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Physical and Chemical Properties of Capsule Shells Based on Plant Analogs of Pharmaceutical Gelatin

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Abstract

Technological operations to produce capsule shells from plant analogs of pharmaceutical gelatin were studied. The following raw materials and components were used in the preparation of capsule shells: plant hydrocolloids—carboxymethyl cellulose, sodium alginate, hydroxypropyl methylcellulose. Organoleptic, physical, and chemical characteristics of the plant analogs of pharmaceutical gelatin from starch was studied. The concentrations of active groups in the solutions of studied plant analogs of pharmaceutical gelatin were determined. By the acidity test of results obtained, it was found that the test samples among plant analogs of pharmaceutical gelatin starch, all the starches samples showed satisfactory characteristics. All the samples of plant analogs of pharmaceutical gelatin from starch, carboxymethyl cellulose, hydroxypropyl methylcellulose, carrageenan, and agar and the mass fraction of total quantity of ash based on dry weight did not exceed the rated value. According to the results of the analysis of organoleptic, physical, and chemical properties of the mixture for the production of capsule shells from plant analogs of pharmaceutical gelatin are expedient to use any representative sample of starch, carboxymethyl cellulose, hydroxypropyl methylcellulose, agar, and carrageenan.

Keywords

Capsule shell; Gelatin; Carrageenan; Plant analog

Introduction

Market analysis of encapsulated medications and biologically active dietary supplements indicates close attention of capsule-manufacturing companies to seek alternatives to traditionally used gelatin in this area. This factor determines the relevance of the development of technology for the production of capsules from nontraditional raw materials, which can act as the composition of hydrocolloids of plant origin [1].

The present work is focused on the development of technological operations for the production of capsules based on plant analogs of pharmaceutical gelatin. The following raw materials and components were used in this project: plant hydrocolloids—carboxymethyl cellulose (CMC), sodium alginate, HPMC.

Currently, the pharmaceutical industry widely uses CMC, sodium alginate, gelatin, collagen, and HPMC [2,3].

Great importance for the use of plant pharmaceutical analogs of gelatin as a gelling conditions are liquid transfer system in the gel state. These conditions should provide sufficiently rapid gelation process flow at a controlled rate. To obtain bulk amounts of products (three-dimensional network of the gel), the methods of thermotropic gel formation are the most convenient. The relatively low rates of metal ions diffusion in solutions of biopolymer ionotropic gelation processes are most effective in obtaining single- and two-dimensional gels, films, and fibers [4,5].

The aim of this study was to determine the organoleptic, physical and chemical, optical, rheological, and structural and mechanical properties of plant analogs of pharmaceutical gelatin for the production of soft capsules, their complex characteristics.

Materials and Methods

The main objects of research in the production process of plant analogs of pharmaceutical gelatin were as follows:

- CMC;
- HPMC;
- Starch;
- Agar;
- Pectin;
- Carrageenan.

The mass fraction of moisture was determined using a thermostatic COP-65 analytical balance and ATL-220-d4-1 (Acculab, USA). The mass fraction of total ash was determined using a muffle furnace PL 10/2.5 (Russia) and analytical balance ATL-220-d4-1 (Acculab, USA). To determine the mass fraction of nitrogen, analytical balance ATL-220-d4-1 (Acculab, USA), digester D8 (Foss Tecator, Sweden), and a semi-automatic analyzer nitrogen/protein Kjeltec 8200 (Foss Tecator, Sweden) were used [6,7].

During the study, the following reagents were used: deionized water MillyQ, hydrochloric acid (Sigma Tek, highly pure, Russia), sodium hydroxide (Sigma Aldrich) [8,9].

The pH units of the solutions were recorded continuously using the pH-meter S20 (Mettler Toledo, Switzerland). During the measurement, the test solution is constantly and vigorously stirred using a magnetic

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stirrer (Biosan, MMS-3000). Hydrochloric acid solution was added by an automatic pipette, in quantities of 1 ml. Addition of the alkali solution was done with a Hamilton syringe. The volume of added portion of alkali solution was from 10 to 25 μl.

We used spectrophotometer Cary 50 for the detection of transparency at a wavelength of 650 nm [10].

During the project, the testing of plant analogs of pharmaceutical gelatin to obtain capsules in terms of chemical and microbiological safety was conducted. Raw materials and components for the production of plant analogs of pharmaceutical gelatin were tested for heavy metals and toxic elements, radionuclides, pesticide residues, and microbiological indicators [11].

Thermodynamic characteristics of solutions of plant analogs of gelatin were determined using a differential scanning microcalorimeter DASM-4 (Puschino, Russia) in a temperature range from 10 to 120°C at a heating rate of 2°C/min and overpressure of 2.5 bar. Comparison model was the Milli-Q water. The scale of the excess heat capacity for each experiment was calibrated using Joule–Lenz law.

The solutions were studied for the following physical and chemical parameters:

- Toxic elements;
- Microbiological parameters;
- Organoleptic characteristics;
- Mass fraction of moisture, ash, protein impurities;
- Acidity.

Studies were performed using standard techniques.

Results and Discussion

The organoleptic, physical, and chemical characteristics of the plant analog of pharmaceutical gelatin from starch

After the complex characteristic of organoleptic properties of all the samples of plant analogs of pharmaceutical gelatin of starch, it was found that all the investigated samples of plant analogs of pharmaceutical gelatin from starch were homogeneous cream powders with an odor of starch.

Indicator	Sample*				Requirements of GOST 51985-2002	Method of analysis
	Starch sample 1	Starch sample 2	Starch sample 3	Starch sample 4		
Amount of specks on 1 dm² of flat gelatin surface seen by the naked eye	79	70	36	24	No more than 300	GOST 23058-89
Moisture content, %	No more than 14	No more than 14	No more than 13	No more than 13	No more than 14	
Mass fraction of total ash based on dry matter, %	0.19	0.19	0.15	0.16	No more than 0.20	
Mass fraction of protein based on dry matter, %	0.5	0.6	0.8	0.8	No more than 0.8	
Acidity, cm³ of 0.1 mol/dm³ of sodium hydroxide in 100 g of dry matter	20.5 ± 0.1	20.2 ± 0.5	15.6 ± 0.1	13.7 ± 0.4	No more than 20	
Sulfur dioxide content, mg/kg	Not detected	Not detected	Not detected	Not detected	No more than 50	
Presence of impurities	Absent	Absent	Absent	Absent	Not allowed	

*Several samples of averaged starch K1 were taken.

Table 1: The results of the analysis of physical and chemical parameters of plant analogs of pharmaceutical gelatin from starch

Substance	Sample*							
	Starch sample 1		Starch sample 2		Starch sample 3		Starch sample 4	
Concentration, %	1	5	1	5	1	5	1	5
pH unit	3.5	3.4	3.6	3.3	4.0	3.8	3.6	3.5
Substance	**CMC sample 1**		**CMC sample 2**		**CMC sample 3**		**CMC sample 4**	
Concentration, %	0.3	1.2	0.3	1.2	0.3	1.2	0.3	1.2
pH unit	3.5	3.8	3.6	3.9	3.7	3.9	3.6	3.8
Substance	**HPMC sample 1**		**HPMC sample 2**		**HPMC sample 1**		**HPMC sample 2**	
Concentration, %	0.5	1.5	0.5	1.5	0.5	1.5	0.5	1.5
pH unit	3.8	3.8	3.0	3.2	3.4	3.2	3.3	3.2
Substance	**Agar sample 1**		**Agar sample 2**		**Agar sample 3**		**Agar sample 4**	
Concentration, %	0.3	1.2	0.3	1.2	0.5	1.5	0.5	1.5
pH unit	8.5	8.9	8.8	8.9	8.6	8.6	9.0	9.0

*Average samples of pharmaceutical analogs of gelatin were taken.

Table 2: pH power values of aqueous solutions of the components investigated for capsules

The results of the analysis of physical and chemical parameters of plant analogs of pharmaceutical gelatin from starch are shown in Table 1.

As it is evident from the data presented (see Table 1), all the investigated samples of plant analogs of pharmaceutical gelatin from starch have shown a satisfactory performance by the mass fraction of moisture (from 8.9 to 11.2%), the mass fraction of protein in the dry matter (from 0.15 to 0.31%), and the number of specks per 1 dm^2 of flat starch surface. The determination results of solutions pH value of pharmaceutical gelatin plant analogs.

The determination results of pH value units. pH values of all samples of solutions of plant analogs of pharmaceutical gelatin from starch, CMC, HPMC, agar, and carrageenan are shown in Table 2.

Aqueous solutions of plant analogs of pharmaceutical gelatin from starch, CMC, and HPMC were characterized by pH values which are close to the range of 3-4 pH units.

The studied samples of plant analogs of pharmaceutical gelatin from agar are almost identical in transparency. Among all the studied hydrocolloids, the solutions and gels were characterized by the most transparency based on sample 1 of carrageenan. At the same time, sample 2 of carrageenan is allocated among the investigated plant analogs of pharmaceutical gelatin from agar and carrageenan by turbidity.

Conclusion

During the study, the complex characteristics of organoleptic, physical, chemical, optical, buffers, rheological, and structural and mechanical properties, chemical reactivity indices of plant analogs of pharmaceutical gelatin, and combinations thereof to produce capsules were determined. Samples of plant analogs of pharmaceutical gelatin from starch, CMC, agar, carrageenan, and hydroxypropyl were characterized.

The research included the study of complex properties of plant analogs of pharmaceutical gelatin, and confirmed the possibility of using plant analogs of pharmaceutical gelatin for soft capsules.

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