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Research Article

STUDY OF STABILITY AND SHELF LIFE OF THE DRY EXTRACT "LEOFLOMIS"

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ABSTRACT

The article presents the results of studies on the ascertainment of storage conditions and shelf life of a dry extract consisting of medicinal plants Regel's gooseberry and Turkestan motherwort, which has a sedative effect. The studies were carried out by a long-term method for determining stability using three types of packaging materials. After laying the samples for storage at time intervals equal to 3 months, the quality indicators were determined. The results obtained indicate that the analyzed dry extract retains the constancy of qualitative and quantitative indicators for 2 years in all types of packaging materials used.

KEYWORDS

Dry extract, stability, quality assessment, long-term testing, packaging material.

INTRODUCTION

Currently, the creation of medicines based on medicinal plant materials is relevant. The development of a technology for obtaining and registration of a new drug require stability studies and determination of expiration dates. The purpose of the stability study is to obtain data on the change in the quality of the medicinal product during storage, on the impact on the quality of various environmental factors, as well as the

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regulation of storage conditions, periods of re-control or expiration dates. It is known that stability is the ability of a medicinal product to maintain its properties within the limits ascertained in the specification during the shelf life when stored under regulated conditions in a commercial package [1]. The creation of sedative drugs with a sedative effect is also relevant, since in recent decades there has been an increase in the range of drugs based on medicinal plants. The reason for this is the comparative safety of drugs based on plant materials compared to synthetic ones, their lower toxicity, a wide range of therapeutic activity, etc. [2,3]. Taking into account the rich flora of the Republic of Uzbekistan, in order to replenish the range of sedatives, using the method of pharmacological screening, we have developed a herbal composition consisting of local medicinal plants: herbs of Turkestan motherwort (Leonurus turkestanicus) and herbs of Regel's gooseberry (Phlomis regelii), containing a fairly rich complex of biologically active substances, among which there are flavonoids. At present, a dry extract of "Leoflomis" has been obtained from the sedative collection [4].

Based on the foregoing, the purpose of these studies was to study the stability of the dry extract "Leoflomis" to ascertain its shelf life and storage conditions.

Materials and methods. The object of the study was the dry extract "Leoflomis" (trademark No. MGU 43107 dated December 02, 2021) with a sedative effect, which was obtained on the basis of project No. Ed-202010086 "Development of a new technology for obtaining a dry extract (substance) of a sedative effect from plants Regel's gooseberry and Turkestan motherwort" [5]. The study of the quality indicators of the analyzed dry extract was carried out in accordance with the requirements of pharmacopoeial articles: "Extracts" (SP XI, issue 2; SP XIII, SP RUz 1st ed. I-II volume) [6,7,8]. To determine the shelf life of the dry extract "Leoflomis" a long-term method was used.

The dry extract was evaluated according to quality indicators: description, authenticity, weight loss upon drying, heavy metals, microbiological purity, quantitative content of biologically active substances (total flavonoids in terms of rutin).

The determination of the above indicators was carried out by the following methods: appearance - organoleptic; authenticity - with the help of qualitative reactions to rutin; loss in mass during drying - according to the SP of the Republic of Uzbekistan 1st ed. II volume 2.8.16.; heavy metals - according to the SP RUz 1st edition. II volume 2.4.27.; microbiological purity - according to the SP RUz 1st edition. I-II volume 2.6.31., 5.1.8.; quantitative content of flavonoids sum in terms of rutin - HPLC method. Dry extract samples were packed in three types of packaging materials: jars according to TSh 64-15390981-03:2014 made of polyethylene according to SSt 16338-85 with screw caps; jars made of colorless glass melt, type according to TC 13-7308001-477-85; jars made of solar-protective glass melt type BDS-25 according to TC 64-228-84. The

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quality indicators of the dry extract were carried out every 3 months.

Results and discussion. Table 1 shows the results of the correspondence between the qualitative and quantitative indicators of samples of "Leoflomis" dry extract before storage.

Table 1

The quality standards of the substance of the dry extract "Leoflomis", controlled when setting the expiration date

№	Studied indicators	Norms for RD	Methods	Norms
1.	**Description**	Free-flowing hygroscopic powder, dark brown in color, with a peculiar sweet smell and taste	Organoleptic	Corresponds
2.	**Authenticity**	*Rutin.* A few drops of ferric chloride solution are added to 1-2 ml of an aqueous solution of the extract, a green color should appear	SP XI, II volume, pp. 327, 343.	Corresponds
3.	**Loss on drying**	No more than 5%	SP RUz 1st ed., I volume 2.8.17.	3.95%
4.	**Heavy metals**	The color developed in the tested solution should not exceed the color of the reference solution.	SP RUz 1st ed., I volume 2.4.27.	Corresponds
5.	**Microbiological purity**	The total number of aerobic bacteria is not more than 10 *4 in 1 g The total number of mushrooms is not more than 10 *2 in 1 g	SP RUz 1st ed. I-II volumes 2.6.31., 5.1.8.	Corresponds

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		Bile-resistant Gram-negative bacteria, not more than 10*2 CFU per 1 g Escherichia coli - must be absent in 1 g Salmonella - must be absent in 25 g		
6.	**Quantitative content**	0.176 ± 0.085%.	HPLC	Corresponds

According to the data obtained, the samples of the analyzed dry extract "Leoflomis" in terms of quality meet the requirements given in the regulatory documentation.

The results of studies to determine the stability of this extract, packed in jars according to TSh 64-15390981-03:2014 from polyethylene according to SSt 16338-85 with screw caps are shown in Table 2.

The results obtained indicate that all the analyzed indicators, despite minor changes, met the requirements of the ND. Thus, the appearance of the dry extract remained unchanged over the entire period of the experiment. However, there was a slight increase in moisture content and volatile substances from 3.95% to 4.35%, which is typical for almost all dry extracts. At the same time, the moisture content by the end of the 2nd year of the experiment did not exceed the regulated 5%. Qualitative reactions to evidence of rutin were also positive over 2 years. The color of the tested solution of the dry extract prepared for the determination of heavy metals did not exceed the color of the reference solution. The analysis of microbiological purity showed that the analyzed dry extract after 2 years according to this indicator meets the requirements of the SP of the Republic of Uzbekistan, 1st edition. I-II volume 2.6.31., 5.1.8.

The pharmacotherapeutic effect of the substance, regardless of the raw material obtained, is determined by the quantitative content of active substances. In this regard, one of the main indicators of the dry extract quality was the compliance of the quantitative content of biologically active substances with the ascertained standards. According to the data shown in Table 1, the content of the total flavonoids in terms of rutin was regularly analyzed, by the end of the 2nd year of research it met the requirements.

Practically similar results of the analysis were obtained for samples of dry extract packed in other packaging materials: jars of colorless glass melt type according to TC 137308001-477-85 and jars of sun-protective glass melt type BDS-25 according to TC 64-228-84, i.e. it can be argued that all three types of packaging ensure the

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constancy of the qualitative and quantitative indicators of the analyzed extract.

Table 2

The study results of the stability of the dry extract "Leoflomis", packed in jars according to TSh 6415390981-03:2014 from polyethylene according to SSt 16338-85 with screw caps

Studied indicators	Regulations according to ND	Results by month							
		after 3 months	after 6 months	after 9 months	after 12 months	after 15 months	after 18 months	after 21 months	after 24 months
Appearance	Free-flowing and hygroscopic powder of dark brown color, with a peculiar sweet smell and taste.	corresp	corresp	corresp	corresp	corresp	corresp	corresp	corresp
Authenticity	*Rutin.* A few drops of ferric chloride solution are added to 1-2 ml of an aqueous solution of the extract, a green color should appear	corresp.	corresp	corresp	corresp	corresp	corresp	corresp	corresp
Loss on drying	No more than 5%	3.95%	4.07%	4.15%	4.09%	4.18%	4.25%	4.30%	4.35%
Heavy metals	The color developed in the tested solution should not exceed the color of the reference solution.	corresp	corresp	corresp	corresp	corresp	corresp	corresp	corresp

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Microbiological purity	The total number of aerobic bacteria is not more than 10 *4 in 1 g. The total number of mushrooms is not more than 10 *2 in 1 g. Bile-resistant gram-negative bacteria no more than 10*2 CFU in 1 g. Escherichia coli - must be absent in 1 g. Salmonella - must be absent in 25 g.	corresp	corresp	corresp	corresp	corresp	corresp	corresp	corresp

CONCLUSION

According to the results of the studies on the stability of the dry extract "Leoflomis", consisting of medicinal plants of Regel's gooseberry and Turkestan motherwort, which has a sedative effect, a shelf life of 2 years was ascertained.

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