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RESEARCH REPORT ON THE DEVELOPMENT OF CAPSULE DOSAGE FORM TECHNOLOGY FOR LECTIN

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ABSTRACT

This study is aimed at developing the composition and manufacturing technology of a capsule dosage form containing lectin obtained from Phaseolus vulgaris. The physicochemical and pharmaceutical-technological properties of the lectin substance were investigated, including particle size distribution, flowability, bulk density, hygroscopicity, and angle of repose. Due to the high hygroscopicity and insufficient technological characteristics of the initial substance, various excipients were selected to improve the quality of the encapsulated mass.

Wet granulation using starch mucilage as a binding agent, followed by drying and stepwise dry mixing, was applied. The influence of maltodextrin, lactose monohydrate, dibasic calcium phosphate, potato starch, and calcium stearate on the technological properties of the mass was evaluated. Based on the obtained results, the optimal formulation was identified as Phaseolus vulgaris extract (300.0 mg, 60%), maltodextrin (190.0 mg, 38%), starch (5.0 mg, 1.0%), and calcium stearate (5.0 mg, 1.0%), filled into hard gelatin capsules of size No. 0.

Quality control studies showed that the developed Lectin capsules comply with the requirements of the national standard O‘zMSt 166:2024, confirming the suitability of the proposed formulation and technology for practical use.

Introduction. Dietary supplements based on natural biologically active compounds have gained increasing attention in confirms of their potential health benefits, safety, and consumer acceptance. Among such compounds, lectins represent a unique group of carbohydrate-binding proteins capable of specific interactions with glycoproteins and glycolipids on cell surfaces. Due to these properties, lectins exhibit a wide range of biological activities, including immunomodulatory, antimicrobial, antitumor, and

diagnostic effects, which makes them promising components for functional foods and dietary supplements.

Plant-derived lectins are of particular interest because of their structural diversity, natural origin, and relatively low production cost. *Phaseolus vulgaris* (common bean) is considered one of the richest natural sources of biologically active lectins. However, despite their pharmacological potential, the practical use of lectins is often limited by their unfavorable physicochemical and technological properties, such as high hygroscopicity, poor flowability, and sensitivity to environmental factors. These characteristics complicate the development of stable solid dosage forms and require careful selection of excipients and processing methods.

Capsule dosage forms are widely used for dietary supplements due to their ease of administration, accurate dosing, and ability to protect active substances from external influences such as moisture, light, and oxygen. The development of a stable capsule formulation for lectin requires a comprehensive study of the substance's pharmaceutical-technological properties and optimization of the encapsulation process.

Therefore, the aim of this study was to develop an optimal composition and manufacturing technology for a capsule dosage form containing lectin from *Phaseolus vulgaris*, ensuring suitable technological characteristics, compliance with regulatory requirements, and high product quality.

Materials and Methods

Materials

The object of the study was lectin obtained from *Phaseolus vulgaris* extract. The following excipients were used in the development of the capsule dosage form: maltodextrin, lactose monohydrate, dibasic calcium phosphate, potato starch, calcium stearate, and purified water. All excipients complied with the requirements of the relevant pharmacopeial standards (BP, Eur. Ph., USP, JP) and national regulatory documents.

Hard gelatin capsules of size No. 0 were used for encapsulation. All materials used in the study were of pharmaceutical grade.

Methods

Study of pharmaceutical-technological properties

The physicochemical and technological properties of the lectin substance and encapsulated mass were evaluated under controlled laboratory conditions at a temperature of 20–25 °C and relative humidity of 45 ± 5%. Particle size distribution was determined by sieve analysis using sieves with mesh sizes of 1000, 800, 500, 300, 200, 150, and 100 μm in accordance with ISO 3310-1 and OFS 1.1.0015.15. The angle of repose, flow rate, and bulk density before and after compaction were determined according to OFS 1.4.2.0016.15. Compressibility index and Hausner ratio were calculated based on bulk density values.

Preparation of encapsulated mass

Granules were prepared using the wet granulation method. Lectin and excipients were mixed, and granulation was carried out using purified water or potato starch mucilage (0.5–2.0%) as a binding agent. The wet mass was passed through a sieve, dried in a drying oven at controlled temperature, and then subjected to stepwise dry mixing with glidant and lubricant. Different formulations were prepared to evaluate the influence of excipients on technological properties.

Capsule filling

The encapsulated mass was filled into hard gelatin capsules of size No. 0 using a pressure-assisted filling method under laboratory conditions. For pilot-scale evaluation, a disc dosing method was applied.

Quality control of capsules

Quality evaluation of the obtained capsules included assessment of appearance and odor (GOST 15113.3), residual moisture content (GOST 15113.4, GOST 24027.2), average weight and weight variation (GOST 24104), and disintegration time (OFS 1.4.2.0013.15). All tests were performed in accordance with the requirements of the national standard O‘zMSt 166:2024. Each analysis was carried out in triplicate, and results were expressed as mean values.

Results and Discussion. The aim of this study was to select the composition, develop the technology, and evaluate the quality of a high-quality, safe, modern, and export-oriented capsule dosage form based on *Phaseolus vulgaris* extract (substance), with high bioavailability and protection against moisture and pressure during the manufacturing process, as well as protection from external factors such as light, moisture, and atmospheric oxygen during storage.

Scientific studies were conducted using a *Phaseolus vulgaris* substance sample. During the research, the ambient air temperature was maintained between 20°C and 25°C, and the relative humidity was recorded at 45 ± 5%.

The following instruments and equipment were used to conduct the scientific research, study the physicochemical and technological properties of the substance, and prepare capsule samples: Leica DM500 microscope (Germany), Aczet CY 4102 technical balance (India), outlet funnel – OFS 1.4.2.0016.15 (Russia), stopwatch – GOST 23350-98 (Uzbekistan), 50 mL and 250 mL graduated cylinders – GOST 1770-74 (Russia), glass Petri dishes (Russia), Stamm protractor (Russia), Aczet MB200 moisture analyzer (India), vacuum desiccator with valve (Russia), LH-95D/C vacuum pump (China), RCZ-6C tablet and capsule dissolution tester (China), KZL-80 granulator (China), NJP200 automatic capsule filling machine (China), HD-100 mixer (China), LB-2D tablet and capsule disintegration tester (China) for quality control analysis of the obtained capsules, ShS-80-01 SPU drying oven-thermostat – TU-9452-010-00141798-2005 (Russia), FA1204B analytical balance (China), and others.

To encapsulate one or more biologically active substances with or without excipients, it is necessary to study the specific physicochemical and technological properties of the filling material. Taking these properties into account, it is possible to select an appropriate formulation and develop a technology using various excipients approved for medical use.

The “Lectin” extract (substance) is a light yellow powder with a characteristic specific odor and taste.

The fractional composition of the substance, angle of repose, flow rate and bulk density, compressibility index, and Hausner ratio were investigated. To determine the fractional composition of the substance, a set of sieves with mesh sizes of 1000, 800, 500, 300, 200, 150, and 100 μm was used in accordance with the international standard ISO 3310-1, and the experiment was carried out according to the monograph OFS 1.1.0015.15 using the mechanical force method (manual operation).

After sieving 100.0 g of the sample for 5 minutes using the above-mentioned method, each fraction was weighed separately on a balance with an accuracy of 0.01 g. The results were expressed as a percentage (%) of each fraction, indicating the portion retained on the sieve (+) and the portion passed through the sieve (–).

The angle of repose, flow rate, and bulk density were determined in accordance with OFS 1.4.2.0016.15. The results of the study are presented in Table 1.

Table 1

Results of the study of technological properties of the lectin substance

Investigated properties	Obtained results	Unit
Fractional composition, µm:		
+1000	3.80	%
−1000 +800	3.40	%
−800 +500	4.46	%
−500 +300	11.40	%
−300 +200	12.85	%
−200 +150	8.33	%
−150 +100	21.18	%
−100	34.58	%
Angle of repose	24.0	degrees
Flow rate	11.3	g/s
Bulk density (before compaction, m/V_0)	0.16	g/mL
Bulk density (after compaction, m/V_{2500})	0.30	g/mL
Degree of hygroscopicity	20.20	%
Compressibility index	47.82	–
Hausner ratio	1.91	–
Residual moisture	5.17	%

Note: p = 0.05; n = 3.

Based on the pharmacopeial standards, the results presented in Table 2 indicate that the substance belongs to the category of very fine and fine powders, exhibits an excellent angle of repose and flowability, and possesses a highly pronounced hygroscopic nature.

It is well known that substances with high hygroscopicity require the selection of suitable excipients that reduce moisture absorption and improve technological properties. Therefore, various excipients in different ratios were used to reduce the hygroscopicity of the lectin substance, optimize its fractional composition, and enhance its pharmaceutical-technological characteristics.

Without changing the amount of lectin in the encapsulated mass, and taking into account its good solubility in water, purified water, 0.5%, 1.0%, and 2.0% potato starch mucilage were used as binding agents. Maltodextrin, dibasic calcium phosphate, and lactose monohydrate passed through a 0.15 mm sieve were used as fillers, and calcium stearate was included as a glidant-lubricant. Four different formulations were prepared, and the pharmaceutical-technological properties of the obtained masses were analyzed (Table 2).

Table 2

Effect of excipients on the quality of the encapsulated mass

Investigated parameters	Sample No. 1	Sample No. 2	Sample No. 3	Sample No. 4
Formulation weight, g	100	100	100	100
Lectin substance, g	60.0 (60.0%)	60.0 (60.0%)	60.0 (60.0%)	60.0 (60.0%)
Maltodextrin, g	–	–	38.0 (38.0%)	20.0 (20.0%)
Dibasic calcium phosphate, g	–	38.0 (38.0%)	–	–
Lactose monohydrate, g	38.0 (38.0%)	–	–	17.5 (17.5%)
Purified water	2.0 (2.0%)	–	–	–
Potato starch mucilage (0.5%, 1.0%, 2.0%), g	–	0.5 (0.5%)	1.0 (1.0%)	2.0 (2.0%)
Calcium stearate, g	1.0 (1.0%)	1.0 (1.0%)	1.0 (1.0%)	0.5 (0.5%)
Hygroscopicity, %	15.8	7.4	6.6	13.7
Residual moisture, %	7.1	4.6	1.6	4.9
Appearance	uniform	uniform	uniform	uniform
Amount of fine powder	high	high	low	low

During the conducted studies, it was observed that the incorporation of excipients into the composition of the encapsulated mass led to a significant reduction in its hygroscopic properties. However, formulation No.1 exhibited high hygroscopicity and residual moisture, formulation No. 2 contained a large amount of fine powder, formulation No.3 demonstrated optimal characteristics, whereas formulation No.4 showed a relatively higher hygroscopicity level. Therefore, further studies were continued to determine the pharmaceutical-technological properties of the mass with formulation No.3. The results of these studies are presented in Tabl 3.

Table 3

Results of the study of technological properties of the encapsulated mass

Investigated properties	Obtained results	Unit
Fractional composition, µm:		
+1000	–	%
−1000 +800	3.87	%
−800 +500	18.12	%
−500 +300	25.23	%
−300 +200	22.90	%
−200 +150	11.17	%
−150 +100	14.11	%
−100	4.60	%

Investigated properties	Obtained results	Unit
Angle of repose	22.0	degrees
Flow rate	24.7	g/s
Bulk density (before compaction, m/V_0)	0.506	g/mL
Bulk density (after compaction, m/V_{2500})	0.674	g/mL
Compressibility index	25	–
Hausner ratio	1.33	–
Degree of hygroscopicity	6.6	%
Residual moisture	1.57	%

Note: p = 0.05; n = 3.

Based on the pharmacopeial standards, the results presented in Table 4 indicate that the encapsulated mass of formulation No. 3 belongs to the category of coarse powders, exhibits good flowability, is slightly hygroscopic, and represents granules with a very favorable angle of repose.

As expected, the addition of calcium stearate and maltodextrin positively affected the bulk density, angle of repose, and flowability of the substance. Granules obtained by wet granulation using a 1% starch mucilage demonstrated optimal technological properties. The study of the technological characteristics of the mass showed that there is no need to add more than 1% calcium stearate per 300 mg of the substance. Increasing the amount of calcium stearate beyond 1% does not significantly affect the moisture absorption properties of the mass; moreover, the excessive use of excipients leads to unjustified costs and negatively affects the production cost of the finished product.

Therefore, based on the conducted studies, formulation No. 3 was identified as the optimal encapsulated mass. The selected formulation consisted of *Phaseolus vulgaris* lectin – 300.0 mg (60%), maltodextrin – 190 mg (38%), starch – 5 mg (1.0%), and calcium stearate – 5 mg (1.0%). A size No. 0 capsule was selected to fill the encapsulated mass with an average weight of 500 mg. This choice was based on the fact that the capacity of a size No. 0 capsule ranges from 408 mg (at a bulk density of 0.6 g/mL) to 816 mg (at a bulk density of 1.2 g/mL), while the bulk density of the encapsulated mass after compaction was 0.674 g/mL. Considering the available resources, the encapsulation process was carried out under laboratory conditions using the pressure-assisted filling method.

Evaluation of Quality Parameters and Stability of Lectin Capsules

During the scientific studies, the quality parameters and stability of the obtained Lectin capsule dosage form were evaluated using the methods specified in the national standard **O‘zMSt 166:2024**, which establishes requirements for dietary supplements, as well as other relevant regulatory documents. Based on the selected formulation and the developed technology, capsules of batch No. **010325** were produced. The quality parameters of the capsules, including appearance and odor, residual moisture of the capsule fill, average weight and weight variation, and disintegration time, were analyzed.

The appearance and odor were determined in accordance with **GOST 15113.3**. The capsules were hard gelatin capsules of size No. 0, dark red or other colors, containing a light yellow powder. All tested samples complied with this specification.

The residual moisture content of the capsule mass was determined according to **GOST 15113.4** and **GOST 24027.2**. For analysis, 20 capsules from each batch were randomly selected. The contents of the capsules were removed, mixed, and the residual

moisture was determined using an **Aczet MB200 moisture analyzer** at a temperature of 100–105 °C according to the specified method. The analysis was performed in triplicate. According to the requirements, the moisture loss should not exceed 10.0%. The average residual moisture content of the capsule mass of batch No. 010325 was **0.4%**, indicating that the samples comply with the specification.

The average weight of one filled capsule and weight variation were determined in accordance with **GOST 24104**. Twenty capsules were randomly selected, and the weight of each capsule was measured using an **FA1204B analytical balance** with an accuracy of 0.0001 g. The average mass of the filled capsules and deviations were calculated, and the results are presented in Table 5.

For the selected optimal formulation, the average mass of one filled capsule was **0.500 g** (total encapsulated mass: 500 mg + empty size No. 0 capsule – 96 ± 6 mg). Therefore, the acceptable weight range was **0.566–0.626 g**. As shown in Table 5, the average weight of capsules from batch No. 010325 was **0.599 g**, with deviations ranging from **–0.77% to +0.56%**. These results confirm that the average weight and weight variation of the investigated Lectin capsules meet the requirements of regulatory documentation and the national standard **O‘zMSt 166:2024**.

Table 4

Results of average weight and weight variation analysis of Lectin capsules
Batch No.: 010325

i	xi, g	di, %	i	xi, g	di, %
1	0.594	−0.77	11	0.601	0.40
2	0.600	0.23	12	0.596	−0.44
3	0.600	0.23	13	0.602	0.56
4	0.594	−0.77	14	0.597	−0.27
5	0.594	−0.77	15	0.600	0.23
6	0.601	0.40	16	0.595	−0.61
7	0.600	0.23	17	0.599	0.07
8	0.596	−0.44	18	0.601	0.40
9	0.599	0.07	19	0.600	0.23
10	0.602	0.56	20	0.601	0.40

$\bar{x}$ = 0.599 g; min −0.77%; max +0.56%
($p < 0.05$; $n = 3$)

The disintegration test of the capsules was performed according to the method described in **OFS 1.4.2.0013.15**. The results of the disintegration time determination for Lectin capsules are presented in Table 5.

Table 5

Results of disintegration time determination of Lectin capsules

Batch No.	Complete disintegration time (t), min	tmax, min
	1	2
010325	18	16

($p < 0.05$; $n = 6$)

According to the national standard **O‘zMSt 166:2024**, the disintegration time of capsules should not exceed **45 minutes**. The results presented in Table 6 demonstrate that the Lectin capsules comply with this requirement.

Compliance of packaging and labeling with the requirements of **O‘zMSt 166:2024** was also verified. The results showed that the packaging and labeling materials of Lectin capsules produced in the experimental batch No. 010325 met the requirements specified in the regulatory technical documentation. Studies on the stability of the Lectin dietary supplement capsules during storage and determination of shelf life are currently ongoing.

Conclusions. Based on the analysis of the physicochemical and pharmaceutical-technological properties of *Phaseolus vulgaris* extract, the composition and technology of its capsule dosage form were developed. According to the study results, the optimal formulation was determined as follows: *Phaseolus vulgaris* extract – 300.0 mg (60%), maltodextrin – 190.0 mg (38%), starch – 5.0 mg (1.0%), and calcium stearate – 5.0 mg (1.0%). It is recommended to fill this encapsulated mass into empty size No. 0 capsules (96 ± 6 mg) at 0.5 g ± 5% per capsule (filled capsules 596 mg ± 5%) for production.

The quality parameters of the “Lectin” dietary supplement capsules of batch No. 010325, obtained based on the optimal formulation and developed technology, complied with the requirements for dietary supplements established by the national standard **O‘zMSt 166:2024**.

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