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Selection of the optimal composition and technology of the recommended capsules "PROSTAD"

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Abstract: In the process of searching for new effective drugs for the treatment of prostate and prostate adenoma, special attention should be paid to drugs based on natural origin. It is generally accepted that drugs obtained from natural origin are less toxic. The action of these drugs is carried out through ready-made dosage forms that are easy to use. The purpose of our work is to develop the composition and technology of an encapsulated dosage form based on Fireweed.This article presents the results of studies on the development of tablet technology based on the recommended dry extract "Prostad". An encapsulated dosage form, unlike others, does not require the mandatory introduction of excipients if the drugs have satisfactory technological properties. They can be filled into gelatin capsules, which significantly simplifies the technological process of production.

Having a complete description of the properties of the compressed substance, it is possible to scientifically approach the solution of this problem.

Keywords: Hygroscopicity, humidity, substance, dry extract, compressibility, fractional composition, bulk density, flowability, physicochemical.

Introduction: Selection of the optimal composition and technology of the recommended capsules "Prostad". The main important technological properties of powders - substances in relation to solid dosage forms include the following indicators: appearance, fractional composition, solubility, flowability, bulk density, angle of repose, porosity, compactibility, hygroscopicity, residual moisture [1].

Based on the above (Chapter II), in preliminary studies we studied the obtained dry extracts according to our recommended technology and conditions. The obtained extract is dry hygroscopic, finely dispersed powders from red to dark brown color with a specific odor. When shaken with water, it forms a colloidal solution. It has a unique smell and taste. Microscopic examination of the powders was carried out using a Neophot-21 microscope manufactured by Carl Zeiss at a magnification of 170 times, followed by photography. The results of the study showed that the dry extract "Prostad" is a finely dispersed homogeneous powder with particle sizes from 2.9 µm to 4.8 µm. The increased force of attraction between the particles of the extract, due to the particle size (2.75-4.62 µm), is the reason for poor flowability and relatively low bulk density. Along with the above, it should be noted that the fractional composition of the extract is the following indicators: -3000 + 2500 µm ~ 14.91%, -2500 + 1000 µm - 29.65% - 1000 + 315 µm - 40.18%, - 315 + 250 µm - 10.99%, -250 µm - 4.34%.

The above results of the study indicate that the dry extract "Prostad" is an amorphous, finely dispersed powder and in a free state is prone to the formation of conglomerates. Such powders in relation to their solid dosage forms are difficult and to achieve the necessary technological properties of the mass it is necessary to use the appropriate compositions of auxiliary substances, as well as to carry out special technological methods. The study of the physicochemical properties

of the dry extract of Fireweed showed that the extracts are dry hygroscopic, finely dispersed powders of dark brown color with a specific odor, the loss in mass during drying was 3.56%, heavy metals 0.0092, when determining the moisture content of the dry extract of the extract is equal to 4.77%, the quantitative content of biologically active substances is 91.78%.[2-6].

The recommended dry extract is characterized by hygroscopicity, insufficient flowability, the angle of natural slope it is not possible to obtain granules (for the preparation of, for example, encapsulated dosage forms) without introducing auxiliary substances into the composition that improve the technological characteristics of the mass.

Experimental section

METHODS

This study develops encapsulated dosage forms from Epilobium angustifolium (narrow leaved fireweed) extract utilizing an experimental, analytical, and comparative methodology which integrates an approach designed to address the potential pharmaceutical use of this extract to treat prostatitis and prostate adenoma. The extract was evaluated systematically in terms of physicochemical and technological properties including moisture content, bulk density, flowability and compressibility. The moisture absorption kinetics of the dry extract and encapsulated mass were analyzed using advanced gravimetric techniques in response to varied environmental humidity conditions. Excipients were selected in order to improve technological parameters of the extract and thus optimize the formulation process by the achievement of higher flowability, compactness and diminished hygroscopicity. Further study of the technological properties of dry extract showed that when developing the technology of solid dosage forms, it will be necessary to use a set of auxiliary substances and technological operations. Since when studying the technological indicators (fractional composition, bulk density, flowability, angle of natural repose, compressibility coefficient, compactibility coefficient, porosity, residual moisture...) unsatisfactory values of almost all technological properties were predicted.

RESULTS AND DISCUSSIONS

Selection of the optimal composition and technology of the recommended capsules "Prostad". The study of the physicochemical and technological properties of the substance have a predictive value in the selection of the optimal composition and technology of dosage forms [2].

Further study of the technological properties of the dry extract showed that when developing the technology of solid dosage forms, it is necessary to use a set of auxiliary substances and technological operations. Since when studying the technological indicators (fractional composition, bulk density, flowability, angle of natural repose, compressibility coefficient, compactibility coefficient, porosity, residual moisture ...) predicted unsatisfactory values of almost all technological properties. Since the dry extract is characterized by hygroscopicity, poor compressibility, insufficient flowability, it is not possible to obtain granules (for the preparation of, for example, tablets, encapsulated dosage forms) without introducing auxiliary substances into the composition that improve the technological characteristics of the mass.

Further research was devoted to studying the fractional composition of the dry extract [3].

The results of the study of the fractional composition of the dry extract "Prostad" are shown in Figure 1.

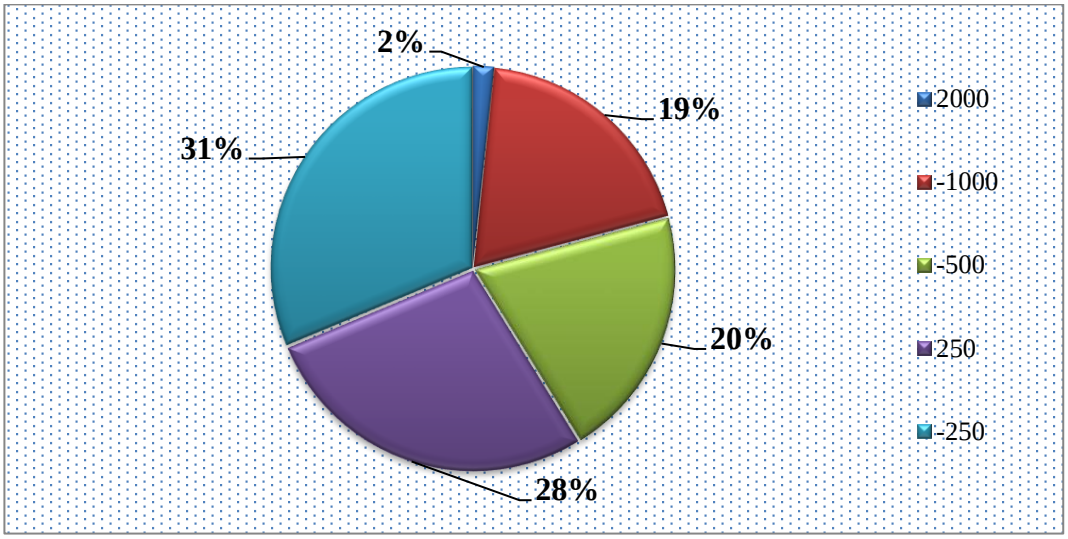


Fig. 1. Results of the study of the fractional composition of the dry extract "Prostad"

As can be seen from Figure 3.1, the main part of the dry extract 31% is contained in the -250 fraction. This in turn shows that the dry extract is a fine powder. The nature of the fractional composition in turn affects the technological parameters.

Therefore, the research continued with the study of the technological properties of the dry extract "Prostad" obtained by us using the recommended technology. The following technological properties were studied: appearance, flowability, natural slope carbon, bulk density. In appearance, the extracts are dry hygroscopic, amorphous powders from red to dark brown in color with a specific odor. Research on the technological properties of the recommended dry extract such as flowability, natural slope carbon, bulk density, dry extract, as can be seen from the obtained research results, show negative properties of the dry extract such as flowability and natural slope angle [4,5]. The results of the study of the technological properties of the recommended dry extract are presented in Table 1.

Table 1

Results of the study of the technological properties of the recommended dry extract "Prostad"

Studied indicators	Dry extract
Appearance	Powders from brown to dark brown in color
Flowability, 10^{-3} кг/с	0,575±0,354
Angle of natural slope, degrees	59,46±3,11
Bulk density, кг/м^3	578,42±3,09
Compaction coefficient	1,85±3,65
Residual moisture, %	4,76±3,22

The following studies were devoted to the development of the technology of Prostad capsules based on the dry extract obtained by us using the recommended methods and conditions. Since the dry extract is characterized by hygroscopicity, insufficient flowability, and the angle of natural repose, it is not possible to obtain granules for the preparation of encapsulated dosage forms without introducing auxiliary substances into the composition that improve the technological characteristics of the dry extract. Encapsulation of drugs obtained from medicinal plants is a complex and labor-intensive process that requires a thorough study of the structural, mechanical and technological properties of the substance, granulated materials, which has a predictive value for determining the technological process [5, 6].

To select the optimal composition of the recommended capsules under the conventional name "Prostad" based on the dry extract, certain excipients were used and their corresponding quantities were calculated based on the study of the effectiveness, mechanisms of action, and influence on the properties of the active substance.

In order to develop the composition and technology of capsules, more than twenty compositions were studied. The compositions were selected taking into account the negative physicochemical and technological properties of the dry extract "Prostad". Since the dry extract is characterized by hygroscopicity, poor compressibility, insufficient flowability, it is not possible to obtain granules for the preparation of encapsulated dosage forms without introducing excipients into the composition that improve the technological characteristics of the mass. Since the selection of the type and quantity of excipients when developing a dosage form is based on the feasibility of improving the substance indicators.

Based on the above studies, it was found that the dry extract has almost no flowability, they have a low angle of natural repose. Based on the analysis of the obtained technological properties of the dry extract, to eliminate the identified deficiencies and obtain high-quality capsules with maximum therapeutic effect with minimum side effects, it was used to improve the negative technological properties of the dry extract. Also, as an encapsulated dosage form, unlike others, does not require the mandatory introduction of auxiliary substances into the composition if the drugs have satisfactory technological properties. They can be used to fill gelatin capsules, which significantly simplifies the technological process of production. If the required conditions for filling capsules are not met, it is necessary to introduce auxiliary substances that would improve the technological properties of drugs. To determine the type and amount of auxiliary substances when developing capsules with dry extract "Prostad", the above physicochemical (Chapter II) and technological properties of the extract were taken into account.

Based on the results of previous studies, auxiliary

substances were used that would reduce caking, reduce the moisture absorption property and improve the negative technological properties in the production of capsules. To select the most rational composition, we used mathematical planning of the experiment using the Latin square 3×3 method and conducted dispersion analysis. When selecting the components of the composition from auxiliary substances, fillers (A), binders (B) and antifriction substances (C) were used. The parameters of the Latin square for selecting auxiliary substances in the capsule composition are given in Table 2.

Table 2
The meaning of the Latin square for the selection of excipients in the composition of the capsule "Prostad"

Excipients				
Fillers (A)	A_1	A_2	A_3	A_4
	Starch+lactose +MCC	Starch + lactose + magnesium oxide	Starch + lactose	Starch + lactose + sucrose
Binding (B)	B_1	B_2	B_3	B_4
	2%-10% starch paste	5% PVP solution	Ethanol	Purified water
Antifriction substances (C)	C_1	C_2	C_3	C_4
	Calcium stearate	Magnesium stearate	Stearic acid	Aerosil

Pharmacological studies established a therapeutic dose of 0.3 g of the dry extract "Prostad", on the basis of which, taking into account the above factors, the optimal capsule size was selected. Based on the bulk density of the extract, the volume occupied by 0.3 g of the drug was calculated. The study continued with the selection of the optimal capsule size. For this, based on the bulk density of the dry extract, the volume occupied by 0.3 g of the drug was calculated [5,6,7].

Based on the analysis results, capsules No. 3 (Table 3) can be selected for filling.

The selection of larger capsules will lead to an unjustified increase in the amount of excipients (over 50%).

Table 3
Choosing the optimal capsule size

Capsule number	Average capsule capacity, cm3	Объем, который занимает 0,3г сухой экстракт %	Volume occupied by 0.3g dry extract %
000	1,37	12,3	87,7
00	0,95	17,2	82,8
0	0,68	24,4	75,6
1	0,50	31,9	68,1
2	0,37	41,7	58,3
3	0,30	53,4	46,6
4	0,21	75,9	24,1
5	0,13	> 100	—

To establish the optimal composition of capsules with dry extract "Prostad", we conducted a study of the technological characteristics of mixtures of the extract with various auxiliary substances (Table 4).

Table 4

Technological characteristics of the compositions of dry extract "Prostad" with excipients

Studied technological properties	Mixture of extract with excipients			
	Dry extract with fillers			
	Starch+lactose +MCC	Starch + lactose + magnesium oxide	Starch + lactose	Starch + lactose + sucrose
Flowability, g/sec	6,21 ± 0,15	3,99 ± 0,23	3,87 ± 0,45	4,68 ± 0,14
Bulk density kg/m3	0,52± 0,09	0,59 ± 0,17	0,58 ± 0,12	0,51 ± 0,07
Angle of natural slope, deg	39 ± 2,67	29 ± 3,34	35 ± 2,54	33 ± 2,95
Bulk density, g/cm3	0,79 ± 0,09	0,77 ± 0,11	0,78 ± 0,05	0,75 ± 0,14
Residual moisture, %	3,38 ± 0,11	3,98 ± 0,06	3,67 ± 0,15	4,36± 0,08
Studied technological properties	Dry extract with antifriction substances			
	Calcium stearate	Magnesium stearate	Stearic acid	Aerosil
Flowability, g/sec.	5,42 ± 0,31	5,97 ± 0,54	4,65 ± 0,14	7,44 ± 0,15
Насыпная масса кг/м^3	0,58 ± 0,21	0,46 ± 0,34	0,49 ± 0,25	0,56 ± 0,04
Bulk density kg/m3	37 ± 2,45	34 ± 3,61	36 ± 2,32	36 ± 2,54
Bulk density, g/cm3	0,78 ± 0,11	0,78 ± 0,19	0,79 ± 0,08	0,76 ± 0,17
Residual moisture, %	3,87 ± 0,14	4,59 ± 0,03	3,99 ± 0,11	3,22± 0,05

As can be seen from Table 3, the results of the obtained data showed that almost all compositions of auxiliary substances showed positive data except for flowability, angle of repose. Of the obtained research results, the most positive data is shown by the composition starch + lactose + MCC. Next, we studied the compositions of dry extract with antifriction substances. The obtained data on flowability and moisture absorption of the composition are most significantly affected by the presence of aerosil, which shows the most positive data on flowability (- 7.44 ± 0.15) and on residual moisture indicators (3.22 ± 0.05). In addition, close values of bulk density and bulk density of this mixture predict that it will not compact (press) under different conditions - during transportation and storage. The other indicators were closer and more positive.

The next stage of the study was devoted to the selection of the concentration of aerosil. According to literature, aerosil in a concentration of 0.05-1% improves the flowability of the powder mixture, and in 1-2% it is a good loosening agent. Therefore, it was advisable to determine the optimal concentration of aerosil, which would allow obtaining the required mass. For this purpose, the effect of different concentrations of aerosil on the flowability of the dry extract "Prostad" was studied. The results of the studies showed that with the addition of 0.3-0.5% of aerosil, the flowability of the composition increases from 1.2 to 1.5 times. Increasing the content of aerosil did not improve the flowability by more than 1.6 times. Therefore, as an antifriction substance, it is sufficient to take aerosil in an amount of 0.3-0.5%. At a concentration of 2%, aerosil contributes to a significant

decrease in the moisture-sorption properties of the extract. Further increase in the aerosil content (more than 2%) does not lead to significant changes in the moisture absorption properties of the composition. Therefore, the most optimal concentration of aerosil is 2%.[18-22].

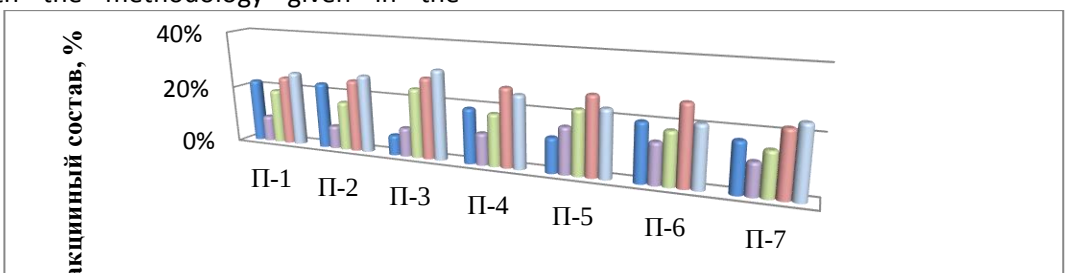
Based on the bulk density of aerosil, we calculated that the volume occupied by it together with the active substance is insufficient to fill capsules No. 3 (0.185 cm3). Therefore, we conducted research on the choice of filler and, based on the data obtained, chose MCC.

Thus, as a result of the research, a composition of capsules with dry extract "Prostad" was developed, excipients - 46.6%. Hard gelatin capsules No. 3, average weight 0.04 g. Average weight of one filled capsule - 0.5 g. When developing the technology, the properties and state of powders, losses during grinding and the quantitative ratio of ingredients were taken into account. Table 4 shows 7 compositions of capsules "Prostad" selected for the study.

Table 5
Recommended compositions of Prostad capsules

Ingredients	Составы						
	П-1	П-2	П-3	П-4	П-5	П-6	П-7
Dry extract "Prostad"	0,3	0,3	0,3	0,3	0,3	0,3	0,3
Sucrose		0,053					0,053
Lactose M-80			0,053	0,053	0,053		
Lactose M-200	0,053					0,053	
Magnesium oxide	0,042			0,042			0,052
Potato starch	0,095	0,095	0,095	0,095	0,090	0,090	0,090
Microcrystalline cellulose		0,042	0,042		0,052		
Aerosil	0,01	0,01	0,01	0,01			
Calcium stearate					0,005		
Stearic acid						0,005	
Magnesium stearate							0,005
Average weight	0,50	0,50	0,50	0,50	0,50	0,50	0,50

In further studies, comparative technological properties of granulated masses obtained from the above-mentioned compositions were studied. Technological properties were determined in accordance with the methodology given in the literature [8-11].The study of the fractional composition of granulated masses obtained from seven recipes is shown in Fig. 2.



	П-1	П-2	П-3	П-4	П-5	П-6	П-7
150+100	22%	23%	7%	19%	12%	20%	17%
2000 +1000	9%	8%	10%	11%	16%	14%	11%
1000 +500	19%	17%	24%	18%	22%	18%	15%
500 +250	24%	25%	28%	27%	27%	27%	22%
250+150	26%	27%	31%	25%	23%	21%	24%

Fig. 2. Results of a comparative study of the fractional composition of granulated masses

As can be seen from the obtained values, the P-3 composition shows a more positive value of the fractional composition. However, other masses also give a forecast for improved technological properties of granules by fractional composition than dry extract powders separately. The results of a comparative study of flowability and bulk density of the granulated mass are shown in Fig. 3 and 4. The study of the technological characteristics of the granules showed that the flowability of the obtained granules increased compared to the powder mixture (3.87 g / sec.). It can also be noted that the highest (7.99 g / sec.) indicator relates to the P-3 composition. According to the results of the study, it is clear that the bulk density indicators are almost the same as the mixture of these recipes. Other technological properties (angle of repose, residual moisture) of the encapsulated mass were close to powder mixtures. [16-18].

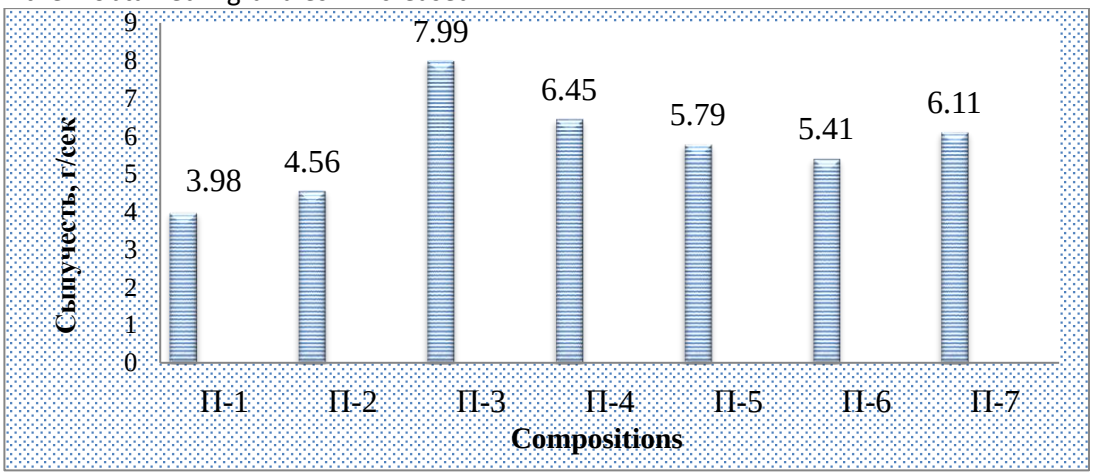


Fig. 3. Results of a comparative study of the flowability of the granulated mass

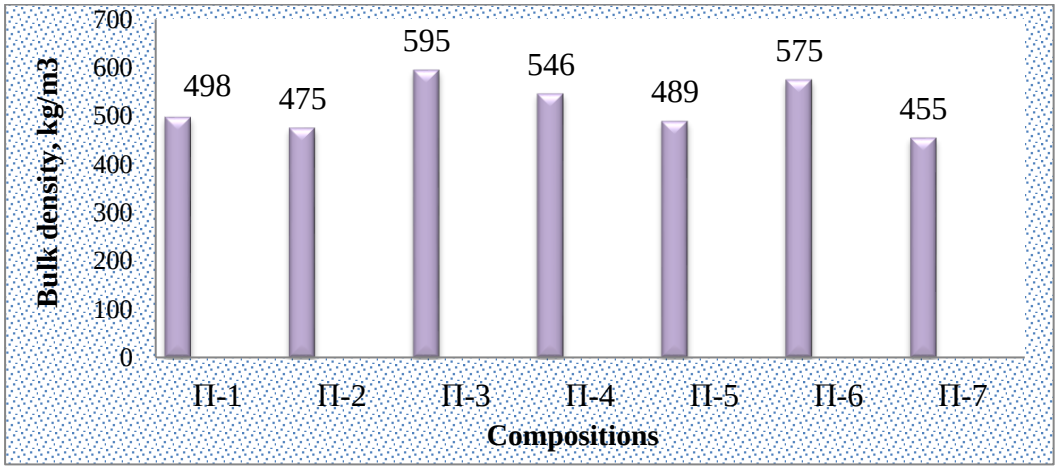


Fig. 4. Results of a comparative study of the bulk density of the granulated mass

In the future, we used the method of obtaining capsules after preliminary granulation by the wet method according to the scheme of granulated powder shown in Figure 4.

As can be seen from the figure, the initial stage of the technological process of preparing the production workshop, equipment, personnel, raw materials.

In the next stages of the technological process according to the recommended technologies, which is given above, the technology itself begins according to the selected composition. Study of quality indicators of the recommended capsules "Prostad". The research was continued with the study of the quality of the recommended capsules "Prostad". The study of the quality of capsules obtained in the recommended composition was carried out on the basis of the State Pharmacopoeia of the Republic of Uzbekistan, literary sources and relevant ND [18-23]. The following quality indicators were studied: appearance, average weight and deviation, disintegration, solubility, etc. The results obtained are presented in Table 6.

Table 6.
Results of the study of quality indicators of capsules "Prostad"

Compositions	Appearance	Average weight and deviations from it, g, %	Capsule disintegration, min	Solubility of capsules, %
P-1	Size No. 3, white gelatin capsules, encapsulated mass of pale brown color with inclusions, with a peculiar smell.	0,502±3,35	21	79,67
P-2	-//-	0,502±2,87	20	79,84
P-3	-//-	0,502±3,09	14	88,95
P-4	-//-	0,501±3,64	22	81,31
P-5	-//-	0,501±3,78	20	81,78
P-6	-//-	0,498±3,78	20	80,19
P-7	-//-	0,499±3,83	22	83,71

Рекомендуемый Based on the results of the study, it was determined that the obtained encapsulated mass in all formulations met the requirements for appearance.

The color of the encapsulated mass is pale brown with inclusions, with a peculiar odor. According to the other parameters studied, the granules prepared on the compositions P-1, P-4 and P-7 did not meet the requirements of the State Pharmacopoeia of the Republic of Uzbekistan for disintegration (21-22 min.). Also, the encapsulated masses P-1 and P-4 did not meet the solubility requirements, i.e. the values were equal to the requirement. However, this fact can change during storage of dosage forms. Therefore, it was considered unsatisfactory. [22-25].

Based on the above, the composition shown in Table 6 was selected for further research.

Table 7.
Recommended composition of the capsule "Prostad"

Name of ingredients	Количество	
	г	%
Dry extract "Prostad"	0,3	60
Лактоза М-80	0,053	10,6
Potato starch	0,095	19
Microcrystalline cellulose	0,042	8,4
Aerosil	0,01	2
Average weight	0,5	100

CONCLUSIONS

Thus, the above results indicate a rational approach to selecting the excipient complex during the development of encapsulated dosage form technology. The study results showed that at 100% relative humidity, the granulated mass lost its flowability within 5 days, absorbing 22.16% moisture. By the end of the 7th day, it had absorbed 29.42% moisture and turned into a wet mass. At 58% and 79% relative humidity, the 0 50 1 2 3 4 5 6 7 Moisture Absorption% Time, days 58% 79% 90% 100% 167 granulated mass absorbed 4.02% and 9.44% moisture, respectively. Samples placed in all three containers retained their flowability until the end of the experiments, absorbing between 1.06% and

1.21% moisture. Based on the results, it can be concluded that increasing the surface area of the sample slightly enhances the moisture absorption properties of the studied mass.

Tsvet kapsuliruemoy massy bledno korichnego tsveta s vkrapleniyami, svoeobraznym zapaxom. Po ostalnym izuchaemym parametram granuly, prigotovlennye na kompozitsiyax P-1, P-4 i P-7, ne sootvettvovali trebovaniyam GF RUz po raspadaemosti (21-22 min.). Takje kapsulirovannye massy P-1 va P-4 ne

udovletvoryala trebovaniyam po rastvorimosti, t.e. znachenie byli ravny trebovaniyu. Odnako etot fakt mumkin byt izmenen pri hranenii lekarstvennyx form.

Rezultaty issledovaniy pokazali, chto pri dobavleii 0,3–0,5% aerosila supchest kompozitsii povyshaetsya ot 1,2 dan 1,5 gacha. Uvelichenie soderjaniya aerosila ne uluchshalo sypuchest bolee chem v 1,6 raza. Sledovatelno, qanday antifriksionnoe veshchestvo aerosil dostatochno vzyat v kolichestve 0,3–0,5%. V kollegiali 2% aerosil sposobstvuet znachitelnomu snijeniyu vlagosorbtionnyh svoystv ekstrakta. Dalneyshee uvelichenie soderjaniya aerosila (bolee 2%) ne qabul k sushchestvennym izmeneniyam vlagosorbtionnyh svoystv kompozisiya. Poetomu naibolee optimalnoy yavlyaetsya konsentratsiya aerosila 2%.

Ishodya iz nasypnoy massy aerosila, my rasschitali, chto ob'em, zanimaemyy im vmeste s deystvushhim veshchestvom, nedostatochen uchun zapolneniya № 3 kapsul (0,185 sm3). Poetomu nami byli provedeny issledovaniya po vyboru napolnitelya va po poluchennym dannym vybrali MKTs.

Takim obrazom, natijada provedennyh issledovaniy razrabotan sostav kapsul va suxim ekstraktom «Prostad», vspomogatelnyh veshchestv - 46,6%. Tverdye jelatinovye kapsuli № 3, sredney massoy 0,04 g. Srednyaya massa odnoy napolnennoy kapsuli - 0,5 g.

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