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GOSPODARKA I INNOWACJE

LABORATORIUM WIEDZY Artur Borcuch

Volume: 33 | 2023

Economy and Innovation
ISSN: 2545-0573

For more information contact: editor@gospodarkainnowacje.pl

STUDYING THE TERMS AND METHODOLOGY OF STORAGE OF CAPSULES WITH ADAPTOGENIC EFFECT

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A R T I C L E I N F O.

Keywords: Adaptogen, dry extract of ginseng, capsule, expiration date, storage conditions.

Annotation

It is known that ginseng dry extract belongs to the group of adaptogenic substances and has been used since ancient times, and hundreds of studies have been devoted to its properties. Given the above, the authors conducted research on the development of a capsule dosage form based on a dry extract of ginseng. This report presents the results of stability studies of this drug. Based on the dry extract of ginseng, the qualitative and quantitative indicators of the capsule dosage form were determined in full compliance with the established standards for 9 months.

Relevance. Ginseng dry extract has many useful properties, it restores human health, stabilizes energy balance, improves immunity, improves memory, is used in stressful situations, and for the prevention of diabetes. [1,3,4].

At present, the capsule is a widely developing and promising form of medicine in the world, and attention to it is growing in our republic. Especially dry extracts are hygroscopic, can absorb moisture from the air and undergo some changes during storage. [3,4]. The capsule protects the medicinal substance not only from moisture, but also from sunlight and other external influences, stability is ensured, and it is also aesthetic, convenient to take, and all technological processes are mechanized and automated. Considering this, it was considered necessary to create a kind of capsule preparation intended for drinking, based on the dry extract of Indian ginseng. [2,5,6].

Target. Study of expiration dates and storage conditions of capsules based on dry extract of Indian ginseng.

Materials and methods. The shelf life of medicines is one of the main indicators of quality. The study of the stability of drugs allows obtaining information about the change in their therapeutic efficacy and quality indicators under the influence of the external environment (humidity, temperature, light). This is of great importance, since this indicator determines the period of sale of the drug and the duration of its effective use. The shelf life of a pharmaceutical product is the main quality indicator that determines its stability during storage.

Shelf life is the period of time during which the medicinal product is produced and stored in full compliance with all requirements of regulatory documents. The determination of the stability of

capsules obtained on the basis of the proposed dry extract of Indian ginseng was carried out in natural conditions and equipped with various containers, which are considered methods of natural preservation over a long period of time.

To study the stability of the tested dry extract capsule, we placed it in the following two packaging containers:

1. OST 64-074-91 cellular packaging with PVC film according to GOST 25250-88,
2. Brown glass containers according to TU 64-228-84.

Results: At the last stage of our research aimed at creating a capsule dosage form based on a dry extract of Indian ginseng, we studied its stability in natural conditions and the method of natural storage for a long time. During the quality control of these samples, the following indicators were always monitored: appearance, average weight of the capsule and deviation from it (gr.%), average weight and deviation from the mass inside the capsule (gr.%), disintegration (min), dissolution (%), amount of active ingredient (%). The results are presented in the table.

As a result of the analysis of capsules stored in a natural way of storage, the following was established: the appearance of the capsules did not change for 9 months, that is, they were dark green capsules with white number 00. The encapsulated mass has a dark brown color with a specific smell.

The average weight and deviation from it should be within 0.405-0.495 g as required, and the deviation should not exceed ± 10.0%.

The average weight of the encapsulated mass in the capsule ranged from 0.530 to 0.538, that is, it did not exceed the established range (0.540-0.660 g). The deviation from this weight was at the required level and did not exceed ±10.0%.

According to the 14th edition of the State Pharmacopoeia, the dissolution time of the capsule should not exceed 20 minutes. Within 9 months, this indicator did not exceed 11 minutes 45 seconds, that is, it met the requirement.

Disintegration of the capsule: at least 75% of the active substance must be released within 45 minutes at a rotation speed of 100 rpm. The dissolution rate of the capsules analyzed by us based on the dry extract of Indian ginseng was in the range of 90.2-90.1%. The amount of dry ginseng extract in these capsules should be at least 0.0182 g (in 1 capsule) of the total amount of panaxosides compared with Escin from 0.0181 to 0.0183 g for 9 months. This research is ongoing.

Specified indicators	**Necessary**	**Reported results**			
		original sample	**in 3 months**	**in 6 months**	**in 9 months**
Appearance	White capsules numbered 00, with a dark green cap, dark brown encapsulated mass, with a specific odor.	corresponds	corresponds	corresponds	corresponds
Average weight and deviation from it, (g,%)	0,405-0.495 (±10,0%)	0.403±0.476%	0.404±0.473%	0.401±0.469%	0.404±0.487%

The average mass of the mass inside the capsule and its deviation, (g, %)	0,540-0,660 (±10, 0%)	0.512±0.42%	0.530±0.63%	0.536±0.65%	0.538±0.68 %
Disintegration of the capsule, min	It should not be less than 75% within 45 minutes.	89,8%	90,2%	90,4%	90,1%
Melting, %	It should decompose within 20 minutes	12 minutes 35 seconds	12 minutes 10 seconds	11 minutes 50 seconds	11 minutes 45 seconds
Quantity	Aggregation of panaxosides against escin 0.0182 g, not less in 1 capsule	0,0179	0.0181	0.0180	0.0183

Conclusions: Experiments to determine the shelf life and storage conditions of capsules based on dry extract of ginseng were carried out in 2 different packaging materials, and today it has been proven that the capsules have a shelf life of 9 months under natural storage conditions.

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