



STORAGE CONDITIONS AND SHELF-LIFE DETERMINATION OF THE HEPATOPROTECTIVE HERBAL TEA “HEPAGAL”

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This article presents the results of scientific research aimed at determining the shelf life and storage conditions of the “HEPAGAL” herbal tea. The optimal composition and production technology of this hepatoprotective herbal tea, developed on the basis of locally sourced medicinal plant raw materials, were established, and its quantitative and qualitative indicators were evaluated through a comprehensive analysis. At the initial stages of the study, the appearance, color, moisture content, particle-size (fineness) fraction, mass per individual tea bag, and total flavonoid content (expressed as rutin equivalent) of the herbal tea were determined, and the measurement results were recorded. The prepared herbal mixture was packed into filter tea bags approved for use in medical practice and stored under natural conditions, at room temperature, for 30 months. Throughout the storage period, the above-mentioned quality indicators of the herbal tea and the dynamics of the release of biologically active substances into hot water were investigated on a regular basis. The results obtained confirmed the qualitative stability and satisfactory performance of the samples stored in all filter-bag packaging materials. On this basis, the guaranteed shelf life of the “HEPAGAL” hepatoprotective herbal tea was established at 2 years.

Keywords: hepatoprotectors, plant raw materials, biologically active substances, assessment of quality indicators, sachet bag, filter tea bag, natural storage conditions, shelf life.

Herbal teas are beverages prepared from various parts of plants — leaves, flowers, roots, and fruits — and are distinguished by their therapeutic and general restorative properties. Such plant-based teas are widely used not only in the treatment of various diseases but also for prophylactic purposes, since they serve to activate the body’s natural defense mechanisms and to improve the overall state of health.

At the same time, it should be emphasized that the efficacy and safety of herbal teas are directly linked to compliance with proper storage conditions and the observance of the established shelf life. Improperly stored or expired plant teas may lose their beneficial properties as a result of the degradation or reduction of the biologically active substances they contain, and in some cases they may even cause adverse effects. For this reason, strict adherence to storage rules is of great importance in ensuring the maximum therapeutic and prophylactic efficacy of herbal teas [1, 2].

The shelf life of herbal teas is directly dependent on their composition, preparation technology, and type of packaging. In practice, many manufacturers usually set the shelf life of herbal teas within a range of 1–3 years. However, strict observance of this period is essential, because once the shelf life has expired, the biologically active substances contained in the plant teas may degrade, leading to a significant reduction in their medicinal properties.

A number of factors are taken into account in a comprehensive manner when determining the storage conditions and shelf life of herbal teas. In particular, the type of plant raw material plays an important role: raw materials consisting of leaves and flowers generally lose their biological activity more rapidly than root and bark parts. The form of the product is likewise significant: teas packed into filter bags, being in a finely dispersed state, are more sensitive to the influence of external factors and may therefore have a shorter shelf life. In addition, the methods of processing and drying the raw material also affect storage stability; for example, plants dried under natural conditions may possess greater stability. Improper storage conditions, in turn, lead to a deterioration in the quality of the herbal tea, the degradation of biologically active substances, and a decline in the expected therapeutic efficacy of the prepared infusion, even when the official shelf life of the product has not yet expired. For this reason, determining the storage conditions and shelf life of herbal teas is a complex process that requires a thorough analysis of the raw-material composition, chemical stability, and storage conditions. Adherence to proper storage and usage rules, in turn, serves to preserve the bioactive properties of plant teas and to ensure their maximum therapeutic efficacy [3–9].

Aim of the study. To conduct comprehensive research on optimizing the storage conditions of the “HEPAGAL” hepatoprotective herbal tea and on establishing its shelf life on a scientific basis.

Experimental part

Materials and methods. The “HEPAGAL” herbal tea, containing locally sourced medicinal plant raw materials, was selected as the object of the study. The composition of this herbal tea included the following components: milk thistle seeds (*Silybum marianum*) – 1.0, and medicinal marigold (*Calendula officinalis*).

In the studies aimed at determining the storage conditions for the filter-bag form of the “HEPAGAL” herbal tea as a biologically active supplement (BAS), the effect of the packaging (container) type on the quality indicators of the finished product was investigated. During the experiments, the following principal indicators were evaluated: appearance, moisture content (%), particle-size (fineness) (mm), mass per package (g), content of water-soluble extractive substances (%), microbiological purity, and total flavonoid content (expressed as luteolin equivalent, %). The finished product was stored under natural conditions, that is, at room temperature (20 ± 2 °C) and at a relative humidity of 50–65%, for 30 months. Over this period, the quality indicators determined were compared with the initial values, and the effect of the packaging type on the quality stability of the product was analyzed comprehensively [10]. The “HEPAGAL” herbal tea in the form of a biologically active supplement (BAS) was packed into containers approved for medical use:

As the primary packaging, paper filter bags made in accordance with the requirements of GOST 33772–2016 were used, with cardboard boxes in accordance with GOST 12301–2006 as the secondary packaging. In addition, nylon filter bags conforming to GOST 12302–2013 were used as the primary packaging, with cardboard boxes in accordance with GOST 12301–2006 as the secondary packaging. Furthermore, reusable aluminum-foil bags conforming to the requirements of GOST 745–2014 were used as the primary packaging, with cardboard boxes as the secondary packaging.

The storage of the biologically active supplement in the form of the "HEPAGAL" herbal tea under natural conditions was carried out over 2.5 years, and its quality indicators and quantitative composition were monitored regularly every 6 months.

Results and discussion.

According to the results of the study, it was established that the qualitative and quantitative indicators of the "HEPAGAL" hepatoprotective herbal tea stored in the three different types of packaging materials remained stable throughout the 30-month period. At the same time, it was observed that the quality indicators of the samples stored in paper- and nylon-based filter bags were comparatively lower than those of the samples stored in aluminum-foil bags.

On the basis of the results obtained, the effectiveness of the packaging materials was recorded in the following order: aluminum-foil bag > nylon bag > paper filter bag.

As a result of the experiments conducted, it was established that all the selected packaging types ensured the quality stability of the product and yielded positive results. On the basis of these results, the guaranteed shelf life of the "HEPAGAL" hepatoprotective herbal tea was set at 2 years.

Table 1

Determination of the shelf life of the "HEPAGAL" hepatoprotective herbal tea packed into a paper filter bag (GOST 33772-2016) under natural storage conditions

No.	Indicators studied	Regulatory document requirement	Storage period / results obtained					
			Initial	6 mo	12 mo	18 mo	24 mo	30 mo
1	Appearance	RUz State Pharmacopoeia, 1st ed.: the milk thistle plant ranges in color from light brown to dark brown; the fruit kernels are small, hard, oblong nutlets, slightly compressed laterally with somewhat distinct edges, or fragments thereof. The medicinal marigold (<i>Calendula officinalis</i>) raw material consists of flower parts and their fragments, ranging in color from deep orange	complies	complies	complies	complies	complies	complies

No.	Indicators studied	Regulatory document requirement	Storage period / results obtained					
			Initial	6 mo	12 mo	18 mo	24 mo	30 mo
		to light orange-deep orange, sometimes with an additional brownish-yellow tint. The raw material has a characteristic pleasant odor, with a somewhat bitter and distinctive taste. The herbal tea has a characteristic, fragrant, pungent odor. The aqueous extract prepared from the herbal tea has a sour-bitter, pungent, slightly astringent, and mucilaginous taste.						
2	Authenticity	RUz State Pharmacopoeia, 1st ed.: 2% alcoholic solution of aluminum chloride	A yellow color characteristic of flavonoids develops	complies	complies	complies	complies	complies
3	Moisture content, %	RUz State Pharmacopoeia, 1st ed.: milled herbal tea, not more than 13%	9±1.4	9±1.4	9±1.6	9±1.6	9±1.8	9±1.9
4	Particle size (fineness), mm	RUz State Pharmacopoeia, 1st ed.: for milled herbal tea, particles not passing through a sieve of 7 mm mesh diameter – not more than 3%; for milled herbal tea, particles passing through a sieve of 0.2 mm mesh diameter – not more than 5%	2.4±0.15 0.1±0.2	2.4±0.20 0.1±0.2	2.3±0.85 0.1±0.1	2.3±0.45 0.1±0.5	2.2±0.95 0.1±0.1	2.2±0.15 0.1±0.2

No.	Indicators studied	Regulatory document requirement	Storage period / results obtained					
			Initial	6 mo	12 mo	18 mo	24 mo	30 mo
5	Mass of package contents (1 bag), g	TS requirement: $\pm 5\%$ at a nominal mass of 2.0 g	2.0 ± 1.3	2.0 ± 2.5	2.0 ± 3.2	2.0 ± 3.3	2.0 ± 3.6	2.0 ± 3.9
6	Mass fraction of water-soluble extractive substances, %	TS requirement: not less than 20%	23 ± 0.7	23 ± 0.8	23 ± 0.3	23 ± 0.9	23 ± 0.7	23 ± 0.3
7	Microbiological purity	The herbal tea belongs to category 4 A (medicinal plant raw material used as an infusion prepared with hot water). Total number of microorganisms – not more than 10^7 CFU per 1 g; total number of yeast and mold fungi – not more than 10^5 CFU per 1 g; Escherichia coli – not more than 10^2 CFU per 1 g.	complies	complies	complies	complies	complies	complies
8	Total flavonoid content (as rutin), %	not less than 0.20 ± 1.40	0.212 ± 1.69	0.212 ± 1.65	0.212 ± 1.49	0.212 ± 1.43	0.212 ± 1.41	0.212 ± 1.35

Table 1 presents the results of determining the shelf life of the “HEPAGAL” hepatoprotective herbal tea packed into a paper filter bag (GOST 33772-2016) under natural storage conditions; on the basis of these results, the shelf life of the herbal tea can be established at 2 years.

Table 2

Determination of the shelf life of the “HEPAGAL” hepatoprotective herbal tea packed into a nylon filter bag (GOST 12302-2013) under natural storage conditions

No.	Indicators studied	Regulatory document requirement	Storage period / results obtained					
			Initial	6 mo	12 mo	18 mo	24 mo	30 mo
1	Appearance	RUz State Pharmacopoeia, 1st ed.: the milk thistle plant ranges in color from light brown to dark brown; the fruit kernels are small, hard, oblong nutlets, slightly compressed laterally with somewhat distinct edges, or fragments thereof. The medicinal marigold (<i>Calendula officinalis</i>) raw material consists of flower parts and their fragments, ranging in color from deep orange to light orange–deep orange, sometimes with an additional brownish-yellow tint.	complies	complies	complies	complies	complies	complies

No.	Indicators studied	Regulatory document requirement	Storage period / results obtained					
			Initial	6 mo	12 mo	18 mo	24 mo	30 mo
		The raw material has a characteristic pleasant odor, with a somewhat bitter and distinctive taste. The herbal tea has a characteristic, fragrant, pungent odor. The aqueous extract prepared from the herbal tea has a sour-bitter, pungent, slightly astringent, and mucilaginous taste.						
2	Authenticity	RUz State Pharmacopoeia, 1st ed.: 2% alcoholic solution of aluminum chloride	A yellow color characteristic of flavones develops	complies	complies	complies	complies	complies
3	Moisture content, %	RUz State Pharmacopoeia, 1st ed.: milled herbal tea, not more than 13%	9±1.4	9±1.4	9±1.5	9±1.6	9±1.6	9±1.8



No.	Indicators studied	Regulatory document requirement	Storage period / results obtained					
			Initial	6 mo	12 mo	18 mo	24 mo	30 mo
4	Particle size (fineness), mm	RUz State Pharmacopoeia, 1st ed.: for milled herbal tea, particles not passing through a sieve of 7 mm mesh diameter – not more than 3%; for milled herbal tea, particles passing through a sieve of 0.2 mm mesh diameter – not more than 5%	2.4±0.15 0.1±0.2	2.4±0.18 0.1±0.3	2.4±0.23 0.2±0.3	2.4±0.26 0.1±0.3	2.4±0.34 0.1±0.5	2.4±0.39 0.1±0.7
5	Mass of package contents (1 bag), g	TS requirement: ±5% at a nominal mass of 2.0 g	2.0±1.3	2.0±1.3	2.0±1.4	2.0±1.7	2.0±1.7	2.0±1.9
6	Mass fraction of water-soluble extractive substances, %	TS requirement: not less than 20%	23±0.7	23±0.7	23±0.8	23±0.8	23±0.9	22±0.2
7	Microbiological purity	The herbal tea belongs to category 4 A (medicinal plant raw material used	complies	complies	complies	complies	complies	complies

No.	Indicators studied	Regulatory document requirement	Storage period / results obtained					
			Initial	6 mo	12 mo	18 mo	24 mo	30 mo
		as an infusion prepared with hot water). Total number of microorganisms – not more than 10^7 CFU per 1 g; total number of yeast and mold fungi – not more than 10^5 CFU per 1 g; Escherichia coli – not more than 10^2 CFU per 1 g.						
8	Total flavonoid content (as luteolin), %	not less than 0.20 ± 1.40	0.212 ± 1.23	0.212 ± 1.22	0.212 ± 1.22	0.212 ± 1.21	0.212 ± 1.19	0.211 ± 1.15

Table 2 presents the results of determining the shelf life of the “HEPAGAL” hepatoprotective herbal tea, packed into nylon filter bags in accordance with the requirements of GOST 12302-2013, under natural storage conditions. On the basis of the results obtained, the shelf life of the herbal tea may be established at 2 years.

Table 3

Determination of the shelf life of the “HEPAGAL” hepatoprotective herbal tea packed into an aluminum-foil bag (GOST 745-2014) under natural storage conditions

No.	Indicators studied	Regulatory document requirement	Storage period results obtained /					
			Initial	6 mo	12 mo	18 mo	24 mo	30 mo
1	Appearance	RUz State Pharmacopoeia, 1st ed.: the milk thistle plant ranges in color from light brown to dark brown; the fruit kernels are small, hard, oblong nutlets, slightly compressed laterally with somewhat distinct edges, or fragments thereof. The medicinal marigold (Calendula officinalis) raw material consists of flower parts and their fragments, ranging in color from deep orange to light orange-deep orange, sometimes with an additional brownish-yellow tint. The raw material has a characteristic pleasant odor, with a somewhat bitter and distinctive taste. The herbal tea has a	complies	complies	complies	complies	complies	complies

No.	Indicators studied	Regulatory document requirement	Storage period / results obtained					
			Initial	6 mo	12 mo	18 mo	24 mo	30 mo
		characteristic, fragrant, pungent odor. The aqueous extract prepared from the herbal tea has a sour-bitter, pungent, slightly astringent, and mucilaginous taste.						
2	Authenticity	RUz State Pharmacopoeia, 1st ed.: 2% alcoholic solution of aluminum chloride	A brown color characteristic of flavones develops	complies	complies	complies	complies	complies
3	Moisture content, %	RUz State Pharmacopoeia, 1st ed.: milled herbal tea, not more than 13%	9±1.4	9±1.4	9±1.5	9±1.5	9±1.5	9±1.6
4	Particle size (fineness), mm	RUz State Pharmacopoeia, 1st ed.: for milled herbal tea, particles not passing through a sieve of 7 mm mesh diameter – not more than 3%; for milled herbal tea, particles passing through a sieve of 0.2 mm mesh diameter – not more than 5%	2.4±0.15 0.1±0.2	2.4±0.15 0.1±0.2	2.3±0.20 0.1±0.2	2.3±0.22 0.1±0.3	2.2±0.29 0.1±0.3	2.2±0.38 0.1±0.5

No.	Indicators studied	Regulatory document requirement	Storage period results obtained /					
			Initial	6 mo	12 mo	18 mo	24 mo	30 mo
5	Mass of package contents (1 bag), g	TS requirement: $\pm 5\%$ at a nominal mass of 2.0 g	2.0 ± 1.3	2.0 ± 1.3	2.0 ± 1.3	2.0 ± 1.6	2.0 ± 1.6	2.0 ± 1.9
6	Mass fraction of water-soluble extractive substances, %	TS requirement: not less than 20%	23 ± 0.7	23 ± 0.7	23 ± 0.7	23 ± 0.8	23 ± 0.9	22 ± 0.9
7	Microbiological purity	The herbal tea belongs to category 4 A (medicinal plant raw material used as an infusion prepared with hot water). Total number of microorganisms – not more than 10^7 CFU per 1 g; total number of yeast and mold fungi – not more than 10^5 CFU per 1 g; Escherichia coli – not more than 10^2 CFU per 1 g.	complies	complies	complies	complies	complies	complies
8	Total flavonoid content (as rutin), %	not less than 0.20 ± 1.40	0.212 ± 1.23	0.212 ± 1.23	0.212 ± 1.23	0.212 ± 1.19	0.212 ± 1.15	0.212 ± 1.05

Table 3 presents the results of the studies conducted on the storage of the "HEPAGAL" hepatoprotective herbal tea, packed into aluminum-foil bags in accordance with the requirements of GOST 745-2014, under natural conditions. On the basis of the results obtained, the shelf life of the herbal tea may be established at 2 years.

Conclusions. The prepared herbal mixtures were placed into filter bags approved for use in medical practice and stored under natural conditions, at room temperature, for 30 months. Throughout this period, the principal quality indicators of the herbal tea were investigated on a regular basis. As a result of the studies conducted, the samples stored in all tested packaging types proved to be qualitatively stable and yielded positive results. On the basis of the results obtained, the guaranteed shelf life of the "HEPAGAL" hepatoprotective herbal tea was established at 2 years on a scientifically substantiated basis.

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