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A STUDY OF THE QUALITY INDICATORS OF "NEYROGLABTAN" CAPSULES

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ABSTRACT

This article presents the results of research conducted to study the quality indicators of a biologically active supplement in capsule form, provisionally named "Neyroglabtan." Developed from a dry extract of the Rhus glabra L. plant, the supplement was evaluated based on current regulatory standards. During the study, the following parameters were examined: the capsule's appearance, the average weight of the capsule and its contents and any deviations, disintegration time, qualitative and quantitative analysis, heavy metal content, and microbiological purity.

Introduction. Scientists recommend producing biologically active substances isolated from plants in capsule form based on their physicochemical properties. The study of the structural-mechanical and technological properties of dry extracts makes it possible to produce them in a specific dosage form. Taking into account the hygroscopic properties of pure biologically active substances and dry extracts obtained from plant raw materials, it is advisable to introduce them into medical practice in capsule form. At the same time, biologically active substances remain at the center of attention in the pharmaceutical market due to their preservation of therapeutic activity, suitability for the treatment and prevention of various diseases, and increasing demand [1,2].

The complex multi-component nature of the plant composition and the necessity of studying the quality indicators of herbal medicinal products recommended for a specific composition and technology by combining traditional methods with modern analytical methods are necessary to ensure their safety, efficacy, and quality [3,4].

The study of a new generation of drugs with neuroprotective effects used in neurodegenerative diseases of plant origin is aimed at scientifically studying their effective effect on chronic diseases of the brain by protecting impulses reaching nerve cells. [5; pp. 2-3, 6].

In recent years, research scientists have paid special attention to the production of new drugs with neuroprotective effects from substances of natural plant origin. Analysis of the studied literature shows that it is necessary to develop drugs that treat neurodenerative diseases or slow down the pathogenesis of the disease and prevent it. Taking this into account, research was conducted to study methods for obtaining a dry extract from the Rhus glabra L. plant, which grows locally in our republic, and to develop a technology and standardize a biologically active additive in capsule form based on it.

Purpose of the research work. Study of the quality indicators of the "Neuroglabtan" biologically active supplement in capsule form, developed based on a dry extract obtained from the Rhus glabra L. plant.

Materials and research methods. The biologically active additive "Neuroglabtan," developed on the basis of a dry extract obtained from the naked sumac plant, is subject to the requirements of O'zMSt 166:2024, TSt 42-01:2002 "Standards for the quality of medicines. Basic rules" and in the DF of the Republic of Uzbekistan, and standardized according to the following indicators: external appearance, average weight of the capsule and capsule mass and deviations from it, decomposition, heavy metal content, quantitative analysis, and microbiological purity indicators [7, 8, 9, 10].

Results and their discussion. When evaluating the appearance of the capsules visually, it was established that they are blue, transparent, and solid gelatinous capsules of size No. 0, consisting of an encapsulable mass ranging from orange to light brown.

The average weight of the capsule and the mass inside the capsule, as well as the deviation from it when determined by the gravimetric method on AS220R analytical scales, amounted to 0.630+3.7 and 0.501+3.5%, respectively. The results obtained did not exceed the requirement for capsules established in O'zSt 166:2024.

The authenticity of the biologically active substances contained in the capsule was determined using the thin-layer chromatography method, as specified in paragraph 2.2.27 of the State Standard of the Republic of Uzbekistan. To conduct the experiment, standard and test solutions were prepared. The value of Rf for the point formed on the chromatogram plate of the test solution corresponded to the value of Rf for the point on the chromatogram of the standard solution.

The results obtained during the study of the quality indicators of the capsule during the experiments are presented in Table 1.

Table 1

Results of the study on the quality indicators of neuroglobtan capsules

№	The name of indicators	Norms for NTD	Results received
1.	Description	Blue, transparent, solid gelatin capsules, size № 0	pass

2	Average weight, g ± dev. from average mass, %	0,599-0,661 ±5%	0,630±3,7
3	Average mass of content, g ± dev. from average mass contents, %	0,475-0,525 ±5%	0,501±3,5%
4	Validity analysis	Method TLC. The rf value of the reference solution must correspond to the rf value of the test solution.	pass
5.	Quantitative analysis	Method HPLS: 1. the amount of flavonoids must be at least 2%; 2. the amount of gallic acid must be at least 0.4%.	>2% >0,4%
6.	Disintegration	It must be completely disintegratied within 40 minutes.	22 minutes
7.	Heavy metals	< 0,001%	pass
8.	Microbiological cleanliness	The total amount of yeast and mold fungi, as well as gram-negative bacteria resistant to bile (Enterobacteria), should not exceed 104 CFU/g, and the total amount of aerobic microorganisms in 1 g of the preparation should not exceed 105 CFU/g. 1 g of the preparation must not contain Escherichia coli, and 10 g of the preparation must not contain Salmonella.	pass

The disintegration of "Neuroglabtan" capsules was carried out using laboratory methods described in Section 2.9.1 of the DF RUz. In this case, the disintegration of our capsules took 22 minutes.

When obtaining an extract from plants, a complex of biologically active substances (BAS) is transferred to it. It was deemed appropriate to determine the total amount of flavonoids relative to rutin and the amount of gallic acid relative to tannin in the prepared capsule. The metrological characteristics of the BMF content in the "Neuroglabtan" capsule are presented in Table 2.

Table 2.

Metrological characteristics of the quantitative analysis of biologically active substances in the "Neuroglabtan" capsule (N-5)

№	BAS	f	$\overline{X}$	t(pt)	P, %	S^2	S	SX_{aver}	ΔX	$\Delta\overline{X}$	E %	E_{aver} %
1.	Flavonoid	4	2,422	2,78	95	0,00412	0,06418	0,02870	0,17844	0,07980	7,37	3,29
2.	Gallic acid	4	0,526	2,78	95	0,00014	0,01197	0,00535	0,03330	0,01489	6,33	2,83

Note: **N**- is the number of samples taken for the experiment, **f** - is the number of degrees of freedom, $\overline{X}$ **-** is the arithmetic mean, **t (rt)-** is Student's t-test, **P**- is the significance level, S^2- is the variance, **S** - is the standard deviation, SX_{aver} - is the standard error of the mean value, **ΔX** - is the error of the individual value, $\Delta\overline{X}$ **-** is the absolute error of the analysis, **E%** - is the relative error, E_{aver}**%** - is the mean relative error.

When studying the amount of the active substance for "Neuroglabtan" capsules using the HPLC method, the flavonoid content was 2.42% relative to rutin and 0.52% relative to gallic acid.

Analysis of the heavy metals in the proposed "Neuroglabtan" capsules was conducted using the plasma-induced optical emission spectrometry method, based on the methodology and requirements recommended in the 11th and 12th literature. According to the results obtained, the heavy metal content in the capsule was less than 0.001%.

Conclusions: The quality indicators of the biologically active supplement "Neuroglabtan," which has a neuroprotective effect, were studied in accordance with current regulatory documents, and the results obtained were positively evaluated. For the quantitative analysis of the capsule, a modern method of HPLC was recommended.

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