Original Article

Development of foaming shampoo base for the treatment of Seborrheic Dermatitis

Inna Baranova[1], Sergei Zaika[1], Yuliia Bezpala[1]*, Olena Roik[2], Svitlana Zaporozhska[3] Liubov Shostak[4]

[1] Department of Commodity Science, National University of Pharmacy, Kharkov, Ukraine. [2] Department of Pharmacy and Industrial technology of drugs, Bogomolets National Medical University, Kiev, Ukraine. [3] Department of Industrial Technology of Drugs, National University of Pharmacy, Kharkov, Ukraine. [4] Department of Pharmacy International University, Dean of the Pharmaceutical Faculty, Kyiv, Ukraine.

Correspondence: Yuliia Bezpala, Department of Commodity Science, National University of Pharmacy, Kharkov, Ukraine, 4, Valentinivska Street, 61121, Ukraine. Email: yuliyabespalaya5 @ gmail.com

ABSTRACT

Introduction: Seborrheic dermatitis (SD) is a chronic inflammatory recurrent dermatosis characterized by erythematous-squamous rashes in areas with hypertrophied and hyperactive sebaceous glands. The key factor in the pathogenesis is changes in the functional activity of the sebaceous glands by various exogenous and endogenous factors, accompanied by the activation of Malassezia genus. Topical glucocorticosteroids, and antimicrobial and antifungal agents are used to treat the disease. However, most of them have short-term effects, so finding new treatment approaches is necessary. **Materials and Methods:** Samples with active pharmaceutical ingredients and surface-active agents were provided. The anionic (disodium Laureth sulphosuccinate, sodium Laureth sulfate, sodium myreth sulfate, sodium lauroyl sarcosinate, magnesium Laureth sulfate), amphoteric (disodium cocoamphodiacetate, Cocamidopropyl betaine), and nonionic (ethoxylated rape oil amide, cocamide DEA, PEG–7 glyceryl cocoate, and PEG–200 glyceryl palmitate) surfactants were selected. The foaming ability of samples was determined by the modified method of Ross-Miles. The pH of the test samples was determined by potentiometry. The quality of the bases prepared was assessed according to appearance, organoleptic indicators (color, odor), pH, and foaming ability. **Results and Discussion:** This study devoted to the rational combination of anionic, amphoteric, and nonionic surfactants and studies of their foaming ability for the development of stable shampoo to treat seborrheic dermatitis. **Conclusion:** All foaming bases with anionic surfactants, namely, disodium laureth sulphosuccinate, sodium Laureth sulfate, sodium myreth sulfate, and sodium and magnesium Laureth sulfate had satisfactory physicochemical indicators. The obtained data will be considered at the next stage of our research, when it is planned to introduce into the elaborated foaming bases a complex of active pharmaceutical ingredients, the concentration of which is substantiated based on biological and microbiological researches. There is also planned research regarding the study of foam structure by microphotography method.

Keywords: surfactants, foaming base, foaming property, seborrheic dermatitis

Introduction

Nowadays, one of the most unpleasant problems of the scalp and hair especially for men is dandruff. For many people, seborrheic scalp and dandruff are the same things. Misunderstanding of this problem leads to inappropriate treatment. It should be understood that seborrheic dermatitis (SD) is a chronic inflammatory recurrent dermatosis characterized by an erythematous-squamous rash in areas with hypertrophied and hyperactive sebaceous glands [1, 2]. Seborrheic dermatitis occurs most often in children, usually within the first

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3 months of life, and in patients aged from 30 to 70 years [3, 4]. The incidence and severity of the disease appear to be regulated by genetic factors, emotional or physical stress, and climate (the condition usually worsens in cold weather). Also, seborrheic dermatitis may be more common or more severe in patients with neurological disorders (especially Parkinson's disease) or HIV / AIDS [5-7].

However, many factors that contribute to the development of the disease are pointed out. These are heredity, seborrheic status, immune and endocrine disorders, infectious agents, nervous system disturbance, diseases of the digestive tract, medicinal preparations, etc., although none of them is universal to substantiate the mechanisms of development of seborrheic dermatitis. However, the key factor in the pathogenesis is the changes in the functional activity of the sebaceous glands under the influence of various exogenous and endogenous factors, accompanied by the activation of yeast-like fungi of Malassezia genus [8, 9].

In treatment, the agents, which contain topical glucocorticosteroids, antimicrobial and antifungal agents (for example zinc pyrithione, selenium sulfide, tar, salicylic acid, sulfur, etc.) are most commonly used. However, the application of most of them produces a short-term effect, so finding new approaches to seborrheic dermatitis treatment remains an urgent task [5, 8].

To achieve this goal, most often special foaming agents are used - shampoos, which contain a complex of surfactants and active pharmaceutical ingredients, by which the process of treatment of this pathology is carried out [10-14].

Therefore, to achieve this goal and namely elaborate a dermatological foaming agent, we have thoroughly analyzed and selected some modern surfactants with anionic, amphoteric, and nonionic characteristics.

Materials and Methods

Based on the data obtained from the literary-patent search, recommendations of the contemporary foaming agents' manufacturers, as well as analyzing the modern market of Ukraine, we selected many modern surfactants (anionic, amphoteric, and nonionic). The principal (anionic) surfactants included disodium laureth sulfosuccinate («Euronaat LS 3», «EOC», Belgium), sodium Laureth sulfate («SLES», «EOC», Belgium), sodium more sulfate («Texapon K 14», «EOC», Belgium), sodium lauroyl sarcosinate («Medialan LD», «EOC», Belgium), and magnesium Laureth sulfate («EOC», Belgium»). Also, when analyzing the compositions of dermatological foaming agents, we noted that in combination with anionic surfactants, amphoteric ones such as disodium cocoamphodiacetate («BETADET THC 2», «EOC» Belgium) and Cocamidopropyl betaine («KAO», Japan), as well as nonionic Ethoxylated rape oil amide (PEG-4 Rapeseedamide, «Amidet®N», «KAO», Japan), cocamide DEA (Cocamide DEA, «EOC», Belgium), PEG-7 glyceryl cocoate, and PEG-200 glyceryl palmitate («Neopal LIS 80» Industria Chimica Panzeri S. R. L, Italy) are used [13, 15-17].

Samples with active pharmaceutical ingredients and surface-active agents were provided by the public joint-stock company "Chervona zirka" Chemical-pharmaceutical Plant (Kharkiv, Ukraine). Lactic acid was used as a regulator of the foaming bases (Lactic Acid, Galactic, Belgium), which is considered to be an optimal component. Lactic acid is a part of the skin acid mantle and it is also allowed in the application of foaming products ((EU) Regulation №1223/2009) [18].

All samples were prepared according to the conventional technology: the required amount of the surfactant was calculated and dissolved in water at the desired temperature (40 – 45 °C). For further studies, 5 % aqueous solutions of the surfactant obtained were adjusted to the required temperature (37 °C). The time for preparing the samples was from 30 to 60 min. All samples were prepared and calculated regarding 100 % substance). These studies were carried out at the premises of the Research laboratory of the Commodity Science Department of the National University of Pharmacy.

One of the main physicochemical indicators of any foaming agent is the foaming ability, namely foam number (mm) and foam stability (conv.units). According to the current normative documents, namely DSTU 4315: 2004 "Cosmetics for cleaning skin and hair" and TU U 20.4-36257034-019: 2017 "Cosmetics for the care and purification of the skin, scalp, and hair" the foam number should not be less than 145.0 mm and the foam stability should not be less than 0.8-1.0 conventional units [19, 20].

The Ross-Miles foam analyzer is the most widely used device for obtaining a foam and the assessment of its stability and volume. It was approved by the American Society for Testing and Materials (ASTM) as a standard device for measuring the foaming ability of soaps and synthetic detergents. The Ross-Miles foam analyzer is suitable both for studies of foam in dilute solutions with the low viscosity of the completely soluble surfactants and for measuring the stability of the poorly soluble foam. However, it should be noted that the Ross-Miles foam analyzer, as well as many other devices, allow studying only some of the properties of the foam; at the same time, until today, there is no single method that would be universal and suitable for complete characterization of the properties of the foam. Thus, the foaming ability of the test samples was determined by the method specified in DSTU ISO 696:2005 "Determination of the foaming ability by the modified method of Ross-Miles" and GOST 22567.1-77 "Synthetic detergents) [21]. The method for determining the foaming ability". To perform this test, the Ross-Miles foam analyzer, the ultrathermostat UT-15, a stopwatch timer, a rubber squeeze bulb, the analytical balance of the accuracy class 3 for general purposes, pipettes: 1-2-50, pipettes: 1-2-1-2(10), flasks: 1-1000-2, and measuring glasses: B-1-100(500)(1000) TC were used. The water jacket was connected to a thermostat, switched on, and the temperature of the liquid in the water jacket was adjusted to (37 ± 2) °C. Simultaneously, 300 cm^3 of the solution of the surfactant studied was adjusted to the same temperature. Of this amount, 50 cm^3 of the solution was taken and poured down the sides of the graduated cylinder in order not to form the foam. In 10 min using a rubber squeeze bulb or a pump, the test solution of the surfactant in the volume of 200 cm^3 was introduced into the pipette in such a way that no foam could form. The pipette with the solution was fixed to the stand so that its outlet was at a distance of 900 mm from the level of the liquid in the cylinder, and the flow could get to the center of the liquid. Then the tap of the pipette was opened. When there was no solution in the pipette, a stopwatch timer was switched on, and the number of the foam column formed (mm) was measured. The measurement was carried out in 30 s. In 5 min, the number of the foam column formed (mm) was measured again.

The determination of rheological indicators was carried out on a Brookfield DV-II + PRO (USA) viscometer using a rotary adapter with a system of coaxial cylinders. The coaxial geometry of the viscometer consists of a cylindrical spindle and a cylindrical chamber that provide accurate control of the measurement of the rheological parameters of the Newtonian fluids [22, 23].

The quality of the bases prepared was assessed according to the following criteria: appearance, organoleptic indicators (color, odor), pH value, and foaming ability (foam number, foam stability). These indicators were considered for the qualitative assessment of the current foaming detergents according to DSTU 5009:2008 «Perfume and cosmetic products. Rules of acceptance, sampling, methods of organoleptic tests» and TU U 24.5-31640335-002:2007 [20, 24].

The pH level of the test samples was determined by potentiometry (SPhU 1.2, 2.2.3) using a "pH Meter Metrohm 744" device (Germany) [25].

Results and Discussion

The first stage of our research was devoted to the rational combination of the selected anionic and amphoteric surfactants and studies of their foaming ability. All these surfactant samples were prepared in terms of 100% substance. As it is known from the literature, primary surfactants (foaming agents) should be from 10.0 to 30.0% in the formulation, and the concentration of the secondary surfactants should be 20.0-30.0% of the concentration of the primary surfactant, i.e. in the ratio of 1:3 - 1:4 [2, 13]. Initially, we studied the combination of selected anionic surfactants with amphoteric surfactants, namely with Cocamidopropyl betaine, which is used to increase foam level, stabilize the formulation, and enhance the growth of their purification properties in combination with selected anionic surfactants. Its recommended maximum concentration is up to 12%. Based on well-known literature data, we selected the following combinations of surfactants, which are presented in Table 1.

Table 1. Studies of foaming ability of experimental samples with Cocamidopropyl betaine

№	Examined samples	Foaming ability		pH Value
		Foam number, mm.	Foam stability Conv. units	
1	disodium laureth sulphosuccinate -10.0 cocamidopropyl betaine – 5.0	216.0±1	0.87± 0.02	5.5± 0.2
2	sodium laureth sulfate – 10.0 cocamidopropyl betaine – 5.0	239.0±1	0.89 ± 0.01	5.7± 0.1
3	sodium myreth sulfate – 10.0 cocamidopropyl betaine – 5.0	214.0±1	0.92 ± 0.01	5.4± 0.2
4	sodium lauroyl sarcosinate – 10.0 cocamidopropyl betaine - 5.0	220.0±1	0.93 ± 0.02	5.6± 0.1
5	magnesium laureth sulfate – 10.0 cocamidopropyl betaine – 5.0	225.0±1	0.88 ± 0.03	5.7± 0.1

Note. n = 3, P = 95 %

All experimental samples were prepared using conventional technology at room temperature at a low rotation speed of the mixing machine (20 rpm) to prevent air formation. The required amount of the selected anionic surfactants was dissolved in water and purified at 35-40 °C. After complete dissolution, in approximately 45-60 minutes, Cocamidopropyl betaine was added at the same rotation speed of the mixing machine, which was dissolved completely within 5 - 10 min. As a result, we obtained transparent, homogeneous solutions with a specific odor of raw materials. The pH of the experimental samples ranged from 6.0 to 7.2. The recommended pH for this foaming agents group is 5.4 - 5.7. Therefore, at this stage and in further investigations, the pH value was adjusted with lactic acid to the required pH value.

From the obtained results shown in Table 1, we can conclude that all the experimental samples had the corresponding foaming ability, which is currently regulated by the current normative document, namely DSTU4315: 2004 - foam number of not less than - 145.0, foam stability of 0.8 - 1.0.

However, we noticed that samples No. 2 (239.0 mm), 4 (220.0 mm), and 5 (225.0 mm) had the highest foam number as compared to samples No. 1 (216.0 mm) and 3 (214.0 mm).

Analyzing the foam stability indicators, it was noted that samples No. 3 (0.92 conv. units) and 4 (0.93 conv. units) had slightly higher values as compared to samples No. 1 (0.87 conv. units), 2 (0.89 conv. units), and 5 (0.88 conv. units). But despite this, all the experimental samples had met the established standards of the applicable normative documentation.

Based on the literature-patent sources, the analysis of the foam agents' composition of this group, as well as the works of Ukrainian scientists, we decided to research the combination of disodium cocoamphodiacetate and Cocamidopropyl betaine in the foaming base, which is being elaborated. According to the obtained data, first, the two selected and combined amphoteric surfactants have a potentiating effect on each other (they increase the foaming ability indicators), secondly, the decrease in their concentration is possible, which is economically profitable in the industrial production of these agents. As we studied the selected surfactants at a concentration of 5.0% and the obtained data met the requirements of the current normative documentation, we decided to investigate the selected combination of amphoteric surfactants at a total concentration of 5.0% (disodium cocoammonium acetate - 2.5% and Cocamidopropyl betaine - 2, 5%).

Using similar technology, we prepared 10.0% solutions of the selected anionic surfactants and Cocamidopropyl betaine were added step by step, and after its complete dissolution, disodium cocoamphodiacetate was added. The result was a homogeneous solution with a specific odor of the raw materials. The results are presented in Table 2.

Table 2. Study of foaming ability of experimental samples with Cocamidopropyl betaine and disodium cocoamphodiacetate

№	Sample and surfactant concentration. %	Foaming ability		pH Value
		Foam number. mm.	Foam stability Conv. units	
1	disodium laureth sulphosuccinate - 10.0 cocamidopropyl betaine – 2.5 disodium cocoamphodiacetate – 2.5	215.0±1	0.91± 0.02	5.3±0.2
2	sodium laureth sulfate – 10.0 cocamidopropyl betaine – 2.5 disodium cocoamphodiacetate – 2.5	243.0±1	0.92± 0.02	5.5±0.1
3	sodium myreth sulfate – 10.0 cocamidopropyl betaine – 2.5 disodium cocoamphodiacetate – 2.5	273.0±1	0.91± 0.01	5.7±0.1
4	sodium lauroyl sarcosinate – 10.0 cocamidopropyl betaine - 2.5 disodium cocoamphodiacetate – 2.5	231.0±1	0.91± 0.02	5.4±0.2
5	magnesium laureth sulfate – 10.0 cocamidopropyl betaine – 2.5 disodium cocoamphodiacetate – 2.5	201.0±1	0.89± 0.04	5.5±0.1

Note. n = 3, P = 95 %

The obtained data proved that the combination of the selected surfactants affects the foaming ability of the examined samples. Thus, the value of the foam number and foam stability increase, except for sample No. 5. As compared to the previous research, the foam number was 201.0 mm and foam stability was 0.89 Conv. units that are somewhat lower during the introduction of amphoteric surfactants individually. However, the obtained foaming ability data of sample No. 5 still meet the requirements of DSTU4315: 2004. Therefore, this sample is not excluded from further research.

As it is known, non-ionic surfactants are introduced into the composition of any foaming agents to reduce the irritant effect of anionic surfactants. This group of substances constitutes approximately 20% of the total surfactant production and is a multifunctional group, providing solubilization and foam stabilization functions (enhances the foam life), as well as contributes to softening and refatting effects. Also, nonionic surfactants in the foaming agents act as thickeners. Therefore, the next stage of work was dedicated to nonionic surfactants' selection justification.

To minimize the saturation of the foaming agent, which is being elaborated, various nonionic surfactants (derivatives of higher fatty acids, esters of higher acids, oxyethyl alcohols, alkyl amides, amine oxides, etc.) which in turn would perform different functions in a foaming base, (for example, stabilize the foam, increase the value of the foaming action, act as a thickener, etc.) we decided to incorporate into the composition multi-component surfactants of nonionic nature.

For this research, we selected two nonionic surfactants - ethoxylated rape oil amide, and DEA cocamide. They are most commonly used by Ukrainian manufacturers in the elaboration of foam cleaners. The concentration of the selected substances for the foaming agents is ethoxylated rape oil amide from 3.0 to 5.0% and cocamide DEA from 1.0 to 3.0%. The experimental samples were prepared using the following technology: 3.0, 4.0, and 5.0% ethoxylated rape oil amide were added into the obtained solutions of the selected surfactants. In parallel, there were prepared samples of foaming base with 1.0, 2.0, and 3.0% cocamide DEA. The result was a homogeneous solution with a specific odor of the raw materials.

Analyzing the obtained data, we found that the addition of ethoxylated rape oil amide and DEA cocamide to the elaborated foaming base affected all indicators of foaming ability, namely, an increase in both foam number and foam stability was observed.

However, with the increase of concentrations of the selected non-homogeneous surfactants (ethoxylated rape oil amide to 5.0% and DEA cocamide to 3.0%), there was a slight decrease in foaming ability. Firstly, it is related to the change in the foam structure, it became coarse-grained and lost its volume (the "foam life" indicator decreased), and secondly, the structural viscosity of the elaborated samples increased (Table 3).

Table 3. Structural viscosity of the experimental samples with ethoxylated rape oil amide and DEA cocamide

№	Sample and surfactant concentration %	Concentration of ethoxylated rape oil amide	Structural viscosity, mPa·s (20 rounds/minute)	Concentration of DEA cocamide	Structural viscosity, mPa·s (20 rounds/minute)
1	disodium laureth sulphosuccinate - 10.0	3.0	**119**	1.0	**130**
	cocamidopropyl betaine – 2.5	4.0	126	2.0	138
	disodium cocoamphodiacetate – 2.5	5.0	134	3.0	142
2	sodium laureth sulfate – 10.0	3.0	**123**	1.0	**136**
	cocamidopropyl betaine – 2.5	4.0	129	2.0	140
	disodium cocoamphodiacetate – 2.5	5.0	136	3.0	148
3	sodium myreth sulfate – 10.0	3.0	**120**	1.0	**129**
	cocamidopropyl betaine – 2.5	4.0	125	2.0	133
	disodium cocoamphodiacetate – 2.5	5.0	133	3.0	144
4	sodium lauroyl sarcosinate – 10.0	3.0	**115**	1.0	**120**
	cocamidopropyl betaine - 2.5	4.0	123	2.0	127
	disodium cocoamphodiacetate – 2.5	5.0	130	3.0	134
5	magnesium laureth sulfate – 10.0	3.0	**119**	1.0	**129**
	cocamidopropyl betaine – 2.5	4.0	128	2.0	138
	disodium cocoamphodiacetate – 2.5	5.0	137	3.0	145

Note. n = 5, P = 95 %

From the Table, it was understood that the viscosity increase was observed in two cases when ethoxylated rape oil and DEA cocamide were added to the foaming bases. However, it can be seen from Table 3 that the addition of more DEA cocamide contributed to a greater thickening of all samples at lower concentrations as compared to the ethoxylated rape oil amide.

However, based on the values obtained from the previous research (foaming ability), we decided at this stage of the foaming base elaboration to remove the samples with DEA cocamide from further research. This is because of lower foam number and foam stability due to higher structural viscosity (resulting in a thick mass that loses its flow property).

Considering the above-mentioned information, for further research, we selected samples with a concentration of ethoxylated rape oil amide at a concentration of 3.0%, since at a concentration of 4.0%, the indicators had little difference, so an increase in the concentration in our opinion was not rational.

For further stabilization of the foaming ability and softening of the anionic surfactants, we additionally introduced a mixture of nonionic surfactants such as PEG-7 glyceryl cocoate and PEG-200 glyceryl palmitate. It is practicable to add this detergent to formulations containing sulfosuccinates, sarcosinates, and acylglutamates, which are difficult to thicken due to the electrolytic thickening mechanism, such as sodium chloride. The concentration of "Neopal LIS 80" recommended by manufacturers in the elaboration of foaming cleaners for scalp and hair is from 0.5 to 5.0%. "Neopal LIS 80" was added to the investigated foaming bases at 35 to 45 °C at a low rotation of the mixing machine. In the experiment, it was observed that the addition of the selected surfactant at the concentrations of 2.5 to 5.0%, the structural viscosity of the foaming bases increased, and the obtained bases did not have satisfactory consumer characteristics (they were sticky and became cloudy after settling-out). Therefore, for further study, we selected the following concentrations of "Neopal LIS 80" - 0.5, 1.0, 1.5, and 2.0 % (Table 4).

Table 4. Foaming ability and structural viscosity of the researched samples

№	Sample and surfactant concentration, %	PEG – 7 glyceryl cocoate and PEG – 200 glyceryl palmitate concentration	Structural viscosity, mPa·s (20 rounds/minute)	Foam number, mm.	Foam stability Conv. units
1	disodium laureth sulphosuccinate - 10.0	0.5	**124**	**237.0**±1	**0.93**±0.02
	cocamidopropyl betaine – 2.5	1.0	136	241.0±1	0.90±0.03
	disodium cocoamphodiacetate – 2.5	1.5	144	259.0±1	0.92±0.01

	ethoxylated rape oil amide - 3.0	2.0		257.0±1	0.90±0.02
2	sodium laureth sulfate – 10.0	0.5	**133**	**257.0**±1	**0.92**±0.02
	cocamidopropyl betaine – 2.5	1.0	139	260.0±1	0.90±0.02
	disodium cocoamphodiacetate – 2.5	1.5	147	273.0±1	0.91±0.01
	ethoxylated rape oil amide - 3.0	2.0	156	279.0±1	0.90±0.03
3	sodium myreth sulfate – 10.0	0.5	**130**	**273.0**±1	**0.93**±0.01
	cocamidopropyl betaine – 2.5	1.0	135	275.0±1	0.91±0.02
	disodium cocoamphodiacetate – 2.5	1.5	140	282.0±1	0.90±0.03
	ethoxylated rape oil amide - 3.0	2.0	143	289.0±1	0.90±0.02
4	sodium lauroyl sarcosinate – 10.0	0.5	**125**	**246.0**±1	**0.93**±0.01
	cocamidopropyl betaine - 2.5	1.0	133	251.0±1	0.90±0.02
	disodium cocoamphodiacetate – 2.5	1.5	146	254.0±1	0.91±0.02
	ethoxylated rape oil amide - 3.0	2.0	150	260.0±1	0.92±0.02
5	magnesium laureth sulfate – 10.0	0.5	**129**	**230.0**±1	**0.92**±0.01
	cocamidopropyl betaine – 2.5	1.0	128	246.0±1	0.90±0.03
	disodium cocoamphodiacetate – 2.5	1.5	135	243.0±1	0.89±0.03
	ethoxylated rape oil amide - 3.0	2.0	147	251..0±1	0.91±0.01

Note. n = 3, P = 95 %

From this experiment, we determined that the addition of this component had practically no effect on the structural viscosity properties of the studied bases, but did affect the foaming ability of the samples. The value of foaming ability, namely the foam number, increased in all the experimental samples. However, we noted that when the foaming base "Neopal LIS 80" at a concentration of 2.0% was added, there was a decrease in the indicators of both the foam number and foam stability of almost all experimental samples. At a concentration of "Neopal LIS 80" 1.0-1.5 %, on the contrary, we noted the increase in foam number, but at the same time, the decrease in the foam stability value. Therefore, we decided to choose a concentration of "Neopal LIS 80" - 0.5%, because at this concentration, the experimental samples had the highest foam stability, and the foam number was not significantly different from the samples with a concentration of "Neopal LIS 80" 1.0-1.5 %.

Conclusion

According to the results of the research, it was understood that all foaming bases with many anionic surfactants, namely, disodium laureth sulfosuccinate, sodium Laureth sulfate, sodium myreth sulfate, and sodium and magnesium Laureth sulfate had satisfactory physicochemical indicators (appearance, organoleptic characteristics, foaming ability), regulated by the state standards of Ukraine.

The obtained data will be taken into consideration at the next stage of our research, when it is planned to introduce into the elaborated foaming bases a complex of active pharmaceutical ingredients, the concentration of which is substantiated based on biological and microbiological investigations. There is also planned research regarding the study of foam structure by the method of microphotography.

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