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DETERMINING THE STORAGE STABILITY OF "CHONDROTEX" CAPSULES AND DETERMINING THE SHELF LIFE

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ABSTRACT

This article presents the results of scientific research on the study and determination of storage conditions for the complex combination of capsules containing curcumin, potassium and calcium. In the studies, the conditions of storage and shelf life of capsules, their appearance, the results of quantitative analysis of biologically active substances, the disintegration of capsules and deviation from their average weight were evaluated.

In our country, efforts are being made to improve the organization of medical care and the provision of medicines to the population, in particular, to bring the pharmaceutical sector to world standards. Since the beginning of the pandemic around the world, the number of patients with musculoskeletal diseases has been increasing year by year. Scientific research is being conducted to identify serious diseases during the acute period of COVID-19 and as a result of it. Also, methods of preventing and treating the development of post-COVID complications are of scientific interest to scientists around the world. The COVID-19 pandemic, a new coronavirus infection, declared a pandemic by the World Health Organization (WHO) on March 11, 2020, has put the entire global community at risk, and as a result of the complications of this pandemic, people are more prone to developing chronic non-communicable diseases, in particular, osteochondrosis and osteoarthritis.[1]As a result of our ongoing scientific research and studies, the proposed “Chondrotex” capsules containing a complex combination of curcumin, potassium and calcium were selected as the most alternative composition that has a positive effect on diseases of the musculoskeletal system..

It should be noted that the stability and quality of drugs are closely related to each other. The influence of external environmental factors during the storage of drugs is of great importance. For example, temperature, humidity and light. During the storage of drugs, various conditions occur and the chemical structure of substances changes, which can lead to a decrease in pharmacological activity. The stability of a substance can

be affected by a number of factors, including its physicochemical properties, type of packaging, light, environmental influences, storage conditions, temperature, and others[2].

Turmeric is a major source of the polyphenol curcumin, which has therapeutic activity in the treatment of arthritis, hyperlipidemia, metabolic syndrome, and inflammatory processes. It is also used to treat inflammation and muscle pain caused by exercise, and improves performance. Most of these benefits are explained by its antioxidant and anti-inflammatory effects [3].

Potassium is a mineral element. It occurs in the form of potassium chloride or potassium nitrate and plays an important role in the production of nerve signals necessary for the contraction of skeletal and cardiac smooth muscles. Potassium helps maintain normal blood pressure. Most of the potassium in our bodies is found in muscle cells and muscle tissue, where it is easily absorbed by the body.[4]

Calcium is one of the most abundant minerals in the body and is found in some foods, pharmaceuticals, and dietary supplements. Calcium forms a major part of the structure of bones and teeth and helps the body function normally by keeping tissues hard, strong, and flexible. Small amounts of ionized calcium in the circulatory system and various tissues mediate the contraction and dilation of blood vessels, muscle function, blood clotting, the nervous system, and hormonal secretion. Almost all (98%) of the body's calcium is stored in bones, and the body uses bones as a source of calcium to maintain calcium homeostasis.

The purpose of the work. The aim of our work was to determine the storage stability and shelf life of "Chondrotex" capsules, which contain a complex compound consisting of curcumin, potassium, and calcium.

Experimental part. The following equipment was used in our studies: analytical balance (Ohaus Corp., China), pH meter "Five Easy FE20" (Mettler Toledo, China), filter paper "White lent", atomic absorption spectrophotometer "Zeenit 700 p" (Analytik Gena, Germany). Only one method is allowed to be used to study the storage conditions and determine the shelf life of phytopreparations obtained from medicinal plants. This method is carried out under natural conditions, and the following types of packaging were used in the studies: contour cell strip packaging (OST 64-074-91) and cans (TU 64-228-84) made of polyvinyl chloride film (GOST 25250-88) and varnished aluminum foil (TU 48-21-270-78).

At the initial stages of scientific research and research, the quality control of the finished capsules was carried out, their appearance, authenticity, average weight of the capsules and their deviation, disintegration, microbiological purity, as well as the quantitative indicators of the biologically active substances contained in them were analyzed.

The capsules used and tested for our study are hard gelatin capsules with the number “0” of the yellow color, filled with a brown mass. The determination of the deviation of the mass of the capsules and their contents from the average weight was carried out according to the method given in Table 2.9.5.-1 of the State

Pharmacopoeia of the Republic of Uzbekistan, Volume 1, Part 1, I/I/I, and it is established that the deviation of this indicator should not exceed 10%. The results of the studies show that this deviation in the capsules was 2% for properly filled capsules and 1.2% for the mass of the capsule. In accordance with the State Pharmacopoeia, the disintegration time of the capsules was controlled and required not to exceed 20 minutes. The disintegration time of the "Chondrotex" capsules was 11-12 minutes. The accuracy of the mass of the "Chondrotex" capsules was confirmed by a chemical reaction carried out in relation to the curcumin contained in it. To do this, 0.1 g of the drug was placed in a flask, 60 ml of acetic acid was poured on top, and the reflux condenser was connected. The solution was heated to 90 for 60 minutes. After the specified time, 2 g of boric acid and acetic acid were added to it, and the solution was colored dark red. The quantitative analysis of "Chondrotex" capsules was based on the amount of potassium and calcium in their composition. Potassium and calcium in the biologically active supplement capsules were determined by the YSSH method, and their amount in 1 capsule was Ca-13.56 mg and K-26.43 mg. The "Dissolution" indicator of the capsules was carried out using the "rotary cajava" apparatus according to the method given in the State Pharmacopoeia.± ± ±℃

Table 1

Results of analysis of quality indicators of "Khondrotex" capsules

Index name	Requirements	Analysis results
Appearance	They are hard gelatin capsules with the number "0" in a yellow color, filled with a brownish mass.	It fits.
Truth	0.1 g of the drug is placed in a flask, 60 ml of acetic acid is poured over it, and it is connected to the refrigerator. The solution was heated to 90 for 60 minutes. After the specified time, 2 g of boric acid and oxalic acid are added to it, and the solution turns dark red.℃	It fits.
Deviation of the weight of the capsule mass from the average weight	According to Table 2.9.5.-1 of the Federal Law of the Republic of Uzbekistan, the permissible deviation should not exceed ±7.5% if the average mass of capsules is 300 mg or more.	±2% It fits.
Disintegration	Should not exceed 20 minutes	11 -12 minutes
Calcium content	Should not be less than 12 mg/cap.	13.56 mg/cap. It fits.
Potassium quantity	Should not be less than 25 mg/cap.	26.43 mg/cap. It fits.
Microbiological cleanliness	It is required not to have Staphylococcus aureus, Escherichia coli, and the number of some gram-negative bacteria should not exceed 10^2	It fits.

According to the data in Table 1, “Chondrotex” capsules meet the requirements for their quality indicators. At the next stage of the research, “Chondrotex” capsules were packaged in the following packaging: - in contour cell strip packaging made of polyvinyl chloride film (GOST 25250-88) - in contour cell strip packaging made of varnished aluminum foil (TU 48-21-270-78) (OST 64-074-91) - in cans (TU 64-228-84). During the research, analyses were conducted every 6 months on the appearance of the capsules, their disintegration, average mass and deviation from it, as well as the preservation of the active substance in their composition, and the shelf life was 2 years. Despite the fact that it takes a long time to study the capsule form of medicine in a "natural" way, the obtained results help to draw a clear and convincing conclusion (Table 2).

Table

The results of determining the shelf life of "Chondrotex" capsules based on curcumin, calcium and potassium in contour cell strip packaging made of PVC film and lacquered aluminum foil

Lot No.	date	23°C ± 2°C shelf life	Appearance – hard gelatin capsules	The taste and smell are characteristic of the raw materials used	Appearance of the capsule mass (brown mass)	Disintegration, no more than 20 minutes	The average mass of the capsule mass 0.560±10 %	Amount of calcium-5.76Not less than %	Amount of potassium-7.26Not less than %	Conclusion
01	01.01.23 01.07.23 01.02.24 01.08.24 01.01.25	- 6 months 1 year 1 month 6 months 2 years	Satisfactory -“- -“- -“- -“- -“-	Satisfactory . -“- -“- -“- -“- -“-	Satisfactory -“- -“- -“- -“- -“-	10-11 min. Satisfactory Satisfactory Satisfactory Satisfactory Satisfactory	0.561 Satisfactory -“- -“- -“- -“-	0.575 -“- -“- -“- -“- -“-	0.716 -“- -“- -“- -“- -“-	Satisfactory -“- -“- -“- -“- -“-
02	01.01.23 01.07.23 01.02.24 01.08.24 01.01.25	- 6 months 1 year 1 month 6 months 2 years	Satisfactory -“- -“- -“- -“- -“-	Satisfactory -“- -“- -“- -“- -“-	Satisfactory -“- -“- -“- -“- -“-	9-10 minutes. Satisfactory Satisfactory Satisfactory Satisfactory Satisfactory	0.558 Satisfactory -“- -“- -“- -“-	0.540 -“- -“- -“- -“- -“-	0.695 -“- -“- -“- -“- -“-	Satisfactory -“- -“- -“- -“- -“-
03	01.01.23 01.07.23 01.02.24	- 6 months 1 year 1 month 6 months	Satisfactory -“- -“- -“- -“- -“-	Satisfactory . -“- -“- -“- -“- -“-	Satisfactory -“- -“- -“- -“- -“-	11-12 min. Satisfactory Satisfactory Satisfactory	0.560 Satisfactory -“- -“- -“- -“-	0.576 -“- -“- -“- -“- -“-	0.726 -“- -“- -“- -“- -“-	Satisfactory -“- -“- -“- -“- -“-

	01.08.24 01.01.25	2 years		-"-		Satisfactory Satisfactory Satisfactory				

According to the results in Table 2, "Chondrotex" capsules met all the requirements for 2 years for all types of capsule drugs in the State Pharmacopoeia of the Republic of Uzbekistan. The mass content of "Chondrotex" capsules did not change during the specified period. The amount of curcumin in the capsules during storage was 5.76 mg of Ca and 7.26 mg of K in 1 capsule. At the same time, when analyzing the microbiological purity of the capsules, it was found that this indicator was within the limits of deviations in regulatory documents. It was required that Staphylococcus aureus, Escherichia coli, and the number of some gram-negative bacteria did not exceed 10 [5].[2]

Conclusion: According to the results of the analysis, the shelf life of "Khonrotex" capsules, which contain a complex compound of curcumin potassium and calcium, was determined to be 2 years. Experiments are ongoing.

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