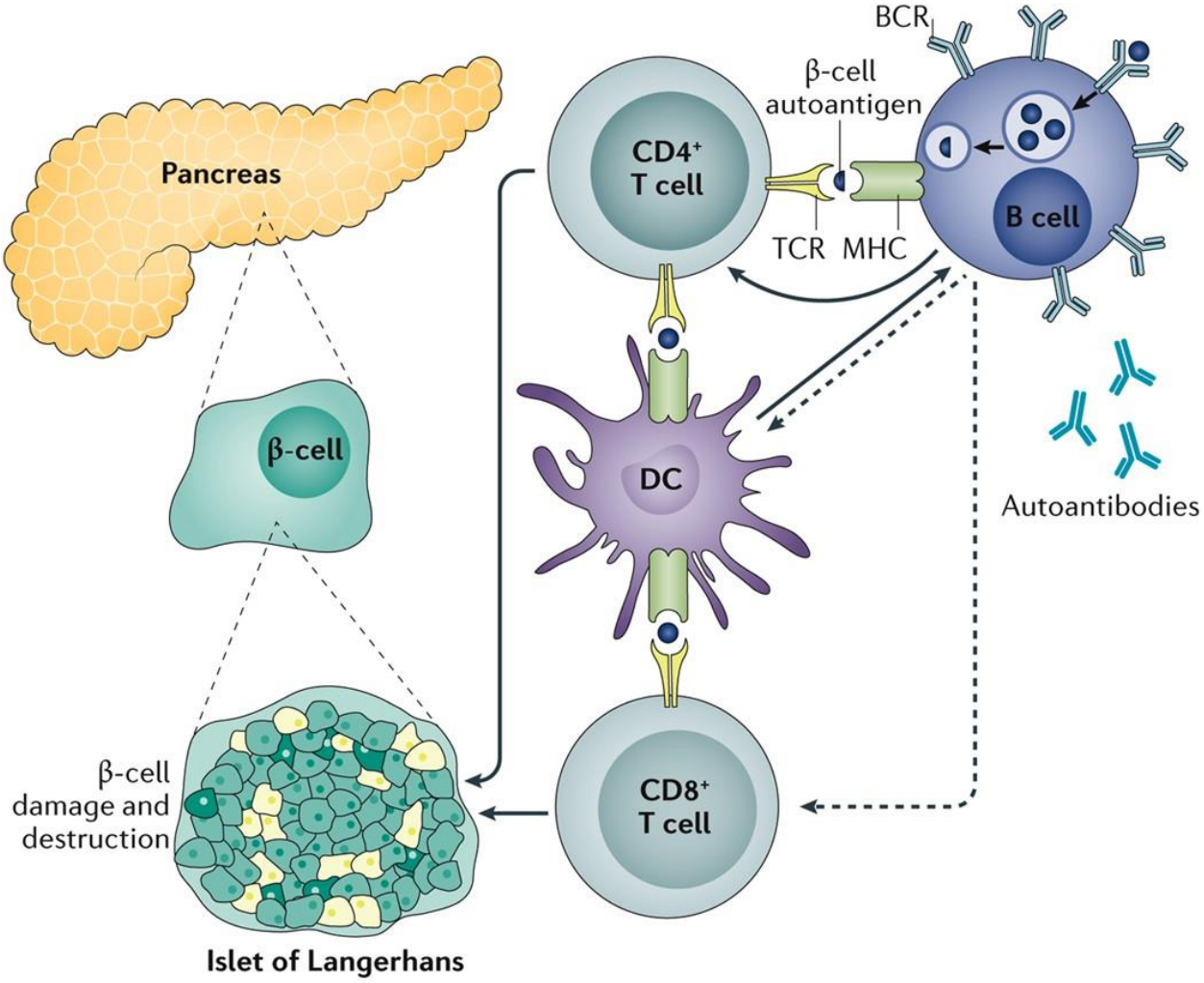

Fig. 1.4. The development of type 1 diabetes mellitus is caused by processes of autoimmune aggression.

Insulin receptor activation is the process of phosphorylation of insulin receptor substrate proteins (IRS -1 and IRS -2), which are important components signal lines PI 3 K / Akt and MAPK . In particular, PI3K / Akt pathway ensures the

transport of glucose into cells through the translocation of the GLUT 4 transporter to the cell membrane , regulates glycogen synthesis and performs the function of inhibiting apoptosis - control cell death process. In the case of type 2 diabetes mellitus , there is a disruption in the phosphorylation of IRS proteins , in the result why the activation of the signal cascade is reduced PI3K / Akt . This negatively affects the ability of muscle and fat cells to absorb glucose . from the blood, activates the process of gluconeogenesis in cells liver and the cause of the eye is the emergence the phenomenon of insulin resistance.

Pancreatic β-cells , which plays the role of the central regulator of glycemic homeostasis in humans organ . Chronically elevated Blood glucose levels (hyperglycemia) and the toxic effects of excess lipids (lipotoxicity) contribute to a decrease in the activity of genes responsible for the synthesis and secretion of the hormone insulin . These genes include the genes for insulin itself , glucokinase , and the transcription factors PDX - 1 and MafA . Deficiency in their activity leads to gradual depletion of β - cells and a significant reduction in the amount of insulin in the body .

Processes are updated activation of β - cell apoptotic mechanisms caused by oxidative stress and inflammation cit ok i n am i . At sugar on the stove type 1 diabetes progress pathology has a uto and munny a characteristic associated with a specific immune response organism. In this process are involved T -lymphocytes and macrophages that actively infiltrate the islets of Langerhans of the pancreas, provoking the death of β - cells and the development of severe insulin deficiency.

From the beginning to the extent The development of insulin resistance is significant chronic low – grade ignition m . IN In this context, the role of adipose tissue at obesity, which actively produces a number of pro - inflammatory cytokines, such as tumor necrosis factor α (TNF-α), interleukin-6 (IL-6) , and monocyte.

Conclusions to Chapter 1

1. Analysis of epidemiological data indicates a rapid increase in the prevalence of diabetes mellitus in the world, which causes its significant medical, social and economic burden. The pathogenesis of diabetes mellitus is multifactorial and includes impaired insulin secretion and action, the development of chronic hyperglycemia, microangiopathy, neuropathy and a decrease in the immune response. The combination of these mechanisms leads to structural and functional changes in the skin, disruption of its barrier function and a decrease in regenerative potential.
2. Skin lesions in diabetes mellitus are a common complication of the disease and are manifested by the development of dryness, xerosis, itching, dermatitis, chronic wounds and trophic ulcers. Chronic hyperglycemia, oxidative stress and the formation of advanced glycation end products create favorable conditions for inflammatory processes, infection and delayed healing of skin lesions.
3. Thus, the close relationship between epidemiology, pathogenetic mechanisms of diabetes mellitus and the development of dermatological diseases justifies the need for a comprehensive approach to treatment, which includes not only the correction of metabolic disorders, but also the use of effective local therapies for the prevention and treatment of skin lesions in patients with diabetes mellitus.

Chapter 2

OBJECTS AND METHODS OF RESEARCH

2.1. Research objects

Oat extract dry (CAS : 117-39-5)

Product name: Oat extract dry

Latin name: *Avena Sativa L.*

Specification ratio: 10:1; 1%-80% (oat glucan);

Appearance: Brown to white powder;

Testing method: UV;

Active ingredients: β-glucan and flavonoids;

Oat extract is extremely complex and consists of a multitude of biochemical components, and for many centuries **oat extract** (*Avena sativa*) has been used to treat and soothe various irritating skin conditions associated with dry sensitive skin, especially atopic dermatitis.

Oat extract powder comes from the stems and leaves of the immature Avena sativa plant and is high in iron, manganese and zinc. The extract is made from rolled oat kernels (*Avena Sativa*). Oat soap has a history of cosmetic use in face masks and as an additive in bath soap to relieve irritation and itching. Appearance: Light- to

medium-yellow liquid. Extract (20%) in water (40%), glycerin (40%), preserved with phenoxyethanol. pH Value: 4.0-6.5. Odor: Characteristic. Water soluble.

Its constituents include polysaccharides such as beta-glucan, flavonoids, silica, triterpenoid saponins (including avenacosides), and phenolic compounds (avenanthramides).

These ingredients are known to have anti-inflammatory, reparative, and moisturizing properties.

Almond oil (lat . Oleum Amygdalarum), also known as Amygdalae oil virginum (PhEur), Almond oil (BP , USP - NF , CAS No. 8007-69-0) , or bitter almond Oil is a fatty substance consisting mainly of glycerides of linoleic and palmitic acids . According to PhEur 2005 , oil is cold weather pressing of ripe seeds of two types of almonds , common and sweet (Amygdalus common L. , var. sweet D . C .) and bitter (*Amygdalus common L.* , var. amara D . C .) or their mixture . If necessary , antioxidants may be added . According to USP 23 , this oil is required by pressing *Prunus seeds amygdala Batsch* from the Rosaceae family . Almond oil has appearance transparent fatty relatives, which can be a bo matte pale yellow shade. Her inherent pleasant oily-nutty taste and the absence of It does n't dry out. on in the wind and remains liquid and transparent even at a temperature of –10 ° C . Physico - chemical properties of almonds oils: temperature samosa and mannya – 320 °C, melting temperature – 18 ° C , density – 0.910–0.915 g/ s m³, ki s lot n e number - no more than 2.0 , iodine numeric – 95-105 , numbering – 190-200.

Good oil miscible with chloroform and ether, and also soluble in anhydrous alcohol . Use of almond oil The oil has a wide range of uses . It is used as a solvent, in particular in pediatrics as a gentle laxative in the form of emulsions , for the preparation of solutions and suspensions for subcutaneous and intramuscular injections, in the production of nasal sprays and preparations for topical application to the skin. The oil can be sterilized at a temperature of 150 °C for an hour.

It is characterized by high stability and does not become bitter over a long period of time. It is recommended to store the oil in a well-closed container, placed in a cool, dry place, protected from sunlight . light and background .

Calendula oil (Oleum Calendulae) is obtained by extraction from the flowers of the medicinal marigold (*Calendula officinalis*), which belongs to the Asteraceae family . This product is oily extract, made from flower baskets and marginal flowers of the plant. From the bottom oil It appears as a golden yellow to greenish liquid. Water time from durable save and save she more and more n a was a is orange vision.

X and powerful oil storage rich in isoprene compounds, such as monoterpenes, sesquiterpenes, diterpenes, triterpenitatetraterpeny. Among the monoterpenes, bicyclic substances predominate , including camphene, borneol, and camphor. The composition also includes triterpene alcohols (monols , diols , triols), which are mostly esterified with lauric , palmitic , myristic and acetic acids .

Monools include α-amyrin, ψ-taraxasterol (heterolupeol), taraxasterol, β-amyrin , and lupeol. In addition to this, Calendula oil contains triterpenoids, carotenoids, flavonoids, essential oil, phenolic acids, sterols and bitter - tasting sequiterpene lactones (in particular Calendula). Chamomile oil has a light yellow color and a light aroma , characteristic for her flowers : herbaceous-sweet with fruity and notes . It is prepared by method of extraction from chamomile flower baskets using fatty vegetable oil.

Chamomile oil contains flavonoids, glycosides, organic acids, vitamins (B1, B2, carotene), bitterness, triterpene alcohols, fatty oil, choline, phytosterols , coumarins, macro- and microelements . The product also contains up to 8% essential blue oil , The main component of it is chamazulene. I'll get some daisies too . from the inflorescences of the plant and found wide open application in pharmacy and cosmetology . The most valuable component of this the product is hamazulene , which manifests power anti - inflammatory, sedative and analgesic properties . Chamazulene – It is a thick blue liquid and makes up about 6% of chamomile essential oil .

Lanol P (palmitic acid ester) is a white flake used as a component in the fat phase during heating. This substance acts as an emollient, thickener and stabilizer for oil-in-water emulsions. It is compatible with a large number of emulsifiers and

is used in soft medicines presented in the store. In creams, Lanol P provides thickening, stability and improvement of tactile characteristics of emulsions.

Key properties of Lanol P:

- Acts as a structure-forming agent.
- Works effectively as a thickener and ensures the stability of emulsions.
- Reduces the aggressive effect of surfactants (surfactants).
- Prevents dry skin.
- Provides a moisturizing effect.
- Has a conditioning effect.
- Optimizes the absorption of emulsions even with a high fat content in the composition.

Lanol P is an absolutely safe component, does not cause an allergic reaction, is easily applied to the skin without leaving greasy marks and does not clog pores. It combines perfectly with other emulsifiers, demonstrating particularly good results of interaction with emulsifiers of the Montanov series. The peculiarity of Lanol P lies in the ability to create formulas with a high level of absorption, which makes it an extremely promising ingredient for cosmetic products.

2.2. Research methods

Determination of organoleptic characteristics – according to the State Pharmacopeia of Ukraine, 2.0.

The appearance and main organoleptic properties of the samples were checked, in particular, color, aroma, texture, and other important characteristics were analyzed. [17].

Definition of homogeneity

The homogeneity of samples created using the proposed technology was assessed according to the method described in SFU 1.1 on page 511. [16].

Determination of colloidal stability

During the experiment, the test tubes were filled with the samples under study to level, which was approximately two - thirds of their total volume. This

corresponded to the mass about 9.0 g of the drug for each test tubes. Special attention was paid to ensuring that the mass of the filled tubes did not exceed allowable breakup within ± 0.02 g from the set value. To achieve this weighing accuracy , an analysis was performed using scales with a sensitivity of up to 0.01 g. After the stage weighing the prepared test tubes were placed in a water bath, where was supported temperature 42.5 °C with an allowable fluctuation of ±2.5 °C, for a period of 20 minutes.

After the end of external heating The surface of the test tubes was thoroughly dried to remove from moisture or condensation, after which they were carefully inserted into the centrifuge slots. The centrifugation process was carried out for five minutes at a speed of which was equal to 6000 revolutions per minute. Estimate stability of the studied samples was by through a detailed visual inspection . Particular attention was paid to the homogeneity of the samples and the absence of any signs of delamination or visible phase separation [26] .

Determination of thermal stability

A test tube containing 8.0±2.0 grams of the test sample was initially placed in a thermostat , where was supported temperature (40±2) °C . IN this is it The sample was in the environment for one week , What allowed us to appreciate its stability to influence at elevated temperature for a long time . In the next stage the test tube was stirred. in cold storage and with temperatures n and m regime (1 0±2) °C, where investigated material in trymuv al i a n analog i chno — seven days period. So change in conditions was small in order to detect potential changes in the sample in an environment with reduced temperature indicators. The final part of the procedure consisted in keeping the tube at room temperature, which varied from 1 to 25 °C. This stage lasted three days and made it possible to provide additional analysis of the state of the sample under normal ambient temperature conditions. The overall stability and quality of the studied material were determined using a visual method, which included careful observation of the absence of delamination or other undesirable changes in the structure of the sample . [26].

pH determination

The pH of the aqueous extract was determined in accordance with the requirements of the State Pharmacopoeia of Ukraine (SFU) 1.2, section 2.2.3, page 46. [16].

CHAPTER 3

RESEARCH ON THE DEVELOPMENT OF THE COMPOSITION AND TECHNOLOGY OF EXTEMPORAL CREAM

3.1 Research into the physical and technological properties of oat extract.

Oat extract (*Avena sativa*) is a promising plant substance for use in extemporaneous topical dosage forms. Its physical and technological properties determine the possibility of inclusion in gels and creams, the stability of the drug, and its consumer characteristics.

Table 3.1

Physical and technological indicators

Indicator	Characteristic
Appearance	Finely dispersed powder of light brown or yellowish-cream color
Scent	Weak, specific, herbal
Degree of dispersion	Finely dispersed
Hygroscopicity	Moderate
Swelling ability	Pronounced, due to the presence of β-glucans
Colloidal properties	Forms colloidal systems in the aquatic environment
Thermal stability	Stable in the process temperature range
pH of aqueous solution	5.5–7.0

Oat extract is characterized by a high level of compatibility with most excipients used in the manufacture of extemporaneous gels and creams. It combines well with hydrophilic gelling agents such as carbomer, sodium alginate, hydroxyethyl cellulose, ensuring the formation of stable drug systems.

Oat extract is compatible with humectants and plasticizers (glycerin, propylene glycol, sorbitol), which help increase skin hydration and improve the organoleptic properties of the dosage form.

Table 3.2

Results of determination of solubility of oat extract

Solvent	Solubility	Nature of the solution
Purified water	Well soluble	Colloidal or true solution
Water-alcohol mixtures (30–70%)	Well soluble	Transparent or slightly opalescent
Ethyl alcohol 96%	Limitedly soluble	Partial dissolution
Glycerin	Moderately soluble	Viscous solution
Vegetable oils	Practically insoluble	—

The combination of oat extract with preservatives in recommended concentrations does not change its physicochemical characteristics. At the same time, the use of strong oxidants and aggressive surfactants is inappropriate, as it may cause degradation of biologically active components.

3.2. The rationale for choosing the main and auxiliary components of the ointment is based on its functional purpose.

Skin and Diabetes mellitus is a significant component of the overall quantity diseases that affect millions of people in the world . Dermatology as a medical discipline focuses on the study of over 400 types of skin diseases and their manifestations , constituting a significant part (15–30 %) of outpatient medical care. The field of dermatology offers a wide range of diagnostic, therapeutic and aesthetic methods. Skin diseases have been known to mankind since ancient times, partly due to related to their visible sym p tom a we, i ki contribute early recognition . Historical references to various nosologies are still encountered from the period big civilizations on which modern Western medicine was built . In particular , Egyptian

papyri provide first of all hygiene activities , skin treatments and the use of medicinal plants .

Natural ingredients, such as vinegar. It was used for skin care , today are becoming increasingly popular in modern formulations. Under term " natural " property on components created by nature or extracted from natural resources resources (of plant or animal origin) without chemical processing. Sources of such ingredients include herbs, fruits, flowers , leaves, minerals, water and soil. The effectiveness of natural components in dermatological products depends on both their activities in laboratory conditions (in vitro) and in practice (in vivo), as well as from the basic composition of the product into which they are integrated .

Plants for medicinal purposes may be ancient history, but what I reached for it and it is my own. the roots of the beginning of human civilization. I am waiting, what will be on the market in the coming years active will appear now products, which will contain natural oils and extracts. Before the era of synthetic substances with similar properties , plants were the basis for the creation of medicinal products. killed. Even today's natural communities and growth origin cause significant scientific interest.

However, the use of such extracts requires careful approach to selection extraction technologies, proportions of raw materials and solvent, as well as determination of the amount of active components. The popularity of products based on plant extracts and oils in dermatology has a demand both from the medical side and from the specialists, as well as among consumers, who increasingly prefer environmentally friendly products . However , it is worth remembering that even natural products are complex mixtures. numerous chemical compounds and can potentially cause adverse reactions.

To minimize such risks and safety safe for users , scientists focus on in detail in chemical component analysis plant raw materials. Before using in products, their cytotoxic effect should be checked using in vitro testing on various human cell lines. This is the approach to promote me creation safe products, what responsible for the high consumer expectations.

Within the scope of our research It was proposed to introduce into the composition of ointments certain components useful for the treatment of various type dermat and those in. Almond oil in the same day gained popularity thanks to their own properties and often becomes the object of research in the field Dermatology. Its has long been used to treat skin diseases such as dermatitis, psoriasis, and eczema.

It is known that the main component of the oil – oleic acid (omega -9) – acts as a conductor , enhancing penetration of other useful something in other in the skin. Like a dream almonds oil ba ha ta on vitamin E (tocopherol), how powerful is it antioxidant. Thanks to these properties, it improves the barrier skin function , reduce inflammation and stimulates the self - synthesis of ceramides, necessary for hydration and health of the epidermis . Vitamin F in its composition normalizes the work of the sebaceous glands; retinol restores elasticity and promotes creation new epithelial cells; ascorbic acid stimulates the regeneration of the epidermis; fatty acids nourish the skin, soften it and retain moisture in the intercellular spaces. Thanks to Due to its texture and high oleic acid content, almond oil is easily distributed and quickly absorbed, providing the skin with moisture and elasticity.

Almond oil, obtained from the seeds of sweet almonds (*Prunus amygdalus dulcis*) (Fig. 3.1), is widely used in dermatology and pharmacy due to its favorable chemical composition and high safety profile. It is a source of monounsaturated and polyunsaturated fatty acids, in particular oleic and linoleic, and also contains vitamins A, E, group B, phytosterols and antioxidants.

One of the key dermatological properties of almond oil is its pronounced emollient and moisturizing effect. The oil helps restore the skin's lipid barrier, reduces transepidermal moisture loss and increases the elasticity of the epidermis. This justifies its use in cases of dry skin, xerosis, peeling and atopic conditions.

Almond oil is characterized by good penetration into the upper layers of the skin and does not cause a comedogenic effect, which allows it to be used for the care of sensitive and irritated skin. Thanks to its anti-inflammatory and antioxidant properties, it helps reduce erythema, irritation and itching.

Fig. 3.1 Almond oil

In dermatological practice, almond oil is used as an auxiliary component in creams, ointments, emulsions and gels for the treatment of dermatitis, eczema, skin cracks, as well as in skin care products for patients with chronic diseases, in particular diabetes mellitus. It is also used as a base for oil solutions of medicinal substances and as a component of extemporaneous dermatological preparations.

Due to its high stability, good compatibility with other active and excipients, as well as the low risk of allergic reactions, almond oil is a valuable ingredient in modern dermatology and pharmaceutical technology of topical dosage forms.

Fig. 3.2 exhibits the ability to normalize the painful processes and reduce the discharge sebum, effectively narrowing pores and eliminating from burning. Penetrating head and shoulders in the skin of the dermis, it reduces risk of acne formation and with a runs development of comedones and pimples. This product take care too care is by dry skin – soothes it, removes irritated cells, eliminates peeling and redness.

Calendula oil, obtained by maceration of marigold flowers (*Calendula officinalis*) in vegetable oils, is widely used in dermatology due to its pronounced anti-inflammatory, antiseptic and reparative properties. Its therapeutic effect is due to the presence of a complex of biologically active substances, among which

flavonoids, triterpene saponins, carotenoids, essential oils and organic acids play a leading role.

Fig. 3.2 Calendula oil

One of the key pharmacological properties of calendula oil is its anti-inflammatory effect, which is realized by inhibiting the synthesis of inflammatory mediators and reducing vascular permeability. This justifies its use in dermatitis of various etiologies, eczema, allergic skin lesions and irritations.

Calendula oil exhibits pronounced wound healing and reparative properties, stimulating epithelial cell proliferation and accelerating tissue regeneration processes. It helps cleanse the wound surface, reduce the risk of secondary infection, and form a full-fledged epithelial layer, which is especially important in chronic and poorly healing wounds.

The antiseptic and antibacterial activity of calendula oil makes it effective in the prevention and treatment of infectious skin lesions. In addition, due to the presence of carotenoids and antioxidants, it protects skin cells from the effects of free radicals and helps reduce oxidative stress.

In dermatological and pharmaceutical practice, calendula oil is widely used as an active or auxiliary component in ointments, creams, gels, emulsions and extemporaneous dosage forms. It is well tolerated by the skin, has a low risk of

adverse reactions and can be used to care for sensitive and damaged skin, including in pediatric practice.

Thus, calendula oil is an effective and safe topical herbal remedy that occupies an important place in dermatology due to its combination of anti-inflammatory, antiseptic, and regenerative properties.

Chamomile oil, obtained from the flowers of the medicinal chamomile (*Matricaria chamomilla* L.) or Roman chamomile (*Chamaemelum nobile*) (Fig. 3.3), is a valuable herbal remedy widely used in dermatology due to its pronounced anti-inflammatory, antiseptic and soothing properties. Its pharmacological activity is due to the rich content of biologically active compounds, among which azulenes (in particular chamazulene), flavonoids, sesquiterpene lactones and essential components play a key role.

Fig. 3.3 Chamomile oil

The main dermatological property of chamomile oil is its anti-inflammatory effect, which is realized by inhibiting the release of histamine and other inflammatory mediators. This helps reduce erythema, edema, itching and pain, which justifies its use in dermatitis, eczema, allergic reactions and skin irritations.

Chamomile oil has a pronounced soothing and antipruritic effect, making it especially useful for sensitive and irritated skin. It helps normalize the barrier function of the epidermis and reduce transepidermal moisture loss, which has a positive effect on the condition of dry and damaged skin.

Due to its antiseptic and antibacterial properties, chamomile oil is used to prevent secondary infection of skin lesions and as part of complex therapy for superficial wounds, burns and cracks. In addition, the presence of antioxidant components provides protection of skin cells from oxidative stress and promotes regeneration processes.

In dermatological and pharmaceutical practice, chamomile oil is used as an active or auxiliary component in ointments, creams, gels, emulsions and extemporaneous dosage forms. It is well tolerated, but requires careful use in people with hypersensitivity to plants of the Asteraceae family.

Thus, chamomile oil occupies an important place in dermatology as an effective topical herbal remedy that combines anti-inflammatory, antiseptic, soothing, and regenerative properties.

The use of oats (*Avena sativa*) for medicinal purposes has a centuries-old history. The first mentions of the use of oats for skin care are found in ancient sources, where decoctions and infusions of oat grains were used to soften the skin, reduce irritation and treat inflammatory processes. In medieval medicine, oat baths and compresses were used for itching, eczema, dermatitis and poorly healing wounds.

In the 19th and 20th centuries, interest in oats in dermatology increased significantly due to the development of phytotherapy and pharmaceutical technologies. It was found that the biologically active substances of oats have a pronounced anti-inflammatory and soothing effect on the skin. This contributed to the introduction of oat extracts in ointments, creams, powders and baths for the treatment of atopic dermatitis, allergic rashes and irritations.

Modern dermatology widely uses standardized dry oat extracts, which ensures the reproducibility of the composition, stability, and predicted pharmacological effects of medicinal and cosmetic products.

Pharmacological effects of dry oat extract

Dry oat extract is characterized by a rich chemical composition, which determines its diverse dermatological activity. The main biologically active

components are β-glucans, flavonoids, saponins, avenanthramides, phenolic compounds, B vitamins and trace elements.

Anti-inflammatory effect.

Oat extract is able to inhibit the production of pro-inflammatory cytokines and inflammatory mediators, which helps reduce erythema, edema, and itching. Avenanthramides, characteristic of oats, play a key role in reducing the inflammatory response of the skin and suppressing oxidative stress.

Dermatoprotective and emollient effect.

Due to its high polysaccharide content, oat extract forms a protective film on the skin surface, which reduces transepidermal moisture loss and helps restore the barrier function of the epidermis. This is especially important for dry skin, cracks and chronic dermatoses.

Reparative and wound healing effect.

Oat extract stimulates the proliferation of epidermal cells, activates collagen synthesis and accelerates regeneration processes. These properties justify its use for superficial skin lesions, microcracks and wounds, including in patients with diabetes.

Antioxidant effect.

Phenolic compounds and avenanthramides neutralize reactive oxygen species, reducing oxidative damage to skin cells. This helps slow down skin aging processes and reduce the risk of developing chronic inflammation.

Antipruritic and soothing effect.

Oat extract reduces the intensity of itching and skin irritation, making it especially valuable in the treatment of atopic dermatitis, contact dermatitis, and allergic reactions.

At the present stage, dry oat extract is widely used in dermatological medicines and medical and cosmetic products. It is included in creams, gels, emulsions, ointments and extemporaneous preparations for topical use. Due to its

high safety profile, oat extract is approved for use in products for sensitive skin, as well as in pediatric and geriatric practice.

Thus, centuries-old experience in the use of oats, confirmed by modern pharmacological studies, indicates the feasibility of using dry oat extract in dermatology as an effective, safe, and scientifically based topical agent.

Regarding the quantitative composition of each component, the selection was made on the basis of data provided in literary sources (Table 3.3).

Table 3.3

Composition of the oil phase of the ointment being developed

Component	Amount in the ointment	
	%	g / drops
Almond oil	5	2.5
Calendula oil	5	2.5
Chamomile oil	5	2.5
Total mass of oil phase	*15*	*7.5*

To form the emulsion system , you have chosen Lanol emulsifier P , which is characterized by the ability to easily emulsify and contributes creating sustainable emulsion with a high level of fat absorption even after conditionally significant content of the fatty phase.

Present emulsifier is a product exclusively of plant origin, developed in France, the main component of which is palm oil , which ensures its high quality and environmental safety. In order to create an aqueous phase for the emulsion base, it was used thoroughly cleaned water, which served as the basic ingredient in the recipe.

The main task of the researchers was the need to determine the optimal amount of the selected emulsifier to ensure the formation stable and long - lasting emulsion system. For conducting the experiment was prepared and various samples of ointments were studied in detail, which I found out equal concentration emulsifier.

Recommendations were taken into account regarding the minimum recommended concentration, which is 2% of the total mass of the ointment, and a maximum permitted, which can reach up to 10% (Table 3.4).

Thus, a thorough analysis of the effectiveness of each sample was carried out to determine the best conditions for using the emulsifier in further production.

Table 3.4.

Development of ointment samples

Component name	%	Sample No.				
		1	2	3	4	5
Almond oil	5	2.5				
Calendula oil	5	2.5				
Chamomile oil	5	2.5				
Oat extract	10	5.0				
Lanol P	2-10%	1.0 (2%)	2.0 (4%)	3.0 (6%)	4.0 (8%)	5.0 (10%)
Purified water	up to 100	36.5 ml	35.5 ml	34.5 ml	33.5 ml	32.5 ml
Total	*100*	*50.0*	*50.0*	*50.0*	*50.0*	*50.0*

Samples of ointments were created taking into account the physicochemical characteristics their components. The composition of the ointment includes substances with different properties that determine the method of their administration :

- Almond , calendula and chamomile oils were used to prepare a mixture of vegetable fatty oils , which interact well with each other with a fight;

- Oat extract is a water - soluble component , so it was mixed with a certain amount of purified water;

- Emulsifier of the first type in Lanol P according to the literature of J. E. May to be introduced into the oil phase. It was added to a mixture of fatty oils (almond , calendula and chamomile), constantly maintaining the optimum temperature of the

mixture . The best temperature for introduction the temperature of this emulsifier is about 60°C.

Table 3.5.

Organoleptic characteristics of sample No. 1 (Lanol P, 2%)

Indicator	**Time**			
	after preparation	**24 hours**	**48 hours**	**72 hours**
1	**2**	**3**	**4**	**5**
Color	White with a yellowish tint	White with a yellowish tint	White with a yellowish tint	White with a yellowish tint
Scent	specific	specific	specific	specific
Homogeneity	homogeneous	The mass is heterogeneous, with noticeable stratification and the appearance of oil droplets on the surface.	The mass is heterogeneous, with noticeable stratification and the appearance of oil droplets on the surface.	The mass is heterogeneous, with noticeable stratification and the appearance of oil droplets on the surface.
pH	5.8	No determination was made.	No determination was made.	No determination was made.

The ointment samples were evaluated according to the parameters given in Section 2, namely appearance, color, odor, ease of application, acidity (pH), thermal stability, and colloidal stability. The results of the experimental studies are presented in Tables 3. 5–3.9.

The stratification of the ointment sample with the release of oil droplets on the surface indicates insufficient emulsion stability of the system, which is probably

due to an inappropriate emulsifier content or a violation of the balance between the hydrophilic and lipophilic phases.

Table 3.6.

Organoleptic characteristics of sample No. 2 (Lanol P, 4%)

Indicator	**Time**			
	after preparation	**24 hours**	**48 hours**	**72 hours**
1	**2**	**3**	**4**	**5**
Color	White with a yellowish tint	White with a yellowish tint	White with a yellowish tint	White with a yellowish tint
Scent	specific	specific	specific	specific
Homogeneity	Homogeneous	Homogeneous	The mass is heterogeneous, with noticeable stratification and the appearance of oil droplets on the surface.	The mass is heterogeneous, with noticeable stratification and the appearance of oil droplets on the surface.
pH	6.1	6.3	-	-

N=3 .

From the data in the tables, it can be seen that sample 1, 1 day after preparation, delaminates with the release of oil drops on the surface of the ointment mass, therefore, pH determination was not performed on it and it was excluded from further studies.

In samples under numbers 2 and 3 in 48 the hour of the beginning of the rules, clear signs of the expansion process were detected. As a result of this was it was decided not to determine the pH value for of these rare ones. Given their non-

compliance with the stability criteria, these samples were excluded from further analysis, research stage.

Table 3. 7.

Organoleptic characteristics of sample No. 3 (Lanol P, 6%)

Indicator	**Time**			
	after preparation	**24 hours**	**48 hours**	**72 hours**
1	**2**	**3**	**4**	**5**
Color	White with a yellowish tint	White with a yellowish tint	White with a yellowish tint	White with a yellowish tint
Scent	specific	specific	specific	specific
Homogeneity	Homogeneous mass	Homogeneous mass	Layering	Layering
pH	6.6	6.6	-	-

N=3 .

Table 3.8.

Organoleptic characteristics of sample No. 4 (Lanol P, 8%)

Indicator	**Time**			
	after preparation	**24 hours**	**48 hours**	**72 hours**
1	**2**	**3**	**4**	**5**
Color	White with a yellowish tint	White with a yellowish tint	White with a yellowish tint	White with a yellowish tint
Scent	specific	specific	specific	specific
Homogeneity	+	+	+	+
pH	6.3	6.5	6.7	6.3

N=3

Table 3.9.

Organoleptic characteristics of sample No. 5 (Lanol P, 10%)

Indicator	Shelf life			
	after preparation	24 hours	48 hours	72 hours
1	2	3	4	5
Color	White with a yellowish tint	White with a yellowish tint	White with a yellowish tint	White with a yellowish tint
Scent	specific	specific	specific	specific
Homogeneity	+	+	-	-
pH	6.2	6.3	6.3	6.2

N=3

Example of a number 4 demonstrated stability for three day, draft o m which were implemented observation for estimates their properties . Thanks to this, this particular composition was chosen.

3.3. Description of the technological process of preparing the cream

Emulsion ointments belong to soft dosage forms, the basis of which is a system of the type "oil in water" (o/w) or "water in oil" (w/o), stabilized by emulsifiers. The choice of the type of emulsion is determined by the physicochemical properties of the active pharmaceutical ingredients, the purpose of the drug and the desired rheological characteristics of the finished form.

Raw material preparation

At the initial stage, the preparation of active and auxiliary substances is carried out, which includes weighing the components according to the recipe, checking their

quality and compliance with regulatory documentation. Fat-soluble components (oils, emulsifiers of lipophilic nature) are referred to the oil phase, while water-soluble substances and hydrophilic components are referred to the aqueous phase.

Preparation of phases

The oil phase is prepared by melting the fatty components and emulsifier in a water bath at a temperature of 65–75 °C until a homogeneous mass is formed. The aqueous phase is prepared separately by dissolving water-soluble active substances in purified water or an aqueous solution of excipients at a similar temperature.

Emulsification

After reaching the same temperature of both phases, the aqueous phase is slowly introduced into the oil phase or vice versa (depending on the type of emulsion) with constant intensive stirring. The emulsification process is carried out until a stable, homogeneous emulsion system is formed without signs of stratification.

Cooling and administration of thermolabile substances

The resulting emulsion is cooled to a temperature of 35–40 °C, after which thermolabile components, such as extracts of medicinal plants, essential oils, preservatives or flavorings, are introduced. Mixing is continued until the ointment is completely homogenized.

Homogenization

To improve the dispersion and stability of the emulsion ointment, additional homogenization is carried out by mechanical or manual methods until a plastic, homogeneous consistency is obtained.

Quality control and packaging

The finished ointment is subjected to quality control for organoleptic indicators (appearance, color, odor), physicochemical parameters (pH,

homogeneity, stability) and, if necessary, microbiological indicators. After that, the ointment is packaged in appropriate containers and labeled in accordance with current requirements. The flow chart of technology and quality control is shown in the figure. 3. 4.

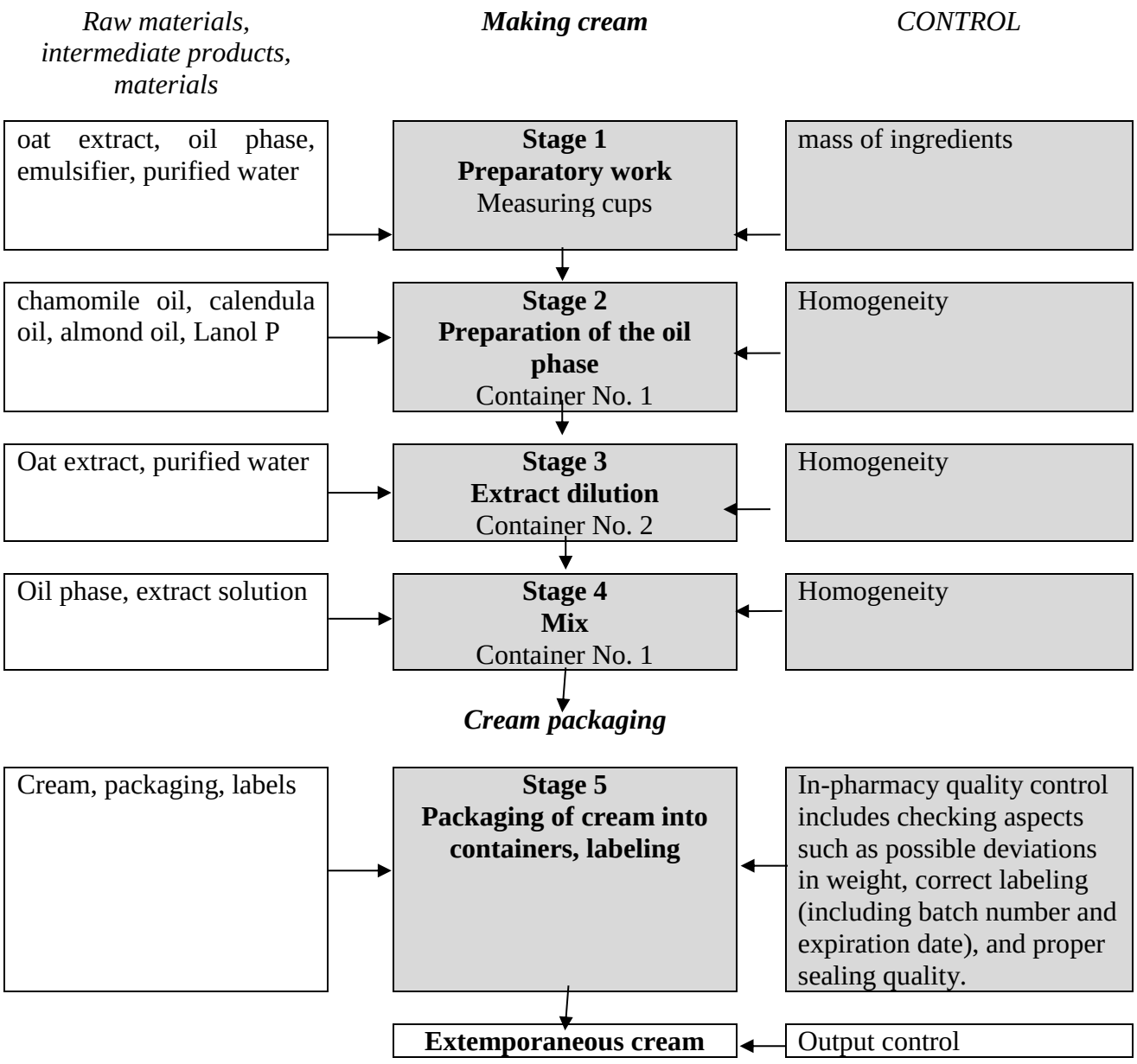

Fig. 3.4. Technological scheme of cream preparation in pharmacy conditions

The finished cream has a uniform texture and a pleasant characteristic aroma. After preparation, it is distributed into glass or plastic containers and hermetically packaged .

Conclusions to Chapter 3

1. Based on theoretical and experimental studies, the optimal composition of an extemporaneous cream containing dry oat extract was determined. This cream was developed taking into account the pharmacological properties of the active component, which has anti-inflammatory, regenerative and antiseptic effects.
2. Theoretical studies have confirmed that oat extract helps accelerate tissue healing processes and reduces inflammation. Due to this, the cream may be effective in treating superficial skin lesions, burns, dermatitis, and other skin diseases in diabetes.
3. The developed composition of the cream ensures comfortable application, uniform distribution on the skin surface and optimal penetration of active substances into the deep layers of the epidermis.
4. Studies have confirmed that the rational composition of the gel, which includes the emulsifier Lanol P at a concentration of 8% ensures optimal product properties. The selected base demonstrates high structural, mechanical and physicochemical characteristics that meet consumer needs.
5. Based on the research conducted, an effective cream preparation technology suitable for use in pharmacies was created.

GENERAL CONCLUSIONS

1. A thorough analysis of modern scientific sources devoted to the study of oat (Avena sativa), its chemical composition, pharmacological properties and possibilities of application in pharmaceutical practice was conducted. Special attention was paid to the use of medicinal products based on plant raw materials as part of the complex therapy of dermatological pathologies in diabetes mellitus, which allowed determining the prospects of the selected phytosubstrate.
2. Based on theoretical and experimental studies, the composition of an extemporaneous cream with oat extract was substantiated.
3. The research that was conducted allowed us to select the rational composition of the cream matrix – emulsifier – Lanol P at a concentration of 8% . It is shown that the selected base has optimal structural, mechanical, and physicochemical properties for the consumer.
4. Based on the research conducted, an effective cream preparation technology suitable for use in pharmacies was created.
5. It was found that the developed cream has properties that ensure its plasticity and ease of application to the affected areas. This structure of the cream contributes to its stability during manufacture and use.

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Ф А 2.2.1–36-366

National University of Pharmacy

Faculty pharmaceutical faculty
Department Pharmaceutical Technology of Drugs

Level of higher education master

Specialty 226 Pharmacy, industrial pharmacy
Educational and professional program Pharmacy

APPROVED
The Head of Department
Pharmaceutical Technology of Drugs
_ Liliia VYSHNEVSKA
"_01_" _September 2025

ASSIGNMENT
FOR QUALIFICATION WORK
OF AN APPLICANT FOR HIGHER EDUCATION

Sekkat AMANE ALLAH

1. Topic of qualification work: «Scientific justification and development of the formulation of an extemporaneous cream for the treatment of dermatitis in patients with diabetes mellitus», supervisor of qualification work: Natalia POLOVKO, Doctor of Pharmaceutical Sciences, Professor,

approved by order of NUPh from "06" of October 2025 № 266

2. Deadline for submission of qualification work by the applicant for higher education: May 2026.

3. Outgoing data for qualification work: development of the composition and technology of an extemporaneous ointment.

4. Contents of the settlement and explanatory note (list of questions that need to be developed): including conducting a thorough analysis of the current practices in pharmaceutical preparation of soft medicinal forms. Additionally, we aim to examine the available variety of modern emulsion ointment bases used for personalized pharmaceutical compounding. The research seeks to substantiate the need for expanding the range of emulsion bases to accommodate the production of customized ointments and to experimentally establish their composition. Another crucial aspect involves designing an optimal technological process for preparing these bases, rooted in extensive physical, chemical, technological, and microbiological investigations.

5. List of graphic material (with exact indication of the required drawings):
9 tables, 10 figures

6. Consultants of chapters of qualification work

Chapters	Name, SURNAME, position of consultant	Signature, date	
		assignment was issued	assignment was received
I Chapter	Natalia POLOVKO, professor of higher education institution of department Pharmaceutical Technology of Drugs	10.10.2025	10.10.2025
II Chapter	Natalia POLOVKO, professor of higher education institution of department Pharmaceutical Technology of Drugs	05.12.2025	05.12.2025
III Chapter	Natalia POLOVKO, professor of higher education institution of department Pharmaceutical Technology of Drugs	14.01.2026	14.01.2026

7. Date of issue of the assignment: «_01_» _September_ 2025

CALENDAR PLAN

№ з/п	Name of stages of qualification work	Deadline for the stages of qualification work	Notes
1.	Analysis of literature data. Treatment of nervous system diseases, analyze of pharmaceutical market of homeopathic drugs and their dosage forms.	October - November 2025	**done**
2.	Researches of active substances and excipients	December 2025	**done**
3.	Justification of the results	January – March 2026	**done**
4.	Registration of qualification work	April 2026	**done**

An applicant of higher education _____ Sekkat AMANE ALLAH

Supervisor of qualification work _____ Natalia POLOVKO

ВИТЯГ З НАКАЗУ
По Національному фармацевтичному університету

«06» жовтня 2025 р. **№ 266**
Фармацевтичний факультет

Затвердити теми кваліфікаційних робіт здобувачам вищої освіти 5 курсу 2025-2026 н. р., група Фм21(4,10д)англ-01, освітньо-професійна програма «Фармація», спеціальність «226 Фармація, промислова фармація», галузь знань «22 Охорона здоров'я», рівень вищої освіти другий (магістерський), денна форма здобуття освіти, термін навчання 4 роки 10 місяців, мова навчання англійська.

Прізвище, ім'я здобувача вищої освіти	Тема кваліфікаційної роботи (українською мовою)	Тема кваліфікаційної роботи (англійською мовою)	Керівник кваліфіка-ційної роботи	Рецензент кваліфіка-ційної роботи
Кафедра аптечної технології ліків				
Секкат Аман Аллах	Наукове обгрунтування та розроблення складу екстемпорального крему, призначеного для лікування дерматитів при цукровому діабеті	Scientific justification and development of the formulation of an extemporaneous cream for the treatment of dermatitis in patients with diabetes mellitus	проф. Половко Н.П.	проф. Хохленкова Н.В.

Підстава: подання декана фармацевтичного факультету доцента Олександра ГОНЧАРОВА

Ректор
Вірно. Секретар

ФА28-03-317

ВИСНОВОК

експертної комісії про проведену експертизу

щодо академічного плагіату у кваліфікаційній роботі

здобувача вищої освіти

«04» травня 2026 р. № 3324567839

Проаналізувавши кваліфікаційну роботу здобувача вищої освіти Секкат Аман Алах групи Фм21(4,10д)анпл, спеціальності 226 Фармація, промислова фармація, освітньої програми «Фармація» очної (денної) форми здобуття освіти на тему: «Наукове обґрунтування та розроблення складу екстемпоральної крему, призначеного для лікування дерматитів при цукровому діабеті / Scientific justification and development of the formulation of an extemporaneous cream for the treatment of dermatitis in patients with diabetes mellitus», експертна комісія дійшла висновку, що робота, представлена до Екзаменаційної комісії для захисту, виконана самостійно і не містить елементів академічного плагіату (компіляції).

Заступник голови Комісії,
заступник директора інституту
в складі ЗВО ННІПФ,
доцент Олена НОВОСЕЛ

Ф А 2.2.1-36-353

REVIEW

of scientific supervisor for the qualification work of the master's level of higher education of the specialty 226 Pharmacy, industrial pharmacy

Sekkat AMANE ALLAH

on the topic: "Scientific justification and development of the formulation of an extemporaneous cream for the treatment of dermatitis in patients with diabetes mellitus"

Relevance of the topic. The relevance of treating dermatological diseases in patients with diabetes mellitus is обусловлена the high prevalence of skin lesions associated with this disease and their significant impact on the course of the underlying pathology and patients' quality of life. According to clinical observations, various dermatological manifestations occur in the majority of patients with diabetes mellitus and are often among the first signs of impaired carbohydrate metabolism.

Chronic hyperglycemia leads to micro- and macroangiopathies, impaired microcirculation, reduced regenerative capacity of the skin, as well as dysfunction of the immune system. As a result, susceptibility to bacterial, fungal, and viral skin infections increases, while xerosis, pruritus, diabetic dermopathy, necrobiosis lipoidica, trophic ulcers, and diabetic foot syndrome may develop. Delayed or inadequate treatment of such lesions significantly increases the risk of infectious complications, chronic progression of the condition, and even amputations.

A comprehensive approach to the treatment of dermatological diseases in patients with diabetes mellitus is of particular importance. Such an approach combines optimal glycemic control, timely dermatological therapy, prevention of infections, and appropriate skin care. Early detection and correction of skin manifestations not only help prevent severe complications but also improve patient adherence to treatment, reduce disability rates, and increase the overall effectiveness of diabetes management.

Therefore, the treatment of dermatological diseases in patients with diabetes mellitus represents an important medical and social issue that requires

interdisciplinary collaboration among specialists and the implementation of modern, evidence-based approaches into clinical practice.

Practical value of conclusions, recommendations and their validity. The approaches proposed by the acquirer to the development of the optimal composition of extemporaneous ointment can be used in the production process of pharmacies in the production of soft dosage forms.

Assessment of work. The work was performed at a sufficient theoretical and practical level of scientific research. The qualification work contains substantiated conclusions and has practical significance.

General conclusion and recommendations on admission to defense. The qualifying work of **Sekkat AMANE ALLAH** was completed at the appropriate scientific level and can be submitted for defense to the Examination Commission of the National University of Pharmacy.

Scientific supervisor _____ Natalia POLOVKO

12 May 2026

Ф А 2.2.1-36-353

REVIEW

of scientific supervisor for the qualification work of the master's level of higher education of the specialty 226 Pharmacy, industrial pharmacy

Sekkat AMANE ALLAH

on the topic: "Scientific justification and development of the formulation of an extemporaneous cream for the treatment of dermatitis in patients with diabetes mellitus"

Relevance of the topic. Natural products are one of the sources of drugs in the pharmaceutical industry, one of the most famous sources of natural products are medicinal plants. Medicinal plants are able to treat some specific diseases and can be a potential source of drugs.

Many important medicines are natural products or are derived from them. Thus, almost 39% of all drugs approved by the Food and Drug Administration (FDA, USA) are of natural origin, and 48.6% of all cancer drugs registered from the 1940s to today are or are natural products or their derivatives. Natural products are important sources in the drug discovery process. There are more than 200,000 natural metabolites that have different bioactive properties, which indicates the importance of products of natural origin for the creation of new medicines based on them.

Theoretical level of work. The work carried out by the acquirer on the analysis of literature data on the researched issue is thorough and systematized.

Author's suggestions on the research topic. Based on the analysis of literature data and the conducted experiment, the author proposed the optimal composition of the dosage form.

Practical value of conclusions, recommendations and their validity. The results of the work can be used in the production process of pharmacies in the production of soft dosage forms.

Disadvantages of work. The work contains unsuccessful expressions, spelling and grammatical errors, incompleteness of conclusions.

General conclusion and assessment of the work. The composition and content of **Sekkat AMANE ALLAH** qualifying work meets the requirements and can be submitted for defense to the Examination Commission of the National Pharmaceutical University .

Reviewer _____ prof. Natalia KHOKHLENKOVA

14 May 2026

Ф А2.2.1-91-230

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ВИТЯГ З ПРОТОКОЛУ № _14_
«_15_» _травня_ 2026 року
м Харків

засідання кафедри
аптечної технології ліків
(назва кафедри)

Голова: завідувачка кафедри, професор Вишневська Л. І.
Секретар: докт. філ., ас. Боднар Л.А.

ПРИСУТНІ:

проф. Половко Н.П., проф. Семченко К.В., проф. Зуйкіна С.С., доц. Ковальова Т.М., доц. Буряк М.В., доц. Олійник С.В., доц. Марченко М.В., ас. Іванюк О.І.

ПОРЯДОК ДЕННИЙ:

1. Про представлення до захисту кваліфікаційних робіт здобувачів вищоїосвіти.

СЛУХАЛИ: проф. Вишневську Л. І. – про представлення до захисту доЕкзаменаційної комісії кваліфікаційних робіт здобувачів вищої освіти.
ВИСТУПИЛИ: Здобувач вищої освіти групи Фм21(4,10д)англ–01 спеціальності 226 «Фармація, промислова фармація» Секкат Аман Алах – з доповіддю на тему «Наукове обґрунтування та розроблення складу екстемпорального крему, призначеного для лікування дерматитів при цукровому діабеті » (науковий керівник, проф. Наталя ПОЛОВКО).

УХВАЛИЛИ: Рекомендувати до захисту кваліфікаційну роботу.

Голова
Завідувачка кафедри, проф. _____ **Лілія ВИШНЕВСЬКА**
(підпис)

Секретар
асистент _____ **Любов БОДНАР**
(підпис)

Ф А2.2.1-36-042

НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ПОДАННЯ
ГОЛОВІ ЕКЗАМЕНАЦІЙНОЇ КОМІСІЇ ЩОДО ЗАХИСТУ
КВАЛІФІКАЦІЙНОЇ РОБОТИ

Направляється здобувач вищої освіти Секкат Аман Алах до захисту кваліфікаційної роботи за галуззю знань 22 Охорона здоров'я
спеціальністю 226 Фармація, промислова фармація
освітньою програмою Фармація
на тему: «Наукове обґрунтування та розроблення складу екстемпорального крему, призначеного для лікування дерматитів при цукровому діабеті».

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____/ Олександр ГОНЧАРОВ /

Висновок керівника кваліфікаційної роботи

Здобувач вищої освіти Секкат Аман Алах представив магістерську роботу, яка за об'ємом теоретичних та практичних досліджень повністю відповідає вимогам до оформлення магістерських робіт.

Керівник кваліфікаційної роботи

_____ Наталя ПОЛОВКО

«12» травня 2026 року

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Секкат Аман Алах допускається до захисту даної кваліфікаційної роботи в Екзаменаційній комісії.

Завідувачка кафедри аптечної технології ліків

_____ Лілія ВИШНЕВСЬКА

«15» травня 2026 р.

Qualification work was defended

of Examination commission on

« 09» of June 2026

with the grade _____

Head of the State Examination commission,

Doctor of Pharmaceutical Sciences, Professor

_____/ Volodymyr YAKOVENKO /