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NATIONAL UNIVERSITY OF PHARMACY
Pharmaceutical faculty
Department pharmaceutical technology of drugs

QUALIFICATION WORK

on the topic: «**DEVELOPMENT OF THE COMPOSITION OF THE EMULSION BASE FOR EXTEMPORANEOUS OINTMENTS**»

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ANNOTATION

As a result of the conducted research, the composition of the extemporaneous base for the preparation of cream was substantiated. The stability and technological properties of the emulsion base were studied. Its technology was proposed.

Organoleptic and physicochemical indicators of model samples were determined according to the methods of the pharmacopoeia. According to the results of the conducted research, the stability of the developed emulsion base was established.

The work is laid out on 48 pages, includes 8 tables, 6 figures, and 37 literature sources.

Key words : skin diseases, symptomatic therapy, technology, composition, extemporaneous basis.

АНОТАЦІЯ

В результаті проведених досліджень обґрунтовано склад екстемпоральної основи для приготування крему. Вивчено стабільність та технологічні властивості емульсійної основи. Запропонована її технологія.

Органолептичні та фізико-хімічні показники модельних зразків визначали згідно з методиками фармакопеї. За результатами проведених досліджень встановлено стабільність розробленої емульсійної основи.

Робота викладена на 48 сторінках тексту, включаючи 8 таблиць, 6 рисунків і 37 літературних джерел.

Ключові слова: захворювання шкіри, симтоматична терапія, технологія, склад, екстемпоральна основа.

CONTENTS

INTRODUCTION

Actuality of theme. The pharmaceutical industry in Ukraine has made significant advancements, now manufacturing over a hundred varieties of soft medicinal forms, most of which are monocomponent products. Despite this expanding assortment of ready-made pharmaceutical products, the importance of preparing medicines based on individual prescriptions remains unwavering. Personalized, or extemporaneous, preparation of soft medicinal formulations provides the flexibility to tailor the selection of active components, therapeutic substances, and auxiliary excipients to meet specific patient needs, taking into account their unique medical conditions, the nature and progression of their illnesses, and other individualized factors.

It is noteworthy that a considerable proportion of extemporaneous ointments are formulated as multi-component combinations. This approach enables the integration of various active ingredients within a single formulation, thereby facilitating more comprehensive pharmacological and therapeutic actions. The efficacy of these soft medicinal forms is known to rely not only on the careful selection of active substances but also on the choice of appropriate excipients, specifically ointment bases that form the foundation of the preparation.

Currently, pharmacies predominantly rely on traditional ointment bases such as Vaseline and a lanolin-Vaseline mixture. However, selecting a suitable base for any specific preparation requires thoughtful consideration of multiple factors, including the desired therapeutic outcome, the region of application on the body, the intended duration of contact with the skin, and several other parameters. This necessity underscores the importance of expanding the range of available ointment bases to enhance their suitability for diverse therapeutic applications and specific formulations.

The purpose. Given this context, addressing the challenge of broadening the assortment of ointment bases for extemporaneous preparations is both pertinent and timely. As such, the primary goal of our research is focused on developing an

innovative composition and technology for creating a new type of emulsion-based ointment applicable to extemporaneous preparation.

To realize this goal, several specific objectives have been outlined, 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.

Through this methodical approach, our work aspires to contribute tangible advancements in both the composition and technological processes underlying emulsion-based ointment preparations. This progress holds strong potential to not only improve customization capabilities within pharmacies but also elevate therapeutic effectiveness tailored directly to patient needs.

Research objects. Biological active substances, glycerin, purified water; model samples of ointment bases.

Subject of study. Pharmaco -technological studies of ointment bases.

Research methods. Organoleptic, physicochemical, pharmacotechnological, statistical

Practical significance of the obtained results. Physico-chemical studies (description, homogeneity, pH) of the ointment for the treatment of dermatological diseases were conducted .

The obtained results of experimental studies can be used in the development of the technology of this medicinal product .

Scientific novelty. For the first time, the main physicochemical parameters of the new ointment for the treatment of dermatological diseases were investigated.

CHAPTER 1

SOFT MEDICINAL FORMS – CHARACTERISTICS, ADVANTAGES, AND ESSENTIAL REQUIREMENTS

1.1. Characteristics of ointments as medicinal form

In contemporary pharmacotherapy, soft medicinal formulations hold a vital role in the management and treatment of various skin diseases. These formulations offer localized and targeted therapeutic effects on pathogens, effectively mitigating inflammation and alleviating or eliminating symptoms associated with dermatological conditions. This method has gained prominence due to its dual impact on addressing localized issues while minimizing systemic complications.

One of the key advantages of soft medicines lies in their significantly lower risk of systemic side effects compared to parenteral or oral medications. As a result, the topical application of such medicines on the skin is extensively employed not only for dermatological treatments but also for systemic therapies. For example, in the case of local antirheumatic therapy, soft medicinal formulations are utilized to reduce gastrointestinal side effects commonly associated with non-steroidal anti-inflammatory drugs (NSAIDs). This makes these formulations an essential component in a wide array of therapeutic strategies.

It is well established that external application of medicinal products offers several pharmacokinetic benefits. By bypassing the gastrointestinal tract and the liver’s first-pass metabolism, these formulations help avoid fluctuating concentrations of active substances in blood plasma, a challenge commonly encountered with oral medicines that are rapidly excreted. This stability ensures a more consistent therapeutic effect and reduces the frequency of potential side effects.

Soft medicinal forms intended for external use often exhibit emollient and protective properties, making them ideal for both local action and transdermal delivery of active ingredients. These formulations typically consist of a base—either

simple or complex—into which one or more active ingredients are dissolved or dispersed. Depending on the composition of the base, the activity, penetration, and efficacy of these medicines can be significantly influenced, thereby enhancing their therapeutic potential.

The ointment base itself may be composed of either natural or synthetic substances and can be formulated as single-phase or multiphase systems, depending on the desired characteristics. Depending on their specific pharmacological action, these bases can exhibit hydrophilic or hydrophobic properties, enabling a tailored delivery mechanism based on the nature of the disease condition being addressed.

The pharmaceutical market in Ukraine currently offers an extensive range of medicinal products, exceeding 10,000 items. Among these are numerous elastic-viscous formulations classified as soft medicinal forms. These include commonly used categories such as ointments, creams, gels, liniments, and pastes. Each formulation type plays a critical role in catering to various therapeutic needs and ensuring optimal patient outcomes by providing effective and efficient treatment options specifically designed for external application and targeted delivery (illustrated in Figure 1.1). This diversity underscores the significance of soft medicines as an integral component of modern healthcare solutions.

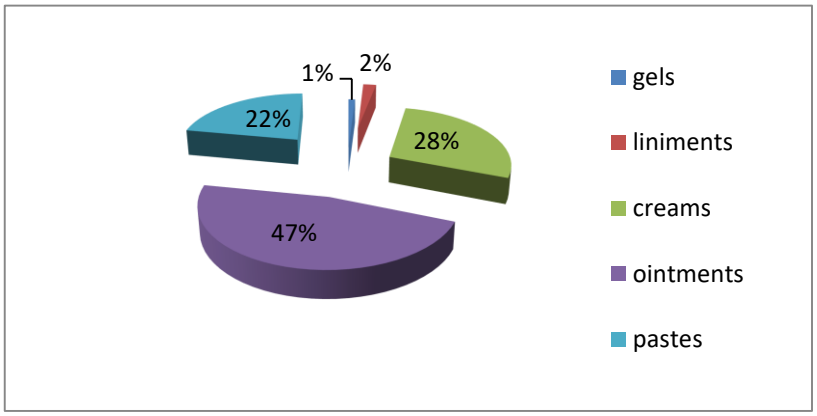

Fig. 1.1. Assortment of soft medicines in the pharmaceutical market of Ukraine

The data presented in Fig. 1.1 highlights the prominent market distribution for soft medicines within Ukraine's pharmaceutical sector. Ointments dominate with a share of 47%, followed by creams at 28%. Pastes hold the third-largest share with 22%, while liniments and gels account for 2% and 1%, respectively.

Currently, the market for soft medicines in Ukraine is supported by 21 companies and 8 pharmaceutical factories. Among these, the "Borschagovsky Chemical and Pharmaceutical Plant" leads with 26 product titles, followed by "Chervona Zirka" Chemical and Pharmaceutical Plant with 22 titles. "Darnitsa" Pharmaceutical Factory produces 18 titles, "Viola" Pharmaceutical Factory offers 13, while Mykolayiv Pharmaceutical Factory and "Quantum-Service" each produce 10 titles.

Soft medicines feature active substances from diverse pharmacological classes. Hormones and their analogs are particularly prevalent in ointments. Corticosteroid-based medicines possess anti-inflammatory, antipruritic, and antiallergic properties, making them highly effective for various treatments. Ointments infused with nonsteroidal anti-inflammatory agents are utilized for their anti-inflammatory and analgesic benefits, often prescribed for managing inflammatory conditions affecting the musculoskeletal system.

Antibiotic-containing ointments demonstrate strong antimicrobial properties and are commonly used to treat septic wounds, burns, pyoderma, and dermatitis. For conditions requiring pain relief in the initial stages of wound healing or for hemorrhoid treatment, combination ointments with anesthetic agents are employed. Furthermore, keratolytic ointments target skin diseases that involve hyperkeratosis.

Soft medicines are broadly categorized into the following formulations:

- Ointments
- Creams
- Gels
- Pastes
- Poultices
- Medical plasters

Key characteristics shared by these formulations include:

1. Their intended external application delivers both local and systemic effects.

2. They exist as one-phase, two-phase, or multiphase systems.

3. They contain various excipients that significantly influence the physical and chemical (rheological) behavior of the dosage forms.

Ointments, specifically, are structured heterogeneous dispersed systems comprising solid and liquid phases designed for external application. As defined by the State Pharmacopoeia of Ukraine (SPU), ointments are soft medicines formulated for local use. Their dispersion medium exhibits non-Newtonian flow properties and demonstrates high rheological parameter values at prescribed storage temperatures.

1.1.1. Scope of Application of Ointments

The external administration of medication in forms such as gels, creams, ointments, liniments, and other similar formulations allows for the direct delivery of active substances to affected areas. This method is especially beneficial for conditions involving compromised skin integrity, such as diaper rash, bedsores, burns, or damaged mucous membranes. The transdermal route is considered among the safest drug delivery methods, as a significant portion of the dosage remains localized on the surface and can be adjusted by partially removing the applied product.

Soft medications can be administered through several approaches:

1. Applying a thin or thick layer consistently on affected areas.

2. Using multiple layers if different formulations are required—such as applying a gel first, followed by an ointment.

3. Treating problem areas before application, including cleaning with surfactants, volatile solvents, hydrogen peroxide, antiseptic solutions, or by removing necrotic tissue.

4. Vigorous rubbing of the ointment into specific areas such as joints, muscles, or other affected regions.

Regardless of the chosen method, applying medication to clean, uncontaminated surfaces enhances its effectiveness and decreases overall treatment time. Soft

medicinal products today play a crucial role across various medical fields, including dermatology, surgery, cardiology, ophthalmology, otolaryngology, proctology, gynecology, neurology, rheumatology, traumatology, oncology, and dentistry.

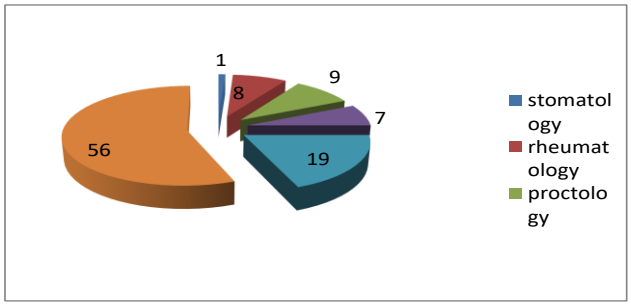

Fig. 1.2. Application area of ointments in medical practice

An extensive range of medicinal substances incorporated into ointments plays a crucial role in determining their effectiveness and suitability for addressing a wide spectrum of diseases and medical conditions, as illustrated in Figure 1.3. This versatility allows ointments to be tailored for specific therapeutic purposes, making them an indispensable component in the treatment of numerous health issues.

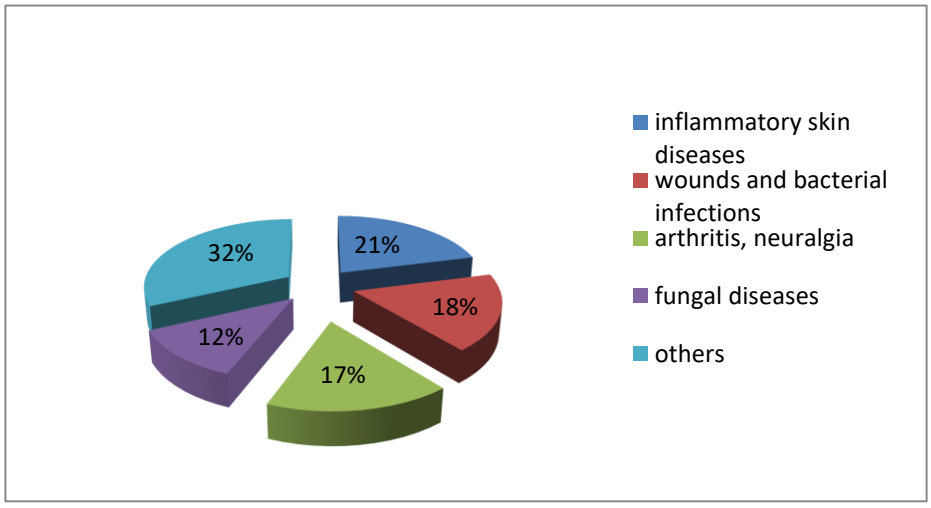

Fig. 1.3. The use of ointments for various skin diseases

As illustrated in Fig. 1.3, ointments are among the most commonly used topical formulations across various medical and non-medical applications. Among these, they find the most frequent use in managing inflammatory skin conditions, accounting for 21% of all applications. Wounds and bacterial infections follow closely, comprising 18%, while the treatment of arthritis, neuralgia, sciatica, and multiple joint diseases of varied origins makes up 17%. Furthermore, 12% of ointment usage is devoted to combating fungal infections affecting the skin and mucous membranes.

Cosmetic ointments, on the other hand, serve numerous purposes related to skin and hair care. These include softening and nourishing the skin, addressing pigmentary changes such as age spots, and general hair treatment. Depending on their intended function, cosmetic ointments are broadly categorized into hygienic, decorative, and medicinal types.

In addition to therapeutic and cosmetic uses, ointments play a critical role as personal protective agents. They are widely employed across diverse industrial settings and even in domestic environments to shield the skin from harmful substances like organic solvents, acids, alkalis, and allergens. These types of ointments are known as protective ointments. Their primary mechanism involves creating an artificial barrier over the skin upon application, effectively isolating it from potential irritants and safeguarding it against various environmental factors.

Another specific category includes electrode ointments and pastes. These formulations are pivotal in enhancing the accuracy of diagnostic procedures like electrocardiography (ECG), encephalography (EEG), and electromyography (EMG). Their main value lies in ensuring adequate contact between electrodes and the skin or mucosal surfaces while simultaneously securing the electrodes in place during the procedure.

Beyond these targeted applications, certain ointments exhibit additional pharmacological properties such as astringent, drying, local irritating, antiparasitic, or other therapeutic actions. Depending on their usage within clinical practice, medicinal ointments are further sub-divided into various specialized groups:

1. Dermatological ointments, also referred to as "proper ointments" (Unguenta dermatologica seu Ung. propria), which are specifically formulated for application on the skin.

2. Surgical ointments that are applied directly to wounds, burns, or other pathological injuries to promote healing.

3. Ophthalmic ointments (Unguenta ophthalmica seu oculenta), designed for application under the eyelid to treat eye-related conditions.

4. Nasal ointments (Unguenta nasalis seu unguenta rinales), intended for application to the nasal cavity's mucous membranes.

5. Rectal ointments (Unguenta rectales), used for conditions requiring treatment via rectal administration.

6. Vaginal ointments (Unguenta vaginales), formulated specifically for treating conditions of the female reproductive tract.

7. Other miscellaneous categories based on specific or unique needs.

The classification system established by SPU further divides ointments based on their composition and physical properties:

Hydrophobic Ointments: These types are typically formulated on a hydrocarbon base like Vaseline or Vaseline oil and may include additional lipophilic excipients such as vegetable oils, animal fats, waxes, or synthetic glycerides. Due to their composition, hydrophobic ointments can accommodate only minimal amounts of water or aqueous solutions. When applied to the skin, they create an occlusive layer that helps retain moisture by preventing air exposure. They also have a softening effect but are challenging to wash off with water and exhibit limited interaction with wound exudates.

Emulsion Ointments: These formulations can incorporate significant water content and exist as either water-in-oil (w/o) or oil-in-water (o/w) emulsions, depending on the type of emulsifier used:

- For w/o emulsions, emulsifiers such as wool wax alcohols, sorbitol esters, monoglycerides, and fatty alcohols are commonly utilized.

- For o/w emulsions, emulsifiers like polysorbates, macrogol esters, macrogol-based fatty acid esters, or fatty alcohols are employed.

This diversity in formulation enables emulsion ointments to accommodate varying levels of moisture while fulfilling a wide range of therapeutic and cosmetic functions corresponding to patient needs. Hydrophilic ointments are pharmaceutical formulations characterized by their water-compatible base, primarily composed of a blend of liquid and solid macrogol (polyethylene glycol). These preparations may also incorporate a specific amount of water, ensuring a balance between the hydrophilic and hydrophobic components conducive to optimal application and efficacy. Such a composition is well-documented in various pharmacological studies.

From a dispersion-based classification perspective, ointments are categorized into two main types: homogeneous systems and heterogeneous systems.

Conditionally homogeneous ointments consist of components that are either mutually soluble or capable of being uniformly mixed without forming distinct phase boundaries. These are further classified into specific subtypes:

1. Ointments-solutions are created by dissolving active ingredients within the dispersive medium, such as water-soluble substances dissolved in hydro gels or polyethylene bases.

2. Ointments-alloys are formed through the fusion of multiple components, where thermal processes facilitate the blending.

3. Extractive ointments arise through the extraction of bioactive substances from plant-based or animal-derived raw materials, utilizing hydrophobic liquid mediums to isolate the desired constituents.

In contrast, heterogeneous ointments contain multiple phases, typically manifesting as emulsions, suspensions, or combined disperse systems:

- Ointments-suspensions represent two-phase systems where finely powdered active substances, which remain insoluble in water and oils, are evenly distributed as a suspension.

- Ointments-emulsions are two-phase systems comprising a distinct interface between immiscible liquid phases.

- Combined ointments involve formulations containing several active pharmaceutical ingredients with differing physical or chemical properties, necessitating diverse preparation techniques.

Beyond these classifications, additional categories of topical soft medicines are recognized:

1. Pastes are external formulations containing a high proportion of solid particles distributed evenly throughout the base. These are typically denser than standard ointments.

2. Liniments refer to medicinal products designed to melt at body temperature, making application more efficient. This category may encompass ointments, creams, gels, and specific types of pastes exhibiting this characteristic.

3. Creams, multiphase medicinal preparations, typically possess non-Newtonian flow properties with rheological behaviors dependent on storage conditions. These formulations act as heterogeneous dispersive systems wherein fine droplets of one immiscible liquid (disperse phase) are distributed within another liquid (dispersion medium). Cream emulsions can be further categorized into water-in-oil (w/o), oil-in-water (o/w), or even complex "multiple" emulsions where dispersed droplets themselves serve as dispersion media for further emulsified phases. Medically, heterogeneous systems like creams play vital roles due to their ability to regulate the bioavailability of active substances, minimize irritative effects on skin and mucous membranes, and efficiently deliver therapeutic agents. Hydrophobic creams (composed predominantly of water-repelling ingredients) and hydrophilic creams (water-compatible formulations) are distinguished based on emulsion type.

4. Gels stand out as versatile formulations for localized treatment areas, existing in one-phase, two-phase, or multiphase formats. Gels employ a liquid dispersion medium whose rheological properties derive from the use of gelatinizing agents at low concentrations. Depending on their medium:

- Hydro gels feature aqueous dispersion mediums offering high compatibility with water-soluble drugs.

- Oil gel, conversely, are based on hydrophobic liquids such as vegetable oils or Vaseline combined with lipophilic gelatinizators like polyethylene or zinc soaps.

- Organic gels use liquid hydrocarbons as their dispersion medium.

Hydrophobic gels are formulated using bases comprising hydrophobic solvents like vegetable oil or Vaseline in conjunction with gelatinizers with lipophilic properties. In contrast, hydrophilic gels employ bases with water and sometimes other polar solvents (such as ethyl alcohol, glycerol, or PEO-400), combined with hydrophilic gelatinizing agents like carbomer and cellulose derivatives.

Comprehensively, the diverse classifications and preparation techniques of these topical medicinal forms enhance their therapeutic applicability across varied medical scenarios. By tailoring composition and physical characteristics to specific clinical needs, these formulations ensure targeted action, patient comfort, and overall treatment efficiency.

1.1.2. Fundamental Requirements for Soft Medicinal Products

Soft medicinal preparations, commonly applied to areas exhibiting various pathological conditions such as skin or mucous membranes, serve a crucial role in targeted therapeutic interventions. These regions often present distinct symptoms, including dryness, wetness, or irritation, necessitating customized formulations that cater to specific physical and chemical requirements while achieving desired therapeutic outcomes. For instance, drying ointments may be prescribed for addressing oozing rashes, while moisturizing compositions prove beneficial in alleviating the discomfort caused by dry eczema. Additionally, certain ointments might simultaneously provide local or general protective effects, contributing to both preventive and restorative treatments.

Given these specialized applications, ointment formulations should meet a set of fundamental and specific criteria to maximize efficacy and ensure safety:

- The active ingredients integrated into the ointment formulations must be effortlessly and thoroughly released. In the case of ointments designed for resorptive action, the medicinal substances should penetrate deeply into the skin and subcutaneous layers, ensuring entry into the bloodstream and lymphatic system for systemic effectiveness. Conversely, in ointments with surface-level action, the active substances must remain localized and avoid absorption into the systemic circulation.

- Stability over time is another key requirement. Extemporaneous (custom-prepared) ointments should maintain their therapeutic properties for up to 10 days as per pharmacological standards (SPU), while industrially manufactured ointments should remain stable for a minimum of two years under prescribed storage conditions.

- Homogeneity is essential for the uniform distribution of medicinal substances throughout the ointment base, ensuring consistent effectiveness across applications.

- Structural and mechanical characteristics are vital for user convenience; the ointment should be easily dispensed from its packaging—such as a tube—and should adhere effectively to the targeted skin or mucosal area without excessive spread or displacement.

- Resistance to microbial contamination is critical to prevent infection or spoilage during usage and storage.

- The formulation should be free from any irritant properties or sensitizing effects that could potentially provoke allergic reactions or exacerbate discomfort in the affected area.

- The pH level of the ointment should align closely with the natural pH of the skin or mucosal surface being treated. This compatibility influences multiple factors such as ease of application (minimizing pain), release efficiency of active substances from the ointment matrix, long-term stability, and safeguarding against disruption of the skin’s protective barriers.

These considerations collectively underscore the complexity and precision required in developing effective ointment formulations tailored to specific medical needs. Each parameter plays a critical role in ensuring both therapeutic benefit and patient satisfaction during treatment.

1.2. Benefits of soft medicines

The advantages of soft medicines can be summarized as follows:

1. They enable the incorporation of medicinal substances in various aggregation states (liquid, soft, or solid) into ointments.

2. Ointments can be tailored for both local application and resorptive (systemic absorption) effects.

3. They allow for the achievement of high concentrations of medicinal substances in the skin, tissues, and biological fluids.

4. Compared to other dosage forms such as injections or oral medications, ointments are relatively simple to use and offer greater safety.

5. Ointments are highly effective in delivering medication.

6. Their soft texture ensures ease of application on the skin and mucous membranes while facilitating the release of medicinal substances.

7. Ointments with polyethylene oxide (PEO) bases exhibit unique attributes compared to traditional drugs, including a complex action profile, strong osmotic effects, and broad-spectrum antimicrobial activity.

8. The use of fatty bases such as lanolin-Vaseline in wound treatments prevents the inactivation of substances by wound exudates. However, achieving minimum inhibitory concentrations (MIC) of the antimicrobial component can be challenging.

9. Cover ointments soften dry epidermis, prevent dehydration and contamination, and protect damaged skin from infections and microbial exposure.

10. Ointments with resorptive properties produce systemic effects and can enhance or complement internally administered medicines, especially when other methods of administration are inconvenient or unfeasible.

These advantages significantly enhance patient compliance with the use of soft medicines, making them a preferred choice in many therapeutic scenarios.

1.3. Biopharmaceutical Considerations in the Formulation of Soft Medicinal Products

The focal mission in the field of biopharmaceutics within drug technology revolves around optimizing the therapeutic effects of medicines while simultaneously mitigating their potential adverse impacts on the human body. Achieving this dual objective is contingent upon thorough consideration of various pharmaceutical factors that influence the biological efficacy of medicinal products. These factors are categorized into distinct groups:

1. The physical state of the medicinal substance, which involves characteristics such as amorphous or crystalline formation as well as size and shape considerations.

2. Chemical modifications of the substance, which can be as simple as the addition or replacement of chemical ions.

3. Excipients, inclusive of their nature, physical state, and precise quantities, play a fundamental role.

4. Dosage form coupled with the method of administration into the body, which determines the speed and depth of absorption.

5. The technological processes involved during manufacturing add another layer of influence on the therapeutic output.

A pivotal aspect in enhancing existing ointments and developing innovative formulations lies in understanding these key factors thoroughly. From studying the release dynamics of medicinal substances to evaluating their absorption rates, targeted tissue effects, and interactions with bodily fluids, biopharmaceutical investigations form the backbone of progress in this area. An intricate examination of these elements allows for targeted enhancements in drug delivery systems, particularly those involving topical applications like ointments.

Influence of Physical and Chemical State of Medicinal Substances

Advancements in this domain rely heavily on understanding how the physical and chemical characteristics of medicinal compounds affect their behavior under various circumstances. Factors such as particle size, surface properties, shape, degree of purity, and crystallinity are critical determinants impacting drug stability during storage and subsequent therapeutic efficiency. These parameters influence the absorption rate, bioavailability, distribution within biological fluids, and elimination from the body.

Empirical evidence highlights the importance of particle size in drug efficacy because it directly correlates with absorption speed and concentration levels in biological systems. Excessive reduction in particle size, however, may lead to undesirable outcomes such as accelerated excretion or a decline in drug stability, sometimes causing unintended side effects. For optimal results, a balanced degree of grinding is essential to ensure desirable pharmacokinetic properties and sufficient bioavailability.

Additionally, in ointments that contain diluted medicinal substances, the dissociation degree emerges as a vital factor. Biomembranes only permit undissociated molecules to permeate; thus, controlling dissociation through pH regulation becomes indispensable for drug effectiveness. Furthermore, pharmacokinetic behavior is influenced by particle dispersion levels due to their impact on dissolution rates within ointment bases and ability to penetrate skin barriers like the stratum corneum. As dispersion increases, the medicinal substance diffuses more freely from its base to concentrate on the skin-ointment interface — ultimately enhancing its therapeutic impact.

Suspension-based ointments and creams may be deemed therapeutically equivalent when identical concentrations yield evenly dispersed particles of similar size upon application. Variations in particle size post-manufacturing can be minimized by judiciously selecting a base that harmonizes with the physicochemical properties of the active ingredient.

Substances exhibiting low water solubility (e.g., norsulfazol, chloramphenicol) tend to release from hydrophilic ointment bases more effectively than hydrophobic ones. Specific cases like benzocaine demonstrate slightly reduced diffusion from emulsion bases of oil-in-water types as compared to water-in-oil types. Meanwhile, substances that are highly water-soluble (e.g., neomycin sulfate) show greater release rates from hydrophilic bases than from hydrophobic alternatives or water-in-oil emulsion types.

Effect of Simple Chemical Modification

Chemical modifications of a substance represent another impactful factor in biopharmaceutics. Modifications often involve retaining the pharmacologically crucial component of a molecule while introducing variations in its ionic composition or structure — for instance, salts of procaine, caffeine paired with sodium benzoate, among others.

While maintaining consistent therapeutic efficacy across variations, different compounds exhibit unique pharmacokinetic behaviors due to their structural adjustments. This nuanced approach entails altering specific cations or ions within a molecule while preserving its core function to achieve desirable pharmacotherapeutic changes. Such modifications allow researchers to enhance various properties such as stability under storage conditions, bioavailability during administration, and overall therapeutic outcome — enabling both cost reduction and improvements in drug efficacy.

Clinical practices and large-scale pharmaceutical manufacturing frequently employ these targeted chemical modifications to tailor drug performance to specific needs. When adequately incorporated into production workflows or pharmacy preparations, they provide desirable benefits such as heightened efficiency during treatment interventions and extended shelf-life for medicinal formulations.

By assessing these factors meticulously during development processes — particularly through biopharmaceutical research — scientists can refine drug delivery systems to ensure maximum therapeutic outcomes with minimal adverse effects while meeting contemporary medical standards.

Impact of Excipients' Nature and Quantity

Excipients, a diverse group of substances derived from both natural and synthetic sources, serve as crucial components in the formulation of dosage forms. These substances impart key physical, chemical, and pharmacological characteristics to the final medicinal product. The State Pharmacopoeia of Ukraine (SPU) categorizes excipients based on their functionality into several groups:

1. Soft bases like Vaseline and lanolin.

2. Agents enhancing melting points and viscosity, such as paraffin, spermaceti, hydrogenated plant oils, waxes, and high-molecular-weight polyethylene glycols.

3. Hydrophobic solvents, including mineral oils, vegetable oils, and benzyl benzoate.

4. Hydrophilic solvents like ethyl alcohol, isopropyl alcohol, polyethylene glycol, propylene glycol, and glycerol.

5. Oil-in-water emulsifiers such as sodium lauryl sulfate, emulsifier No. 1, polysorbates, polyethylene glycol fatty alcohol esters, castor oil derivatives, and stearic acid esters.

6. Water-in-oil emulsifiers including higher fatty alcohols, cholesterol, and wool wax alcohols.

7. Gelatinizing agents like carbomer, alginic acid, cellulose derivatives, polyethylene compounds, colloidal silicon dioxide, and gelatin.

8. Antimicrobial preservatives such as benzalkonium chloride, benzoic and sorbic acids, benzyl alcohol, cresol, and ethyl alcohol.

9. Antioxidants like alpha-tocopherol, ascorbic acid derivatives.

10. Solubilizers utilizing hydrophilic surfactants.

11. Odorants such as menthol, essential oils, and phenyl ethyl alcohol.

12. pH stabilizers including citric acid and phosphate salts.

Certain excipients function as stabilizers for dispersed systems—for example, gelatinizing agents, emulsifiers, and materials raising the base's temperature or viscosity. Complex mixtures like anhydrous lanolin and combinations such as

Vaseline alloyed with wool wax alcohols also embody adjuvant properties. Historically regarded simply as neutral fillers, excipients were initially required to be pharmacologically inactive while ensuring appropriate technological attributes for the medicine. Today, their role is acknowledged as central to influencing the overall medicinal properties of drugs.

Excipients possess distinct physical and chemical characteristics dependent on their composition and the conditions under which dosage forms are produced and stored. They can interact dynamically with active ingredients and environmental factors—a phenomenon that underscores their significance beyond mere auxiliary status. In nearly every instance of medicinal formulation, excipients influence how the drug interacts within the body. Improper selection or usage of these substances risks compromising the therapeutic efficacy by inducing interactions between the active pharmaceutical ingredients and excipient components during formulation or post-administration. Such interactions—primarily involving chelation or adsorption—can significantly modify the absorption rate and completeness of active constituents.

Role of Dosage Forms and Administration Routes

A dosage form represents the practical embodiment of a medicine's pharmacological potential. It is vital in optimizing therapeutic outcomes with minimal adverse effects while ensuring convenient administration and storage. The effectiveness of a medication hinges on its incorporation into a rational dosage form that facilitates optimal release and absorption processes. The selection of appropriate dosage forms profoundly influences the therapeutic benefits of medicines while simultaneously dictating administration routes.

A dosage form should meet modern pharmacotherapy standards by emphasizing efficiency, convenience, cost-effectiveness, and adherence to medicinal pharmacodynamics. It must strike a balance between aesthetic and functional requirements to provide maximum efficacy with streamlined usability.

Impact of Technological Processes

Pharmaceutical technology plays a pivotal role in determining how medicinal substances behave within the body. The manufacturing methodology directly impacts the stability of dosage forms, release rates of active compounds, absorption intensity, and overall therapeutic effectiveness.

The preparation techniques employed can alter the physical-chemical characteristics of medicinal substances, affecting solubility and bioavailability in the body. Rational technological approaches should ensure dosage forms exhibit several essential characteristics:

- Compatibility with intended therapeutic purposes.
- Accurate dosing of active ingredients.
- Adequate homogeneity and dispersion within formulations.
- Stability in chemical-physical properties during processing.
- Long-term stability during storage.
- User-friendly application.

Research aimed at developing improved formulations for topical medicines such as ointments increasingly relies on biopharmaceutical studies to refine production methodologies and enhance therapeutic outcomes at pharmacy practice levels.

Conclusions to chapter 1

1. Soft medicines have become increasingly prevalent in modern medical practice. These formulations often contain active ingredients from various pharmacological groups, enabling their application across a wide range of diseases.
2. Healing ointments are categorized based on their intended use and the type of disperse systems they involve.
3. Soft medicines are composed of active substances alongside excipients, which form the ointment base. The composition of this base plays a crucial role, as it can significantly influence the efficacy of the active ingredients.
4. In Ukraine's pharmaceutical market, the distribution of soft medicines is as follows: ointments account for 47%, creams for 28%, pastes for 22%, while liniments and gels constitute 2% and 1%, respectively.
5. A critical aspect in developing new ointments and enhancing the quality of existing ones lies in biopharmaceutical research. Such studies emphasize understanding factors that impact the release of medicinal substances from ointments, as well as their absorption rate, effectiveness, and targeted action on tissues and body fluids.

CHAPTER 2

OBJECTS AND METHODS

The study focused on the creation of extemporaneous emulsion-based ointment formulations, utilizing excipients that comply with pharmaceutical standards.

2.1. Objects of research

Cetostearyl alcohol (Alcohol cetylicus et stearylikus, European Pharmacopoeia 4, 01/2002:0702, C. 867): This material is characterized as a white or pale yellow waxy substance available in forms such as plates, flakes, or granules. It is practically insoluble in water but dissolves effectively in ether, alcohol (90% v/v), and light petrolatum. In its molten form, it blends seamlessly with fatty oils, liquid paraffin, and melted wool fat.

Emulsifier No. 1 (Pharm. Article 42У-209-1043-99): A mixture comprised of sodium salts of sulfuric acid esters derived from high alcohols (carbon atoms 16-18) and free higher alcohols such as cetyl, in a 3:7 ratio. It is a solid, brownish substance that feels oily to the touch. Though practically insoluble in water, it dissolves readily in ether and chloroform and is compatible with fats, vegetable oils, and mineral oils.

OS-20 (GOST 10730-82): Monoalkyl polyethylene glycol ethers synthesized from primary alcohols, conforming to the general chemical formula SnH2n+1O(C2H4O)mH, where n=18 and m=20. With an HLB of 13.4, it is classified as a nonionic emulsifier of the first type.

Distilled monoglycerides MGD 90 (Specifications 10-1197-95): A nonionic emulsifier of the second kind, composed of stearic and palmitic acid esters along with minor traces of di- and triglycerides. The monoester content exceeds 90%, free glycerin is limited to 1.5%, and the acid number remains below 3.0. It has a melting point ranging between 65°C and 80°C and forms stable emulsions when used alongside other surfactants.

Vaseline (Vaselinum album, SPU 1.2, P.381): Identified as a translucent white or almost white substance with a soft texture. In its molten state, it exhibits slight fluorescence under daylight. Practically insoluble in water, it is soluble in methylene chloride but demonstrates minimal solubility in 96% alcohol or glycerol.

Vaseline oil (Paraffinum liquidum, SPU 1.2, P.382): A purified blend of saturated liquid hydrocarbons derived from petroleum. It is transparent, colorless, oily, and non-fluorescent under daylight conditions. Virtually insoluble in water but soluble in 96% alcohol, it is compatible with hydrocarbons.

Purified water (Aqua purificata, SPU 1.1, P.308): Clear and colorless liquid without any detectable taste or smell.

2.2. Methods of research

The organoleptic, physical, and chemical properties of the tested samples were extensively evaluated using modeling techniques as outlined in the State Pharmacopoeia of Ukraine (SPU). These methods were employed to ensure the quality, consistency, and stability of the samples under investigation across various parameters.

Specification of Organoleptic Properties

The appearance and organoleptic attributes, such as color, odor, texture, and general characteristics of the samples, were carefully assessed. Additionally, the bases were systematically examined to identify any evidence of rancidity or indicators of physical instability, including particle aggregation, coalescence, coagulation, or stratification. Such assessments are critical in ensuring the formulation's suitability for its intended purpose.

Determination of Homogeneity

The homogeneity of the samples was determined adhering strictly to the procedures outlined in SPU 1.0, p. 511. Four individual subsamples, each weighing approximately 20-30 mg, were taken from each sample. These subsamples were applied in pairs onto glass slides, covered with a second slide, and pressed until a stain with an approximate diameter of 2 cm was formed. The stains were then

inspected visually from a distance of 30 cm to identify any visible particles, foreign matter, or signs of physical instability like aggregation or coalescence. A sample was classified as homogeneous only if all four subsamples were devoid of such abnormalities. In cases where even one subsample failed to meet these criteria, an extended trial involving an additional eight subsamples was conducted. For the sample to achieve a conclusive rating of homogeneity, all eight additional subsamples had to withstand the test.

Determination of Thermal Stability

To evaluate thermal stability, 5-6 glass tubes of dimensions 15 mm in diameter and 150 mm in height were filled with 8-10 ml of each sample. These tubes were subjected to controlled temperature changes: they were first placed in a thermostat set at 40-42 ˚C for one week, subsequently moved to a refrigerator maintained at 10-12 ˚C for another week, and finally left at room temperature for three days. The samples were inspected visually after these temperature variations for any signs of stratification. The absence of such stratification was indicative of adequate thermal stability.

Determination of Colloidal Stability

Colloidal stability testing was carried out using a laboratory centrifuge equipped with specialized sample tubes, a mercury thermometer capable of measuring temperatures ranging from 0 to 100 ˚C with an accuracy of 1 ˚C, a stopwatch, and a water bath. Each test tube was filled to two-thirds of its volume (approximately 9.0 g) with the sample under evaluation. The weight variance among tube contents did not exceed 0.02 g as measured by an analytical balance with an accuracy of 0.01 g. The tubes were then preconditioned by immersion in a water bath set to a temperature of 42.5 ± 2.5 ˚C for 20 minutes before being dried externally and loaded into the centrifuge. The centrifugation process lasted for five minutes at a rotational speed of 6000 revolutions per minute (equivalent to a relative centrifugal force of approximately 5000 g). A sample was deemed colloidally stable if no stratification or sediment formation was observed in any of the centrifuged tubes. However, if even one tube exhibited signs of instability, the test was repeated with

fresh portions of the ointment base. Should the second trial yield similar results showing instability in even one tube, the sample was concluded to lack colloidal stability.

Microbiological Purity

The microbiological purity of the hydrophobic ointment bases was evaluated in compliance with SPU guidelines (1.0), specifically sections §5.1.4, 2.6.12, and 2.6.13. The examination took place at the Institute of Microbiology and Immunology named after Mechnikov under the National Academy of Medical Sciences of Ukraine. In their dedicated laboratory for microbial biochemistry and culture media, stringent tests were employed to ensure that all samples met microbiological safety and purity standards.

Statistical Analysis

The findings from all evaluations were subjected to statistical analysis in accordance with SPU provisions (1.1), as detailed on page 187. This comprehensive analysis ensures reliability and reproducibility of the results by applying robust statistical tools.

By utilizing such rigorous methods across organoleptic, physical, chemical, thermal stability, colloidal stability, and microbiological purity evaluations along with statistical validation, all aspects critical to ensuring the quality and effectiveness of the samples were thoroughly examined. The adherence to standardized protocols underscores the robustness and reliability of these investigations.

CHAPTER 3

INVESTIGATION INTO CONTEMPORARY OINTMENT BASES

3.1. Analytical evaluation of pharmaceutical manufacturing processes for soft medicinal products

The investigation into the practice of extemporaneous compounding in pharmacies across Kharkov revealed that among the category of soft medicinal formulations, liniments, ointments, and pastes remain the most frequently prescribed by healthcare professionals. Upon conducting a more in-depth examination specifically focusing on ointment prescriptions, it became clear that a broad array of soft pharmaceutical preparations are actively utilized for localized treatment of various ailments. These findings underscore the diversity and adaptability of such medicines in addressing different clinical needs. The detailed outcomes of this study are systematically structured and provided in Table 3.1 below, which highlights the prescription trends and usage patterns observed in Kharkov's pharmaceutical sector.

Table 3.1

Analysis of ointments prescriptions pharmacies

Active ingredients	***Number of prescriptions***
Chloroform, turpentine oil, menthol, camphor, methyl salicylate, iodine, paraffin, iodoform, glycerin, bile medical, propolis, dimeksid	**8**
Propolis, eucalyptus oil, menthol, camphor, vinilin, turpentine, ephedrine hydrochloride, prednisolone, diphenhydramine, silver nitrate, dikain, diphenhydramine, hydrocortisone acetate, benzocaine, boric acid, protargol	**13**
Xeroform, tar, castor oil, dermatol, vinilin	**3**
Zinc oxide, Vitamin A, norsulfazol, resorcinol, bismuth nitrate basic, prednisolone, benzocaine, streptocid, boric acid, Ichthyol, salicylic acid, diphenhydramine, menthol, camphor ointment, tannin	**19**
Benzyl, green soap, precipitated sulfur, calcium carbonate, tar, camphor ointment	**3**
A solution of retinol acetate oil	**1**
Ichthyol, vinilin, precipitated sulfur, castor oil, tar, xeroform, zinc oxide, salicylic acid	**6**
Salicylic acid, sulfur precipitated, resorcinol, xeroform, bismuth nitrate basic, zinc oxide, diphenhydramine, tincture of valerian, motherwort, Ichthyol, procaine, benzocaine, menthol	**19**
Silver nitrate, vinilin, dermatol, corn oil, sodium tetraborate, furazolidone, Novocain	**5**
Anestezin	**1**

Novocain, dermatol, benzocaine, corn oil, sodium tetraborate, furazolidone	**7**
Anestezin, bismuth basic nitrate, furazolidone, Novocain	**2**
Tar, sulfur precipitated	**1**
Salicylic acid, benzocaine, resorcinol, Ichthyol, menthol, extracts of belladonna	**4**
Resorcinol, salicylic acid, iodine, carbolic acid solution	**3**
Diphenhydramine, benzocaine, menthol, Burov liquid	**1**
Benzyl, castor oil, salicylic acid	**2**

Based on the data presented in the table, it becomes evident that the medicinal substances most commonly employed in the preparation of extemporaneous ointment prescriptions include menthol, camphor, zinc oxide, salicylic acid, vitamin A, among other compounds. This observation aligns with the findings of our study, which analyzed ointment prescriptions issued by Kharkov Pharmacy No. 9. Several illustrative examples from these prescriptions are provided in the following sections to further substantiate these conclusions.

Rp.: Mentholi 0,15
Camphorae 0,2
Lanolini 2,0
Vaselini 8,0
M., f. ung.
D.S. Apply the lining of 2-3 times a day

Rp.: Acidi borici 1,3
Zinci oxydi 1,7
Bismuthi subnittatis 5,0
Lanolini
Vaselini aa 17,0
M., f. ung.
D.S.

Rp.: Zinci oxydi 10,0
Acidi salicylici 2,0
Dimedroli 3,0
Acidi borici 2,0
Aq. purificatae 20,0
Vaselini 40,0
Lanolini anhydrici 40,0
M., f .ung. D.S.

Rp.: Acidi salycilici 0,25
Sol. Vit. A oleosae
Sol. Vit. D aa 5,0
Sol. Vit. E 3,0
Olei Ricini 8,0
Aq. purificatae 10,0
Lanolini 35,0
M., f. ung. D. S.

Rp.: Ung. Ac. salycilici 5%-20,0
D. S. Apply to the affected skin.

Rp.: Acidi salycilici 8,0
Acidi borici 4,0
Vaselini 48,0
M., f. ung. D.S.

Rp.: Kalii iodidi 5,0
Lanolini 15,0
Zinci oxydi 0,5
Lanolini 2,0
Vaselini 8,0
M., f. ung.
D.S. Ophthalmic ointment

Rp.: Zinci oxydi 5,0
Talci 5,0
Resorcini 0,5
Ol. Persocorum 5,0
Vaselini 5,0
M., f. ung.
D.S.

As you can see, today preparing medicines for prescriptions does not lose its value because the extemporaneous preparation of soft medicines allows individual selection of components depending on the patient, the nature of the disease, despite the growing range of finished products. Among the most frequently used soft medicines in pharmacies prepare ointments-suspensions (28.5 %), ointments-emulsions (14.3 %) and combined ointments (57.2 %).

3.2. Rationale for broadening the variety of emulsion-based ointment platforms in pharmaceutical manufacturing

In modern pharmaceutical practice, Vaseline is frequently employed as an ointment base. However, it is not the most suitable option. Current research suggests that emulsion-based formulations made from components such as sunflower oil, peach oil, and similar substances are more effective. To stabilize these oil-in-water (o/w) emulsion-based ointments, various emulsifiers are utilized. These bases have the versatility to incorporate a wide range of active ingredients, including antibiotics, sulfonamides, nonsteroidal anti-inflammatory agents, and glucocorticoids. Emulsion bases ensure optimal release of medicinal components and enhance bioavailability. Additionally, they help maintain the skin's normal water balance, improve softness and elasticity, reduce inflammation, and are applied uniformly without difficulty.

Soft medication bases are broadly categorized into three groups:

1. Hydrophobic bases: Includes fats, carbohydrates, silicone bases, and polypropylene bases.

2. Hydrophilic bases: Comprises protein gels, carbopol gels, collagen gels, and polyethylene oxide (PEO) gels.

3. Amphiphilic (diphasic) bases: Primarily absorption bases in the form of either o/w or water-in-oil (w/o) emulsions.

Fats

Fats are mixtures of various esters derived from glycerol and monobasic acids. They are insoluble in water, sparingly soluble in alcohol, but dissolve well in solvents such as hydrogen sulfide, ether, and chloroform. While chemically neutral and compatible with numerous substances, fats are biodegradable and can break down into free fatty acids, aldehydes, and other secondary compounds that may react with ointment ingredients. This decomposition can also irritate the skin.

Refined pig fat is an example of such a base—it consists of triglycerides from palmitic, stearic, oleic, and linoleic acids with trace amounts of cholesterol. However, raw oils quickly oxidize and are unsuitable for ointments containing oxidants. Hydrogenation can stabilize fatty oils derived from sources like sunflower, soybean, peanut, or castor oil. Hydrogenated fats vary in consistency from liquid to solid, offer better mixing properties with water, but exhibit slower absorption.

Fatty oils extracted via pressing from seeds or fruits—such as safflower or peach oils—are added in small quantities to improve the absorption characteristics of ointment formulations for medicinal substance delivery.

Waxes (Fat-like Substances)

Waxes consist of esters formed from higher monohydric alcohols paired with higher fatty acids. They are chemically inert and highly stable while being compatible with water. Key waxes include:

1. Lanolin: A purified substance containing cholesterol esters combined with palmitic acids. Due to its high viscosity and emollient properties, it is often used alongside other bases.

2. Spermaceti: Composed of cetyl esters derived from palmitic acid. It is a fatty, crystalline white mass that combines readily with Vaseline, fats, and other waxes. However, it is prone to decomposition when exposed to air.

3. Beeswax: Extracted by melting honeycombs; white beeswax is obtained through bleaching yellow wax under sunlight. Beeswax acts as a sealant and viscosity enhancer for ointments but has limited emulsifying capacity.

Hydrocarbon Bases

These bases visually resemble fats but are composed primarily of long-chain hydrocarbons. They exhibit excellent chemical stability during storage and resist oxidation or drying out. However, they are not absorbed by the skin or easily washed off. Examples include:

1. Vaseline: Produced via oil refinement and available in yellow or white varieties with similar properties. It is chemically inert, stable, non-irritating to the skin, and often combined with lanolin for eye ointment formulations.

2. Solid Paraffin: A white crystalline product derived from petroleum refining that is stable but poorly miscible with water.

3. Vaseline Oil: A colorless liquid added to solid bases to render a softer consistency.

4. Refined Naphthalene Oil: Thick, black liquid with a greenish fluorescence.

5. Petrolatum: A light brown mass produced from dewaxing petroleum oils; it is a blend of paraffin and mineral oil.

Silicone Bases

Comprised of macromolecular organosilicon compounds with chains made of silicon and oxygen atoms substituted by methyl, ethyl, or phenyl groups. Silicone bases are chemically stable and diverse in application.

Hydrophilic Bases

These bases are predominantly mixtures of fats or fat-like substances that mix readily with water but demonstrate chemical instability due to their reactivity with certain compounds.

Hydrophilic bases are substances that incorporate fats and fat-like compounds, allowing them to mix in any proportion with water. While they are effective for various purposes, they tend to be chemically unstable and may react with certain substances.

1. Celatin-Glycerin Base: This type of base is a mixture composed of gelatin (1-3%), glycerol (10-20%), and water (70-80%). It dissolves many drugs efficiently but has poor stability due to its susceptibility to microbial growth. It is primarily used in the formulation of protective ointments.

2. Stearate Bases: These bases consist of a suspension containing stearic acid, lye, glycerin, and water. They are well absorbed by the skin, compatible with many substances, and remain stable during storage. They are commonly used in the production of cosmetic ointments.

3. PEO (Polyethylene Oxide) Bases: These are produced by the polymerization of ethylene oxide in the presence of water and alkalis. PEOs are characterized as diatomic alcohols, are soluble in water and alcohol, chemically stable, pharmacologically neutral, and retain stability during storage. They serve as effective carriers, facilitating the delivery of drugs into the skin.

Hydrophilic-Lipophilic Bases: This category includes alloys of lipophilic bases combined with emulsifiers. Examples include:

1. Higher alcohols derived from spermaceti, such as cetyl and stearyl alcohol.

2. Macromolecular cyclic alcohols like hydrolan and deodorized lanolin.

3. Derivatives of polymerized glycerol.

4. Spans—partial esters of sorbitan and fatty acids.

5. Tweens—compounds derived from the treatment of spans with ethylene oxide.

6. Pentol—a mixture of ethers, alcohols, and oleic acids.

Ointments made using hydrophilic-lipophilic bases are well absorbed by the skin and facilitate the efficient release of their active substances.

Today it is known that the therapeutic effect of the product is ensured by a complex interaction of active ingredients and excipients, which is why much attention is paid to the properties of ointment bases, which provide the necessary pharmacological properties and structural and mechanical properties of ointments. This is the most significant factor in justifying rational composition and technology of soft medicines.

In modern scientific studies are published data that bases for ointments for their ability to provide release and resorption of medicinal substances can be arranged in the following order: solutions and gels of hydrophilic substances - emulsion base type oil/water - emulsion type water/oil – absorption bases – hydrophobic bases.

Ointment base is indifferent in the sense and in almost all instances somehow acts on the system medicinal substance - macro organism. Base provides not only the necessary consistency of ointments, but also the stability characteristics of the release of drugs.

In addition, the physical and chemical properties of substances, mostly of the base, depends a shelf life of ointments.

Nature of a base has a great influence on the medicinal substances that were introduced into its structure, may enhance or weaken their pharmacological properties. With proper choice of base can ensure maximum activity of the medicine in this dosage form or significantly reduce its toxicity.

In the study of extemporal prescriptions of soft medicines (Chapter 3, paragraph 3.1), we have found that currently there is a lack in the pharmacies of new and more efficient from a technological point of view emulsion ointment bases. Therefore, the aim of our research is expanding the range of extemporaneous emulsion bases for the preparation of ointments.

Conclusions to chapter 3

1. In the study of extemporal prescriptions of soft medicines in Kharkov pharmacies was found that today there are many ointments that are used for topical treatment of various diseases, among active substances most commonly are used zinc oxide, boric acid, salicylic acid and menthol.
2. The range of modern ointment bases, which are classified into hydrophobic, hydrophilic and dyphilic, is studied.
3. As an ointment base in pharmaceutical practice often use Vaseline or Vaseline-lanolin base. But Vaseline is not the most suitable base, according to the latest research better to use emulsion bases.
4. The need of expanding the range of emulsion ointment bases for the preparation of pharmaceutical drugs is justified.

CHAPTER 4

FORMULATION AND EXPERIMENTAL INVESTIGATION OF EXTEMPORANEOUS EMULSION-BASED OINTMENT PLATFORMS

4.1. Justification for the composition of the base

The development of an ointment base composition requires careful consideration of specific criteria to ensure compatibility with the skin's natural functions. The skin plays an essential role in metabolism, thermoregulation, respiration, and excretion, so the base must not interfere with these processes. In certain dermatological conditions, moisturizing the skin surface becomes a priority, which is achieved by selecting an appropriate base. Moreover, the choice of base significantly influences the penetration and absorption of active ingredients into skin cells.

In designing the base composition, several essential requirements were prioritized:

- It should have a positive impact on the skin.

- It must allow for easy application, ensuring rapid absorption.

- Stability across a wide range of storage temperatures (-10 °C to 40 °C) is necessary.

- The base should possess a pleasant odor.

Our objective centered on developing an extemporaneous emulsion ointment base with optimal functionality. Due to its physical and chemical properties, the proposed base delivers both high efficiency and stability, ensuring the effective incorporation of biologically active substances. Featuring an exceptionally high water content of 70%, the base restores lost skin moisture, spreads easily on the surface, absorbs quickly, and leaves no greasy residue. Additionally, its preparation is economical and straightforward.

One of the critical factors influencing the base's performance is selecting a suitable emulsifier. Stability, dispersion, viscosity, and plasticity are all largely dependent on this choice. To identify the most appropriate structure-forming

component for our formulation, we explored several emulsifiers, including cetostearyl alcohol, Complex Emulsifier No. 1, and a mixture of OS-20 and MGD-90 emulsifiers of both primary and secondary types.

The physical and chemical stability of emulsion ointment bases relies significantly on the micelle colloidal properties of the adsorption layer formed by emulsifiers, as well as their structural and mechanical characteristics. Furthermore, stability depends on their ability to establish a rigid spatial network through hydrophobic interactions between molecule centers. To determine the optimal concentration of emulsifiers, we conducted experiments assessing the physical and chemical stability of various model emulsion samples (results detailed in Table 4.1). Known methodologies were used to prepare the emulsion bases.

Thermal stability and colloidal structure were evaluated visually at room temperature (20 °C), elevated temperatures (40 °C), and reduced temperatures (5 °C). Additionally, the bases underwent testing through cycles of freezing and thawing to ensure consistent performance under varying environmental conditions.

Table 4.1

Composition of model emulsions (%)

Model emulsion	***Vaseline oil***	***Cetostearyl alcohol***	***Emulsifier No. 1***	***OS-20 and MGD 90***	***Vaseline***	***Purified water***
1	25,0	30,0	-	-	30,0	15,0
2	15,0	20,0	-	-	25,0	40,0
3	10,0	15,0	-	-	25,0	50,0
4	25,0	-	30,0	-	30,0	15,0
5	15,0	-	20,0	-	25,0	40,0
6	10,0	-	15,0	-	25,0	50,0
7	25,0	-	-	30,0	30,0	15,0
8	15,0	-	-	20,0	25,0	40,0
9	10,0	-	-	15,0	25,0	50,0

The composition of model emulsions typically involves a carefully selected combination of immiscible substances, often consisting of oil and water phases,

stabilized by the addition of emulsifying agents or surfactants. These mixtures are designed to mimic the behavior, properties, and dynamics of real-world emulsions observed in various industries such as food production, pharmaceuticals, and cosmetics. Generally, a model emulsion includes oils or fats, whether natural or synthetic, as the dispersed phase, while water serves as the continuous phase. Alternatively, the roles can be reversed depending on the formulation requirements, resulting in either oil-in-water (O/W) or water-in-oil (W/O) emulsions.

Emulsifiers, such as lecithin or Tween 20, play a critical role in stabilizing these systems by reducing surface tension at the interface between oil and water. In some cases, co-emulsifiers or stabilizing agents like polymers, proteins, or clays may also be included to enhance stability or modify the texture and appearance. The formulation process often considers additional components such as preservatives, antioxidants, or pH adjusters to ensure the long-term viability and functionality of the emulsion.

The choice of ingredients and their respective concentrations depends on the intended application and desired properties of the model emulsion. For example, creating an emulsion to study rheological behavior requires precision in the oil-to-water ratio and droplet size distribution. Moreover, factors such as temperature, mixing speed, and duration during preparation can significantly influence the structure and performance of the resulting emulsion. These compositions are invaluable tools for researchers aiming to simulate complex systems and test variables under controlled conditions.

Extensive studies revealed that Model Emulsion Base No. 1 exhibited a significantly dense texture, making it difficult to evenly apply to the skin, with negligible absorption observed during testing. This issue was attributed to the excessive presence of emulsifier in its formulation. Further analysis suggested that the composition may require adjustments to enhance usability and improve its overall performance.

In contrast, Emulsion Base Models No. 2 and No. 3 displayed promising results across various conditions. After their initial preparation and subsequent

storage for 30 days at controlled temperatures of 5°C, 20°C, and 40°C, both models maintained structural stability without signs of degradation. Additionally, subjecting these emulsions to five cycles of freeze-thaw testing, with temperature variances ranging from -10°C to +45°C, reinforced their resilience under extreme thermal transitions. Despite this stability, it was observed that Model Emulsion Base No. 3 featured a notably more liquid consistency compared to its counterpart.

On the other hand, further examination of ointment bases numbered 4 through 9 exposed significant vulnerabilities in their compositions. They were unable to endure rigorous testing procedures designed to evaluate colloidal and thermal stability, leading to their exclusion from consideration for continued development.

Based on these findings and the evident superiority of certain formulations, the emulsion system chosen for subsequent detailed investigation and refinement consists of the following composition.

Vaseline	**25.0**
Vaseline oil	**15.0**
Cetostearyl alcohol	**20.0**
Purified water	**up to 100.0 (40 ml)**

4.2. Technological development of extemporaneous emulsion-based ointment foundations

Upon thorough review of the experimental data, we have embarked on an in-depth investigation into developing a more intelligent and efficient process for creating an extemporaneous ointment base. The preparation of this base was carried out using two distinct variations of the phase inversion method, each aiming to optimize the physical and chemical properties of the resulting product. The detailed methodology is outlined below.

In the first method:

A precise amount of cetostearyl alcohol, equivalent to 20.0 ± 0.05 g, was carefully measured and transferred into a porcelain beaker. This material was placed in a water bath and subjected to controlled heating with continuous stirring until it completely melted at a temperature of 56.0 ± 2.0 °C. Subsequently, Vaseline in the quantity of 25.0 ± 0.05 g was weighed meticulously and added to the melted cetostearyl alcohol within the same container. This mixture was further melted under similar conditions, maintaining the temperature at 50.0 ± 2.0 °C while ensuring constant stirring throughout the process.

In parallel, 15.0 ± 0.05 g of Vaseline oil was accurately weighed and set aside in an intermediate glass container. Following this step, the Vaseline oil was introduced into the porcelain cup containing the previously melted mixture of cetostearyl alcohol and Vaseline. The composite ingredients were reheated and stirred thoroughly to reach a consistent temperature of around 50.0 ± 2.0 °C.

Simultaneously, in another intermediate glass container, exactly 40 ml of purified water was measured and subsequently heated in a water bath to achieve a temperature of 50.0 ± 2.0 °C. Once all components had reached their respective target temperatures, the blend from the porcelain beaker was carefully transferred into a pre-warmed mortar that had been maintained between 50-55 °C. While continuously stirring, the heated aqueous phase was gradually introduced into the oil phase.

This addition was performed incrementally to facilitate uniform emulsification, ultimately achieving an ointment base with the desired consistency.

Following preparation, the resulting ointment base was artificially cooled to stabilize its structure and then transferred into dedicated ointment jars for subsequent study and evaluation.

The second method of preparation differed in the sequence and integration of the water and oil phases. In this approach, the purified water was initially transferred to a pre-warmed mortar, where it served as the primary phase. The oil phase, previously heated to a suitable temperature, was then incrementally introduced into the aqueous phase with constant stirring until an ointment-like consistency was formed.

The physical and chemical characteristics of the ointment bases prepared via these two methods were systematically analyzed and documented in Table 4.2. From these results, it became evident that the base prepared using the second method failed to meet critical criteria such as colloidal and thermal stability. Specifically, this base exhibited signs of emulsion separation under stress conditions, which compromised its homogeneity and practical usability.

Conversely, the first method demonstrated clear superiority as a rational and reliable approach for preparing the ointment base. This technique resulted in a homogeneous product characterized by a uniform white appearance, pleasant odor, and considerable stability under both colloidal and thermal assessments.

Table 4.2

Physical and chemical characteristics of the model base samples

No. of sample	***Color***	***Smell***	***Homogeneity***	***Colloidal stability (visually)***	***Thermal stability (visually)***
1	whine	pleasant	homogeneous	stable	stable
2	whine	pleasant	homogeneous	non stable	non stable

In conclusion, based on the conducted experimental research and comparative analysis, Method 1 has been concretely established as the optimal technology for developing a stable extemporaneous ointment base. The step-by-step technological procedure for preparing this base is comprehensively illustrated in Figure 4.1 for further reference and application.

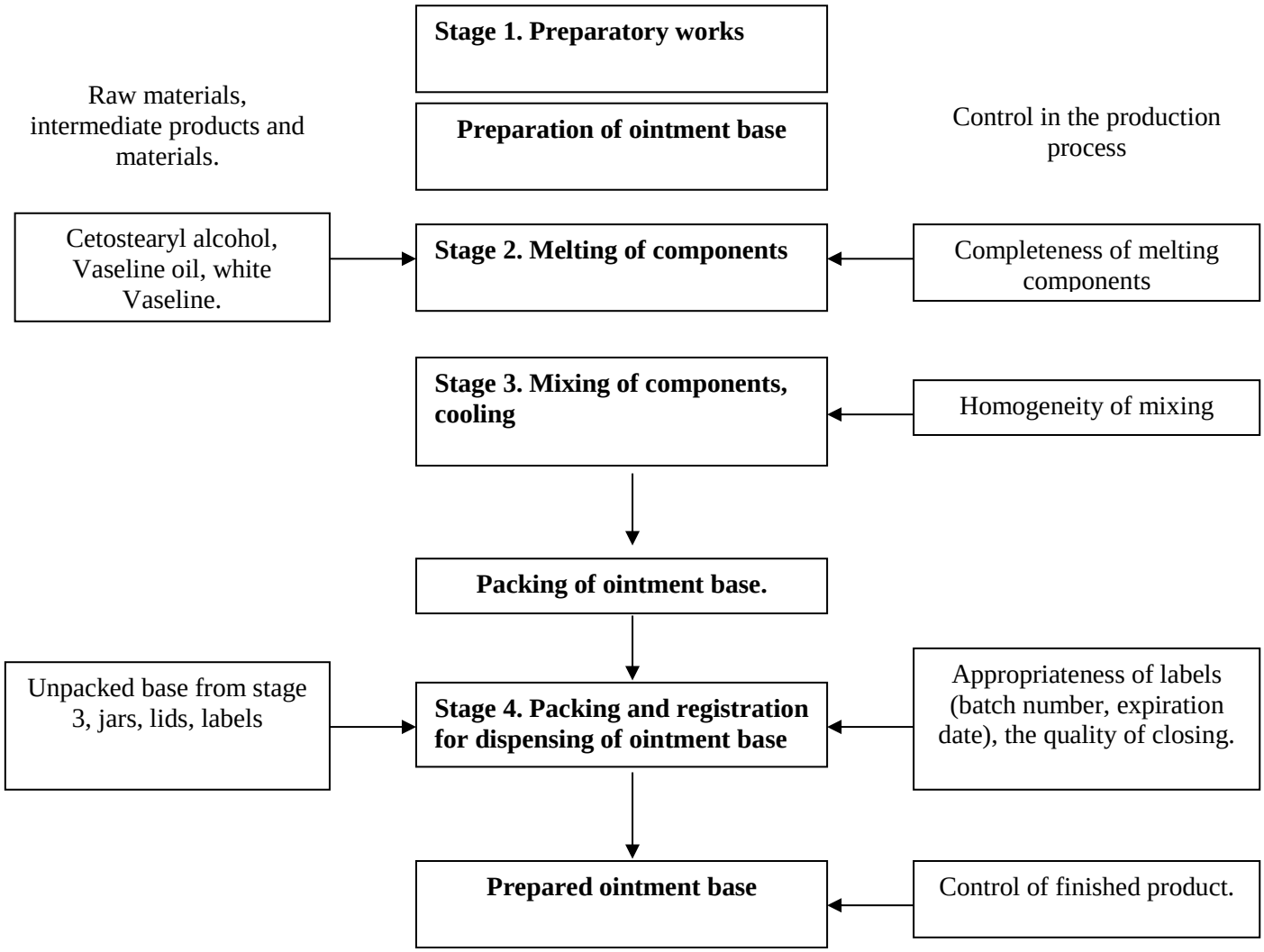

Figure 4.1 illustrates the block diagram outlining the process for preparing the ointment base.

Additionally, a stability study was performed to evaluate the behavior of the extemporal ointment base over the storage period, as summarized in Table 4.3.

Table 4.3

Analyzing the stability of a transient emulsion ointment base over the course of storage

At a temperature 15-25 °C				
	1 month	**2 months**	**3 months**	**5 months**
Color	white	white	white	white
Smell	pleasant	pleasant	pleasant	pleasant
Homogeneity	homogeneous	homogeneous	homogeneous	homogeneous
Colloidal stability (visually)	stable	stable	stable	stable
Thermal stability (visually)	stable	stable	stable	stable
At a temperature 8-15 °C				
Color	white	white	white	white
Smell	pleasant	pleasant	pleasant	pleasant
Homogeneity	homogeneous	homogeneous	homogeneous	homogeneous
Colloidal stability (visually)	stable	stable	stable	stable
Thermal stability (visually)	stable	stable	stable	stable

According to the data presented in Table 4.3, the prepared base maintains its properties for a duration of five months under two different storage temperatures. These findings were corroborated by microbiological studies outlined in Table 4.4, conducted at the state institution, Institute of Microbiology and Immunology named after Mechnikov of the Medical Sciences of Ukraine, within the Laboratory of Biochemistry of Microorganisms and Media.

Table 4.4

Test results of extemporally prepared emulsion ointment base for microbiological purity

Preparation	**Microorganism Count: Logarithmic measure of growth degree as observed when cultured on a solid nutrient medium**			
	Method of deep drilling 1.0 g of the drug		*Method of surface drilling 1.0 g of the drug*	
	Nourishing agar 35 °C 3 days	*Saburo medium 25 °C 5 days*	*Nourishing agar 35 °C 3 days*	*Saburo medium 25 °C 5 days*
Ointment base	1,2±0,2	No growth of fungi	2,9±0,5	No growth of fungi

Notes: *n = 5; P = 95 %*

Research on stability remains ongoing. Future studies will prioritize enhancing methods for both qualitative and quantitative analyses of the base's components. Additionally, efforts will be directed towards designing technological guidelines and informational materials regarding the preparation of the base in pharmacies.

Conclusions to chapter 4

1. The formulation of an appropriate ointment base is governed by specific requirements and distinct characteristics. It must preserve the natural physiological functions of the skin, ensure adequate hydration of the absorption surface, among other essential considerations.
2. Following comprehensive technological, physical, and chemical analyses, the optimal formulation for the extemporaneous emulsion ointment base has been identified. This composition comprises Vaseline, Vaseline oil, cetostearyl alcohol, and purified water.
3. A systematic and efficient process for developing the extemporaneous emulsion ointment base has been established. The preparation methodology employs the technique of phase inversion, ensuring a rational approach to its formulation.

GENERAL CONCLUSIONS

1. The analysis and summary of literature data on the use of soft medicines reveal that ointments play a crucial role in treating skin diseases, with the transdermal route of medicine administration recognized as the safest method.
2. A study of the modern selection of soft medicines available in Ukraine's pharmaceutical market highlights that, despite the increasing variety of finished dosage forms, extemporaneous compounding remains significant and valuable.
3. Extemporaneous prescriptions for soft medicines in Kharkov pharmacies have been examined. Findings indicate that Vaseline or a Vaseline-lanolin combination is frequently utilized as the base in the preparation of these medicinal formulations.
4. The need to broaden the range of modern extemporaneous emulsion ointment bases has been substantiated.
5. A proposed formulation for an extemporaneous emulsion ointment base consists of Vaseline, Vaseline oil, cetostearyl alcohol, and purified water.
6. A rational technique for developing an extemporaneous emulsion ointment base has been devised, utilizing the method of phase inversion during its preparation.

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APPLICATIONS

Ф А 2.2.1–32-366

National University of Pharmacy

Faculty pharmaceutical
Department drug technology
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
"_02_" _May 2025

ASSIGNMENT
FOR QUALIFICATION WORK
OF AN APPLICANT FOR HIGHER EDUCATION

Mohammed FANCHANI

1. Topic of qualification work: «Development of the composition of the emulsion base for extemporaneous ointments », supervisor of qualification work: Marina BURYAK, associate professor of higher education institution of department pharmaceutical drugs technology, PhD, approved by order of NUPh from "31" of March 2025 № 81

2. Deadline for submission of qualification work by the applicant for higher education: October 2025.

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

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):
8 tables, 6 figures

6. Consultants of chapters of qualification work

Chapters	Name, SURNAME, position of consultant	Signature, date	
		assignment was issued	assignment was received
I Chapter	Marina BURYAK, assistant professor of higher education institution of department Pharmaceutical Technology of Drugs	11.05.2025	11.05.2025
II Chapter	Marina BURYAK, assistant professor of higher education institution of department Pharmaceutical Technology of Drugs	13.06.2025	13.06.2025
III Chapter	Marina BURYAK, assistant professor of higher education institution of department Pharmaceutical Technology of Drugs	29.08.2025	29.08.2025

7. Date of issue of the assignment: «_02_» _May_ 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.	May 2025	**done**
2.	Researches of active substances and excipients	May 2025 – June 2025	**done**
3.	Justification of the results	September 2025	**done**
4.	Registration of qualification work	October 2025	**done**

An applicant of higher education _____ Mohammed FANCHANI

Supervisor of qualification work _____ Marina BURYAK

ВИТЯГ З НАКАЗУ №81

По Національному фармацевтичному університету

від 31 березня 2025 року

Затвердити теми кваліфікаційних робіт здобувачам вищої освіти 5-го курсу першого циклу Фм21*(4,10д)англ-01 2025-2026 навчального року, освітньо-професійної програми – Фармація, другого (магістерського) рівня вищої освіти, спеціальності 226 – Фармація, промислова фармація, галузь знань 22 Охорона здоров'я, денна форма здобуття освіти (термін навчання 4 роки 10 місяців), які навчаються за контрактом (мова навчання англійська).

Прізвище, ім'я здобувача вищої освіти	Тема кваліфікаційної роботи		Посада, прізвище та ініціали керівника	Рецензент кваліфікаційної роботи
• **по кафедрі аптечної технології ліків**				
Фаншані Мохаммед	Розроблення складу емульсійної основи для екстемпоральних мазей	Development of the composition of the emulsion base for extemporaneous ointments	к.фарм.н. Буряк М.В.	д.фарм.н. Гриценко В.І.

Ректор

Вірно. Секретар

ФА28-03-317

ВИСНОВОК

експертної комісії про проведену експертизу

щодо академічного плагіату у кваліфікаційній роботі

здобувача вищої освіти

«24» листопада 2025 р. № 332691424

Проаналізувавши кваліфікаційну роботу здобувача вищої освіти ФАНШ АНІ Мохаммед, групи Фм21*(4,10д)-01, спеціальності 226 Фармація, промислова фармація, освітньої програми «Фармація» очної (денної) форми навчання на тему: «Розроблення складу емульсійної основи для екстемпоральних мазей /Development of the composition of the emulsion base for extemporaneous ointments», експертна комісія дійшла висновку, що робота, представлена до Екзаменаційної комісії для захисту, виконана самостійно і не містить елементів академічного плагіату (компіляції).

В.о. ректора НФаУ,
професор Олександр КУХТЕНКО

Ф А 2.2.1-32-353

REVIEW

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

Mohammed FANCHANI

on the topic: " Development of the composition of the emulsion base for extemporaneous ointments "

Relevance of the topic. Almost everyone has encountered skin problems. Acne and pimples, oily sheen, enlarged or blocked pores, blackheads, white subcutaneous "grains", vascular defects, skin peeling, pigmentation, etc. This list can be continued. But the only question that worries the owners of these defects is what to do to solve the issue of problematic skin. According to statistics in Ukraine, 85% of young people aged 12 to 25 and 11% over 25 have problem skin.

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 **Mohammed FANCHANI** 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 _____ Maryna BURYAK

03 October 2025

REVIEW

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

Mohammed FANCHANI

on the topic: " Development of the composition of the emulsion base for extemporaneous ointments "

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 **Mohammed FANCHANI** qualifying work meets the requirements and can be submitted for defense to the Examination Commission of the National Pharmaceutical University .

Reviewer _____ prof. Vita GRYTSENKO

10 October 2025

Ф А2.2.1-91-287

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ВИТЯГ З ПРОТОКОЛУ № _3_
«_27_» _жовтня_ 2025_
рокум. Харків

засідання кафедри
аптечної технології ліків
(назва кафедри)

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

ПРИСУТНІ:

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» Фаншані Мохаммед – з доповіддю на тему «Розроблення складу емульсійної основи для екстемпоральних мазей» (науковий керівник, доц. Марина БУРЯК).

УХВАЛИЛИ: Рекомендувати до захисту кваліфікаційну роботу.

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

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

Ф А2.2.1-32-042

НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ПОДАННЯ
ГОЛОВІ ЕКЗАМЕНАЦІЙНОЇ КОМІСІЇ ЩОДО ЗАХИСТУ КВАЛІФІКАЦІЙНОЇ РОБОТИ

Направляється здобувач вищої освіти Фаншані Мохаммед до захисту кваліфікаційної роботи за галуззю знань 22 Охорона здоров'я
спеціальністю 226 Фармація, промислова фармація
освітньо-професійною програмою Фармація
на тему: «Розроблення складу емульсійної основи для екстемпоральних мазей».

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____/ Олександр ГОНЧАРОВ /

Висновок керівника кваліфікаційної роботи

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

Керівник кваліфікаційної роботи

_____ Марина БУРЯК

«03» жовтня 2025 року

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Фаншані Мохаммед допускається до захисту даної кваліфікаційної роботи в Екзаменаційній комісії.

Завідувачка кафедри аптечної технології ліків

_____ Лілія ВИШНЕВСЬКА

«27» жовтня 2025 р.

Qualification work was defended

of Examination commission on

« 26» of November 2025
with the grade _____

Head of the State Examination commission,

Doctor of Pharmaceutical Sciences, Professor

_____/ Volodymyr YAKOVENKO /