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SOME DEVELOPMENT RESEARCH TECHNOLOGIES OF DRY EXTRACT TABLETS

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Abstract

The development of new medicines is one of the main problems of modern medicine. In this regard, the development of complex drugs is of particular interest. Their use makes it possible to expand the range of pharmacotherapeutic action, strengthen certain aspects of the therapeutic effect, and reduce undesirable toxic manifestations. This report presents the results of a study on the development of dry extract tablet technology. Theinfluence of the tableting process on the quality of recommended tablets is studied. The technological properties of the obtained tablet masses and the finished product are studied.

Keywords: Dry extract**,** direct pressing, wet pressing, quality, technological properties.

Introduction

A medicinal plant contains one or more substances that, under certain conditions, can exhibit certain healing properties in the human and animal bodies. In comparison with synthetic drugs, medicinal plants are known to be less toxic. Therefore, in modern pharmacy, creating a medicinal product based on medicinal

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plants is an urgent task. It is known that vegetable raw materials serve as a source of obtaining more than a third of all medicines [1].

People with kidney failure are at risk for health reasons. Under these conditions, the search and development of new diuretics based on medicinal plants becomes particularly relevant. Recently, medicinal plants around the world have increased significantly. They are not perceived as foreign and, unlike synthetic drugs, are not rejected by the body's defense systems. Among herbal preparations, such medicinal plants as yarrow, licorice and zizifera officinalis are widely used in medical practice zizifera.Potassium-sparing diuretics have little effect on the level of sodium and fluid in the body, as well as on blood pressure as such. They do not have an independent value in the treatment of hypertension, but are often used in combination with other diuretics to enhance their effect and avoid excessive loss of potassium by the patient's body. Currently, the development of new, easy-to-use, stable medicinal products from local medicinal plants is one of the main problems of modern pharmacy [2,4,6].

Taking into account the properties of herbal preparations, the Department of Pharmacognosy at the Tashkent Pharmaceutical Institute conducted research work on the creation of the "Dry Extract" collection. This fee consists of equal parts: Dill - Foeniculum officinalias, Calendula officinalis, Horsetail - Equisetum arvense, Rubia, Yarrow - Achillea filipendulin. In connection with the above, the question of creating an easy-to-use, standardized tablet dosage form from dry extract with sufficient biological availability and stability during storage has become relevant.

Taking into account the above, цthe main purpose ofscientific research was to study the pharmacological-and technological aspects of the development of technology for certain domestic diuretic drugs and preparations and the introduction of the developed dosage forms into domestic production.

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Purpose of the Research

Taking into account the above, the aim of the scientific research was to study the pharmaco-technological aspects of the development of technology for individual domestic diuretic drugs and preparations and the introduction of the developed dosage forms into domestic production.

Materials and Research Methods

Dry extract obtained by us using the recommended technology was used as objects of research. Dry extract is a dry hygroscopic, finely dispersed powder from red to dark brown color with a specific smell. Theanalysis of the technological characteristics of the dry extract and auxiliarysubstances was performedon devices manufactured by Erweka (Germany), and the particle size was evaluated by microscopy using the video test program. To develop tablets, we tested formulations with different вспомонutrient compositionsгательных and their ratios. The main requirements for this group of excipients are: stability during storage, good compressibility, the ability to quickly and completely release the active substance and form strong tablets. The analysis of tablets was carried out according to the current regulatory documentation.

Discussion of the Obtained Results

Based on the technological properties of the dry extract, we initially studied the possibility of obtaining tablets by direct pressing, which, as is known, has a number of advantages. Analysis of the obtained technological parameters of the dry extract showed the need for adding auxiliary substances that improve flowability. Various excipients recommended by GF XI were used both individually and in combinations: glucose, lactose, potato starch, microcrystalline cellulose, calcium carbonate, magnesium oxide, and calcium stearate. Direct pressing eliminates 3-4 technological operations and thus has an advantage over tableting with pre-granulation of powders. However, despite the apparent

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advantages, direct pressing of this substance does not give the required quality of the finished product. This is explained by the fact that for productive operation of tablet machines, the pressed material must have optimal technological characteristics (flowability, compressibility, humidity, etc.) [3,5].

The dry extract obtained by us does not have such characteristics. The studied compositions are presented in Table 1.

The essence of this method is that the required amount of dry extract is mixed with auxiliary substances to a homogeneous mass. In this mass, first of all, calcium stearate is added with constant stirring. The tablet mass obtained in this way is pressed in a manual hydraulic press in the pressure range from 100 - 180 MPa. Tablets obtained by direct pressing did not meet the requirements of GF XI.

Table 1 Formulations for preparation of tablets from dry extract by direct pressing

Ingredients	Number of ingredients, g				
	Series				
	I	II	III	IV	V
Dry Extract	0,3	0,3	0,3	0,3	0,3
Sucrose		0,0975			
Lactose	0,095		0,08	0,0975	0,08
MCC		0,0975	0,095		
Calcium carbonate carbonate	0,01		0,020	0,0975	0,095
Potato starch		0,005			0,020
Calcium Stearate	0,005		0,005	0,005	0,005
Average weight	0.5	0.5	0.5	0.5	0.5

In subsequent studies, the technological properties of the obtained tablet masses of dry extract prepared for direct pressing were studied. In the table.2 shows the results of studying the technological properties of the above studies.

It follows from the data in the table that the introduction of excipientso leads to a change in the fractional composition and, accordingly, other technological

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indicators. Compressibility in the mixture decreased from 80 to 41. The obtained data indicate a decrease in the degree of hygroscopicity from 10.42 to 5.71 and the adhesive properties of powders. These are positive indicators. Some differences in the compaction coefficients and the bulk density of the pressed masses of 95, 32-100, 12% are noted due to the close bulk density of the excipients used.

Table 2 Results of studying the technologicalproperties of the pre-pressed mass prepared for direct pressing (n=5)

Studied indicators	Values of indicator				
	I	II	III	IV	V
Fractional composition, microns, %:					
	15,19	11,10	9,10	12,52	14,05
+2000	22,50	24,05	23,06	21,43	31,34
-2000+1000	37,19	39,23	36,85	36,45	27,67
-1000+500	19,87	21,57	25,32	24,71	21,79
-500+250	5,25	3,60	5,67	4,89	5,20
-250					
Flowability, 10-3^{-3} kg /s	2,55	2,42	3,45	4,34	2,67
Natural slope angle, degree	35,56	40,16	37,96	34,11	39,78
Bulk density, kg/ m^3	721,34	754,32	767,04	744,34	765,81
Compressibility, N	32,56	37,45	41,23	39,11	40,77
Compaction coefficient	1,99	1,54	1,78	1,80	1,65
Residual humidity	4,98	5,71	4,81	5,07	4,89

In the table.3 shows the results of studying the quality indicators of dry tablets obtained by direct pressing.

As can be seen from the data presented in Table.3, dry extract tablets obtained in five series by direct pressing meet the requirements for appearance, the ratio of tablet height to diameter, the quantitative content of the active substance, and

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solubility. However, according to other indicators, they do not meet the requirements for tablet dosage forms.

Table 3 Results of studying the quality indicators of dry extract tablets by direct pressing

Investigated Properties	Indicators of Series				
	I	II	III	IV	V
V Appearance	Brown tablets, with inclusions	-//--	//--	//--	//-
Tablet height-to-diameter ratio, %	40	37	35	40	39
Average weight and deviation from average weight, %	0,501±3,39	0,511±5,12	0,490±5,56	0.501±6.33	0.502±3.67
Fracture strength, N	25	26	35	30	25
Abrasion resistance, %	85.33	87.45	80.78	85.45	84.20
Disintegration, min	16	14	15	12	17
Quantitative content of active substance, %	98.94	97.95	99.90	98.92	98.78
Solubility, %	97.5	90.4	97.8	96.1	97.7

In connection with the above, in further studies, we conducted research on the development of technology for dry extract tablets by wet granulation.

The required amount of binding substances was determined experimentally for each tableted mass. In order for the powder to granulate at all, it must be moistened to a certain extent. The sufficiency of moisture was judged as follows: a small amount of mass (0.5-1g) was squeezed between the thumb and index finger; the resulting "cake" should not stick to the fingers (excessive moisture) and crumble when falling from a height of 15-20 -cm (insufficient moisture).

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To prepare the tablet mass, 7 series of pressed masses from dry extract were prepared according, to the instructions presented in Table.4. In the studies, excipients were selected, that differ from each other both in type and in the amount of excipients used. Taking into account the physicochemical and technological properties of the dry extract, the possibility of using such fillers as lactose, sucrose, starch, cellulose derivatives MCC, GMPC, and calcium carbonate was studied in the development of the composition and technology. Potato starch was used as bakingpowder, and calcium stearate was used as an antifriction agent.

Preliminary selection of fillers was also carried out on the basis of their ability to reduce moisture absorption by the substance.

Experimental samples of tablets were prepared from dry extract with the addition of excipients in various proportions and combinations. Table 4 shows the compositions of seven prescriptions for tablets, which differ from each other both in type and in the amount of excipients used. The choice of these quantitative fillers was carried out on the basis of previous experiments.

The essence of wet granulation is as follows: the required amount of active substance and filler are mixed until a homogeneous mass is obtained. The resulting homogeneous mass is moistened with a corresponding amount of wettingм liquid, and the wet mass is dried in air-cooled drying cabinets at a temperature of 40-50^{0}C. The drying time is determined experimentally to the optimal residual humidity. Then the mass is granulated and powdered with a mixture of starch and calcium stearate. Purified water, sugar syrup, and ethyl alcohol of various concentrations were used for moistening- 30, 40, 50, 70%, 90% and 2-10% starch solutions.

In subsequent experiments, moistening was performed with starch paste of various concentrations. According to the results of the study, it was found that low concentrations of starch extend the disintegration time of metal tablets, and also high concentrations of starch paste affect the reduction of strength.

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When using water and sugar syrup, lumps formed, which worsened the quality of the finished product. Ethyl alcohol of different concentrations also did not give the desired effect. Therefore,afterых numerous experiments, wetting was carried out with 70% ethylыalcohol, since it provided good granulation of the tablet mass. When moistening the mass with alcohol, the granule after drying turned out to be strong, the resulting tablets had a high-quality appearance.

Table 4 Investigated compositions for obtaining tablets prepared by wet granulation

Ingredients	Prescription number and number of ingredients, g						
	1	2	3	4	5	6	7
Dry extract	0,3	0,3	0,3	0,3	0,3	0,3	***0,3***
Lactose	0,095				0,020		
Sucrose		0,0975					
Potato starch	0,100	0,0975	0,020	0,1000	0,080	0,090	***0,095***
MCC			0,080		0,095	0,150	***0,100***
GMPC				0,0975			
Calcium carbonate			0,095				
Calcium stearate	0,005	0,0050	0,005	0,0050	0,005	0,005	***0,005***
Average weight	0,5	0,5	0,5	0,5	0,5	0,5	***0,5***

Studying the properties of the obtained tablets according to seven prescriptions, we made sure that the prepared tablets according to the 7 composition met all the requirements presented in GF X1. The disintegration parameters of tablets according to composition 1 and 5 did not meet the requirements of GF X1. Tablets obtained by composition 2 and 3 had a disintegration time of about 15 minutes. Therefore, we have not selected these compounds for the following experiments.

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The best indicators on demand were given by tablets obtained according to the 7 composition.

Further research was carried out with tablets obtained according to the 7 composition. Thus, when selecting the composition of tablets, the effect of excipients on the quality of the finished product was studied.

The technological properties of the pressed mass according to its composition were studied, and the results obtained are shown in Table 5.

Fractional composition, bulk density, flowability, natural slope angle, porosity, compaction coefficient, compressibility coefficient and residual moisture were studied as technological indicators of the pressed mass и. Determination of the above parameters was carried out according to the methods of GF XI and the corresponding NTD. The used excipients improved some technological properties of the substance - flowability, bulk density.

Also, according to Table 5, it can be noted that the flowability of the dry extract in granules increased, the bulk mass doubled. The results of granulation indicate a significant coarsening of the particle size, where the bulk of the mass corresponds to the fraction of -1000+500 microns. Such technological indicators as bulk density (625 kg/m^3), flowability (6.5·10-3^{-3} kg/s), natural slope angle (30 degrees), compressibility coefficients (1.23), compaction (2.5), etc. had more positive values for the pressed mass than for the extract, which indicates that correct selection of excipients and the progress of the technological process. The optimal residual humidity is in the range of 3.22-3.5 %.

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Table 5 Results of studying the technologicalproperties of theapplied mass

Studied indicators	Unit of measurement	Indicator values
Appearance		Uniform granules of cream color, sweet taste, odorless
Fractional composition: +2000 -2000+1000 -1000+500 -500+250 -250	microns, %	 10,14 27,55 37,19 17,87 7,25
Flowability	$10\text{-}3^{-3}$ kg /s	6,5
Natural slope angle	degree	30
Bulk density	kg/ m^3	625
Compressibility	H	40
Compressibility coefficient		1,23
Compaction coefficient		Compaction coefficient 2,5
Residual moisture	%	3,2
Porosity	%	52

It should also be noted that the pressure of pressing tablets directly contributes to the indicators of such important properties as physical and mechanical properties, tablet strength, disintegration, and abrasion resistance. Therefore, a number of experimental studies were devoted to studying the effect of pressing pressure on the quality of tablets. At the same time, laboratory manual hydraulic presses were used. In the range from 50 to 350 MPa, studies were conducted on the selection of the optimal tablet pressing pressure, (Fig.3.5 the results obtained show that the quality of the finished product depends on the pressing pressure (the required parameters change depending on the pressing pressure). Also, according to the results , pressing pressures of 100-180 MPa are optimal for pressing tablets.

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The method of wet granulation was used to obtain the tablets. The technological scheme for obtaining tablets by wet granulation is as follows: crushed and sifted through a sieve (hole diameter - 0.15 mm) and the calculated amount of substance and MCC were mixed and then moistened with a binder solution of 90% ethyl alcohol. The wet mass was dried at a temperature of 30-40°C to a residual humidity of 3.5 %.

Next, the dried mass was wiped through a granulator with holes of 1 mm, powdered with a mixture of potato starch and calcium stearate, and the mass was tableted on a 0.5 g impact tablet machine with a diameter of 11 mm. The mass was pressed well, without sticking and easily pushed out of the mold, and the resulting tablets met the requirements of GF XI. Tablets of the above compositions were made on manual hydraulic presses. The specific pressing pressure was 100-180 MPa.

Subsequently, the quality indicators of the obtained tablets were studied in accordance with the requirements of GF XI, as well as other generally accepted methods. Their quality was assessed by the following indicators: appearance, geometric shape, height-to-diameter ratio, average mass, quantitative content of active substance, disintegration and dissolution, abrasion and fracture strength. Tablets of all prescriptions meet the requirements of GF XI in terms of strength. Tablets obtained by 1-3 prescriptions are characterized by a long disintegration time, which was more than 120 minutes. This indicates an insufficient loosening ability of starch.

In the composition, where MCC was mixed with an equal amount of starch, the disintegration time of the first tablet was reduced, but the tablets did not meet the requirements of GF XI for strength. It was noted that the use of sucrose caused the granulate to adhere to the surface of the press tool. The most positive indicators of the pressed mass were noted when using MCC, which increases the flowability of the mass and improves the appearance of tablets that meet the requirements of GF XI. For example, the fracture strength of tablets prepared with

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a lactose filler was from 34.4 to 40.8 N, while tablets prepared with a calcium carbonate filler were more, than 2 times higher and ranged from 83.7 to 88.2 N. The disintegration time of tablets also differs depending on the fillers used.
The results obtained experimentally are shown in Tableica.6.
According to these indicators, tablets of composition No. 7 met the requirements of GF XI. Based on the above results, the following composition was selected for further research. The main indicators of the quality of tablets prepared according to the recommended compositions are given in Table 3.11. Based on the results of the table, it can be determined that composition 7, which differs from the previous compositions, meets all the requirements for tablets according to GF XI, completely [5].
According to Table 6, the tablets obtained by us had a good appearance, the tablet indicators for deviation from the average mass, disintegration and strength meet the requirements of GF XI, vol. 2. The strength of tablets ranges from 50 to 68 N. Tablets disintegrate in less than 15 minutes.

Table 6 Results of determining quality indicatorsrecommended tablets

Quality indicators	Values of indicators
Appearance	of the tablet brown color with inclusions, odorless, round shape, biconvex, with a risk on one side
The ratio of the height of the tablets to the diameter, %	40
Average weight and deviation from the average weight, %	0,501±3,45
Fracture strength, N	58,2
Abrasion resistance, %	99,71
Disintegration, min	11
Quantitative content of active substance, %	98,9
Solubility, %	97,5

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Thus, according to the unsatisfactory results of the studied technological parameters, dry extract suggests the need for the use of excipients. The used excipients improve some of the technological properties of the substance - flowability, bulk density and compressibility.

Conclusions

1. As a result of studies conducted taking into account the physicochemical and technological characteristics of substances, the optimal composition and technology of a new diuretic drug based on dry extract was selected
2.Technology for obtaining a high-quality finished product has been developed and selected.
3.The quality indicators of tablets were studied: disintegration, crush resistance and abrasion resistance.

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