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RESEARCH ON THE PHYSICAL-CHEMICAL AND TECHNOLOGICAL PROPERTIES OF DRY EXTRACT WITH ADAPTOGENIC ACTION

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ABSTRACT

In order to substantiate the composition and technology of solid dosage forms, the physicochemical and technological properties of dry extract of common ginseng root (Panax ginseng C.A.Meyer), which has an adaptogenic, tonic, restorative and stimulating effect, were studied. The preparations of this plant stimulate sexual functions, actively influence the central nervous system, increase performance, reduce physical and mental fatigue, and improve appetite. As a result of experimental studies, the feasibility of introducing a complex of excipients into the solid dosage form and using the preliminary wet granulation method was determined.

Relevance: The tradition of using medicinal plants, as well as products of natural origin, in the treatment of various diseases dates back thousands of years. Currently, despite the achievements of chemistry and biotechnology, the relevance and popularity of the use of herbal medicines remains quite high. The peculiarity of the therapeutic effect of drugs from herbal medicinal raw materials is that the therapeutic effect does not occur immediately and is not always pronounced, as when using drugs obtained by chemical synthesis. However, preparations containing biologically active substances (BAS) of plant origin, unlike synthetic ones, do not cause allergies, are low-toxic, have a beneficial effect on the body, and do not have side effects with long-term use. Common ginseng (Panax ginseng C.A. Meyer) is widely used in medicine. The plant has cardiotonic, hemostatic and hypoglycemic properties. Panax ginseng root is used as a tonic, stimulant and adaptogenic agent that increases the body's overall resistance to disease. Common ginseng stimulates the activity of the internal secretion organs, and also increases the body's resistance to infections and ionizing radiation. Herbal medicines have the advantage that they provide a mild pharmacological effect, have low toxicity and are safer than synthetic drugs. However, the development of solid dosage forms with dry extracts in most cases is associated with significant difficulties associated with the unsatisfactory properties of dry extracts for the technology. Therefore, studying the physicochemical and technological properties of dry extracts will help to correctly select the composition and technology of drugs [1-4].

The purpose of the study is to study the physicochemical and technological properties of dry extract of common ginseng (Panax ginseng C.A. Meyer), which will make it possible to come to a common denominator when choosing the main excipients for developing the composition and technology of herbal tablets.

Materials and methods of research. The substance of dry extract of common ginseng was used as the object of study. Dry extract is an amorphous powder ranging from light yellow with a grayish tint or without a tint to brown with a characteristic odor. The powder is easily soluble in purified water, soluble in 95% alcohol, slightly soluble in ethyl acetate, chloroform and practically insoluble in acetone.

Determination of authenticity. ***High performance liquid chromatography***. The retention times of two peaks in the chromatogram of the test solution obtained for quantitative determination must correspond to the retention times of the main peaks in the chromatograms of solutions of standard samples of ginsenoside Rb1 and ginsenoside Rg2.

Quantitation. Determination is carried out by high-performance liquid chromatography.

Buffer solution. 3.5 g of disodium hydrogen phosphate dihydrate and 7.2 g of potassium dihydrogen phosphate are dissolved in water in a 1000 ml volumetric flask, the volume of the solution is adjusted to the same mark with solvent and mixed.

Test solution. About 0.100 g (exactly weighed) of the substance is placed in a 10 ml volumetric flask, dissolved in 5 ml of a buffer solution, the volume of the solution is adjusted to the mark with the same solvent and mixed. 5.0 ml of the resulting solution is applied to a solid-phase extraction cartridge (octadecylsilyl silica gel, 0.50 g/45 μm), pre-activated with 5 ml of methanol and then 20 ml of water. Elution is carried out with 20 ml of water, then 15 ml of methanol 30%. The eluates are checked for the absence of ginsenosides and the cartridge is discarded or replaced with a similar one. Then elution is carried out with 20 ml of methanol, the eluate is collected and evaporated to dryness on a rotary evaporator. The dry residue is dissolved in 2.0 ml of methanol and filtered through a membrane filter with a pore diameter of 0.45 μm.

Standard solution (SS) of dry ginseng extract. About 0.100 g (exactly weighed) of dry ginseng extract SS is placed in a 10 ml volumetric flask, dissolved in 5 ml of a buffer solution, the volume of the solution is adjusted to the mark with the same solvent and mixed. 5.0 ml of the resulting solution is applied to the solid-phase extraction cartridge and then the solution is prepared in the same way as the test solution.

Standard sample solution (SS) of ginsenoside Rb1. About 0.003 g (exactly weighed) ginsenoside Rb1 is dissolved in 5.0 ml of methanol.

Standard sample solution (SS) of ginsenoside Rg2. About 0.003 g (exactly weighed) ginsenoside Rg2 in 5.0 ml of methanol.

Solution for testing the suitability of the chromatographic system. 1.0 ml of a standard sample (SS) solution of ginsenoside Rb1 is mixed with 1.0 ml of a standard sample (SS) of ginsenoside Rg2.

Checking the suitability of the chromatographic system. A chromatographic system is considered suitable if the following conditions are met for the chromatogram of the solution to test the chromatographic system:

- the resolution between the peaks of ginsenoside Rb1 and ginsenoside Rg2 must be at least 1.5;

- the efficiency of the chromatographic column for the ginsenoside Rb1 peak must be at least 15,000 theoretical plates;

- the asymmetry factor for the ginsenoside Rb1 peak should be no more than 1.5%;

- the relative standard deviation calculated from the peak of ginsenoside Rb1 should not exceed 2.0% (6 injections).

Chromatography conditions.

Column	125 × 4.6 mm, sorbent octadecylsilyl silica gel (C18), 5 µm
Movable phase (MP)	MP A: water adjusted to pH 2 with phosphoric acid
	Mp B: acetonitrile
Flow rate, ml/min	1.0
Column temperature, °C	35
Detector	spectrophotometric
Wavelength, nm	203
Volume of injected sample, µl	20

Relative retention time: ginsenoside Rb1 - 1 (about 33 min); ginsenoside Rg2 - about 0.98; peaks with relative retention times of about 0.53 should also be detected; 0.54; 0.88; 1.04; 1.08 and 1.17. The test solution, a standard sample (SS) solution of dry ginseng extract, a standard sample (SS) solution of ginsenoside Rb1 and a standard sample (SS) solution of ginsenoside Rg2 are chromatographed alternately, obtaining at least 3 chromatograms for each solution.

The content of the sum of ginsenosides in terms of ginsenoside Rb1 and absolutely dry substance in percent (X) is calculated using the formula:

$$X = \frac{S \cdot ao \cdot P \cdot 10 \cdot 2 \cdot 100 \cdot 100}{So \cdot a \cdot 5 \cdot 5 \cdot 100 \cdot (100 - W)} = \frac{S \cdot ao \cdot P \cdot 80}{So \cdot a \cdot (100 - W)}$$

Where

S - is the sum of the peak areas of ginsenosides Rb1 and Rg2, as well as unidentified peaks with relative retention times of 0.53; 0.54; 0.88; 1.04; 1.08; 1.17 on the chromatogram of the test solution;

So - is the peak area of ginsenoside Rb1 in the chromatogram of the test solution;

a – weight of the substance, g;

ao – weighed portion of SS of ginsenoside Rb1, g;

W – weight loss when drying the substance, %;

P – content of the main substance in the SS of ginsenoside Rb1, %.

During the research, the following physicochemical and technological quality indicators were also studied: crystal size and shape, solubility, fractional particle size distribution, bulk density before and after shrinkage, fluidity, residual moisture, compressibility, angle of repose, associated impurities, authenticity, quantitative content and other necessary characteristics in accordance with the methods set out in the Global Fund XIII. Bulk density was determined using a model 545R-AK-3 instrument from the Mariupol Process

Equipment Plant. The flowability of the materials under study was determined using a model VP-12A device. Pressability was determined by the resistance to crushing of standard pressings obtained on a hydraulic press at a pressure of 1200 kg/cm2. The angle of repose was measured using a method using a special ruler and scale. To determine the residual moisture, the method of drying with IR rays was used, using an IR moisture meter from Kett.

Initially, the size and shape of the dry extract crystals were assessed. The shape of the powder crystals also affects the orientation of the particles, changing such characteristics of the substance as fluidity, solubility, compressibility, and compactness. The results of crystallographic studies showed that the substance has an amorphous form.

Table No. 1

Results of studying the technological properties of the substance

№	Verified indicators	Units	Results
1	Particle Shape	-	Amorphous
2	Fractional composition: + 1000 - 1000 + 500 - 500 + 315 - 315 + 250 - 250 + 100 - 100 + 50 - 50	µm, %	 7,5 23,4 20,1 19,3 17,7 5,0 7,0
3	Flowability	10^{-3} kg/s	5,0±1,1
4	Natural angle of repose	degree	45,00
5	Bulk density	kg/m ^{3}	855
6	Compressibility	N	60
7	Compaction coefficient	C	2,50
8	Residual humidity (70^0C)	%	5,0

Results and discussions. Analyzing the results of the technological properties of the substance (Table No. 1), we can conclude that this substance has unsatisfactory volumetric characteristics and unsatisfactory fluidity. A high compressibility factor indicates poor fluidity. This is confirmed by the high value of the angle of repose and, accordingly, the irregular shape of the powder particles. The substance has satisfactory compressibility, which can be explained by the complexity of the shape of its particles, large contact surface and cohesive force. Based on the results of crystallographic and technological studies of the substance, it was established that when developing the composition of a dosage form in the form of solid dosage forms, in

order to ensure the necessary technological characteristics of the mass, auxiliary substances should be used that improve the flowability and compressibility of the mass.

Conclusions. Thus, we have studied the physicochemical and technological properties of the dry extract, and established the critical characteristics of the starting raw material that can affect the quality of the finished product. As a result of experimental studies, the feasibility of introducing a complex of excipients into the dosage forms and using the method of preliminary wet granulation was determined.

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