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QUALIFICATION WORK

on the topic: « **ANALYSIS OF THE REQUIREMENTS OF PHARMACOPEIAS FOR THE PREPARATION INFUSION AND DECOCTION IN PHARMACIES** »

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ANNOTATION

This qualification work presents an analytical overview of the pharmacopoeial aspects of preparation of infusions and decoctions in pharmacies. It was found that in many pharmacopoeias (European, British, Italian, French, Czech, Kazakh) there are no instructions regarding the pharmacy technology of these dosage forms at all. Only the pharmacopoeias of Japan, Austria, Belarus and Russia contain separate monographs on the extemporaneous preparation of infusions and decoctions. Taking into account the data of the conducted analysis and the existing national requirements, a generalized approach to the preparation of infusions and decoctions in the conditions of pharmacies is proposed. The work is laid out on 52 pages, includes 6 tables, 47 literature sources.

Key words: pharmacopoeias, infusions, decoctions, extemporaneous technology, quality indicators

АНОТАЦІЯ

У даній кваліфікаційній роботі представлено аналітичний огляд фармакопейних аспектів приготування настоїв та відварів в умовах аптек. Виявлено, що в багатьох фармакопеях (Європейській, Британській, Італійській, Французькій, Чеській, Казахстанській) взагалі відсутні вказівки щодо аптечної технології даних лікарських форм. Лише фармакопеї Японії, Австрії, Білорусії та Росії містять окремі монографії з екстемпорального приготування настоїв та відварів. З урахуванням даних проведеного аналізу та існуючих національних вимог запропоновано узагальнено підходи щодо приготування настоїв та відварів в умовах аптек. Робота викладена на 52 сторінках, включає 6 таблиць, 47 джерел літератури.

Ключові слова: фармакопеї, настої, відвари, екстемпоральна технологія, показники якості

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INTRODUCTION

The study of the current state of the regulatory framework, which regulates the production activity of pharmacies, showed that Ukraine has a high level of legislative regulation of all branches of pharmaceutical activity. However, there are not enough scientific and methodical publications to solve more specific issues. For example, methodological recommendations on certain technological issues of extemporaneous formulation are extremely necessary for the daily work of pharmacists. In addition, issues regarding the approximation of the pharmacopoeia of Ukraine for pharmacy workers remain relevant, in particular, the updating of existing general monographs

The work presents an analytical review of the pharmacopoeial aspects of the preparation of extemporaneous dosage forms, namely infusions and decoctions in pharmacies.

The analysis of the prescription of extemporaneous medicines showed its dependence on the profile of the pharmacy, the specifics of the public service and the treatment and prevention institution. Therefore, it differs both in the types of dosage forms and in terms of purpose. The most common are liquid and soft dosage forms.

A comparison of the state of equipping pharmacies with means of mechanization showed that, at the current stage, modernization of equipment is necessary, which will increase labor productivity and free a person from performing difficult, time-consuming and tiring technological operations. Therefore, the analysis of the obtained results according to section 1 showed the relevance of scientific research that will contribute to the optimization of the production activity of pharmacies in Ukraine and the improvement of the quality of medical supplies.

The purpose of this work is to conduct a comparative analysis of pharmacopoeial requirements for the technology of making infusions and decoctions in pharmacies.

To achieve the set goal, it was necessary to solve a number of the following tasks:

- Learn information about the technology of infusions and decoctions of extemporaneous production;
- Investigate the requirements of world pharmacopoeias regarding the regulation of technology and approaches to quality assessment;
- Make a comparative analysis of the specified requirements.

The subject of research . Theoretical studies and analysis of world pharmacopoeias regarding the technology of making extemporaneous infusions and decoctions in pharmacy conditions

Research objects . Pharmacopoeia, monograph, article, pharmacy, extemporaneous form, infusions, decoctions, production technology, quality indicator.

Research methods . Theoretical, pharmaco-technological, systemic.

Practical significance of the obtained results . Data on the differences and similarities of various world pharmacopoeias regarding the extemporaneous production of infusions and decoctions in pharmacy conditions were identified and entered into the table.

Scientific novelty . For the first time, a comparative analysis of world pharmacopoeias was made regarding the production of extemporaneous medicinal forms , namely infusions and decoctions , in the conditions of a pharmacy.

Structure and scope of qualification work. The qualification work consists of an introduction, a literature review (Chapter 1), an experimental part (Chapters 2 and 3), general conclusions, a list of used literary sources, and appendices. The work is laid out on 53 pages, includes 11 tables, 6 figures, and 45 literature sources.

CHAPTER 1

INFUSIONS AND DECOTIONS AS MEDICINAL FORM

1.1. Characteristics of infusions and decoctions

Currently, complex multi-component, combined medicinal preparations are widely used as liquid medicinal forms, which are obtained by treating plant materials with water under a certain mode of infusion.

The purpose of obtaining aqueous extracts (extracts) is the production of a product containing biologically active components of plant material (alkaloids, glycosides, essential oils, tannins, etc.) [23] .

Along with active substances in hoods, there are always accompanying substances (sugar, starch, etc.). Some of the accompanying substances are pharmacologically indifferent, some are indirectly involved in the therapeutic activity of the extract, facilitating or slowing down the absorption of the active substance, and some of them are the cause of an unwanted side effect. Thus, the content of water extracts is quite complex and does not always lend itself to a full qualitative and quantitative assessment.

Depending on the method of preparation and composition, three groups of aqueous extracts are distinguished: infusions, decoctions, mucus.

Infusions and decoctions are liquid medicinal forms, which are aqueous extracts from medicinal plant raw materials, as well as aqueous solutions of dry or liquid extracts (concentrates) [14].

By physico-chemical nature, aqueous extracts are combined dispersed systems: a combination of true solutions or solutions of the Navy with colloidal solutions. Sometimes emulsified or suspended components pass into the hoods.

Water extracts are widely used in medical practice by themselves, as well as as components of medicinal preparations in the form of mixtures, rinses, lotions, washes, baths, inhalations.

The positive qualities of this dosage form include :

- the maximum therapeutic effect from the action of the complex of biologically active and accompanying substances contained in plant raw materials;
- prolongation of action;
- absence of side effect characteristic of many chemical substances;
– for some active substances contained in the plant material, no methods have been developed to isolate them in their pure form or the chemical structure has not been established, therefore they cannot be synthesized or obtained in any other way;
- ease of manufacture.

The negative qualities of water extracts include [4] :

– instability during storage (microbial, chemical, thermodynamic), which limits storage terms;
- non-standard extractions due to numerous factors affecting their quality during production;
- duration of cooking.

The process of extracting active substances from raw materials is very complex and consists of stages of swelling, formation of primary juice inside cells and mass exchange.

The process of extracting plant material is not a simple dissolution of the constituent parts of the plant. It should be considered as a series of physical and chemical processes that take place both inside the cell and on its surface. Along with the dissolution processes, diffusion, osmosis, adsorption, etc. occur. For extraction, dried material is most often used, in which, due to the loss of moisture, the volume of protoplasm decreases, and the cavities formed in the cell membrane are filled with air.

Swelling stage. In the first moments of contact with the extractant, cells of dry plant material swell. The duration of this process depends mainly on the histological structure of the plant material, on the degree of its grinding, as well as on the nature of the extractant. During the swelling of the cells, the air is displaced from them by

an extractant, which initially extracts both soluble and insoluble substances from the external, mostly destroyed cells [6].

The stage of primary juice formation inside the cells. Then the extractant penetrates through the insoluble membranes into the deeper cells and dissolves the substances contained in them, forming a concentrated solution with a significant osmotic pressure - "primary juice".

Stage of mass exchange. As a result of the high concentration of "primary juice" inside the cells, a significant osmotic pressure is created, which causes a diffusion exchange between the contents of the cells and the surrounding liquid with a lower osmotic pressure. This is the basis of the extraction process, which leads to the dilution of the formed concentrated solution with an extractant located outside the cells. This process of diffusion and osmosis takes place until equilibrium is reached, that is, the concentration of substances passing through the cell membrane is the same inside and outside the cells [25] .

At the same time, molecular and convective diffusion occur.

Molecular diffusion is the transfer of matter carried out due to the chaotic movement of molecules, which depends on the reserve of kinetic energy of particles (molecules). The speed of molecular diffusion depends on the extraction temperature (when it increases, the speed of movement of molecules increases), the size of the surface that separates the substances, and the thickness of the layer through which diffusion takes place. Finally, the movement of matter requires a certain time (the longer diffusion lasts, the greater the amount of matter moves from one medium to another).

Factors affecting the completeness and speed of extraction of active substances. The dynamics of the extraction process, and therefore the quality of infusions and decoctions, are affected by the following factors: the ratio between the amount of raw materials and the extractant; raw material standard; histological structure of raw materials; degree of grinding of raw materials; the material of the used equipment; temperature and time of infusion; influence of enzymes and microflora; chemical composition of active substances; pH of the medium.

The ratio of the amount of raw materials and extractant. Infusions and decoctions can be prescribed in recipes in different ways:

1. The amount of raw plant material and the volume of water extract are indicated. Example:

Rp.: Infusi herbae Hypericiex 10.0 - 200 ml

Yes. Signa: For mouthwash.

According to this prescription, it is necessary to prepare 200 volume parts of infusion from 10 parts by weight of St. John's wort.

2. Only the hood volume is indicated. In this case, the doctor gives the right to the pharmacist to decide on the amount of plant material in accordance with the instructions.

If the amount of medicinal plant raw materials from the general list is not specified in the recipe, infusions and decoctions are prepared in a ratio (1:10). Example:

Rp.: Infusi herbae Leonuri 200 ml

Yes. Signa: 1 tablespoon 3 times a day.

In this case, it is necessary to prepare 200 volume parts of infusion from 20 parts by weight of nettle grass.

An infusion of St. John's wort grass, rhizomes with valerian roots is prepared at a ratio of 1:30 (according to DF X, aqueous extracts of sedum, lily of the valley, celandine root, senegal, blueberry, dog soap, sea onion tubers are prepared in the same ratio).

Extracts from medicinal plant raw materials containing potent substances (thermopsis herbs, digitalis leaves, etc.) are prepared according to a doctor's prescription, and in the absence of instructions on the amount of raw materials - in a ratio of 1:400 and mainly from extracts-concentrates [26] .

To obtain full-fledged extracts, it is necessary to use the maximum amount of water possible under the given conditions, because the doctor indicates the amount (volume) of the finished extract in the recipe, and not the water necessary for its preparation. At the same time, it should be taken into account that part of the liquid

after extraction is always retained (absorbed) by the plant material, so the finished extract is less than the amount of water that was taken. To obtain the required amount of extract, it is necessary to add water, which leads to a partial dilution of the infusion or decoction. This is undesirable, because the loss of active substances is proportional to the amount of liquid that remains in the raw material. By squeezing the raw material, these losses can be slightly reduced, but it is impossible to completely get rid of them, because under the influence of capillary forces, part of the extract will always remain irreversibly in the plant material. In addition, water loss occurs due to evaporation and wetting of the walls of the funnel. In this regard, for the production of water extracts, it is advisable to take a little more water than is necessary according to the recipe of the finished extract.

The amount of water absorbed depends on the histological structure and the degree of crushing of the raw material. Therefore, it is necessary to use individual coefficients of water absorption by raw materials [27] .

The water absorption coefficient (Kv) shows the amount of liquid retained by 1.0 g of plant raw materials of a standard degree of grinding after it has been squeezed in a perforated infuser glass.

For the most frequently used types of raw materials, Kv are given in the DF XI, as well as in the order of the Ministry of Health of Ukraine No. 197 of 09.07.93 (see Appendix 3). If Kv is not specified, it is recommended to use generally accepted coefficients: for roots - 1.5; bark, flowers and herbs - 2.0; seeds - 3.0.

Thus, the amount of water required for making an infusion or decoction is determined by summing up the volume of the extract specified in the recipe and the additional amount of water, which is calculated by multiplying the mass of the raw material by the water absorption coefficient.

For example, to obtain 200 ml of infusion from the nettle grass, you need to take: 200 + (20.0 * 2) = 240 ml of water.

This additional amount of water significantly improves the process of extracting active substances and increases their content in prepared infusions and

decoctions, and the more difficult active substances dissolve in water, the better the effect of adding water.

However, when making hoods taking into account the water absorption coefficient, their volume still turns out to be slightly smaller, therefore, according to DF XI, water is added to the filtered hood after squeezing the raw materials through the same raw materials to the volume prescribed in the recipe [24].

The amount of water required to obtain the extract cannot be reduced, as this will lead to a decrease in the extraction of active substances from the raw materials. Therefore, in multi-component prescriptions of liquid medicinal forms containing aqueous extracts and powdery substances, in the case of preparation of infusions and decoctions from plant raw materials, concentrated solutions of salts cannot be used.

Standardity of raw materials. The composition and concentration of aqueous extracts, the strength and nature of their effect on the body depend on the raw material and, in particular, on the content of active substances in it. The amount of the latter in the plant material varies depending on the conditions and zoning of the plants, the time of collection, the drying regime and other factors. Raw materials that meet the requirements of NTD are called standard. Medicinal raw materials must be delivered to pharmacies with an indication on the packaging label of the content of active substances in percentages or biological activity in units of action (U) [17] .

According to the DF, only standard or raw materials with a high content of active substances and increased biological activity can be used for obtaining water extracts.

In this case, it is necessary to recalculate non-standard raw materials.

For example, the pharmacy received thermopsis grass with a content of 2.5% of alkaloids (the standard of raw materials according to DF is 1.5%), then according to the given recipe:

Rp.: Infusi herbae Thermopsidis ex 0.5 - 200 ml

Yes. Signa: 1 tablespoon 3 times a day. it is necessary to take 0.3 g of thermopsis grass instead of 0.5 g.

It is unacceptable to use raw materials that contain less active substances than prescribed by the DFU, because this leads to obtaining aqueous extracts with an increased content of accompanying substances, which are cloudy and less stable during storage.

Histological structure of raw materials. The speed of extraction largely depends on the structure of cell membranes, which is a significant obstacle to the passage of the extractant, and to a greater degree, the thicker and denser they are. If the cell membrane is very dense, the cell tissue is not loose enough, and there are few intercellular passages and channels, then the extraction proceeds more slowly. The composition of the cell membrane is also of great importance. The skeleton of cellular tissue consists of cellulose. The cellular tissue of many plants is impregnated with cutin, cerine and lignin, which make it difficult to wet the cellulose. Pectins, which are impregnated with cell membranes, swell under the influence of cold water, and form hydrosols in boiling water. The presence of other hydrophobic and hydrophilic substances in the plant material also delays extraction [6] .

When making water extracts, the choice of the method of extraction of plant material is usually determined by its histological structure. Infusions are usually prepared from loose raw materials (flowers, leaves, herbs), decoctions from dense ones (bark, roots, rhizomes). Exceptions: roots with rhizome of valerian (prepare infusion), leaves of plantain, senna, lingonberry (decoctions).

The degree of grinding of plant material. To obtain water extracts, plant raw materials are used in dried, crushed and sifted form. Grinding of plant raw materials is caused by the need to facilitate the penetration of the solvent into the thickness of the material, which has a cellular structure of different anatomical structures and contains an unequal amount of hydrophilic substances that improve the wettability of the raw materials.

With an increase in the degree of grinding of plant raw materials, the surface of its contact with the extractant increases, which facilitates its penetration into the cells, and therefore, the extraction process itself is accelerated.

However, very fine grinding turns out to be irrational in practice. Fine powder clumps together more easily, and with a significant content of pectin substances, mucus and starch in it, the dissolution and swelling of these substances is facilitated and lumps are formed (due to the adhesion of mucus cells), which settle to the bottom of the vessel. All this greatly slows down the extraction process. In addition, with an increase in destroyed cells, the process of leaching increases, which leads to obtaining a cloudy extract, which is more susceptible to spoilage [8] .

According to DF X, it was accepted to grind leaves, flowers, and herbs to 5 mm, leaves of milkweed, eucalyptus, lingonberry, and other leathery leaves to 1 mm; stems, bark and roots - up to 3 mm; fruits and seeds - up to 0.5 mm. The size of the particles of corn cobs should be no more than 10 mm.

However, for each type of plant material, the optimal degree of grinding must be established, which ensures the completeness and speed of extraction of active substances.

Therefore, the DF indicates that plant raw materials must be crushed in accordance with the requirements of NTD (that is, the degree of crushing of certain types of raw materials must be specified in their own articles). The optimal size of raw material particles should not exceed 7 mm. For example, St. John's wort grass - 7 mm, senna leaves - 7 mm, viburnum bark - 7 mm, lingonberry leaves, milk thistle, swamp shoots - 3 mm, eucalyptus leaves - 5 mm, alder fruit - 10 mm. For crushing plant raw materials from all known principles (crushing, cutting, grinding, splitting, grinding, etc.), the following are most often used in pharmacies: cutting (for herbs, leaves, roots) using herb or root cutters, crushing and grinding in a mortar (for seeds and fruits). As a rule, raw materials arrive in pharmacies already crushed, or cut and pressed or briquetted, which is the most optimal, because pieces of raw materials pressed by rollers do not contain air inside .

1.2. Technological features of preparation of infusions and decoctions in a pharmacy

At including in DF and in the official catalog new medicinal plants authors often give technology infusions and decoctions, which differs from general

technologies. To be honest , by individual technology are cooking water extracts with renal tea herbs lamb, birch mushroom and etc. [5, 8, 34] .

Infusion leaf renal tea (orthosiphon) are cooking in ratios 3.5:200. 3.5 Mr raw materials, chopped to 5 mm, pouring 200 Jr boiling water (K_V = 2.0) and insist in warm place for 30 minutes Then hood strain, raw materials squeeze out and prove volume to 200 Jr. Apply at swelling, violations functions kidney, at cholecystitis on 0.5 glasses 2 times in day by 30 minutes to food

Broth herbs lamb are cooking in ratios 10.0:200. 10.0 Mr herbs lamb, chopped to particles not more 5 mm, are placed in co l b u pouring 220 Jr water, boil on weak o m u the lights 15 minutes Then liquid cooling down _ raw materials wring- eat filtered and prove water to 200 Jr. Extract has yellowish-greenish color, bitter taste and grassy scent. They keep in refrigerator not more 2 days Apply for treatment alcoholism and psoriasis By 3–15 minutes to the patient give 3–5 ml of alcohol inside and except that sniff alcohol. Sometimes this procedure re- rush to onset vomiting reaction. They keep according to the list B.

Broth flowers delusion are cooking in ratios 10.0:100. 10.0 Mr chopped flowers delusion pouring 120 Jr hot water and heat up to boiling. Then insist during _ 1–2 hours at room temperature filtered and prove to 100 Jr. Broth are kept in glass dishes in cool place not more 3–5 days

Apply as expectorant means at diseases respiratory ways, and yes oh _ at diseases the stomach of a vegetable tract as antiphlogistic and hemostasis he means.

Broth wolfhound field are cooking in ratios 30.0:500. 30.0 Mr chopped roots wolfhound field pour 1000 Jr of water and boil until 500 ml is obtained. Then hood strain, squeeze out and prove water to necessary the volume of _ Broth are kept in cool place in closed dishes not more 3–5 days

Apply the main way at hemorrhoids for normalization bowel movements (weakening) and reduction was in pain

Infusion birch mushroom are cooking in ratios 1:5. Washed birch mushroom with purpose softening pouring small quantity boiled water, leave on 4 hours, after what mushroom grind on meat grinders or are rubbed on grater On one by the way

part chopped mushroom add 5 voluminous parts boiled water (temperature not above 50 °C), insist for 48 hours, after what liquid drain , remainder squeeze out and to received liquid add water in in which soaked mushroom. Broth are kept not more 4 days Apply as symptomatic means, what improves in some cases well-being patients with different tumors

Broth fruit of virgins cherries are cooking in ratios 1 :200. one st of tin lo zhk u hanging - shenih fruits cherries ordinary grind to particles not more 0.5 mm They pour 200 Jr a heap of barley water and they are boiling for 20 minutes, after what hood filtered _

Infusion herbs mothers are cooking in ratios 1 0.0:200. 10.0 Mr herbs mothers , chopped to values particles 0.5 mm and pouring 220 Jr boiling water , insist 15– 20 minutes at room tempera t uri , filter _ squeeze _ and are drinking in warm the cry of the lady .

Infusion fruits rose hips are cooking in ratios 20.0:400. 1) 20.0 Mr trivial-them fruits rose hips pouring a glass boiling water boil in closed enamelled- mu dishes prot i go m 10 minutes, then insist 22–24 hours and filtered; 2) 20.0 Mr n crushed pl o div rose hips z a lyv a yu t t d v o m a glasses boiling water in boil _ in closed therefore enameled dishes for 10 minutes, insist 2–3 hours and filtered

To special cases technologies water hoods refers to also made by *me multicomponent infusions and decoctions* , what most often is author's prescriptions If in them connect species raw materials, what contain one and that same group biologically active _ substances , it doesn't matter from guest o logical b u dova vyt yazhk u are cooking it 's too early reply _ one to requirements DF XI.

Example, double infusion by by name " **mixture Apartment** »:

Rp. : Infusion i radicibu s V aleriana e e x 10.0

Infusi foliorum Menthae ex 4.0 – 200 Jr

Caffeini-natrii benzoate 0.4

Analgini 0.6

Natrii bromide 3.0

Magnesii sulfates 0.8

Misc. Yes. Signs: On 1 canteen spoons 3 times on day.

Hood are cooking simultaneously in one infusers, ago what both species raw materials contain ethereal oil water take: 200 + (10.0 * 2.9) + (4.0 * 2,4) = 238.6 = 239 Jr. After proving infusion to given volume dissolve prescribed the ingredients and infusion filtered in flak on for vacation

If prescribed hood from raw materials, what requires different regime infusion, hoods are cooking separately with the maximum quantity water, but not smaller 10 times more how many o'clock concerning raw materials with taking into account coefficient in additional absorption .

Rs.: Infusi radicis Althaeae ex 10.0

Infusi herbae Leonuri ex 20.0

Infusi foliorum Farfarae ex 20.0

Decocti cortex Viburni ex 25.0 – 1000 Jr

Misc. Yes. Signs: On 2 dining room spoons 4 times on day.

IN given case must b ut used 3 modes infusion: maceration at room temperature for the root althaea, infusion from herbs dog nettles and leaf under white and broth to ory viburnum, prepared by general rules

Tom in number water share on 3 parts:

– for Althea root infusion : 200 Jr * 1.3 = 260 ml;

– for decoction bark viburnum: 250 Jr + (25.0 * 2) = 300 ml;

– for infusion grass _ dog nettles and leaf under white: 1000 Jr – (200 + 250) + (20.0 * 2.9) + 20.0 * 2) = 648 Jr.

General volume multicomponent water hoods should to fold 200 + 250 + 550 = 1000 Jr.

IN pharmacy practice known number author's prescriptions water hoods , what represent by myself about the bottom - or many components _ _ _ in days hoods with add in _ different medical substances _ Yes , for example mix tour of Wojciechovo , Deryagin , _ Smolensk _ shark oh Schmidt , in these are new whose lying infusion the root in Alerians in different ratios; mix t hurray Ravkina , what contains infusion herbs dog nettles and medical substances soothing Fr character _

However meet and complex multicomponent hoods, as antiasthmatic mixture Traskova, composed with leaf nettles and mint pepper, herbs horsetail field and g orytsvit u, fruits anise and rose hips, needles pine trees with adding medical substances or more more difficult mixture Zdrenko, which is being prepared with two meetings, what contain in amount 34 species vegetable raw materials , and others

Infusions and decoctions you can prepare not only with medical vegetable raw materials, but and by dissolution specially prepared relevant extracts- concentrate t and c.

Extracts-concentrates – it special group extracts, the main thing appointment whose consists of in volume in , in order to serve weekend material for production pharmacy them hoods (infusions and decoctions). By consistency they they can b ut liquid and dry

Liquid extracts (Extracta fluida standartisata) is usually prepared in ratios 1:2. They are cooking concentrates in factory conditions by extraction raw materials are weak alcohol (20–40%) special in ways what give possibility obtaining full compliance hoods by quantity active substances water infusion or take off , open to me with defined quantity raw materials in pharmacy conditions

dry extracts (Extract sicca standardized) receive careful steam by liquid and in eating in them on a full- time basis: mo lo chnog o sugar in dext rin or their with in the bag to correlation active substances 1:1 or 1:2.

Pharmaceutical industry releases concentrates liquid: valerian 1:2, dog nettles 1:2, goritsvit 1:2; dry: Altai the root 1:1, goritsvit 1:1, thermopsis 1:1, to onv aliya 1:1, digitalis 1:1.

They maximum cleaned, are close by accompanying substances and standardized on determined contents active substances

Extracts-concentrates fine dissolve in water with education transparent solutions Using their in conditions pharmacies accelerates process production medicines Extracts- concentrates stable and comfortable at storage and transportation, their application releases from necessity storage vegetable raw materials

However near with certain advantages application concentrates has and negative a hundred wounds

Some dry you concentrate hygroscopic, at storage they often dehydrate what violates correctness dosage and makes it difficult weighing. For elimination this deficiency and stabilization extracts suggested method microencapsulation with using as shells derivatives cellulose, air force, i.e the film forms a sneeze substances

Infusions, prepared with extracts-concentrates and directly with vegetable raw- we often have external divergence by intensity color and degree about- stars, especially infusions with the root altea and althea extract-concentrate dry (1:1). IN patients these divergence _ cause _ with the money of correctness production _ medicines , ago at vacation infusions, prepared with concentrates, is recommended do on recipes or signature appropriate mark in in order to at repetition medicines they can be prepare lazy those the same the way what and the first once in

In accordance to instructions DF XI at manufacturing infusion or decoction by calculated nana extract him take in quantity what responds quantity vegetable raw materials, specified in recipes

Cooking _ infusions with extracts-concentrates responds technologies liquid drugs from dry and liquid medical means IN this case others medical substances they can to be added as in dry in the form of Yes and in in the form concentrated solutions

dry extract - concentration _ _ _ _ _ trace rest t k u to dissolve in water and only after this mix- cotton wool with concentrated solutions of salt At direct mixing concen- dug up solutions of salt from dry extracts-concentrates possible falling out sediment or formation muddy (salting out extractive substances).

Rs.: Infusi radicis Althaeae ex 5.0 – 100 Jr

Natrii benzoate

Elixirs pectoralis a a 1.5

Misc. Yes. Signs: On 1 dessert spoons 2 times on day.

Mixture, what contains infusion with the root is altea, fine soluble in in the day substances in – sodium benzoate , and I smell liquid – December _ elixir, what requires special conditions addition _ _ _

At manufactured _ infusion from su hogo ex t rac tu- concentration r a tu altea, the last little sweat take 5.0 g, what makes up more 3% in volume medical forms Tom in necessary taking into account you coefficient magnification volume, what for su hogo extract altea is equal to 0.61 (see addition 3).

Then number water cleaned will be 100 – (5 □ 0.61) = 97 ml, and if use concentrated solution sodium benzoate (1:10), then 100 – (5 □ 0.61) – (1.5 * 10) = 82 Jr.

In the stand measure 82 Jr cleaned water, dissolve 5.0 g dry (1:1) ext- raktu-concentrate altea, filtered in bottle for vacation and add measured on burette installation concentrated solution sodium benzoate (1:10) 15 Jr. Then by special rules, about which it was said before (see page 214), add pectoral elixir and make out to vacation

For preparation infusions and decoctions with liquid extracts-concentrates instead specified in in writing quantity vegetable raw materials take double (by volume) number extract-concentrate. liquid extracts-concentrates trace introduce after dilution water concentrated solutions salt, in order to avoid formation sediment Tom in their they add as and galena drugs, in the last queue in flak on for vacation (see page 223).

Rp.: Infusi rhizomatis cum radicibus

Valerianae ex 5.0 – 200 Jr

Caffeini-natrii benzoate 0.6 Tinctureae Convallariae 5 Jr

Misc. Yes. Signs: On 1 canteen spoons 3 times on day.

Opalescent mixture, to composition which come in infusion from raw materials, what contains ethereal oils, and soluble in water substance – caffeine benzoate sodium, what refers to to list B. IN flak on for vacation measure 184 Jr hello _ _ 6 Jr 10% order _ caffeine - benzoate _ n atrium (1 : 10), 10 Jr this extract is this concentrate valerian rare _ (1 :2) and 5 Jr tinctures to onv aliya .

Conclusions to section 1

1. Infusions and decoctions (lat. *infusion et decocta*) — liquid dosage forms, which are aqueous extracts from LRS, as well as aqueous solutions of dry or liquid extracts-concentrates.
2. Decoctions (Decoctum) are made mainly from the dense parts of the plant by heating the water-filled raw materials in a water bath for 30 minutes. Infusions (Infusum *)* are made mainly from soft parts of plants, as well as from raw materials that contain volatile and substances that are destroyed by prolonged heating, by heating in a water bath for 15 minutes.
3. After the end of heating, water extracts are cooled at room temperature: infusions — for at least 45 minutes, decoctions — for 10 minutes. When preparing water extracts from LRS with a volume of 1000–3000 ml, the duration of heating in a water bath increases to 25 min for infusions, up to 40 min for decoctions; cooling time remains the same (45 and 10 min, respectively).
4. The following factors affect the quality of water extracts: the ratio between the amount of raw materials and the extractant; raw material standard; histological structure of raw materials; degree of grinding of raw materials; used equipment; temperature and time of infusion; influence of enzymes and microflora; chemical composition of active substances, pH of the environment. If the amount of LRS is not specified in the recipe, infusions and decoctions are prepared in a ratio of 1:10.

SECTION 2
RESEARCH OBJECTS AND METHODS

Each one country in own pharmacopoeias installed different norms production medicines , own nomenclature medicines, certain requirements to substance and vegetable raw materials . Development international cooperation, tourism creates certain inconvenience, when there is a need to use and purchase medicines on the territory of other countries . Therefore, the need to create an International Pharmacopoeia became urgent. Preparation for her edition started in 1865 p. on the first International pharmaceutical Congress in Brunswick.

This an idea developed on the following such forums To creation International Pharmacopoeia joined and World organization protection health (WHO), which for it was founded in 1947 by a committee of experts.

In 1950, at the third meeting of the WHO, it was official approved the first edition International pharmacopoeias – "Pharmacopeia Internacional Edito prima", the first which volume came out in 1951 in English, French, and later in Spanish. The second edition of the International Pharmacopoeia appeared in 1967, and the third – in 1979 p. Position International pharmacopoeias, on difference from national pharmacopoeia , have recommended and not legislative character _

2.1. Research objects

State Pharmacopoeia of Ukraine and

The pharmacopoeial article includes provisions on the manufacture of drugs and determination of their quality, the largest single doses of drugs are determined, and requirements for drugs are established. They are approved only for objects of serial production, which are allowed for medical use and are included in the State Register of Medicinal Products of Ukraine .

of the State Pharmacopoeia of Ukraine was published in 2001, four additional volumes were published in 2004, 2008, 2009 and 2011, respectively, in Ukrainian and Russian languages. The State Pharmacopoeia of Ukraine II edition in Ukrainian was published in 2015, and from January 1, 2017, supplement No. 1 to the II edition

entered into force. The State Pharmacopoeia of Ukraine is almost completely harmonized with the European Pharmacopoeia .

Pharmacopoeia of the Republics and Belarus

The norms related to the State Pharmacopoeia of the Republic of Belarus are contained in the Law of the Republic of Belarus dated July 20, 2006 N 161-З "On Medicinal Products".

The State Pharmacopoeia of the Republic of Belarus 1st edition in 3 volumes was published in 2007-2009. The pharmacopoeia of the Republic of Belarus is almost completely harmonized with the European pharmacopoeia. The structure of most pharmacopoeial articles contains a general part based on the requirements of the European Pharmacopoeia and a national part based on the requirements of the legislation of the Republic of Belarus.

On January 1, 2013, the first volume of the State Pharmacopoeia of the Republic of Belarus II edition was put into effect, and in 2015, the second volume of the State Pharmacopoeia of the Republic of Belarus II edition was published.

Pharmacopoeia of the Republics and Kazakhstan

The provisions establishing the status of the State Pharmacopoeia of the Republic of Kazakhstan are established in the Code of the Republic of Kazakhstan dated September 18, 2009 N 193-IV "On the health of the people and the health care system".

The State Pharmacopoeia of the Republic of Kazakhstan 1st edition was published in 2008-2009 in two volumes in Ukrainian and Russian, in 2014 the third volume of the 1st edition of the State Pharmacopoeia of the Republic of Kazakhstan was published. The pharmacopoeia of the Republic of Kazakhstan is almost completely harmonized with the European pharmacopoeia. The structure of most pharmacopoeial articles contains a general part based on the requirements of the European Pharmacopoeia and a national part based on the requirements of the legislation of the Republic of Kazakhstan.

In 2015, the first volume of the II edition of the State Pharmacopoeia of the Republic of Kazakhstan was published.

International and regional pharmacopoeias

The first volume of the first edition of the International Pharmacopoeia [en] (English: The International Pharmacopoeia) was published in 1951, the second volume — in 1955. In 2006, the 4th edition was published in 2 volumes. In 2008, it was republished together with the first supplement. The international pharmacopoeia is used by countries that do not have their own (national) pharmacopoeias.

The European Pharmacopoeia (English: European Pharmacopoeia; German: PhEur, Europäisches Arzneibuch) contains norms that apply in the territory of the European Economic Region, issued on behalf of the Council of Europe and valid in most European countries.

2.2 . Research methods

These include: analysis, synthesis, abstraction, idealization, generalization, induction, deduction, analogy, modeling, systematic approach, probabilistic (statistical) methods.

Analysis is the division of the object into its constituent parts for the purpose of their independent study. Types of analysis are mechanical separation; definition of dynamic composition; identification of forms of interaction of elements of the whole; finding the causes of phenomena; identifying the level of knowledge and its structure, etc. A type of analysis is the division into classes and subclasses of subjects - classification and periodization. A rigorous analysis is a serious guarantee of the logical presentation of the research material. Hypothetical analysis is carried out using deduction. A deductive premise allows you to develop a certain version of the causal chain that explains the consequences. The opposite is synthesis.

Synthesis – the method of studying the object in its integrity, in the single mutual connection of its parts. Synthesis allows you to generalize concepts, laws and theories. The results of the experiment are summarized with the help of synthesis. In theoretical sciences, synthesis acts as a union of competing, to a certain extent, opposite theories in the form of building deductive theories. One of the forms of

synthesis is the method of going from the abstract to the concrete - a way of building theoretical knowledge about the composition of developing objects.

Analysis and synthesis are interconnected and embody the unity of opposites.

Types of analysis and synthesis:

- the direct (empirical) method is used to select individual parts of the object;
- the reverse (element-theoretical) method is based on ideas about the cause-and-effect relationships of various phenomena;
- a structural-genetic method of extracting from a complex phenomenon such elements that create a decisive influence on the remaining sides of the object.

A systematic approach is a set of general scientific methodological principles (requirements), based on the consideration of objects as systems. These requirements include:

a) detection of the dependence of each element on its place and functions in the system, taking into account the fact that the properties of the whole cannot be reduced to the sum of the properties of these elements;

b) analysis of the extent to which the behavior of the system is determined both by the features of its individual elements and by the properties of its structure;

c) study of the mechanism of interaction between the system and the environment;

d) studying the nature of hierarchy inherent in this system;

e) provision of a comprehensive multi-aspect description of the system;

g) consideration of the system as a dynamic, developing integrity.

Abstraction – a method that allows moving from specific issues to general concepts and laws of development; consists in a significant distraction from non-essential properties, connections, relations, objects and in the simultaneous allocation and fixation of certain aspects of these objects that interest the researcher.

There are different *types of abstractions* :

- identification abstractions;

- isolating abstraction;
- abstraction of actual infinity;
- abstraction of potential feasibility.

Abstractions also differ in level (order). Abstractions from real objects are called first-order abstractions; abstractions from abstractions of the first level - second order, etc. Philosophical categories are characterized by the highest level of abstraction.

Generalization is a method of scientific knowledge, with the help of which general signs and properties of a certain class of objects are fixed and the transition from singular to general, from less general to more general is carried out. General is a philosophical category that reflects similar, repeated features and signs belonging to several single phenomena or all subjects of a given class, and singular expresses the specificity, originality of this particular phenomenon (or group of phenomena of the same quality), its difference from others.

Induction is a method of scientific knowledge during which the transition from individual facts to general propositions (hypotheses) is carried out. Induction operates on a set of incomplete facts and draws a conclusion based on them. which surely follows without making any guarantees as to its truth. Despite this, induction makes it possible to acquire new knowledge that is not obvious when considering the original statements. Examples of inductive inferences are, for example, the following observation/conclusion pairs: This swan is white. All swans are white.

Deduction - a research method that makes it possible to reach partial and isolated conclusions by means of an analysis of general provisions and facts. The conclusion should be based solely on the previously provided evidence, and should not contain new information about the subject under investigation. An example of a deductive conclusion: "All metals are electrically conductive. Iron is a metal. Therefore, iron is electrically conductive." The essence of deduction is the use of general scientific provisions for the study of specific phenomena.

In the process of cognition, induction and deduction are inextricably linked, although one of them prevails at a certain level of scientific research. When

summarizing empirical material and putting forward a hypothesis, induction is the leading method. In theoretical knowledge, deduction is important first of all, which allows you to logically organize experimental data and build a theory based on the logic of their interaction. With the help of deduction, the research is completed.

Analogy - a method of scientific research, thanks to which knowledge of some objects and phenomena is achieved on the basis of their similarity with others.

Analogy requirements:

1. the analogy should be based on essential features and a larger number of common properties;
2. the connections between the compared features must be close;
3. analogy, as a method, should show not only the similarity of objects, but also the difference between them.

The method of analogies, applied to the similarity of indicators, objects and phenomena, is the basis of modeling.

Modeling – a method of cognition, which consists in replacing some object with another object (model) that has similar properties. The modeling method is one of the methods of indirect cognition. Modeling is always a comparison of the known with the unknown by analogy.

Model (French " *modffle* " and " *modello* "):

1) sample;

2) reproduction of the object in a reduced or enlarged form;

3) the subject of an invention in art, a model, a model posing in front of the artist;

4) in foundry - a sample of the object to be cast;

5) a geometric drawing that gives a visual representation of some physical object or process.

Models are analogues whose similarity to the original is significant, and the discrepancy is minimal. The more fully the model reflects the original, the more the model research results will correspond to the results of the research object. A model is a source of information about an object and helps to explain, understand or

improve this object. Models are divided into two types: material and ideal. Material models are embodied in a certain material - wood, metal, glass, polymer products, etc. Ideal models are fixed in such visual elements as a drawing, drawing, graphic image, diagram, computer program, etc.

Stages of the modeling method:

a) setting the task;

b) definition of analogue;

c) creation or selection of a model;

d) design development;

e) model research;

e) transferring knowledge from the model to the original.

The main functions of the models:

- cognitive;

- pragmatic.

Modeling as a method is used together with other methods, often with an experiment and is called a model experiment.

Concretization (from the Latin " *concretus* " "thick", "solid") is a method of studying objects in all their versatility, in the qualitative versatility of real existence, in contrast to the abstract study of objects. At the same time, the state of objects is investigated in connection with certain conditions of their existence and historical development.

System analysis is the study of the research object as a set of elements that make up the system. In scientific research, it involves evaluating the behavior of the object as a system with all the factors that affect its functioning. This method is widely used in scientific research during the comprehensive study of the activities of industrial associations and the industry as a whole, determining the proportions of the development of economic sectors, etc.

Graphical method - visual presentation and presentation of statistical data and their correlations using geometric signs (sets of points, lines, surfaces) and other graphic means for the purpose of their generalization and analysis. With the help of

graphs, the composition and dynamics of phenomena, as well as the interrelationships between them, are studied more deeply. This method plays an especially important role in statistical research, where the complex interrelationships of socio-economic phenomena and processes in the movement of dynamic indicators, as well as the complex interweaving of connections in space, are studied.

Probabilistic statistical methods are based on taking into account the action of a multitude of random factors, which are characterized by a stable frequency. Probabilistic methods are based on the theory of probability, which is often called the science of randomness, and in the opinion of many scientists, probability and randomness are practically inseparable. In the laws of the dynamic type, predictions have a precisely defined unambiguous character. In statistical laws, predictions are not reliable, but probabilistic in nature. The latter, although they do not give unambiguous and reliable predictions, are nevertheless the only possible ones in the study of mass phenomena of a random nature. Probability-statistical methods are widely used in the study of mass phenomena - especially in such scientific disciplines as mathematical statistics, statistical physics, quantum mechanics, synergetics, etc.

Conclusions to section 2

1. The objects of research , which were used in the analysis of world pharmacopoeias, were determined.

2. Research methods have been chosen that allow obtaining complete and reliable results.

SECTION 3.
ANALYSIS OF THE WORLD PHARMACOPEIAS REGARDING REQUIREMENTS FOR THE PREPARATION OF INTENSES AND DECOTIONS

3.1. The role of the State Pharmacopoeia in the general system of ensuring and controlling the quality of medicinal products in Ukraine.

According to the Law of Ukraine "On Medicinal Products", Article 2, the State Pharmacopoeia of Ukraine is a legal act that contains general requirements for medicinal products; pharmacopoeial articles (monographs), as well as methods of quality control of medicinal products. The pharmacopoeia has a legislative nature, that is, its requirements are mandatory for all enterprises and institutions of Ukraine that manufacture, store, control, sell and use medicinal products. It establishes the level of requirements for the quality of medicines that the state guarantees to its citizens.

Citizens or organizations can compare these requirements with the requirements of the Pharmacopoeia of other countries, draw appropriate conclusions and take appropriate actions. DF is a compromise between the state and society (as consumers) striving for the maximum quality of pharmaceuticals and the real capabilities of the national industry, capable of ensure quality.

Legal basis for the creation and implementation of the DFU March 19, 1997 Resolution of the Cabinet of Ministers No. 244 "On measures for the phased implementation in Ukraine of the requirements of European Union directives, sanitary, environmental, veterinary, phytosanitary norms, and international and European standards" December 29, 1997 Ukraine is an observer in the European Pharmacopoeia. March 14, 1998. Technical task of the Pharmacopoeia Committee of the Derzhko-Medbioprom for the development of DFU. 06/11/1998 Decree of the President of Ukraine No. 615/98 "On approval of the strategy of Ukraine's integration into the European Union". 12.06.98 Resolution of the Cabinet of Ministers of Ukraine No. 852 "On the implementation of the mechanism of

adaptation of the legislation of Ukraine to the legislation of the European Union". April 5, 2000 Plan of measures to ensure the implementation of the strategy of Ukraine's integration into the European Union for the year 2000: Decree of the Prime Minister No. 26402/23, section 1, subsection 2, item 9 for the development in 2000 of the SFU, harmonized with European Pharmacopoeia. 03/12/01 Order of the Minister of Health No. 95 "On the Approval and Implementation of the State Pharmacopoeia" The SFU is put into effect from 10/01/01 07/11/01 Order of the Minister of Health No. 281 "On the Implementation of the State Pharmacopoeia of Ukraine, 1st edition".

The SFU affects the interests of various population groups and organizations: consumers, producers, regulatory and expert bodies, educational institutions, etc.

The interests of the SFU industry are an open instrument of industry influence on the requirements for the quality of pharmaceuticals, the legal basis and relations with the registering and controlling bodies, since the requirements of the SFU are also mandatory for them. That is why in developed countries these structures are clearly separated from the SFU (although their employees can participate in the development of the Pharmacopoeia). 54 The introduction of the principles of proper production practice is impossible without increasing the requirements for the quality of pharmaceuticals. The introduction of new methods and requirements to the DFU also creates a need for new equipment, which contributes to the development of the production of analytical and technological equipment.

That is why, for example, a significant part of the requirements of the European Pharmacopoeia was inspired by industry. The interests of the expert and control bodies of the State Federal University of Ukraine are the legislative basis for all other regulatory documents that regulate the quality of pharmaceuticals, the legal basis for the work of expert and control bodies. The SFU regulates the requirements for the content of analytical regulatory documentation, the procedure for conducting tests, preparation and use of reagents, solution titration, etc. The SFU protects expert and control bodies from unfounded accusations of subjectivism.

Expertise. If the MCQ corresponds to the SFU, if the MCQ requirements are found to be insufficient for objective control of the quality of drugs, it is difficult to make claims to the expert. In this case, the responsibility rests with the applicant who did not provide the necessary materials for the examination. If the MKY does not correspond to the SFU, in case of any complications with the LZ data, the responsibility rests with the expert. CONTROL. The SFU is the main tool of the regulatory bodies and gives them significant rights. All MKY must be in accordance with the DFU. If the drug corresponds to the MCQ, but the MCQ itself does not correspond to the DFU, then the drug should still be rejected for non-compliance with the DFU.

For example, there is no "Mechanical inclusions" section required by the Federal State Administration of Medicines in the MKY for an injectable drug. Such a drug should still be checked for compliance with this section and, in case of non-compliance, be deficient. The State Inspectorate for Quality Control of Medicinal Products may allow the use of medicinal products that do not meet any requirements of the Federal Drug Administration (or the Ministry of Health), but in this case it assumes responsibility for all possible consequences of such use.

The main provisions and principles that are given in the SFU The main principles that form the basis of the State Pharmacopoeia of Ukraine:

1. The State Pharmacopoeia of Ukraine (SPU) must be fully harmonized with the European Pharmacopoeia (EP).

2. The level of requirements of the SFU may not be lower than the requirements for medical devices adopted within the framework of the Interstate Commission for Standardization, Registration and Quality Control of Medicinal Products, Medical Products and Medical Equipment of the CIS member countries (ie, to preserve for domestic enterprises the possibility of exporting to the CIS countries).

3. DFU can take into account the real capabilities of the domestic pharmaceutical industry and the quality control system.

4. The SFU can take into account the discrepancy in the quality systems of enterprises that work and do not work under GMR conditions.

5. HFU can be a non-controversial and self-sufficient document.

The pharmacopoeia, including the DFU, contains the following sections:

1. General remarks.

2. Methods of analysis.

3. Equipment.

4. Physical and physicochemical methods.

5. Identification.

6. Testing for the limit content of impurities.

7. Methods of quantitative determination.

8. Biological tests.

9. Biological methods of quantitative determination.

10. Pharmaco-technological tests.

11. Reagents.

12. Monographs

13. General articles on dosage forms and substances

Adapted translation of relevant material of the European Pharmacopoeia. National part: additional tests, informational and other materials This scheme of construction of general articles and monographs is adopted in other pharmacopoeias, in particular, in the British Pharmacopoeia.

Legal status of DFU. The State Pharmacopoeia of Ukraine (SPU) is a legal act that contains general and separate pharmacopoeial articles that establish general requirements for the quality of medicinal products, as well as methods of their control (Law of Ukraine "On Medicinal Products"). According to Clause 5 "Regulations on state registration of normative legal acts of ministries, other executive authorities, economic management and control bodies affecting the rights, freedoms and legitimate interests of citizens or having an interdepartmental nature", approved by Resolution of the Cabinet of Ministers of Ukraine dated 28.12.92 No. 731 (as amended from 15.06.94 No. 420 and from 16.10.98 No. 1640), acts of a

regulatory and technical nature (state standards, building regulations and rules, tariff and qualification guides, reporting forms, etc.) are not submitted for state registration.).

The DFU consists of pharmacopoeial articles, which, according to the Law of Ukraine "On Medicinal Products", are regulatory and technical documents. Therefore, this act is not subject to state registration in the Ministry of Justice in accordance with the Decree of the President of Ukraine dated 03.10.92 No. 493 "On State Registration of Regulatory Acts of Ministries and Other Executive Authorities" (as amended No. 493/98 dated 21.05.98) and may be applied without state registration" (letter of the Ministry of Justice No. 33-28-1664 dated 15.06.01). The legal status of the DFU, reflected in the DFU. The State Pharmacopoeia of Ukraine has a legislative character, its requirements for medicinal products are mandatory for all enterprises and institutions of Ukraine, regardless of their form of ownership, which manufacture, store, control, sell and use medicinal products.

With the entry into force of the State Pharmacopoeia of the USSR, the XI edition of the State Pharmacopoeia of the USSR as the main regulatory document regulating the control and quality of medicinal products has lost its force in Ukraine.

The status of monographs of the DFU. Both parts of general articles and monographs of DFU - European and national - have the same force. The requirements of the national part do not apply to medicinal products that are produced under the conditions of GMR recognized in the European Community ("Introduction").

In the event that the production of the medicinal product is not carried out in accordance with the requirements of good manufacturing practice (GMP) established in the European Community, this medicinal product is subject to alternative requirements specified in the national part of the article, which is indicated immediately after the line ("General remarks ").

In the event that a substance of a certain manufacturer has a Certificate of Conformity to the monograph of the European Pharmacopoeia or a similar permit of an authorized body, its quality can be controlled directly by the corresponding

monograph of the DFU. In the rest of the cases, the quality of substances is controlled according to the Ministry of Internal Affairs, approved by the authorized body. The level of the requirements of the Ministry of Education and Culture should not be lower than the requirements of the corresponding monograph of the Federal University of Ukraine.

Peculiarities of using the DFU monograph

Section production . According to the EF, all medicinal products must be manufactured under GMP conditions. The products described in the Pharmacopoeia can be manufactured in accordance with the requirements adopted in Ukraine. This phrase from the national part makes it possible to bypass the EF requirement.

Property section . If the product described in the monograph does not have an EF or DFU Certificate of Conformity, the information given in this section, in the absence of other instructions, represents the requirements, with the exception of the information given in parentheses ("General remarks"). According to the EF, the section "Properties" ("Description", "Solubility") has an informational, optional character. However, this applies only to those substances that are produced under the terms of GMR. For other substances (and they are still the majority in Ukraine), the requirements of this section are mandatory .

1.2. Analysis of world pharmacopoeias

In modern medical practice, drugs of plant origin occupy an important place, the share of which in the pharmaceutical market of developed countries reaches more than 50%.

Of course, to date, herbal preparations cannot completely replace therapy with drugs of synthetic origin, but they can find effective use in the treatment of various diseases.

However, for the full use of herbal preparations in medical practice, it is necessary to be clearly aware of the fact that the standardization of LRS and the technology of manufacturing phytopreparations is an important condition for their effective use [14, 16].

In this matter, an important document for standardizing manufacturing technology and quality indicators is the State Pharmacopoeia or other normative legal acts. It is worth noting that infusions and decoctions are one of the oldest LF, which does not lose its importance due to its mild effect on the body, high bioavailability and relatively simple technology. These are liquid LF, which are aqueous extracts from LRS, as well as aqueous solutions of dry and/or liquid extracts-concentrates [15].

They are widely used in medical practice both by themselves and as part of complex drugs in the form of mixtures, rinses, lotions, washes, baths, inhalations, etc. The purpose of obtaining hoods is the production of easy-to-use RLF and the maximum complete separation of BAR from raw materials. The main factors affecting the speed and completeness of the release of active substances include: degree of grinding of raw materials; the ratio between the amount of raw materials and the volume of the finished hood; raw material standard; histological structure of raw materials; temperature and time of infusion; influence of enzymes and microflora; chemical composition of active substances; pH of the medium.

The purpose of this is to conduct a comparative analysis of pharmacopoeial requirements regarding the technology of making infusions and decoctions in pharmacies.

To date, there is no monograph "Infusions and decoctions made in pharmacies" at the Federal University of Ukraine. Their production in pharmacies is regulated by the order of the Ministry of Health of Ukraine No. 197 dated 07.09.1993 and the guideline " Requirements for the manufacture of non-sterile medicinal products in pharmacies" (approved by the order of the Ministry of Health of Ukraine No. 398 dated 07.01.2015).

Thus, there was an urgent need to develop a project of a general pharmacopoeial article "Infusions and decoctions made in pharmacies". For this purpose, we analyzed the European, British, Italian, French, Czech, Austrian, Japanese, Belarusian, Kazakhstani, and Russian pharmacopoeias [13, 14, 22, 23, 25].

Based on the analysis of this information, it was found that in the pharmacopoeias where the specified article is present, the definition of this dosage form differs. Their analysis is presented in table. 3.8.

Table 3.1

Comparative analysis of the definitions of the dosage form "Infusions and decoctions" according to the monographs of world pharmacopoeias

The name of the pharmacopoeia	Definition
DF XI "Infusions and decoctions", RF XIII "Infusions and decoctions"	"Infusions and decoctions are liquid LF, which are aqueous extracts from LRS, as well as aqueous solutions of dry and liquid extracts (concentrates)." Medicinal substances, syrups, tinctures, liquid extracts can be added to aqueous extracts, and if necessary, permitted preservatives
Belarusian pharmacopoeia "Infusions and decoctions"	"Infusions and decoctions - freshly prepared aqueous extracts from LRS, collections, herbal teas", as well as "Aqueous solutions of dry or liquid extracts (concentrates) for internal and external use"
Japanese Pharmacopoeia " Infusions and Decoctions"	"Infusions and decoctions are liquid preparations obtained, as a rule, by the method of maceration of medicinal raw materials in water"
European Pharmacopoeia "Herbal teas, instant"	"Instant herbal teas consist of one or more herbal preparations (primarily extracts with or without the addition of essential oils) and are intended for preparation of a solution for ingestion immediately before consumption. May also contain, in addition to vegetable raw materials, auxiliary substances, such as fillers (maltodextrin) and flavorings"

As we can see, from the data presented in the table. 3.8, approaches to determining infusions and decoctions as LF are different. Analysis of pharmacopoeias showed that the article "Infusions and Decoctions" was included in all editions of the Russian Pharmacopoeia, starting with the first (1866).

It should be noted that in the early editions of the pharmacopoeia, in addition to general articles, there were also separate articles on infusions and decoctions of various types of LRS [25].

Starting with the 10th edition (1968), separate articles on specific infusions and decoctions were excluded from the pharmacopoeia. The general article on these LF, regardless of the development of analytical and pharmaceutical chemistry, in all editions of the pharmacopoeia, up to XI, represented specific instructions on the manufacturing technology (extraction conditions, filtering, etc.).

Described in the first edition, they were carried over to subsequent editions with minor additions. In the general pharmacopoeial articles, there were no quality indicators, even organoleptic characteristics of water extracts were not indicated.

According to the Russian Pharmacopoeia, starting from 1936 (DF VIII) and until now, infusions and decoctions are made according to the same technological scheme: LRS raw materials are poured with water at room temperature, infused in a boiling water bath for 15 min (infusions) or 30 min (decoctions), then it is kept for 45 minutes (infusions) or 10 minutes (decoctions) at room temperature and filtered [23].

In the Belarusian Pharmacopoeia, the article on the manufacture of infusions and decoctions in pharmacies was transferred from the Russian Pharmacopoeia XI edition in the same edition.

Analysis of the European Pharmacopoeia showed that there is no monograph on "Infusions and decoctions" in it. But in the EF, in the "General monographs" section, three general articles are presented: "Medicinal herbal remedies", "Medicinal herbal raw materials" and "Medicinal herbal teas".

These articles summarize the definitions of plant raw materials, medicinal products based on them, requirements for their production, conducting tests for

identification, purity and quantitative determination. These articles are listed in full in the edition of the European Union in the British, Italian, Czech and Kazakh pharmacopoeias.

There is no general article on "Infusions and Decoctions" in the US Pharmacopoeia either, but in the "General Chapters" section there is an article on "Vegetable drugs", where the sampling method and a number of pharmacognosy methods (external impurities, total ash, etc.). The list of monographs includes articles on a specific LRS.

In the Japanese Pharmacopoeia, in the "General Notes" section, there is an article "General rules for crude drugs" ("General rules for crude drugs"), which includes a list of raw materials of plant and animal origin, as well as an article "Infusions and Decoctions" [235].

The article describes the general requirements for the size of LRS and the production of infusions and decoctions. So, according to the requirements of the Japanese Pharmacopoeia: leaves, flowers and whole plants - coarsely dispersed particles (Coarsecutting); woody stems, bark, roots and rhizomes – moderately fine cutting; seeds and fruits - small particles.

According to the requirements of the pharmacopoeia, infusions are made by adding 50 ml of purified water to 50.0 g of LRS, followed by infusion for 15 minutes, after which 900 ml of hot water is added and heated for 5 minutes, stirring. The resulting infusion is filtered.

As for making decoctions, the daily dose of LRS is poured into 400-600 ml of purified water and heated for 30 minutes while stirring, then filtered. The obtained infusions and decoctions are packaged in tightly closed containers.

The French Pharmacopoeia of the 10th edition has a general article "Medicinal plant raw materials", which differs in its wording from the EF, but here, too, the concept of plant raw materials and general requirements for its quality control are only briefly stated. Unfortunately, there is no information on the manufacture of drugs from LRS [27].

The Austrian Pharmacopoeia (Österreichisches arzneibuch) contains three general articles that regulate the production of infusions and decoctions, namely: Infusa "Aufgusse", Decocta "Abkochunge", Macerata "Mazerate" [22].

In the articles, special attention is focused on preliminary preparation of raw materials, the degree of grinding is determined in a separate item. Yes, leaves, flowers, grass are sifted through sieve I (hole size - 8000 μm), woody plants, bark, roots, Icelandic lichen, Irish algae - through sieve II (hole size - 6000 μm), fruits, seeds, plants , containing alkaloids, blueberry leaves - through sieve IV (hole size - 750 μm), plants containing saponins, cardiac glycosides - through sieve V (hole size - 300 μm).

The articles also state that before making the infusion and decoction, LRS is soaked for 5 minutes in a mortar with a small amount of water.

If the raw material contains alkaloids in its composition, citric acid is added during preliminary processing in an amount equal to the alkaloid content. When using the bark of the cinchona tree, dilute hydrochloric acid is added in the amount of 0.5 ml per 1.0 g of the drug.

To make infusions and decoctions, crushed LRS is placed in a porcelain infuser and infused in a water bath: decoction - 30 minutes, and infusion - 5 minutes, the decoction is not cooled, and the infusion is cooled at room temperature for 30 minutes. The ratio of raw materials and extractant is also clearly regulated. It is 1:10 for the entire LRS. The article notes that the ratio of raw materials and extractant, as well as the degree of grinding, can be changed only on the doctor's orders.

Slimes are prepared in the ratio of 5 parts by mass of raw materials per 100 ml of purified water.

In the articles, it is also mandatory to note that the prepared infusions, decoctions and slimes must be marked with the label "Shake before use".

In this way, analyzing the technological process of preparation of infusions and decoctions, we observe that the ratio of LRS and extractant and regimes. The summarized data are given in table. 3.3. in the conditions of pharmacies" (approved by the order of the Ministry of Health of Ukraine dated July 1, 2015 No. 398).

Table 3. 3

Comparative analysis of the ratio of components, modes of infusion of infusions and decoctions according to monographs of world pharmacopoeias

Indicator	**Pharmacopoeia**		
	Japanese	*Austrian*	*Russian*
Preliminary preparation of LRS	Regulates the degree of grinding	Regulates the degree of grinding, before preparing LRS, it is soaked in a mortar for 5 minutes with a small amount of purified water	Regulates the degree of grinding
The ratio of LRS: extractant	Infusions: 1:1, followed by the addition of 900 ml of hot water; decoctions: the daily dose of LRS is poured with 400-600 ml of purified water	1:10	Depending on the chemical composition of LRS
Mode of infusion	Infusions: 15 minutes at room temperature, 5 minutes in a water bath; decoctions are heated for 30 minutes, stirring	Infusions: 5 min in a water bath, 30 min cooled at room temperature; decoctions : infuse for 30 minutes in a water bath, do not cool	Depending on the volume, up to 1000 ml; infusions: 15 minutes in a water bath, cool at room temperature for 45 minutes; decoctions: 30 minutes in a water bath, cool at room temperature for 10 minutes

The main approaches to the technology of infusions and decoctions in

pharmacies are given in table. 3. 4.

Table 3.4

Technological principles of extemporaneous production of infusions and decoctions

Indicator	Description
Basic technological instructions	The calculated amount of crushed LRS is poured into a metal/porcelain funnel and filled with a certain volume of water. Decoctions are infused in a boiling water bath under the lid for 30 minutes, infusions - 15 minutes. After that, they are filtered (decoctions - after 10 minutes, and infusions - after 45 minutes), the residue is squeezed and added to hoods. Prepared infusions/decoctions are brought to the prescribed volume with boiled water. Infusions are cooled for at least 45 minutes (because in most cases, API extraction does not end during heating, but continues even when the infusion cools). The necessity of filtering decoctions after 10 min of cooling is explained by the fact that the colloidal solutions contained in LRS and passing into the decoctions increase their viscosity and slow down filtering. Infusions are prepared mainly from above-ground LRS (leaves, flowers, grass), decoctions - from underground (roots, rhizomes, bark). If the volume of the water extract exceeds 1000-3000 ml, the heating time in the water bath increases for infusions to 25 minutes, and for decoctions - to 40 minutes. if the composition of infusions/decoctions includes other substances (salts, syrups, tinctures, extracts), then they are added to filtered infusions/decoctions; salts should be only in dry form, because their addition in the form of concentrated solutions leads to dilution of extracts.
Special cases of preparation of infusions and decoctions	Decoctions from the leaves of the common milkweed, the root of the Tangut Rhubarb, the rhizome of the Perstache erectus, the bark of the oak and other LRS containing tannins, should be filtered immediately after removing from the water bath; decoctions of senna leaves are filtered after complete cooling; in the case of "cito", infusion is carried out in a water bath for 25 minutes, and then the infusion is cooled artificially (with water or ice).
Expiration date	The storage period in a cool place is no more than 3 days.

Appendix B (mandatory) provides instructions on the manufacture of liquid medicinal products in pharmacies, which clearly regulates the technological process of preparing infusions and decoctions.

Conclusions to section 3

1. Each country has its own national characteristics of drug production in pharmacies, which is due to traditions, the difference in conditions and the level of development of the pharmaceutical industry. Due to the mentioned reasons, in the pharmacopoeias of different countries, the questions regarding the definition of ELZ technology are not covered for all LFs.
2. In each state, in accordance with the existing legislation, the concept of quality of ED is formed, taking into account its traditional extemporaneous prescriptions, equipment of production pharmacies, existing problematic issues, etc.
3. It was found that with regard to the extemporaneous production of infusions and decoctions, only the pharmacopoeias of Japan, Austria, Belarus and Russia contain separate monographs on this drug.

GENERAL CONCLUSIONS

1. Infusions and decoctions (lat. infusa et decocta) are liquid dosage forms, which are aqueous extracts from LRS, as well as aqueous solutions of dry or liquid extracts-concentrates.
2. Each country has its own national characteristics of drug production in pharmacies, which is due to traditions, the difference in conditions and the level of development of the pharmaceutical industry. Due to the mentioned reasons, in the pharmacopoeias of different countries, the questions regarding the definition of ELZ technology are not covered for all LFs.
3. In each state, in accordance with the existing legislation, the concept of quality of ED is formed, taking into account its traditional extemporaneous prescriptions, equipment of production pharmacies, existing problematic issues, etc.
4. It was found that with regard to the extemporaneous production of infusions and decoctions, only the pharmacopoeias of Japan, Austria, Belarus and Russia contain separate monographs on this drug.

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Ф А 2.2.1–32-366

National University of Pharmacy

Faculty for foreign citizens' education
Department Technology of Drugs

Level of higher education master

Specialty 226 Pharmacy, industrial pharmacy
Educational program Pharmacy

APPROVED
The Head of Department
Technology of Drugs
_Tatyana YARNYKH
"_28_" _September_ 2022

ASSIGNMENT
FOR QUALIFICATION WORK
OF AN APPLICANT FOR HIGHER EDUCATION

Youssef LANOUARI

1. Topic of qualification work: «Analysis of the requirements of pharmacopeias for the preparation infusion and decoction in pharmacies», supervisor of qualification work: Tatyana YARNYKH, DSc, prof.,

approved by order of NUPh from "1" of September 2022 № 197-ст

2. Deadline for submission of qualification work by the applicant for higher education: April 2023.

3. Outgoing data for qualification work: The purpose of this work is to conduct a comparative analysis of pharmacopoeial requirements for the technology of making infusions and decoctions in pharmacies.

4. Contents of the settlement and explanatory note (list of questions that need to be developed): Learn information about the technology of infusions and decoctions of extemporaneous production; Investigate the requirements of world pharmacopoeias regarding the regulation of technology and approaches to quality assessment; Make a comparative analysis of the specified requirements..

5. List of graphic material (with exact indication of the required drawings):
3 tables, 4 figures

6. Consultants of chapters of qualification work

Chapters	Name, SURNAME, position of consultant	Signature, date	
		assignment was issued	assignment was received
I Chapter	Tatyana YARNYKH, head of department, professor of higher education institution of department drug technology	28/09/2023	28/09/2023
II Chapter	Tatyana YARNYKH, head of department, professor of higher education institution of department drug technology	28/09/2023	28/09/2023
III Chapter	Tatyana YARNYKH, head of department, professor of higher education institution of department drug technology	28/09/2023	28/09/2023

7. Date of issue of the assignment: «_28_» _September_ 2022

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.	September – November 2022	**done**
2.	Researches of active substances and excipients	December 2022 – February 2023	**done**
3.	Justification of the results	March 2023	**done**
4.	Registration of qualification work	April 2023	**done**

An applicant of higher education _____ Youssef LANOUARI

Supervisor of qualification work _____ Tatyana YARNYKH

ВИТЯГ З НАКАЗУ № 35
По Національному фармацевтичному університету
від 06 лютого 2023 року

нижченаведеним студентам 5-го курсу 2022-2023 навчального року, навчання за освітнім ступенем «магістр», галузь знань 22 охорона здоров'я, спеціальності 226 – фармація, промислова фармація, освітня програма – фармація, денна форма здобуття освіти (термін навчання 4 роки 10 місяців та 3 роки 10 місяців), які навчаються за контрактом, затвердити теми кваліфікаційних робіт:

Прізвище студента	Тема кваліфікаційної роботи		Посада, прізвище та ініціали керівника	Рецензент кваліфікаційної роботи
• **по кафедрі технології ліків**				
Лануарі Юссеф	Аналіз вимог фармакопей щодо приготування настоїв та відварів в умовах аптек	Analysis of the requirements of pharmacopoeias for the preparation of infusions and decoctions in pharmacies	проф. Ярних Т.Г.	проф. Хохленкова Н. В

Підстава: подання декана, наказ ректора

Ректор

Вірно. Секретар

Ф А2.8-47-110

ВИСНОВОК

Комісії з академічної доброчесності про проведену експертизу

щодо академічного плагіату у кваліфікаційній роботі

здобувача вищої освіти

№ 113674 від « 25 » травня 2023 р.

Проаналізувавши випускну кваліфікаційну роботу за магістерським рівнем здобувача вищої освіти денної форми навчання Лануарі Юсеф, 5 курсу, _____ групи, спеціальності 226 Фармація, промислова фармація, на тему: «Аналіз вимог фармакопей щодо приготування настоїв та відварів в умовах аптек/ Analysis of the requirements of pharmacopeias for the preparation of infusion and decoction in pharmacies», Комісія з академічної доброчесності дійшла висновку, що робота, представлена до Екзаменаційної комісії для захисту, виконана самостійно і не містить елементів академічного плагіату (компіляції).

Голова комісії,
професор **Інна ВЛАДИМИРОВА**

2%
15%

Ф А 2.2.1-32-353

REVIEW

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

Youssef LANOUARI

on the topic: "Analysis of the requirements of pharmacopoeias for the preparation of infusions and decoctions in pharmacies"

Actuality of theme. The study of the current state of the regulatory framework, which regulates the production activity of pharmacies, showed that Ukraine has a high level of legislative regulation of all branches of pharmaceutical activity. However, there are not enough scientific and methodical publications to solve more specific issues. For example, methodological recommendations on certain technological issues of extemporaneous formulation are extremely necessary for the daily work of pharmacists. In addition, issues regarding the approximation of the pharmacopoeia of Ukraine for pharmacy workers remain relevant, in particular, the analysis of existing general monographs

Practical value of conclusions, recommendations and their validity. The research carried out by the acquirer will allow systematization of information on the requirements of various pharmacopoeias for the production of infusions and decoctions in pharmacies.

Evaluation 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. Qualification work of Youssef LANOUARI completed at the appropriate scientific level and can be submitted for defense to the Examination Commission of the National Pharmaceutical University.

Scientific supervisor _____ Tatyana YARNYKH

12 April 2023

Ф А 2.2.1-32-356

REVIEW

for qualifying work for qualifying work for the degree of higher education master, specialty 226 Pharmacy, industrial pharmacy

Youssef LANOUARI

on the topic: "Analysis of the requirements of pharmacopoeias for the preparation of infusions and decoctions in pharmacies"

Actuality of theme. The work presents an analytical review of the pharmacopoeial aspects of the preparation of extemporaneous dosage forms, namely infusions and decoctions in pharmacies.

The analysis of the prescription of extemporaneous medicines showed its dependence on the profile of the pharmacy, the specifics of the public service and the treatment and prevention institution. Therefore, it differs both in the types of dosage forms and in terms of purpose. The most common are liquid and soft dosage forms.

A comparison of the state of equipping pharmacies with means of mechanization showed that, at the current stage, modernization of equipment is necessary, which will increase labor productivity and free a person from performing difficult, time-consuming and tiring technological operations. Therefore, the analysis of the obtained results according to section 1 showed the relevance of scientific research, which will contribute to the optimization of the production activity of pharmacies in Ukraine and increase the quality of extemporaneous medicinal products .

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.

The author's proposals on the research topic. Based on the analysis of literature data and the conducted theoretical experiment, the author analyzed the requirements of world pharmacopoeias for infusions and decoctions.

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

Disadvantages of work. The work contains unfortunate expressions, spelling and grammatical errors.

General conclusion and evaluation of the work. The composition and content of Youssef LANOUARI qualifying work meets the requirements and can be submitted for defense to the Examination Commission of the National Pharmaceutical University .

Reviewer _____ Proff. Natalia KHOKHLENKOVA

28 April 2023

Ф А2.2.1-91-287

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ВИТЯГ З ПРОТОКОЛУ № _11_
«28» квітня 2023 року
м. Харків

засідання кафедри
___технології ліків___

Голова: завідувачка кафедри, доктор фарм. наук, професор Тетяна ЯРНИХ
Секретар: канд. фарм. наук, асистент Світлана ОЛІЙНИК

ПРИСУТНІ: професор Тетяна ЯРНИХ, професор Олександр КОТЕНКО, професор Юлія ЛЕВАЧКОВА, професор Ріта САГАЙДАК-НІКІТЮК, доцент Марина БУРЯК, доцент Володимир КОВАЛЬОВ, доцент Наталія ЖИВОРА, асистент Світлана ОЛІЙНИК, асистент Єлизавета ЗУЙКІНА

ПОРЯДОК ДЕННИЙ

1. Про представлення до захисту до Екзаменаційної комісії кваліфікаційних робіт здобувачів вищої освіти.

СЛУХАЛИ: проф. Тетяну ЯРНИХ – про представлення до захисту до Екзаменаційної комісії кваліфікаційних робіт здобувачів вищої освіти.

ВИСТУПИЛИ: Здобувач вищої освіти 5 курсу групи Фс18(3,10д) спеціальності 226 Фармація, промислова фармація Лануарі Юсеф з доповіддю на тему «Аналіз вимог фармакопей щодо приготування настоїв та відварівв умовах аптек» (науковий керівник: професор закладу вищої освіти Тетяна ЯРНИХ).

УХВАЛИЛИ: Рекомендувати до захисту кваліфікаційну роботу.

Голова
Завідувачка кафедри, проф. _____ **Тетяна ЯРНИХ**
(підпис)

Секретар
асистент _____ **Світлана ОЛІЙНИК**
(підпис)

Ф А2.2.1-32-042

НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ПОДАННЯ
ГОЛОВІ ЕКЗАМЕНАЦІЙНОЇ КОМІСІЇ ЩОДО ЗАХИСТУ КВАЛІФІКАЦІЙНОЇ РОБОТИ

Направляється здобувач вищої освіти Юсеф ЛАНУАРІ до захисту кваліфікаційної роботи за галуззю знань 22 Охорона здоров'я
спеціальністю 226 Фармація, промислова фармація
освітньою програмою Фармація
на тему: «Аналіз вимог фармакопей щодо приготування настоїв та відварівв умовах аптек».

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____/ Світлана КАЛАЙЧЕВА /

Висновок керівника кваліфікаційної роботи

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

Керівник кваліфікаційної роботи

_____ Тетяна ЯРНИХ

«12» квітня 2023 року

Висновок кафедри про кваліфікаційну роботу

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

Завідувачка кафедри технології ліків

_____ Тетяна ЯРНИХ

«28» квітня 2023 року

Qualification work was defended

of Examination commission on

« ___» of June 2023

With the grade _____

Head of the State Examination

commission, DPharmSc, Professor

_____/ Oleh SHPYCHAK /