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Aspects for the Development of the Composition and Technology of a Fast-Soluble Granules «Sedgran»

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Abstract

Based on the dry extract of Sedex with sedative action, the pharmacotechnological aspects of choosing the composition and developing the technology of instant granules (for suspension preparation) were studied.

Keywords: granule, bioactive substance, dry extract, pharmacotechnological aspects.

Introduction

Today, 40% of the arsenal of drug types corresponds to the medical preparations derived from plants [1,2].

This certainly indicates that medicinal preparations obtained from medicinal plants have a number of advantages. Exactly, the low toxicity, cheapness of these preparations and the presence of our ecology and rich flora increase the need for the types of drugs obtained from them [2,3,7]. Plant raw materials contain bioactive substances such as flavonoids, polysaccharides, mineral substances, amino acids, organic acids, vitamins and this shows that phytopreparations have a wide pharmacological spectrum. Preparations such as extracts, tinctures and decoctions, elixirs, syrups are obtained from medicinal plants, especially in chronic diseases, they are well absorbed by the body, improve metabolism in organism, stimulate the body's defense mechanisms [4,5,6].

The rational use of plant raw materials in the production of phytopreparations, the development of technologies for low-paid and low-waste and easy-to-use, stable preparations are one of the urgent issues today. In addition, it is important to work out a technology that allows the maximum preservation of the pharmacological effect, quality and stability of medicinal plants.

Based on the above, one of the main parameters in the development of the technology of phytopreparations from medicinal plants is to ensure a certain stability..

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The purpose of the research. The purpose of this work was to select the composition and work out the technology of the recommended quick-dissolving granule (intended for preparation of suspension) based on the dry extract of "Sedex".

The fact that granule types of drugs have a number of advantages over powders has aroused interest in the production of this drug technology. These advantages include: good dispersibility, accurate dosing, and the ability to homogenize the mixture of bioactive substances. In addition, they have high bioefficiency.

The object of the research. In our previous articles, we provided information on the selection of specific conditions for obtaining a dry extract of the recommended "Sedex" in conventional name based on medicinal lemon grass (melissa) and lion's tail (leonotis leonurus) and guaranteeing the quality of the finished product [2]. The dry extract of "Sedex" was taken as the object of our this work. Dry extract "Sedex" is a dark-brown powder with a specific smell, hygroscopic. The total amount of flavonoids in the composition is 8.33 ± 0.97 (% compared to rutin). Mass loss during drying is 2.5-5%. The amount of heavy metal is less than 0.01%. The moisture of remnant is 5.51%.

Experience part. The technological properties of the dry extract are of particular importance in the creation of the granule drug type.

Table 1 shows the results of the study of the technological parameters of the dry extract that are of particular importance in the creation of the granule drug preparation.

Table 1. Technological properties of "Sedex" dry extract

Spreadability g/s		Scattered density, g/sm³		Density coefficient	Angle of natural deviation, degrees	Dust fraction %
Without shaking	Shaking	Scattering freely	When it is condensed			
There is no spread	1,25± 0,06	0,491± 0,05	0,647± 0,032	0,236± 0,020	45°±4°	3,71

As can be seen from the indicators presented in Table 1, some technological indicators are negative. These indicators, in turn, lead to difficulties in the packaging and dosing of powders. Therefore, it is necessary to use auxiliary substances, in order to eliminate these negative indicators. Based on the results of the analysis of dry extract "Sedex", we tried to choose excipients, and research focused on the selection of moisturizers.

In order to improve the hygroscopicity and dispersibility of the powder, we included lactose in the granule mass. The resulting excipients were studied by adding them in individual and complex cases. The available excipients were studied in different amounts reported in the literature. Decreasing the

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amount of lactose led to an increase in pollination of mass and a decrease in diffusion. It was observed in studies that the appearance of pollen increased during the preparation of model granules prepared by adding potassium carbonate. Wine acid and sodium bicarbonate were included as gas-generating agents. Magnesium stearate, stearic acid and calcium stearate were obtained from the emollients. It was observed that these emollients dissolved the granule mass to form slurry. The purpose of obtaining potato starch and corn starch was also to improve the dispersibility of the emollient and granule mass.

We used purified water, 96% and 70% ethyl alcohol, starch paste of different concentrations, aqueous and alcoholic 20% solutions of polyvinylpyrrolidone (PVP), 2% solutions of methylcellulose (MTs) as a moisturizing substance.

When moistened with 70% ethyl alcohol, it was observed that the obtained granules were of better quality (composition containing SG-5). Also, the granulation process was easier. The flowability of the mass was improved. The appearance of the granules was at the level of demand. However, the explosive properties of ethyl alcohol indicated that other aqueous wetting substances should be studied in granulation rather than wetting with this moisturizer substance.

In further studies, 2% solution of methylcellulose and 2%, 5%, 7% and 10% solutions of starch gel were used (composition containing SG-1, SG-4, SG-6). Granulation became heavier in these studies. The flowability of the granule mass has deteriorated. The number of conglomerates in the granule mass increased. The appearance was not up to demand.

When using the 20% solution of polyvinylpyrrolidone in ethyl alcohol, it was observed that the dispersibility of the granule mass improved, and the number of agglomerates and conglomerates did not increase (composition containing SG-5).

Table 2 shows the results of the study of the effect of different wetting substances on the technological properties of the model granules.

In these studies, among the technological indicators, dispersibility, scattering density, density coefficient, the amount of pollinating fraction, the progress and quality of the granulation process were studied organoleptically.

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Table 2. The results of the study of the effect of different wetting substances on the technological properties of model granules

№№	Composition, %	Dispersibility g/s		Scatter density, g/sm3		Density coefficient	Pollinating fraction %	Granulation quality
	Wetting substance	Not shaking	Shaking	Scattering freely	Condensing			
1 1	Dry extract-50 Lactose- 50 / 5% Paste starch	11,6	6,9	0,62	0,65	0,067	7,08	During the granulation process, conglomerates were formed
4 3	Dry extract-50 Lactose - 50 / 2% methylcellulose solution	8,8	6,76	0,65	0,7	0,79	10,67	During the granulation process, conglomerates were formed
6 5	Dry extract-50 Lactose - 50 / 70% ethyl alcohol	6,69	5,29	0,59	0,64	0,079	2,56	The granulation process was easy, the mass dried quickly
1 7	Dry extract-50 Lactose -50 / 20% methylcellulose solution	7,25	6,27	0,57	0,618	0,078	5,69	The granulation process was easy and satisfying

As can be seen from the indicators presented in the table, different wetting substances had different effects on the quality of the granules. The high humidity of the granule mass had a direct effect on the organoleptic properties when the mass was moistened with aqueous solutions.

Based on the indicators obtained as a result of the above research, more than 20 contents were

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http://journals.academiczone.net/index.php/rjtds

recommended and studied in the research.

The compositions that showed similar indicators were showed on the Table 3.

Table 3. Compositional contents of the recommended fast-dissolving granules are "Sedgran"

Ingredients	Compositions of "Sedgran" fast-dissolving granules						
	Components						
	SG-1	SG-2	SG-3	SG-4	SG-5	SG-6	SG-7
"Sedex" dry extract	0,300	0,300	0,300	0,300	0,300	0,300	0,300
Sodium citrate	0,175	0,175	0,175	0,175	0,175	0,175	0,175
Citric acid		0,934			0,934		0,934
Wine acid	0,934					0,934	
Malic acid			0,934	0,934			
Sodium bicarbonate					0,895		0,895
Sodium carbonate	0,895		0,895	0,895			
Potassium bicarbonate		0,895				0,895	
Polyvinylpyrrolidone			0,053		0,041		
Lactose					0,045		
Potato starch	0,053			0,053		0,053	
Corn starch		0,053					0,053
Calcium stearate	0,033						0,033
Magnesium stearate		0,033		0,033		0,033	
Stearic acid			0,033				
Average weight	3,965	3,965	3,965	3,965	3,965	3,965	3,965

The next stage of research was devoted to studying the technological properties of the granule mass prepared on the basis of the above compositions.

The results of studying the technological properties of the compositions whose technological properties showed positive indicators presented on the Table 3.

Table 4. The results of studying technological features of "Sedgran" quick-melting granules

Name of granule	Compositions	Scatter density kg/m3	Angle of free fall, degree	Dispersibility, g/s	Residual humidity %	Coefficient of gas formation	Dissolution of granules, minute
"Sedgran"	СГ-1	592,3	37	5,3	3,6	0,86±0,05	5,66±5
	СГ-2	621,2	41	4,2	4,0	0,85±0,03	4,57±8

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	СГ-3	394,9	52	4,5	3,7	0,87±0,06	2,54±6
	СГ-4	563,2	48	7,6	4,8	0,85±0,07	4,47±7
	СГ-5	545,8	42	6,6	3,2	0,89±0,04	1,48±7
	СГ-6	631,4	33	4,5	4,3	0,88±0,03	1,49±6
	СГ-7	562,4	35	4,8	3,5	0,85±0,04	2,37±7

As can be seen from the indicators presented in Table 4, the granule mass obtained from the composition containing SG-5 meets the requirements for all indicators, and in further studies, the mass was moistened with polyvinyl pyrrolidone. In the conducted studies, granules obtained in SG-5 and SG-6 compositions showed the lowest and best solubility (1.48±7 and 1.49±6, respectively).

The angle of free fall of the granule masses showed low values in the granule masses obtained in SG-1, SG-6 and SG-7 compositions (33-35 degrees).

It was observed in the studies that the spreadability showed indicators of 4.2 - 7.6 g/s and showed the best indicators in SG 4 and SG-5 compositions.

When studying the residual moisture content of the granule masses obtained in all compositions, the indicators showed 3.2-4.8%, the highest indicator was shown by SG-4 and the lowest indicator by the granule mass obtained in the SG-5 composition. It was observed that the coefficient of gas formation showed the same and positive amounts in almost all compositions (0.85 – 0.88).

Preparation of the recommended granule masses is carried out using the following technology: all ingredients are made smaller to 50 mm. Then anhydrous citric acid, lactose, sodium bicarbonate (10% sodium bicarbonate is taken for evaporation) and sodium citrate (anhydrous) are mixed in a mixer. It is moistened with 7-20% polyvinylpyrrolidone alcohol solution and granulated. The resulting granulate is dried at 40-500 C to a residual moisture content of 0.1-0.3%, sifted through a 1200 mm sieve, and the remaining ingredients are added and mixed with antifriction substances.

Based on composition and technology, only the granules obtained in SG-5 composition, which differed from other compositions in terms of the amount of agglomerate granules and showed the lowest index, were taken as the basis for the next stage of research.

Thus, the following composition of "Sedgran" granules intended to be placed in a vial for the above studies was selected for further studies.

The recommended content is given in Table 5.

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http://journals.academiczone.net/index.php/rjtds

Table 5. Recommended composition content of "Sedgran" granules

11Ingredients	Amount		
	Single dose, g	%	Tenfold dose, g
"Sedex" dry extract	0,300	12,55	3,00
Sodium citrate (anhydrous)	0,175	7,32	1,75
Citric acid	0,834	39,08	9,34
Sodium bicarbonate	0,995	37,45	8,95
Polyvinylpyrrolidone	0,041	1,72	0,41
Lactose	0,045	1,88	0,45
Average weight, g	2,390	100	23,90

A schematic view of the recommended granule technological process is presented in Figure 1.

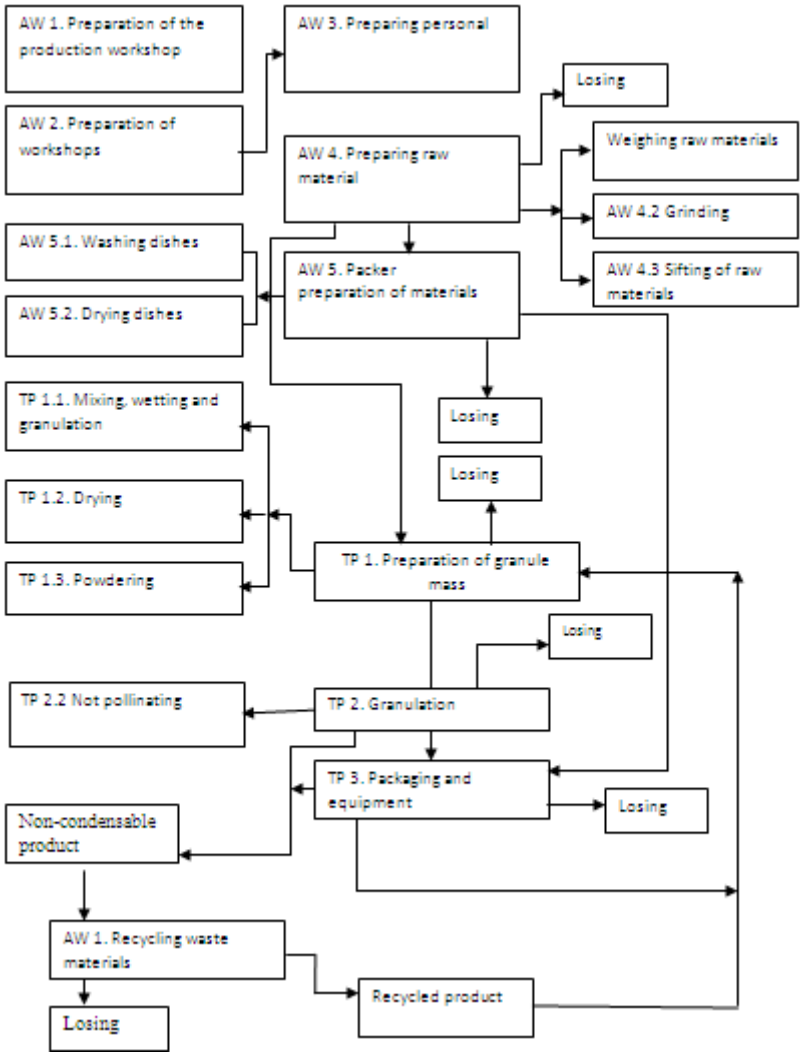


Figure 1. Illustration of the technological process of the recommended "Sedgran" granule production

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http://journals.academiczone.net/index.php/rjtds

Summary. Thus, the pharmacotechnological criteria for the development of the composition and technology of the quick-dissolving granule based on the dry extract of "Sedex" were studied, and the specific composition and technology of the "Sedgran" granule were developed. A technological process for the production of the recommended granules has been prepared.

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