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## **THE PHARMACO-TECHNOLOGICAL STUDIES OF THE TABLET SOLID DOSAGE FORM FOR THE TREATMENT OF OTOLARYNGOLOGICAL DISEASES**

**Key words:** tablets; solid dosage form; pharmaco-technological characteristics; otolaryngological diseases

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## **ФАРМАКОТЕХНОЛОГІЧНІ ДОСЛІДЖЕННЯ ТВЕРДОЇ ЛІКАРСЬКОЇ ФОРМИ У ВИГЛЯДІ ТАБЛЕТОК ДЛЯ ЛІКУВАННЯ ОТОЛАРИНГОЛОГІЧНИХ ЗАХВОРЮВАНЬ**

**Ключові слова:** таблетки; фармакотехнологічні показники; отоларингологічні захворювання

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The prevalence of acute respiratory diseases, the particular severity of their course, as well as the frequent relapses and complications require constant search for new, more effective and safe medicines for their prevention and treatment and introduction of these drugs into clinical practice. Generally, most of the medications used in the treatment of acute respiratory viral infections have a number of side effects, and it is especially dangerous with their prolonged administration.

Modern therapy with antibiotics, which is considered to be the most effective and affordable, has led to the emergence of new resistant strains of various microorganisms over the past decade. In this connection, the creation of natural medicines, in particular of plant origin, with the antimicrobial and bactericidal properties is a topical problem of pharmaceutical technology [1].

Currently, one of the promising areas of pharmacy is the study of biologically active substances, the medicinal plant raw material, and production of extracts and herbal medicines based on them. In recent decades, the value of the application of medicinal plants has immeasurably grown in the pharmaceutical industry. The advantage is their low toxicity, long-term use without the possibility of significant side effects, and their high therapeutic activity [2].

Based on the results of the analysis of literature sources conducted we used clary sage (*Salvia sclarea* L.) leaves growing in Tajikistan as the medicinal plant raw material for further development of a pharmaceutical product for otorhinolaryngology application.

**The aim** of this study is to develop the composition and technology, as well as to perform the pharmaco-technological studies of the tablet solid dosage form obtained on the basis of a thick extract of clary sage with the antimicrobial effect. Bentonite clays of the Tajik deposit were also studied in the present work.

Among a variety of solid dosage forms, tablets that are easy to use, and the most convenient in transportation and storage are considered to be the most common for the treatment of otorhinolaryngological diseases. Another advantage of tablets is efficiency of their production, the possibility of accurate dosing and combination of several medicinal substances in one dosage form [3, 4].

At the initial stage of developing the composition and technology of tablets it was necessary to obtain and standardize the biologically active substance in the form of a thick extract of clary sage. Based on the previous studies on the selection of the type and concentration of the extractant, temperature and time parameters of extraction the optimal technological mode of extraction was determined.

It should be noted that in the step of development of the solid dosage form an important element is the choice of excipients. In this work, we used the method of mathematical planning of the experiment, which allowed establishing the relationship between the composition of the tablet mass and the main pharmaco-technological parameters. In order to select the most appropriate excipients, the quality of tablets was studied according to the requirements of the European Pharmacopoeia (EP) and the State Pharmacopoeia Ukraine (SPhU) (appearance, uniformity of mass, resistance to crushing, tablet friability, disintegration, solubility, etc.) [5, 6].

For the optimal solution of the technology for tablet production it seems important to study the relationship between the physicochemical and volumetric-technological properties of tablet masses, the rationale for approaches to the selection of excipients and the technology for the tableting process.

Excipients in tablet production are intended to give the tablet mass the necessary technological properties that provide the dosage accuracy, mechanical strength, disintegration and stability of tablets during storage.

Bentonite clays are compounds of natural origin, which have been successfully used in the technology of pharmaceuticals for several decades.

It has been experimentally found that when developing solid dosage forms bentonite clays play a dual role. They act as an excipient, as well as have a number of pharmaco-technological properties as an active pharmaceutical ingredient with high adsorption properties.

To obtain the tablet mass with definite pharmaco-technological properties, dextrose monohydrate and finely dispersed bentonite clay were used as fillers. Bentonite clay upon wetting have the ability to adsorb a significant amount of liquid, swell and increase in volume, contributing to loosening. Due to this, the compressed particles are separated, opening up the possibility of penetration of the liquid into tablets [7].

Bentonite clays and talc belong to the class of layered silicates, in which the layers are connected to each other by the residual Van-der-Waals forces, the weakest of all chemical bonds. Such a bond and a high dispersion of particles contribute to sufficient glide, and therefore, the choice of bentonites in combination with aerosil as antifriction components seems to be most appropriate.

Studies by some authors concerning the tableting technology issues indicate the advantage of the wet granulation process [8]. Most powdered substances are exposed to this processing method. In this regard, 5% bentonite solution was used as a granulating liquid.

## Materials and methods

The objects of the study were experimental samples of tablets based on a thick extract from clary sage leaves. The plant materials were collected in the flowering phase of the plant from the Varzob region of Tajikistan in June of 2019. A thick extract of clary sage leaves was obtained by percolation [9]. The concentration of the thick extract in the experimental samples was 0.025 g, and it was confirmed by the data of scientific literature.

Vitamin C, dextrose monohydrate, magnesium stearate, lactose monohydrate, microcrystalline cellulose, 96% ethanol and purified water satisfied the requirements of the EP and SPhU.

Tajik bentonite met the requirements of the pharmacopoeial monograph 42 Tj – 0007-03.

Thick extract folio salvia sclarea of the pharmacopoeial monograph Tj 23-0020-19.

Granulation: «YK-60» apparatus (China) with a manual spray.

Mixing: a laboratory mixer granulator of VG 65/10 type.

Drying: «DHG-9053A» apparatus (China). Intake air temperature: 55–60 °C.

The residual moisture content of the product:  $\leq 0.5\%$ .

The residual moisture measurement: «SARTORIUS MA-150» at 105 °C.

Calibration of finished granules: sieves with a pore size of 2 mm.

Description of the finished granules: Fractional composition: a set of sieves.

The mass of samples of 100 g was used in the study. The determination was carried out in accordance with the requirements of the EP and SPhU.

Flowability: Determining the flow rate through a nozzle and the angle of repose. The flow rate through a nozzle was measured as the ratio of the mass and the time of pouring out on a special device of the GTB series of «ERWEKA» firm (Germany); the built-in laser measured the angle of repose.

The experimental samples of tablets were obtained by wet granulation using various humidifiers subjected to research in accordance with the requirements of the EP and SPhU.

Tabletting: Tablets were prepared using a TDP-5 tablet press (China) equipped with punches (round, biconvex, 12 mm in diameter).

The characteristics of the finished tablets: the mechanical strength of tablets (resistance to crushing and tablet friability) was in the range of 120-160 N. The measurement was carried out using the mechanical strength measuring devices «YD – 1» and «CS – 1» (China).

Twenty tablets were used in the study.

Disintegration: the compositions of tablets were measured in a «RC – 1» apparatus (China). The determination was carried out in accordance with the requirements of the SPhU.

The solubility was studied in accordance with the requirements of the SPhU (2.9.3, «Dissolution») for solid dosage forms in order to determine the release of active medicinal substances. It was performed using an ERWEKAR D-63150 apparatus (Germany) equipped with 4 vessels, at a speed of 100 rpm/min. The dissolution medium was water and 0.1 M HCl solution, 1 000 ml. To perform the dissolution test for tablets with a thick extract of clary sage leaves the differential spectrum of the medicinal substance complex with  $AlCl_3$  in the range from 360 nm to 450 nm in water and in 0.1 M solution of hydrochloric acid was studied. Absorption peaks were observed in the absorption spectra of tablets with a thick extract of clary sage leaves in the aqueous solution and 0.1 M solution of hydrochloric acid; therefore, the specific quercetin absorption index at a wavelength of 410 nm was used to determine the quantitative content of flavonoids. The samples were analyzed with a DU-8200 spectrophotometric device at a wavelength of 410 nm.

# Results and discussions

Based on the analysis of literary sources the concentration of 25 mg was selected (taking into account humidity) in order to calculate the required amount of the active ingredient in a thick extract of clary sage leaves with the anti-inflammatory and antimicrobial effects. The tablets containing this thick extract were experimentally developed. The model compositions of these tablets are presented in Table 1.

Table 1  
Compositions of model samples of tablets containing a thick extract of clary sage leaves ( $n = 5, P = 95\%$ )

Sample	Model compositions, g						
	1	2	3	4	5	6	7
A thick extract of clary sage leaves	0.025	0.025	0.025	0.025	0.025	0.025	0.025
Ascorbic acid (Vitamin C)	0.025	0.025	0.025	0.025	0.025	0.025	0.025
Bentonite	0.12	0.142	0.16	0.18	–	–	–
Dextrose monohydrate	0.622	0.6	0.582	0.562	0.6	0.57	0.54
Lactose monohydrate	–	–	–	–	0.097	0.172	0.135
Microcrystalline cellulose	–	–	–	–	0,045	–	0.067
Magnesium stearate	0.008	0.008	0.008	0.008	0.008	0.008	0.008
Humidifier solution	5% water-alcohol solution of bentonite				water-alcohol solution		
Total	0.80	0.80	0.80	0.80	0.80	0.80	0.80

Wet granulation of the components of the tablet mass was performed in a granulator of type YK-60 (China). Then wet masses granulated through a sieve (stainless steel mesh) with the hole diameter of 2 mm were dried in an oven at a temperature not exceeding 60 °C, and then again rubbed through a sieve with the hole diameter of 2 mm.

During the experiment the modern research methods and laboratory equipment were used. Seven tablet compositions with various set of excipients were developed. The model samples of tablets included the following components: a thick extract of clary sage leaves, ascorbic acid (vitamin C), bentonite clay, dextrose monohydrate, lactose monohydrate, microcrystalline cellulose (MCC), talc, and magnesium stearate. These compositions were assessed for compliance with the requirements of the EP and SPhU monographs.

5% water-alcohol solution of bentonite was used as a moisturizing agent. The granules obtained were subjected to pharmaco-technological research methods, which determined the fractional composition, humidity and flowability (determination of the flow rate through a nozzle and the angle of repose).

The fractional composition or distribution of material particles by size, in a certain way, affects the flowability of powdered materials and, consequently, the smooth operation of tablet machines, the stability of the mass of the resulting tablets, the accuracy of the medicinal substance dosage, as well as the quality characteristics of tablets. The fractional-dispersed composition of the model compositions proposed was determined by the sieve method according to the SPU method. The results are shown in Fig. 1.

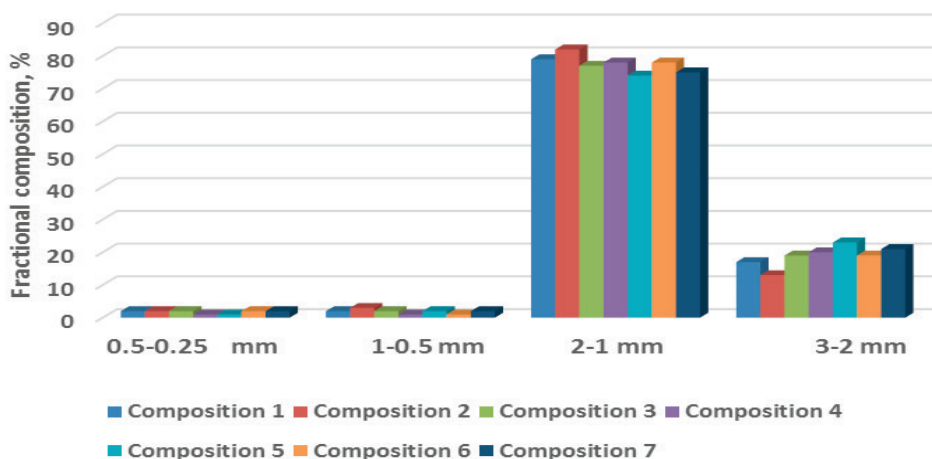


Fig. 1. The fractional-dispersed composition of the model granules for tablets of a thick extract of clary sage leaves

The fractional composition of granulate is heterogeneous due to the different strength of granules. The highest content of particles larger than 2 mm was observed in model compositions 5 and 7 (up to 22%), while the lowest one (up to 9%) – in composition 2, which was also characterized by the highest content of the average fraction with the particle size of 1–2 mm (82%). It indicates a sufficient probability of obtaining tablets with a constant average mass.

The moisture-absorbing activity is an important indicator that affects the flowability of the tablet mass. We studied the dynamics of the tablet mass moisture absorption during the day. The results are represented in Fig. 2.

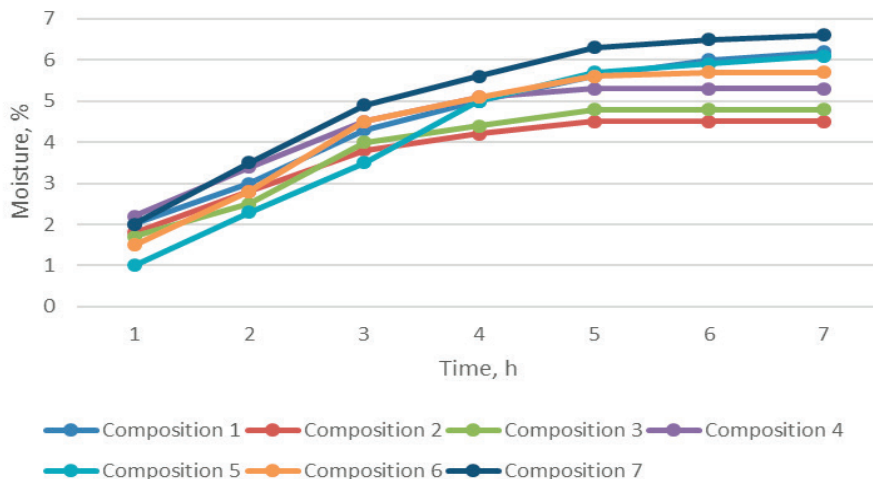


Fig. 2. Dynamics of the tablet mass moisture absorption during the day

As can be seen from Fig. 2, composition 2 (4.5%), which is the most acceptable, has the minimum moisture-absorbing activity.

The flowability allows the powdered material to pour out under its own gravity and provide uniform filling of the matrix channel. To study the flowability the methods of the flow rate determination through a nozzle and the angle of repose were used. The flow rate through a nozzle was measured as the ratio of mass and time of pouring out on a special GTB device of “ERWEKA” firm (Germany). The device is equipped with a small table,

on which granules are poured out of the funnel, resulting in a cone. The laser built into the device determines the angle of repose. The results of the flowability study for passing 100 g of granules through a nozzle are given in Table 2.

Table 2

**The flowability of the tablet compositions under study ( $n = 5, P = 95\%$ )**

Flowability	Model compositions						
	1	2	3	4	5	6	7
The flow rate through a nozzle, sec.	23 ± 0.07	22 ± 0.52	23 ± 0.36	23 ± 0.58	24 ± 0.02	23 ± 0.19	24 ± 0.29
The angle repose, ∠.	31 ± 0.58	24 ± 0.29	29 ± 0.19	33 ± 0.02	30 ± 0.07	32 ± 0.52	35 ± 0.36

Tablets with 12 mm in diameter were prepared with the preliminary wet granulation process using a TDP-5 tablet press (the weight of the tablet was 0.8 g). Tablets of various compositions were subjected to quality control procedures using the EP and SPhU methods by the following parameters: description, average mass and its deviation, disintegration, solubility, mechanical strength (resistance to crushing and tablet friability) and appearance. The results are presented in Table 3.

Table 3

**The pharmaco-technological properties of tablets ( $n = 5, P = 95\%$ )**

Compo- sitions	Disintegra- tion, min	Mechanical strength of tablets		The average mass and its deviation, %	Description
		tablet friability, %	resistance to crush- ing, N		
1	8 ± 0.23	0.5 ± 0.02	50 ± 0.89	3 ± 0.29	+
2	10 ± 0.45	0.3 ± 0.07	68 ± 0.98	2 ± 0.52	+
3	12 ± 1.38	0.4 ± 0.52	55 ± 1.22	5.1 ± 0.10	+
4	15 ± 1.22	0.8 ± 0.19	43 ± 0.45	5.3 ± 0.14	+
5	13 ± 0.89	0.3 ± 0.29	66 ± 0.52	3.5 ± 0.32	+
6	11 ± 0.98	1.1 ± 0.45	36 ± 1.38	5.2 ± 0.17	+
7	8 ± 0.99	0.4 ± 0.23	47 ± 0.99	5.1 ± 0.23	+

According to the results of the studies of pharmaco-technological properties of the tablets prepared it has been found that the test samples are yellow tablets with a flat and smooth surface, and a cylindrical shape. The diameter of a tablet is  $12.0 \pm 0.2$  mm. These compositions by disintegration and appearance meet the requirements of the SPhU.

The parameters of compositions 2, 3 and 5 also correspond to quality control standards (QCS) for tablets. By the indicator of the average mass and strength compositions 1, 4, 6 and 7 do not meet the QCS requirements. Composition 2 containing 5% water-alcohol solution of bentonite as a humidifier significantly exceeds the quality characteristics of samples 3 and 5 by the indicators of disintegration, the average mass and strength. Its resistance to crushing is 68 N, tablet friability – 0.3%; deviation from the tablet average mass does not exceed  $2\% \pm 5\%$ .

Solubility is one of the most important pharmaco-technological characteristics of solid dosage forms, in particular tablets, which enables not only to study the manufacturing technology of the dosage form, but also its bioavailability. The solubility of tablets of a thick extract of clary sage leaves was conducted by absorption spectrophotometry according to the requirements of the SPhU (2.9.3, «Dissolution») for solid dosage forms in order to determine the release of active medicinal substances included in tablets to provide the drug quality, efficiency and safety. Each tablet contained 0.025 g of a thick extract of clary sage leaves.

To prepare samples, tablets from a thick extract of clary sage leaves, excipients and reagents that met the requirements of theSPhU were used. The test met the following requirements: the dissolution medium volume – 500 ml; the dissolution medium content – water and 0.1 M hydrochloric acid solution; the dissolution medium temperature –  $37 \pm 0.5$  °C; the blade rotation speed – 100 rpm; the sampling time – 15, 30, 45, 60 min; the amount of the test sample – 10 ml. The test samples were filtered immediately after sampling; the quantitative determination of flavonoids for tablets with a thick extract of clary sage leaves was carried out by the spectrophotometric method on seven parallel compositions of tablets.

The results of these studies are shown in Table. 4.

Table 4

**The results of studying solubility of tablets from a thick extract of clary sage leaves ( $n = 5, P = 95\%$ )**

Dissolution medium – water				
Indicator	Sampling time, min			
	15	30	45	60
Concentration of the active substance in solution, %	$80 \pm 0.89$	$82 \pm 0.98$	$85 \pm 0.52$	$85 \pm 0.45$
Dissolution medium – 0.1 M HCl				
Indicator	Sampling time, min			
	15	30	45	60
Concentration of the active substance in solution, %	$78 \pm 0.99$	$78 \pm 0.38$	$79 \pm 0.37$	$79 \pm 0.18$

The experimental data indicate that the solubility of tablets from a thick extract of clary sage leaves was rather high. The optimal dissolution time for tablets from this extract was set to an interval of 30–45 minutes.

It was determined that excipients of tablets from a thick extract of clary sage leaves did not affect the nature of the absorption spectrum of the complex of the active substance with  $AlCl_3$ . Therefore, the solubility test for tablets with this extract is recommended to conduct at a wavelength of  $410 (\pm 5)$  nm.

The following conditions of the solubility test were developed for tablets of a thick extract of clary sage leaves: tablets – 10; medium – 0.1 M solution of hydrochloric acid, dissolution medium volume – 1 000 ml; rotation speed – 100 rpm; dissolution time – 30 min. In 30 minutes at least 78% of the declared content of a thick extract of clary sage leaves should be released. Based on the fact that the absorption of tablets from the extract occurred in the stomach 0.1 M solution of hydrochloric acid was used as a dissolution medium with the pH of 1.0 corresponding to the pH of the gastric juice.

Analyzing the results of the pharmaco-technological parameters composition 2 containing 5% water-alcohol solution of bentonite as a humidifier was chosen for further studies.

Table 5

**The composition of one tablet of a thick extract of clary sage leaves ( $n = 5, P = 95\%$ )**

Name	Content	
	g	%
A thick extract of clary sage leaves	0.025	3.125
Ascorbic acid (vitamin C)	0.025	3.125
Bentonitic clay	0.142	17.75
Dextrose monohydrate	0.6	75
Magnesium stearate	0.008	1.0
In total	0.80	100.0

The drug is yellow tablets with a flat and smooth surface, cylindrical shape with a breakline and a bevelled edge, the tablet diameter is  $12.0 \pm 0.2$  mm. By their external parameters tablets meet the requirements of the SPhU.

## Conclusion

Thus, by the results of the pharmaco-technological studies the technology for production of a thick extract of clary sage leaves and tablets based on it has been developed for the treatment of otolaryngological diseases. The present work is of interest for further studies of the drug developed and its introduction into the pharmaceutical production.

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## THE PHARMACO-TECHNOLOGICAL STUDIES OF THE TABLET SOLID DOSAGE FORM FOR THE TREATMENT OF OTOLARYNGOLOGICAL DISEASES

**Key words:** tablets, solid dosage form, pharmaco-technological characteristics, otolaryngological diseases

### ABSTRACT

The prevalence of acute respiratory diseases, the particular severity of their course, as well as the frequent relapses and complications require constant search for new, more effective and safe medicines for their prevention and treatment and introduction of these drugs into clinical practice. Generally, most of the medications used in the treatment of acute respiratory viral infections have a number of side effects. Currently, one of the promising areas of pharmacy is the study of biologically active substances, the medicinal plant raw material, and production of extracts and herbal medicines based on them.

Objective – pharmaceutical development of a scientifically based composition, technology for obtaining anti-inflammatory and antimicrobial tablets developed on the basis of a selected and standardized plant substance – a thick extract of the leaves of sage nutmeg, which grows in Tajikistan.

When solving the task used the methods of evaluating the technological properties of LRS, physico-chemical properties of plant extracts, physical and technological properties of the mass for tableting, pharmaco-technological tests of the developed tablets a study of quantitative content of biologically active substances was determined by Pharmacopoeia methods.

The developed solid dosage form with thick extract of sage leaves can be registered as a medicinal product, and the developed technology of tablets with thick extract of sage leaves can be of interest to manufacturers of medicinal products from plant raw materials. The developed methods can be used in laboratories for the detection and quantitative determination of BAS in plant raw materials of Clary sage leaves and medicinal products from this LRS.

Thus, based on the results of pharmacological and technological research, we have developed a technology for obtaining a thick extract of sage nutmeg and tablets based on it for the treatment of otolaryngological diseases, which in turn is of interest for further research of the developed drug and its introduction into production.

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## ФАРМАКОТЕХНОЛОГІЧНІ ДОСЛІДЖЕННЯ ТВЕРДОЇ ЛІКАРСЬКОЇ ФОРМИ У ВИГЛЯДІ ТАБЛЕТОК ДЛЯ ЛІКУВАННЯ ОТОЛАРИНГОЛОГІЧНИХ ЗАХВОРЮВАНЬ

**Ключові слова:** таблетки, фармакотехнологічні показники, отоларингологічні захворювання

### АНОТАЦІЯ

Поширеність гострих респіраторних захворювань, особлива тяжкість їх перебігу, а також часті рецидиви і ускладнення потребують постійного пошуку і впровадження в медичну практику нових, більш ефективних і безпечних лікарських засобів для їх профілактики та лікування. Як правило, більшість лікарських препаратів, що використовують в терапії гострих респіраторних вірусних інфекцій, мають низку побічних ефектів. Сьогодні одним із перспективних напрямів фармацевції є вивчення біологічно активних речовин сировини рослинного походження і одержуваних на її основі екстракційних і фіто-препаратів.

Мета роботи – фармацевтичне розроблення науково обґрунтованого складу, технології одержання таблеток протизапальної і антимікробної дії, розроблених на основі виділеної і стандартизованої рослинної субстанції – густого екстракту листя шавлії мускатної, що росте в Таджикистані.

При вирішенні поставлених в роботі завдань використовували методи оцінки: технологічних властивостей лікарської рослинної сировини, фізико-хімічних властивостей рослинних екстрактів, фізичних і технологічних властивостей маси для таблетування, фармакотехнологічні випробування розроблених таблеток. Кількісний вмісту біологічно активних речовин визначали фармакопейними методами.

Розроблена тверда лікарська форма з густим екстрактом листя шавлії мускатної може бути зареєстрована як лікарський препарат, а розроблена технологія таблеток із густого екстракту листя шавлії мускатної може представляти інтерес для виробників лікарських препаратів із рослинної сировини. Розроблені методики можуть бути використані в лабораторіях для виявлення та кількісного визначення біологічно активних речовин у рослинній сировині листя шавлії мускатної та лікарських препаратів із цієї сировини.

Таким чином, за результатами фармакотехнологічних досліджень нами була розроблена технологія одержання густого екстракту шавлії мускатної і таблеток на його основі для лікування отоларингологічних захворювань, що, в свою чергу, становить інтерес для подальших досліджень розробленого препарату і впровадження його у виробництво.

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#### ФАРМАКОТЕХНОЛОГИЧЕСКИЕ ИССЛЕДОВАНИЯ ТВЕРДОЙ ЛЕКАРСТВЕННОЙ ФОРМЫ В ВИДЕ ТАБЛЕТОК ДЛЯ ЛЕЧЕНИЯ ОТОЛАРИНГОЛОГИЧЕСКИХ ЗАБОЛЕВАНИЙ

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**А Н Н О Т А Ц И Я**

Распространенность острых респираторных заболеваний, особая тяжесть их протекания, а также частые рецидивы и осложнения требуют постоянного поиска и внедрения в медицинскую практику новых, более эффективных и безопасных лекарственных средств для их профилактики и лечения. Как правило, большинство лекарственных препаратов, используемых в терапии острых респираторных вирусных инфекций, обладают рядом побочных эффектов. В настоящее время одним из перспективных направлений фармации является изучение биологически активных веществ сырья растительного происхождения и получаемых на его основе экстракционных и фитопрепаратов.

Цель работы – фармацевтическая разработка научно обоснованного состава, технологии получения таблеток противовоспалительного и антимикробного действия, разработанных на основе выделенной и стандартизированной растительной субстанции – густого экстракта листьев шалфея мускатного, произрастающего в Таджикистане.

При решении поставленных в работе задач использовали методы оценки: технологических свойств лекарственного растительного сырья, физико-химических свойств растительных экстрактов, физических и технологических свойств массы для таблетирования, фармакотехнологические испытания разработанных таблеток. Количественное содержание биологически активных веществ определяли фармакопейными методами.

Разработанная твердая лекарственная форма с густым экстрактом листьев шалфея мускатного может быть зарегистрирована как лекарственный препарат, а разработанная технология таблеток из густого экстракта листьев шалфея мускатного может представлять интерес для производителей лекарственных препаратов из растительного сырья. Разработанные методики могут быть использованы в лабораториях для обнаружения и количественного определения биологически активных веществ в растительном сырье листьев шалфея мускатного и лекарственных препаратах из этого сырья.

Таким образом, по результатам фармакотехнологических исследований нами была разработана технология получения густого экстракта шалфея мускатного и таблеток на его основе для лечения отоларингологических заболеваний, что, в свою очередь, представляет интерес для дальнейших исследований разработанного препарата и внедрения его в производство.

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