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RESEARCH ARTICLE

Determination of Storage Conditions and Shelf Life Of "Antidiargranat" Capsules

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Abstract

The composition and technology of the "ANTIDIARGRANAT" antidiarrheal capsule-form BPA, obtained on the basis of a dry extract of the peel of a local pomegranate fruit, are proposed, and its quality and quantitative indicators are evaluated. This article presents the results of studies conducted to determine the shelf life and conditions of the "ANTIDIARGRANAT" antidiarrheal capsule-form BPA. In the experiments, the appearance of the capsule, average weight and deviation from it, disintegration, solubility, microbiological purity, and the amount of additives were determined, and the capsules were stored in natural conditions for 30 months at room temperature in packages made of materials permitted in medical practice, and the above-mentioned quality indicators of the capsules were studied. As a result of the experiments, all the capsules packaged in the packaging materials selected for testing showed positive results during the observation period. As a result of the experiments, the shelf life of the "ANTIDIARGRANAT" antidiarrheal drug in capsule form was determined to be 2 years.

KEYWORDS

Medicinal plant raw materials, biologically active additive, quality indicator, natural storage conditions, shelf life.

INTRODUCTION

In recent years, the demand for herbal medicinal products has been increasing year by year. It also requires the development of herbal medicinal products technology, stability studies, shelf life determination, and registration. Studying the effect of various environmental factors on the stability of capsules and determining the shelf life is one of the main tasks in the development of herbal medicinal products technology. Proper storage and shelf life of capsules containing dry extracts of plant origin directly affect their effectiveness and safety, and the shelf life of capsules directly depends on their composition, preparation method, and type of packaging. Usually, the shelf life of capsules is set at 3 years, and it is important to follow the recommendations for the storage conditions and shelf life of the capsules, since the capsules may lose their pharmacological effect after the expiration of their shelf life.

Purpose of the study. Studies on the storage conditions and shelf life of the antidiarrheal capsule "ANTIDIARGRANAT".

METHODS

During the studies, studies were conducted to study the shelf life of biologically active additives in capsule form. Antidiarrheal capsules were prepared in 5 series and packaged in 3 types of packaging approved for use in medical practice, each of 30 pieces, and the studies were conducted under natural conditions at room temperature of 22 ± 2 0C for 2 years and 6 months, at a relative humidity of 50-60%. The quality of the capsule BPA based on the dry extract was assessed by the following parameters: appearance, average weight of the capsule and its removal, disintegration, solubility, microbiological purity, the amount of additives was determined relative to tannin [1.2.3.4.5.6].

"ANTIDIARGRANAT" capsule BPA is approved for use in medicine packed in containers:

- Plastic containers made of food-grade polymer material according to TST 64-0516 for primary packaging;

- Plastic jars with screw caps TST-64-20-87-81, brown glass jars TST-64-2-71-80 for primary packaging;

The stability and storage conditions of the "ANTIDIARGRANAT" capsule-shaped BPF in medical conditions were studied every 6 months for 2.5 years [1.2.6].

RESULTS

The antidiarrheal capsule "Antidiarrheal" packaged in two types of packaging studied retained its quality and quantity indicators throughout the entire observation period (30 months), that is, it fully met the requirements set forth in regulatory documents. Accordingly, the stability of the quality and quantity indicators of "Antidiarrheal" capsules when stored under natural storage conditions was determined to be 2 years.

It was determined that the quality indicators of the antidiarrheal capsules "Antidiarrheal" met the required level, and the containers selected for packaging the drug ensured their stability.

Table 1

The results of the study of the stability of "Antidiaargranat" capsules by the "Natural aging" method (22±20C)

Packaging type	Control indicators	Inspection results, month/year					
		Initial sample	6 months	12 months	18 months	24 months	30 months
Plastic containers made of food polymer material according to TST 64-0516	Appearance	The finished product is a creamy white hard gelatin capsule, the capsule mass is light brown with a characteristic odor	мос келди	мос келди	мос келди	мос келди	мос келди
	Average capsule weight, g and ± deviation from it, %	Not more than 10%	0.5121 - 4,1% +2,5 %	0,5125 - 4,2% +2,7 %	0,5130 - 3,4% +2,4 %	0,5135 - 4,6% +3,1 %	0,5137 - 5,5 % +3,8 %
	Average weight of the mass inside the capsule, and ± deviation from it, %	Not more than 10%	0.4021 - 4,1% +3,2 %	0.4025 - 4,4% +3,5 %	0.4030 - 4,6% +2,5 %	0.4035 - 5,1% +4,1 %	0.4038- 5,1 % +6,5 %

	Decomposition, min	20 min. not to have much	6-30	7-12	7-25	9-10	10-15
	Solubility,%	Not less than 75%	85.2	84.6 %	82.8 6	81.1 4	79.7 9
	Microbiological cleanliness	The total number of aerobic bacteria in 1 g of the preparation should not exceed 1000 CFU; The total number of fungi in 1 g of the preparation should not exceed 100 CFU; 1 g of the preparation should not contain Escherichia coli.	satisf actor y to the stand ard	satisf actor y to the stand ard	satisf actor y to the stand ard	satisf actor y to the stand ard	satis facto ry to the stan dard
	The amount of additives in the capsule in relation to tannin, %	Not less than 5%	fits	fits	fits	fits	fits
Brown glass jars (TST-64-2-71-80) with twist-off plastic lids (TST-64-20-87-81)	Appearance	The finished product is a creamy white hard gelatin capsule, the capsule mass is light brown with a characteristic odor	fits	fits	fits	fits	fits
	Average capsule weight, g and ± deviation from it, %	Not more than 10%	0.51 25 - 4,1% +2,5 %	0,51 25 - 4,2% +2,4 %	0,51 31 - 3,4% +2,7 %	0,51 38 - 4,2% +3,1 %	0,51 40 - 4,6 % +3,8 %
	Average weight of the mass inside the capsule, and ± deviation from it, %	Not more than 10%	0.40 25 - 4,1% +3,2 %	0.40 25 - 4,2% +3,1 %	0.40 31 - 4,1% +3,6 %	0.40 38 - 4,5% +3,9 %	0.40 40 - 4,9 % +4,6 %
	Decomposition, min	20 min. not to have much	6-50	7-15	7-35	9-20	10-35
	Solubility,%	Not less than 75%	85.2	84.6 %	82.8 6	81.7 4	79.7 5

	Microbiological cleanliness	The total number of aerobic bacteria in 1 g of the preparation should not exceed 1000 CFU; The total number of fungi in 1 g of the preparation should not exceed 100 CFU; 1 g of the preparation should not contain Escherichia coli.	satisf actor y to the stand ard	satisf actor y to the stand ard	satisf actor y to the stand ard	satisf actor y to the stand ard	satis facto ry to the stan dard
	The amount of additives in the capsule in relation to tannin, %	Not less than 5%	fits	fits	fits	fits	fits

According to the data presented in the table, the organoleptic properties of the "Antidiargranat" capsules, i.e. the appearance, smell and taste of the capsule mass, did not change for 2 years and met the established requirements.

The disintegration of the "Antidiargranat" capsules in capsules of 2 different packaging did not exceed 20 minutes over a period of 24 months. The average weight of the capsules and the deviation from it did not exceed 10%, and the solubility was determined to be not less than 75%.

In terms of microbiological purity, the capsules met the requirements of the regulatory document, i.e. the total number of aerobic bacteria in 1 g of encapsulated mass did not exceed 103, and the total number of fungi did not exceed 102. Escherichia coli was not detected at all.

Also, the content of tannin as a biologically active substance was determined and determined to be not less than 10% in the capsules of "Antidiargranat" and the amount of active substances in the capsules placed in 2 different types of packaging for 24 months was not less than the specified requirement.

CONCLUSIONS

Based on the results of the above experiment, the antidiarrheal drug "Antidiargranat" in the form of capsules was evaluated according to the quality indicators studied when stored under natural conditions for 30 months and was found to be appropriate for packaging in the selected packaging. Also, their shelf life was determined as 24 months and 2 years.

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