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RESEARCH IN THE FIELD OF DEVELOPMENT OF TECHNOLOGY AND COMPOSITION OF TABLETS OF RUBIAE TINCTORUM EXTRACT

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Abstract
In this study, a scientifically grounded composition and preparation technology for a tablet dosage form with effective therapeutic effects against kidney stone disease were developed based on the natural resources of Uzbekistan. The physicochemical and technological properties of the active pharmaceutical substance were studied, and 70% ethyl alcohol was selected as the composition of the excipients and the binder. The technological parameters of the tablet mass prepared using the wet granulation method have significantly improved. The pressing process was carried out on modern equipment, and the finished tablet fully met pharmacopoeia requirements. The results obtained serve as a basis for creating high-quality and safe import-substituting drugs in the local pharmaceutical industry.

Keywords: Renal calculus, tablets, wet granulation, auxiliary substance, composition, pressing, decomposition, dispersion, compaction coefficient, residual moisture

Introduction

Currently, one of the most important and urgent tasks of pharmaceutical science is the creation of highly effective, safe, and high-quality medicines that serve to strengthen public health, prevent diseases, and treat them effectively. At the same time, one of the main directions facing modern pharmaceuticals is the development of import-substituting, economically viable, and accessible medicines for broad segments of the population, as well as their widespread introduction into practical medicine. This, in turn, is of great importance not only for strengthening the healthcare system but also for ensuring the country's pharmaceutical independence. The Republic of Uzbekistan is considered an extremely rich territory with rich natural resources, especially medicinal plants. Many plant species found in our republic are

sources of biologically active substances, and there are great opportunities for creating effective and safe medicines based on them. The domestic pharmaceutical industry can be developed through the rational and scientifically grounded use of medicinal plants, their in-depth study, and processing based on modern technologies. At the same time, medicines created on the basis of local raw materials are economically cheaper and more convenient for the population than imported preparations.

Today, kidney stone diseases are one of the most common diseases worldwide. This disease occurs not only among the adult population but also among young people and even children, potentially causing serious health complications. The development of the disease is caused by various factors, including poor nutrition, drinking water quality, the environment, metabolic disorders, and genetic predisposition. In our republic, kidney stone diseases are also widespread, and their treatment and prevention remain one of the pressing problems of the healthcare system. At the same time, there is a shortage in the domestic pharmaceutical market of ready-made drugs for kidney stone diseases, manufactured from local raw materials, possessing high biological efficacy and meeting modern requirements. This necessitates the further expansion of research work in this direction, the development of new dosage forms, and the improvement of their technology.

In this regard, the creation of effective drugs against kidney stone disease based on the rich natural resources of our Republic, particularly medicinal plants, is of great scientific and practical importance. In particular, the tablet dosage form is distinguished by its convenience, dosage accuracy, and ease of storage and transportation. Therefore, the development of the composition of this drug form on a scientific basis, the selection of optimal excipients, the improvement of technological processes, and the in-depth study of the quality indicators of the finished product are topical issues. As a result of research in this direction, it will be possible to create highly effective, safe, high-quality, and cost-effective medicines. This, in turn, will contribute to the development of the domestic pharmaceutical industry, the expansion of the range of import-substituting medicines, increasing the availability of medicines for the population, and improving overall health indicators. [1, 2, 3].

Purpose of the Work

To develop a scientifically grounded composition of a tablet dosage form possessing therapeutic effects against kidney stone disease and to create a technology for its preparation. During the research, it is intended to conduct an in-depth study of the physicochemical, technological, and pharmaceutical properties of the selected active pharmaceutical substance, and to evaluate their influence on the process of forming the tablet dosage form.

Also, based on the results of experimental and laboratory studies, one of the main goals of this work is to determine the optimal type and amount of the active substance, evaluate its compatibility with excipients, and create a stable, high-bioefficiency tablet dosage form. Based on the studied chemical and technological properties, it is planned to select the optimal production technology and ensure the quality indicators of the finished product.

Experimental Part

In the process of developing the technology of the tablet dosage form, the correct selection of the type and amount of excipients to be included, as well as the justification of the preparation method, is of great importance. To this end, the technological properties of the active pharmaceutical substance were studied in depth under laboratory conditions using specialized technological equipment to scientifically substantiate the selection of excipients used in tablet technology within the experimental part. Standard methods recommended in the literature were used to determine the main physicochemical and technological indicators of the substance.[4,5.].

The data obtained as a result of the research are presented in Table 1, the analysis of which showed that the studied active substance has unsatisfactory results in a number of technological indicators, including dispersion, dispersion density, and compaction coefficient. These negative indicators indicate that the pressing properties of the substance are insufficient, and the possibility of obtaining high-quality tablets from such substances through direct pressing is limited.

Table 1.Results of the study of the physicochemical and technological indicators of the raw material

Indicator		Unit of measurement	Result
Fractional composition		µm, %	
	+2000		0.5 (±0.2)
-2000	+1000		2.43 (±0.27)
-1000	+500		8.33 (±0.27)
-500	+250		23.8 (±1.50)
-250	+125		56.6 (±2.16)
-125			8.24 (±1.26)
Scattering		kg/sec*10^{-3}	1.18 (±0.07).
Pressure coefficient		%	26.57 (±0.75)
Hausner index		-	1.36 (±0.007).
Hygroscopicity		%	14.47 (±0.23)
Scattered density		kg/m^3	Uncompacted
			525 (±2.5)
			After compaction
			715 (±3.2)
Angle of repose		Degree	49^0 (±1)
Residual moisture		%	3.56 (0.33)

In this regard, the necessity of improving the technological process, optimizing the composition of excipients, and applying alternative technological methods (e.g., wet or dry

granulation) during the development of the tablet dosage form has been scientifically substantiated. These approaches serve to improve the technological properties of the finished medicinal product, ensure stable quality indicators, and increase bioavailability.

The next stage of the research work was dedicated to selecting the appropriate types and optimal amounts of excipients to be included in the tablet dosage form, as well as developing the most technologically optimal preparation method. At this stage, widely used auxiliary substances were selected to improve the technological properties of the tablet mass and achieve stable quality indicators.

Specifically, potato starch, microcrystalline cellulose (MCC, "cotton cellulose"), sodium starch glycolate, calcium stearate, magnesium stearate, and lactose were used as auxiliary substances. Eight different formulations were developed under standard laboratory conditions based on the selected excipients. When forming the tablet mass, a wet granulation method was used in the presence of purified water and ethyl alcohol as a binder, followed by the preparation of tablet dosage forms by pressing.

The technological and quality indicators obtained as a result of the experiments are presented in Table 2, which allowed for the assessment of the influence of the selected excipients and binding systems on the compressibility, mechanical strength, and other key technological properties of the tablet mass.

Table 2.Experimental compositions for the selection of tablet formulations

Components	Composition numbers (gr)							
	1.	2.	3.	4.	5.	6.	7.	8.
Dry extract of sea buckthorn	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Potato starch	0.075	0.077	0.075	0.08	-	0.065	-	0.077
Microcrystalline cellulose	-	0.073	-	0.07	0.076	-	0.15	0.067
Sodium starch glycolate	-	-	-	-	0.07	-	-	-
Lactose	0.070	-	0.072	-		0.085	-	-
Water	Until a moist mass forms	-	-	-	-	-	Until a moist mass forms	-
70% alcohol	-	Until a moist mass forms	Until a moist mass forms	Until a moist mass forms	Until a moist mass forms	-	-	-
96% alcohol	-	-	-	-	-	Until a moist mass forms	-	Until a moist mass forms
Calcium stearate	-	-	0.003	-	0.004	-	0.003	0.006
Magnesium stearate	0.005	-	-	-	-	-	-	-
Average weight	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4

Standard (test) tablets of various compositions were developed using a hydraulic press, and their quality indicators were evaluated. Specifically, the physical appearance of the tablets,

mechanical strength (hardness to fracture), and breakdown indicators were verified in accordance with current pharmacopoeia requirements.

The results of the conducted experiments showed that using 70% ethyl alcohol as a binder during the preparation of the tablet mass using the wet granulation method is the most optimal. This is due to the fact that tablets prepared in the presence of purified water or various concentrations of ethyl alcohol did not fully meet the established quality requirements in terms of appearance, mechanical strength, and breakability. In some cases, deformation of the tablets, insufficient hardness, or abnormalities in the dispersion parameters were observed.

Therefore, as a result of comprehensive experimental studies, 70% ethyl alcohol was selected as the most appropriate and effective binder in tablet technology. It has been established that the use of this binder ensures the stabilization of tablet quality indicators, increases mechanical strength, and ensures compliance with breakability standards. The obtained experimental results are presented in Table 3.

Table 3. Conditions for tablet production and properties of the resulting tablets

Components	Composition numbers (gr)							
	1.	2.	3.	4.	5.	6.	7.	8.
Dry extract of sea buckthorn	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Potato starch	0.075	0.077	0.075	0.08	-	0.065	-	0.077
Microcrystalline cellulose	-	0.073	-	0.07	0.076	-	0.15	0.067
Sodium starch glycolate	-	-	-	-	0.07	-	-	-
Lactose	0.070	-	0.072	-		0.085	-	-
Water	Until a moist mass forms	-	-	-	-	-	Until a moist mass forms	-
70% alcohol	-	Until a moist mass forms	Until a moist mass forms	Until a moist mass forms	Until a moist mass forms	-	-	-
96% alcohol	-	-	-	-	-	Until a moist mass forms	-	Until a moist mass forms
Calcium stearate	-	-	0.003	-	0.004	-	0.003	0.006
Magnesium stearate	0.005	-	-	-	-	-	-	-
Average weight	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4

The next stage of the research work, using a pre-selected and scientifically substantiated complex of excipients using 70% ethyl alcohol as a binder, tablets intended for pressing were

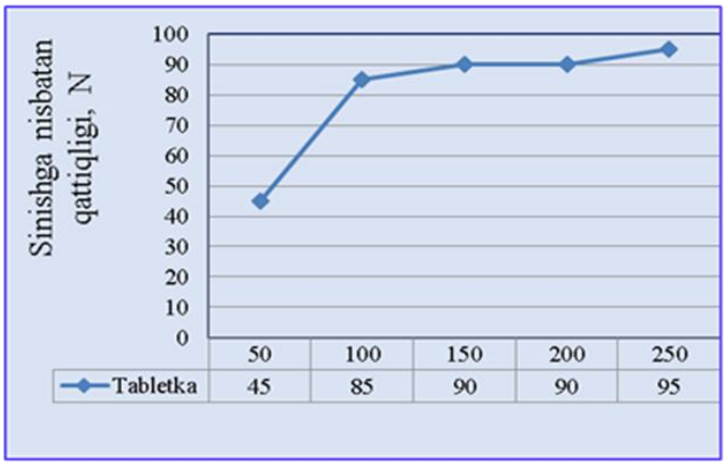
prepared according to eight different compositions. The main goal of this stage was to determine the influence of the selected excipients and the binding system on the technological properties of the pressed masses and to select the most qualitatively optimal composition.

Standard tablets were manufactured from the prepared pressed masses, and their primary quality indicators—external appearance, mechanical strength, decomposition, and uniformity—were evaluated in accordance with current pharmacopoeia requirements. At the same time, the technological properties of the pressed masses were studied in detail, including the degree of dispersion, bulk and compacted density, compressibility, and granule uniformity, based on standard methods presented in scientific literature.

The results of the conducted experiments are summarized in Table 3, and their analysis showed that the technological properties of the pressed masses prepared by the wet granulation method changed sharply in a positive direction compared to the indicators of the initial active pharmaceutical substance. In particular, the disadvantages inherent in the substance, such as low dispersion and insufficient compressibility, were significantly eliminated, and technological indicators were achieved that allow for the production of stable and high-quality tablets suitable for the pressing process.

As a result, it was scientifically confirmed that the wet granulation method used in the presence of the selected complex of excipients and 70% ethyl alcohol is an effective and technologically acceptable method for the development of the tablet dosage form. This approach serves as a solid scientific basis for ensuring the stability of finished product quality, optimizing the production process, and creating a tablet dosage form with high bioavailability.

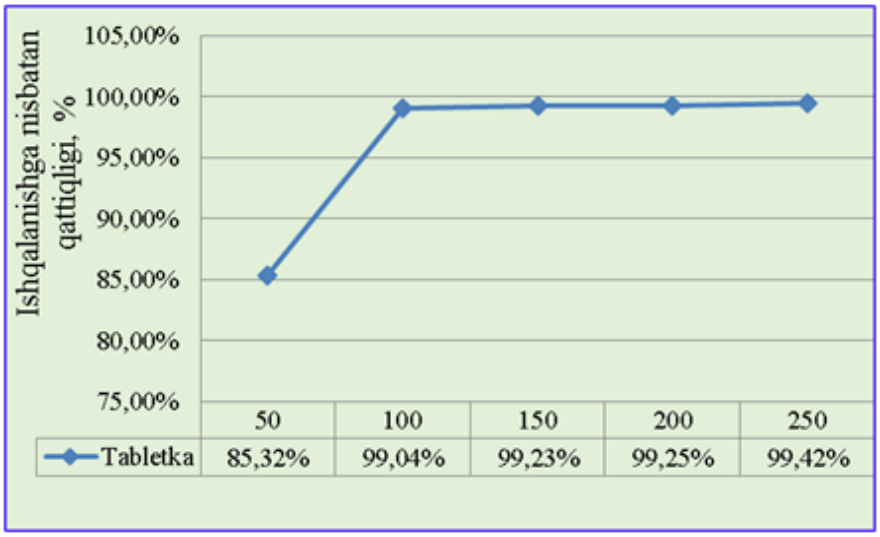
Table 4. Effect of the results of the study on the influence of pressing pressure on the compressive strength of the tablet.



As a result of the conducted experiments, it was established that pressing pressure significantly affects the compressive strength of the tablet. According to research data, the hardness of the tablet at the initial pressure value was 45 N, indicating its insufficient mechanical strength. Such a low indicator is explained by the insufficient formation of bonds between particles. When the pressing pressure was increased by 100 N, a sharp increase in hardness to 85 N was observed. This condition is associated with the expansion of contact surfaces between particles, the intensification of plastic deformation processes, and the formation of a strong internal structure. That is, it is within this pressure range that the tablet

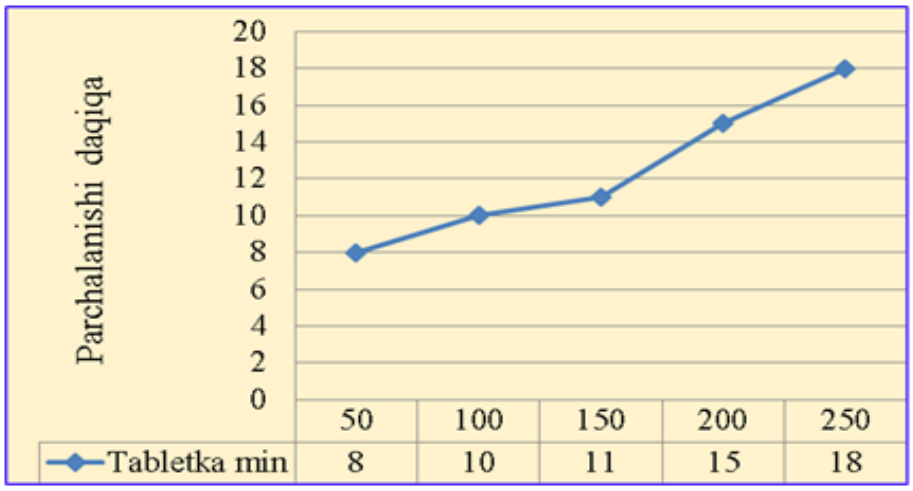
transitions into a mechanically stable state. The application of 150 and 200 N pressure led to the stabilization of the hardness index around 90 N. At a pressure of 250 N, the stiffness increases to 95 N, but this increase is relatively small. This indicates that the system is approaching its maximum compaction level, and a further increase in pressing pressure will not have a significant additional impact on mechanical strength. Thus, there is a direct correlation between pressing pressure and hardness, and a pressure in the range of 100–150 N is considered the most optimal for ensuring optimal mechanical strength.

Table 5. Results of the study on the influence of pressing pressure on the hardness of the tablet relative to friction



According to the results of the conducted research, it was determined that increasing the pressing pressure significantly affects the hardness of the tablet relative to friction. At the initial pressure value, the hardness indicator was 85.32%, which indicates insufficient mechanical strength of the tablet. When the pressing pressure was increased by 100 N, a sharp increase in the hardness index to 99.04% was observed. This condition is explained by an increase in the contact surface area between the particles, their close arrangement, and the formation of strong bonds. As a result, the mechanical stability of the tablet is significantly improved.In the subsequent stages, it was noted that at pressures of 150, 200 and 250 N, the hardness index almost stabilized at values of 99.23%, 99.25% and 99.42%, respectively. This means that the maximum degree of compaction has been achieved in the system, and a further increase in pressing pressure does not significantly affect the hardness. Thus, based on the results obtained, it is determined that the optimal pressure range is within the range of 100–150 units. In this range, high mechanical strength of the tablet is ensured, and the efficiency of the technological process is maintained at an optimal level. Overall, the correct selection of pressing pressure is an important technological factor in controlling tablet quality indicators and plays a decisive role in stabilizing the physical and mechanical properties of the finished product.

Table 6. Effect of pressing pressure on tablet decomposition



The results of the study showed that the pressing pressure also has a significant impact on the tablet's decomposition time. According to the data obtained, the decomposition time of the tablet at a pressure of 50 N was 8 minutes. This value indicates that the tablet has a relatively porous structure and allows the liquid to penetrate easily. It was observed that when the pressing pressure was increased to 100 N, the decomposition time increased to 10 minutes. 150 N, this indicator was 11 minutes. At subsequent pressures, a more significant increase was recorded, reaching 200 N for 15 minutes and 250 N for 18 minutes. This is explained by the fact that as the pressing pressure increases, the internal structure of the tablet becomes denser, the degree of porosity decreases, and as a result, the penetration of the solvent medium into the tablet becomes more difficult. Also, the strengthening of interparticle bonds slows down the decay process.

Consequently, there is an inverse relationship between the pressing pressure and the decomposition time: as the pressure increases, the decomposition time increases. Therefore, at very high pressures, the decomposition properties of the tablet may deteriorate. From a practical point of view, the pressure range of 100–150 N is considered optimal, as under these conditions, the mechanical strength of the tablet is sufficiently ensured, and the decomposition time is maintained at a level consistent with pharmacopoeia requirements.

Based on the results of comprehensive experimental studies, the optimal composition and preparation technology of the tablet dosage form for use against kidney stone disease have been proposed. The selected composition serves to ensure the bioavailability of the active substance, improve the technological properties of the tablet mass, and stabilize the quality indicators of the finished product.

The composition of the recommended tablet dosage form is as follows:

Dry extract of madder - 0.25 g

For starch glycolyate - 0.07g

MKS - 0.076g

Calcium stearate - 0.004

70% ethyl alcohol until a moist mass is formed

The total mass of the tablet is 0.4 g.

The technology developed based on this composition is technologically convenient for the industrial production of the tablet dosage form, allowing for compliance with quality, stability, and therapeutic efficacy requirements. Given the hygroscopic properties of the extract, the granulation process was conducted under laboratory conditions using a coffee grinder. Initially, 0.25 g of dry extract was pre-mixed with 0.07 g of precisely weighed sodium starch glycolate and 0.076 g of microcrystalline cellulose, and thoroughly mixed until a homogeneous mass was formed. During the mixing process, 70% ethyl alcohol was gradually added, and wet granulation was performed.

The resulting wet mass was passed through a system of sieves with diameters of 250 µm and 125 µm. The fraction retained in the 125 µm sieve was separated, and the small part that passed through it was again moistened in a coffee grinder and re-granulated. This process was repeated step-by-step, with large particles being sifted through a sieve, while the small fraction was sent for processing. The granulation process continued until the granules reached a uniform size. The obtained granules were dried in a drying cabinet at a temperature of 55°C for 10–15 minutes. The dried mass was taken in an amount of 0.4 g, pressed under a pressure of 100 N, and converted into a tablet. Calcium stearate was used as a slider during the pressing process, ensuring that the tablets were easily detached from the mold. The resulting tablets exhibited good solubility indicators; no color changes were observed during storage, and their appearance remained stable.

Conclusion

In this study, the dry extract of tall licorice, based on the natural resources of Uzbekistan, was selected as the active ingredient, and a tablet dosage form with high efficacy against kidney stone disease was developed. Optimal amounts of sodium starch glycolate, microcrystalline cellulose, and calcium stearate components were determined as excipients, and 70% ethyl alcohol was successfully used as a binder. The technological properties of the tablet masses prepared by the wet granulation method have significantly improved. Modern equipment of the German brand "ERWEKA" was used in the pressing process, and the prepared tablets had quality indicators that fully meet pharmacopoeia standards. The research results showed that they can serve as a basis for developing an effective and safe tablet dosage form for kidney stone disease and creating import-substituting products in the local pharmaceutical industry.

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