



TECHNOLOGY AND QUALITY CONTROL OF A TABLET WITH HEPATOPROTECTIVE ACTION

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ARTICLE INFO:

Received: 08.10.2026

Revised: 09.10.2026

Accepted: 10.10.2026

KEY WORDS:

*rose hip, turmeric,
corn silk, excipient,
tablet, technology,
quality indicators.*

ABSTRACT

The article presents, for the first time, the results of scientific research on the tablet technology based on a dry extract with hepatoprotective action, recommended for use in liver diseases, and on determining the quality of the obtained tablet. For the first time, scientific research was conducted on tablet technology using MCC-L obtained from the waste of local medicinal plants. On the basis of this research, the expediency of using MCC-L as an excipient in tablet technology was studied.

Relevance. Developing the local pharmaceutical industry and establishing the production of medicines in accordance with international standards is one of the urgent tasks facing every specialist. Taking into account that medicinal plants have significant advantages over synthetic substances in all respects, the industrial-scale production of various teas (including herbal mixtures), tablets, capsules, and galenic preparations is carried out precisely on the basis of these plants. [1].

One of the important tasks facing the field is to conduct scientific research on the use of microcrystalline cellulose (MCC), obtained by means of a special technology from the waste of local medicinal plants, as an excipient in tablet production technology [2].

Taking the above into account, it is important to create a technology for producing tablets that ensure high therapeutic efficacy, complete safety, and convenience, and to bring their quality up to the level of world standards. The dry extract consists of a complex of raw materials such as rose hip flowers, turmeric root, and corn silk. Scientists of the Biopreparations



Laboratory of the Research Institute of Vaccines and Sera recommended using this extract as an agent with hepatoprotective properties. Rose hip contains vitamins C, B-2, P, E, and K, which are important for human health. It is also very rich in carotene, sugars, fats, organic acids, flavonoids, pectin, minerals, and other compounds. This fruit contains minerals such as potassium, iron, manganese, phosphorus, calcium, and magnesium. Corn silk (*Zea mays* L.) contains bioactive compounds such as saponins, tannins, bitter glycosides, flavonoids, alkaloids, essential oils, and vitamin K, as well as microelements such as iron, aluminum, manganese, copper, and chromium. The main benefit of turmeric is associated with the curcumin it contains; it is precisely this compound that gives the plant strong anti-inflammatory and antioxidant properties, that is, its healing potential. Scientific research has been conducted on the use of various medicinal agents in medicine [3,4].

Aim of the study. Taking into account the specific advantages of the tablet dosage form, the aim of this study was to develop the composition and manufacturing technology of a tablet with hepatoprotective action and to evaluate the quality of the finished product.

First, using the methods described in the relevant literature, the pharmacotechnological properties of the mixture, in particular the fractional composition, flowability, bulk density, natural angle of repose, compressibility, and residual moisture content, were studied. The experimental results obtained are presented in table 1.

table 1

Results of studying the pharmacotechnological properties of the dry extract with hepatoprotective action

Studied indicators	Unit	Results obtained
Appearance		Liver-brown mixed with yellow in color, with a characteristic odor and taste
Fractional composition	μm, %	
+3000		0,05
		0,23
+3000		46,5
		32,66
-2000		11,01
+2000		10,64
-1000		
+1000 -250		
+250 -125		



-125		
Flowability	10^{-3} kg/s	9,981
Natural angle of repose	Degrees	42,5
Bulk density	kg/m ³	449
Compaction index		5,20
Compressibility	N	22,0±2,20
Residual moisture	%	2,13

The table shows that the main fractional composition of the mixture consists of fractions with sizes larger than 2000 μm (46,5%) and smaller than 2000 μm (32,66%), which are characterized by unsatisfactory flowability ($9,981 \times 10^{-3}$ kg/s) and an unsatisfactory natural angle of repose (41,5 degrees). The bulk density (448 kg/m^3) is, however, within an acceptable range for mixtures of powders and plant extracts. The compaction index, in turn, deviates sharply from the norm. The value of 5,20 indicates the high cohesiveness of the mixture. The compressibility result is also weak, and the tablets obtained will be unstable against mechanical impacts. The residual moisture (2,13%) is in line with the norm and does not negatively affect the stability of the drug. The analysis of the obtained pharmacotechnological results shows that the natural mixture consisting of corn silk, rose hip fruit, and turmeric root does not meet the requirements of direct compression in its pure form. In particular, the fractional composition of the mixture, the high natural angle of repose ($42,5^\circ$), and the low compressibility properties (22,0 N) negatively affect the uninterrupted operation of the tablet-making equipment and the mechanical strength of the finished dosage form.

Therefore, in order to develop a stable tablet composition based on this mixture, it is scientifically justified to add excipients suitable for the technological mass (flow improvers, binders, and fillers) and to process this mass using the wet granulation method. Positive changes in the technological parameters of the compressible mixture ensure that the physical and mechanical properties of the tablet meet the requirements of the normative documents (ND). The mass of the raw material mixture for the hepatoprotective (liver-protecting) tablet is 0,3 grams; this amount was recommended by pharmacologists as the appropriate therapeutic dose. For the scientific testing of the tablet composition, the compressible mass was prepared separately using the following excipients: MCC as a filler, starch as a binder, calcium stearate as a lubricant, and 70% alcohol as a wetting agent. No change was observed in the appearance of the mass during wetting. The experimental results are presented in table 2.



table 2

Compositions studied for selecting the specific composition of the tablet with hepatoprotective action

Name of the drug substance and ingredients	Compositions, g			
	№1	№2	№ 3	№ 4
Dry extract with hepatoprotective action	0,3	0,3	0,3	0,3
MCC		0,1		0,0211
Potato starch		0,095	0,0165	0,0254
Calcium stearate	0.005	0,005	0,005	0,005
Average mass	0,3500	0,5	0,3500	0,3500

According to the methods described in the literature, the following technological properties of the prepared masses were studied: flowability, natural angle of repose, bulk density, compressibility, and residual moisture. The test results are presented in table 3.

table 3

Technological results of selecting components for a preparation with hepatoprotective action

Compositi on number	Flowabili ty, g/sec	Natural angle of repose, degrees	Bulk density, kg/m ³	Compres sibility, N	Residual moisture, %
1	4,26 ± 0,34	37 ± 5	0,516 ± 0,43	48,0	6,80
2	6,28 ± 0,72	30 ± 5	0,602 ± 0,22	55,0	7,60
3	5,86 ± 0,46	32 ± 5	0,486 ± 0,4	54,0	6,00
4	6,23 ± 0,51	29 ± 5	0,462 ± 0,34	52,0	8,20

The results show that the pharmaco-technological properties of the mixture demonstrated positive indicators relative to the substance. The results obtained showed that the indicators of compositions Nos. 2 and 4 for flowability and bulk density were close to each other, while the indicators of compositions Nos. 1 and 3 for flowability and bulk density were slightly lower than the required level. No significant difference was observed between the results obtained for compressibility and residual moisture. Taking the above results into account, the excipient used in composition No. 2 was selected for further research.



In further studies, the quality indicators of the tablets were evaluated in accordance with the relevant normative documents [5].

Appearance: Yellowish-brown tablets with a slightly speckled surface and a characteristic odor.

Principle of identification.: The identity of the bioactive substance in the tablet was studied by means of qualitative reactions characteristic of flavonoids.

Reaction with aluminum chloride solution. 0,2 g of crushed tablet powder was boiled with 20 ml of 70 % alcohol in a water bath for 5 minutes and filtered through filter paper (GOST 12026-76); then 5 ml of the filtrate was taken, and when 3 ml of a 2 % alcoholic solution of aluminum chloride is added dropwise to it, the formation of a yellowish-green color characteristic of flavonoids is observed.

- Reaction with iron (III) chloride solution. According to the method above, when a few drops of a 5% iron (III) chloride solution are added to 5 ml of the alcoholic solution of the tablet, a dark blue color of flavonoids is observed.

0,10 g of crushed tablet powder was heated with 8 ml of 80% ethyl alcohol in a water bath for 10 minutes and filtered through filter paper (GOST 12026-76). 0,05 g of magnesium powder or magnesium powder in 0,5 ml of concentrated hydrochloric acid was added to the filtrate. As a result, the gradual formation of a red color in the mixture is observed, which is a qualitative reaction characteristic of flavonoids.

Quantitative analysis: The main bioactive substances with hepatoprotective action in the dry extract are flavonoids and coumarins. The quantitative analysis of flavonoids in the tablet was carried out in accordance with the analysis given in the State Pharmacopoeia. The amount of the bioactive substance (flavonoid product) in the tablet was determined spectrophotometrically by recalculation relative to rutin, based on the complex formation reaction with a 2% aluminum chloride solution. For this purpose, 0,5 g (accurate weight) of crushed tablet powder was placed into a 25 ml volumetric flask, 3 ml of a 2% aluminum chloride solution and 1 drop of diluted acetic acid were added, and then the volume of the solution was brought to the mark with 96% ethyl alcohol and mixed thoroughly. It was kept in a dark place for 40 minutes. After that, the solution was filtered through a multilayer paper filter. 5 ml of the solution was taken and placed into a 25 ml volumetric flask, brought to the mark with 96% ethyl alcohol, and mixed. The absorbance of the solution was measured using a spectrophotometer at a wavelength of $\lambda=410\pm 2$ nm in a cuvette with a thickness of 10 mm. As a reference solution, a solution prepared according to the procedure described above, but without the addition of aluminum chloride solution, was used. At the same time, the optical density of the working sample solution was also measured. The amount of flavonoid yield relative to rutin (X) is calculated in percent as follows:



$$x = \frac{D_1 \times 100 \times 25 \times a_0 \times 1 \times 100 \times R}{D_0 \times a_1 \times 3 \times 100 \times 25 \times 100}$$

D_1 - optical density of the solution under test;

D_0 - optical density of the standard rutin sample solution;

a_1 - accurate weight, g;

a_0 - concentration of rutin in the working standard solution, g/ml

R- amount of flavonoids in the tablet composition, g

Preparation of the working sample solution. 0,025 g (accurate weight) of rutin (TU-64-4 -1297-96), a substance pre-dried at a temperature of 130-135⁰ C for 3 hours, was placed into a 100 ml volumetric flask, 85 ml of 96% ethyl alcohol was added, and then the mixture was heated in a boiling water bath until the rutin was completely dissolved (10-15 minutes) and cooled to room temperature. The volume of the solution was brought to the mark with the solvent. It was mixed thoroughly, and 1 ml of the solution was taken and placed into a 25 ml volumetric flask. The shelf life of the working standard solution is 30 days.

In the laboratory, the following methods are used to isolate curcumin and measure its exact percentage (usually around 2–5% in pure turmeric): [1]

1. High-performance liquid chromatography (HPLC):

○ **Principle:** It is the most accurate and standard method. An alcoholic extract of turmeric is introduced into the chromatograph.

○ **Result:** Substances such as curcumin, demethoxycurcumin, and bisdemethoxycurcumin are separated from one another, and their exact amounts are shown in percentages. [1, 2]

2. Thin-layer chromatography (TLC):

○ **Principle:** A turmeric extract is dropped onto special plates and developed using solvents (for example, a mixture of chloroform and methanol).

○ **Result:** Under ultraviolet (UV) light, the characteristic yellow-orange spots of curcumin are identified (by the R_f value). [1]

3. Spectrophotometry (UV-visible range):

○ **Principle:** It is based on the property of an alcoholic solution of curcumin to absorb light at a specific wavelength (usually around 420–425 nm).

○ **Result:** The optical density of the solution is measured, and the curcumin concentration is calculated using a special formula. [1]

The results of the analysis obtained were statistically processed and are presented in table 4.



table 4

**Results of determining the total flavonoid content of the tablet
with hepatoprotective action (n=5)**

Accurate weight, g	Amount	Metrological characteristics
	%	Flavonoids (relative to rutin)
0.4978	6.2506	$F=4$, $t(P\ 95, f) = 2.78$ $X=6.00$ $S^2= 0.18 \cdot 10^6$ $S=0.37 \cdot 10^3$ $S_x=0.19 \cdot 10^3$ $X=0.57 \cdot 10^3$ $X_{\text{mean}}=0.28 \cdot 10^3$ $\sum x\% = 2,72$ $\sum x\% = 1,09$
0.5023	5.8394	
0.5002	5.6501	
0.4898	6.0464	
0.5011	6.2387	

The results of the analysis show that the quantitative analysis of the bioactive substance in the tablet can be carried out using the spectrophotometric method. The quality parameters of the tablet with hepatoprotective action were determined in accordance with the methods described in the relevant literature. The results obtained are presented in table 5.

table 5

**Results obtained for the quality indicators
of the tablet with hepatoprotective action**

Studied indicators, unit of measurement	Results obtained
Appearance	Yellowish-brown tablets with intact edges and a smooth surface
Identity	Satisfactory
Average weight and deviation from it; g, %	$0,52 \pm 2,46$
Strength: - abrasion resistance, %	$98,79 \pm 1,71$
- breaking strength, N	$48,0 \pm 2,04$
Disintegration, minutes	$6,0 \pm 0,07$
Quantitative analysis, %	$0,3891 \pm 0,18$



The results obtained showed that the appearance, identity, average weight and deviation from it, disintegration, and quantitative analysis of the tablets with hepatoprotective action fully meet the requirements of the relevant normative documents.

Conclusion: A composition and technology of a tablet with hepatoprotective action have been proposed. The technological properties of the tablet mass and the quality indicators of the tablet were studied. A spectrophotometric method was recommended for the quantitative analysis of the tablet with hepatoprotective action. The experimental results obtained showed that the use of MCC, a new local excipient, in tablet technology can be recommended.

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