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SELECTION OF THE BASE FOR A TOPICAL PHARMACEUTICAL FORM FOR STUMP CARE AFTER PROSTHETIC FITTING

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The aim of the work. Rehabilitation of patients with amputation of the lower limbs is an urgent task of society. Currently, the pharmaceutical market of Ukraine lacks medicinal products for stump care of domestic production. Therefore, the aim of this work was to research the selection of the basis of soft medicine for the care of stumps after prosthetics.

Materials and methods. The objects of the study were samples of a soft medicinal product on an emulsion basis. Gelling agents (aristoflex, xanthan gum, aerosil) were used as regulators of the structural and mechanical parameters of soft medicine. Research was conducted using a set of studies to determine organoleptic and structural-mechanical indicators.

Results. According to the results of the organoleptic analysis, according to the indicators of homogeneity, the presence of delamination, samples were selected for further research, where aristoflex and xanthan gum were used as a thickener. According to the results of structural and mechanical studies, it was established that the samples with xanthan gum have a satisfactory degree of spreading and adhesiveness, which increases with increasing exposure to mechanical forces. The determined values of static and dynamic coefficients of friction testify to the sliding properties of samples with xanthan gum.

Conclusion. It was established that the addition of xanthan gum to the composition of the base would provide all the necessary characteristics for a soft medicine that is planned to be used in the care of the stump after prosthetics.

Keywords: amputation, prosthetics, complications, therapy, prevention, semi-solid medicine, technology, structural and mechanical properties

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1. Introduction

Amputations are often associated with a high risk of adverse complications. Among patients with traumatically amputated limbs, 51 % suffer from anatomical complications, 63 % of people with amputated limbs suffer from one or more skin problems that lead to limitation of daily activities in a third of these patients [1]. Approximately 70 % of amputees develop phantom limb pain (PLP) or residual limb pain (RLP), 14.5 % of patients with traumatic amputations require revision surgery, and 25–56 % of amputees develop social problems [2]. Transtibial amputation (TTA) occurs in many cases in people with non-healing and/or infected wounds associated with mine blast injuries or complex dysvascular pathologies, such as severe diabetes mellitus (DM) [3]. After amputation, almost 50 % of people have difficulty with more demanding tasks, such as stepping [4]. In addition, 40–50 % of individuals with unilateral TTA suffer from disabling comorbidities such as low back pain, which further impairs functionality and mobility, ultimately affecting quality of life [5]. Consequently, patients with amputated limbs require a long period of treatment and rehabilitation, and infection and damage to soft tissues that may occur during the care of the stump after prosthetics are often a reason to refuse further use of the prosthesis [6].

Creating a safe and comfortable connection between the residual limb and the prosthesis socket in amputees is a critical factor for successful rehabilitation, including ambu-

lation and other activities of daily living [7]. Unwanted rotation within the socket can be a clinical problem for prosthesis users [8]. One of the ways to solve the problems that arise when using a prosthesis in the transverse plane can be to increase the friction forces between the surfaces [9]. It is known that friction at the residual limb/prosthesis interface can be increased by adding a soft drug with defined texture and physicochemical properties [10]. Amputees are known to use 10–40 % more energy than able-bodied people to walk and perform daily tasks [11]. They also have a reduced surface area (approximately 10–15 % less), which affects the ability to transfer heat energy and cool down [12]. Therefore, the body's natural reaction is increased sweating. The use of silicone-only devices creates an even warmer local environment around the residual limb, as they often have poor thermal conductivity [13]. The resulting microclimate is moist, warm and rich in nutrients, which makes it ideal for the growth of bacteria [14]. Sweat lingers on the surface of the limb instead of evaporating, which can lead to skin problems such as dermatitis of various etiologies. It has been established that the choice of components of the medicinal product can reduce the residual temperature [15]. Therefore, the development of medicines considering the possible pathological processes occurring on the surface of the stump during the repair and wearing of the prosthesis is an urgent task. The purpose of this work was to research the selection of a soft medicine for the care of a stump after prosthetics.

2. Research planning (methodology)

The development of the composition of soft medicine began with the substantiation of the optimal composition of the base carrier, which should ensure a more complete achievement of the therapeutic effect. The object of the research was samples of emulsion bases with different contents of silicones, which differed in the degree of viscosity. Silicones can form a microporous structure that can absorb liquid and form a gel, help prevent wound secretions from sticking to the wound surface, and reduce friction and residual temperature [16]. Glycerin and gelling agents (aristoflex, xanthan gum) were used as regulators of the structural and mechanical parameters of the soft medicine. Different surfactants with different HLB values were used as emulsifiers. Grape seed oil and tocopherol acetate were used as components of the oil phase. These substances have anti-inflammatory and regenerative effects [17]. When choosing preservatives, they relied on their safety, so the composition of the samples mainly contained green preservatives [18]. The task of the work was structural and mechanical research of samples of the emulsion bases of the soft medicine, which is planned to be used in the care of the stump. It was planned to evaluate the organoleptic and textural indicators and the ability to spread, spread and reduce friction of the base samples. To achieve the goal of the study, the composition of the samples was developed, and the selection of samples for the study was based on the results of the organoleptic analysis, determination of the degree of adhesion, strength, viscosity, and static and dynamic coefficients of friction.

3. Materials and methods

Research was conducted based on the National Pharmaceutical University (Department of Industrial Technology of Medicines and Cosmetics) and the Department of Drug Technology and Social Pharmacy of the Lithuanian University of Health Sciences (Kaunas, Lithuania) in 2024. The base model samples included polymer compounds, gelling agents: aristoflex (CAS 335383-60-3), Clariant, Switzerland; xanthan gum (CAS: 11138-66-2), Zhishang Chemical, China; emulsifiers: Emulfarma 1000 (cetearyl alcohol (CAS:67762-27-0) 35–45 %, glyceryl stearate (CAS: 31566-31-1) 20–30 %, sorbitan stearate (CAS: 1338-41-6) 20–30 %, cetearyl glucoside (CAS: 246159-33-1) 10–20 %), ERCA Italy; Lanette O (CAS: 36653-82-4), BASF, Germany; Olivem 900 (CAS: 223706-40-9), Hallstar, Italy; silicones: dimethicone 350 (CAS: 63148-62-9/9006-65-9), China, Customized or Hony; cyclomethicone (CAS: 69430-24-6/556-67-2/541-02-6/540-97-6), Basildon Chemical Company Limited, Great Britain; Beausil Wax (CAS: 67762-83-8), GELEST INC, Germany; preservatives: Euxyl PE 9010 (CAS: 122-99-6, 70445-33-9), Ashland, Germany; penetrant and thickener: glycerin (CAS: 56-81-5), Schmidt und Bretten, Germany; oils: grape seed oil (CAS: 8024-22-4), TM “Myroslav”, Ukraine and water (CAS: 7732-18-5).

Experimental samples were prepared according to the rules for obtaining emulsion systems, considering the melting temperature of the components. The samples were produced in laboratory conditions at a temperature of 65 ± 5 °C, the speed of rotation of the stirrer is

300 ± 5 rpm. The selected thickener (xanthan gum, aristoflex or aerosil) was added to purified water and left to swell for 20 minutes. Glycerin was added to the gelling agent solution and mixed thoroughly (phase A). The oil phase was prepared separately (the emulsifier was melted in a porcelain cup in a water bath, and silicones and grape seed oil were added) (phase B). Slowly, with vigorous stirring, add phase B to phase A and add a preservative (which is highly soluble in organic solvents and sparingly in non-polar solvents and water).

Determination of colloidal stability. The research was carried out by centrifugation for 5 minutes at a frequency of 5000 rpm.

The viscosity of the samples was measured using a rotary viscometer of the Alpha series (Fungilab, Barcelona, Spain). Equal amounts (50 ± 0.01 g) of samples were analyzed with the L4 spindle at different shear rates (20–100 rpm). Measurements were performed at room temperature [19].

A TA.XT.plus texture analyzer (Stable Micro Systems Ltd, Godalming, Surrey, UK) was used to measure the strength of the bioadhesive bond. For this, a sample of ointment with a layer of 3 mm was placed in a hole (10 mm) between two plates. Next, the P/0.5R nozzle was pressed with a force of 5 N for 60 seconds, after which the probe was detached from the sample, measuring its adhesiveness. The samples were tested at a temperature of 25 °C, as well as at a temperature of 37 °C with the addition of a small amount (1–2 drops) of sodium chloride solution [20].

The back extrusion test was performed using the Back Extrusion Rig A/BE of a TA.XT Plus (Stable Micro Systems Ltd., Surrey, Great Britain) texture analyzer. The sample (50.0 g) was placed in a standard container and was compressed by a disk with a diameter of 40 mm, which penetrated to a depth of 10 mm at the rate of 2 mm/s. As a result, a plot of force versus time was obtained for each sample. The following parameters were determined: firmness (g), consistency (g·s), index of viscosity (g·s), and cohesiveness (g) [21].

The spreadability test was performed using the TTC Spreadability Rig HDP/SR of a TA.XT Plus (Stable Micro Systems Ltd., Surrey, Great Britain) texture analyzer. The sample was placed in a standard container and compressed by conical probe which penetrated to a depth of 5 mm at the rate of 2 mm/s. The following parameters were determined: firmness (g), and spreadability (g·s) [22].

Spreading under the influence of weight was determined by measuring the diameter of the spot formed by a sample weighing 1 g and measuring the diameter of this spot after a load of 100 g.

An indirect method was used to determine the friction force. The method of determining the static coefficient of friction consists of measuring the angle at which the object begins to slide on a slope or an inclined surface and is calculated according to the formula:

$$fr = \tan(a).$$

The method of determining the kinetic coefficient of friction consists of measuring the time required

for the object to stop and is calculated according to the formula:

$$fr=v/(g*t).$$

A 21 cm long glass plate coated with a 0.9 % sodium chloride solution was used to measure these parameters. To determine the initial movement angle of a sample weighing 5 g, the angle of inclination of the plate was changed in steps of 10° [23].

The statistical reliability of the experimental results was determined using the Statistica 6.0 program.

4. Results

Based on the analysis of literature data, the composition of the samples was developed for conducting research, which is shown in Table 1.

In order to select samples for further research, at the first stage of the work, an organoleptic analysis of the

obtained samples was carried out, the results of which are shown in Table 2.

As can be seen from the results shown in Table 2, samples No. 2, 7–16 had delamination and were heterogeneous. The samples also differed in consistency. The organoleptic analysis made it possible to conclude that according to the indicators of stability, homogeneity, and consistency, it is advisable to use samples No. 1, 3, 4, 5, and 6 for further research.

Since the textural properties of the composition also affect the consumer characteristics of the soft medicines and, as a result, the effectiveness of the therapy, our goal was to investigate the textural properties of the studied samples. The results of reverse extrusion of soft medicines are shown in Table 3.

According to the results of all the investigated indicators (strength, consistency, cohesiveness) presented in Table 3, the samples can be arranged in the following order: No. 3<No. 4<No. 1<No. 6<No. 5.

Table 1

| Composition of samples | | | | | | | | | | | | | | | | |
|------------------------|--------------|-------|-------|-------|-------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|
| Name | No. 1 | No. 2 | No. 3 | No. 4 | No. 5 | No. 6 | No. 7 | No. 8 | No. 9 | No. 10 | No. 11 | No. 12 | No. 13 | No. 14 | No. 15 | No. 16 |
| Glycerin | 3.0 | 1.0 | 0.65 | 0.65 | 3.0 | 3.0 | 0.65 | – | – | 1.02 | 0.98 | 0.94 | – | 0.67 | – | – |
| Grape seed oil | 3.0 | 2.0 | 1.25 | 1.25 | 3.0 | 3.0 | 3.0 | 3.0 | – | – | – | – | 3.0 | 1.33 | 15.0 | 30 |
| Vitamin E | – | – | – | – | – | – | – | – | – | – | – | – | 0.5 | – | 0.5 | 0.5 |
| Dimethicone 350 | 20.0 | 15.0 | 12.0 | 12.0 | 20.0 | 20.0 | 12.0 | – | 20.0 | – | – | – | – | – | – | – |
| Dimethicone 250 | – | – | – | – | – | – | – | 20.0 | – | 36.74 | – | – | – | – | – | – |
| Dimethicone 200 | – | – | – | – | – | – | – | – | – | – | 35.29 | 33.96 | – | 24 | – | – |
| Dimethicone 100 | – | – | – | – | – | – | – | – | – | – | – | – | 20.0 | – | 5.0 | – |
| Cyclomethicone | 15.0 | – | 11.0 | 11.0 | – | – | – | – | – | 36.74 | 35.29 | 33.96 | – | 24 | – | – |
| Aristoflex | 1.0 | – | – | 0.5 | – | – | 2.0 | – | – | – | – | – | – | 0.67 | – | – |
| Xanthan gum | – | – | – | – | 0.5 | 1.5 | – | – | – | – | – | – | – | – | – | – |
| Aerosil | – | – | – | – | – | – | – | – | – | – | 3.92 | 7.55 | – | – | – | – |
| Beausil Wax | – | 4.0 | – | – | – | – | – | – | – | 5.1 | 4.90 | 4.72 | – | 3.33 | – | – |
| Lanette O | – | – | 1.25 | 1.25 | – | – | 1.25 | – | – | – | – | – | – | – | – | – |
| Euxyl PE 9010 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | – | – | – | – | – | – | – | – | – | – |
| Emulfarma 1000 | 8.0 | – | 5.0 | 5.0 | 8.0 | 8.0 | 5.0 | – | – | – | – | – | – | – | – | – |
| Olivem 900 | – | – | – | – | – | – | – | – | – | – | – | – | – | – | – | – |
| LekoGuard MPP | – | – | – | – | – | – | 1.0 | 1.0 | 1.0 | – | – | – | 1.0 | – | – | 1.0 |
| Olivatis-18 | – | – | – | – | – | – | – | 8.0 | 8.0 | – | – | – | 8.0 | – | 5.0 | 8.0 |
| Cosphaderm® Leo | – | – | – | – | – | – | – | – | – | – | – | – | – | 0.67 | 2.5 | – |
| Water | up to 100 ml | | | | | | | | | | | | | | | |

Table 2

| Results of organoleptic analysis | | | | | | | | | | | | | | | | |
|----------------------------------|------|------|-------|-------|-------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|
| Indicator | No.1 | No.2 | No. 3 | No. 4 | No. 5 | No. 6 | No. 7 | No. 8 | No. 9 | No. 10 | No. 11 | No. 12 | No. 13 | No. 14 | No. 15 | No. 16 |
| Delamination | – | + | – | – | – | – | + | + | + | + | + | + | + | + | + | + |
| Homogeneity | + | – | + | + | + | + | – | – | – | – | – | – | – | – | + | – |
| Consistency | 1 | d | d | d | d | d | 1 | d | 1 | 1 | d | 1 | 1 | 1 | 1 | 1 |

Table 3

| Indicators of strength, consistency, cohesiveness and viscosity index of the samples | | | | |
|--|-------------|--------------------|-----------------|-------------|
| Sample | Firmness, g | Consistency, g·sec | Cohesiveness, g | IV, g·sec |
| No. 1 | 114.69±0.98 | 419.87±13.06 | 99.10±1.24 | 81.18±3.95 |
| No. 3 | 327.56±1.33 | 1100.06±115.10 | 288.82±24.86 | 165.03±9.64 |
| No. 4 | 247.96±2.47 | 850.06±60.90 | 213.87±4.40 | 147.09±4.48 |
| No. 5 | 38.37±0.29 | 162.44±2.15 | 31.17±1.29 | 23.89±0.60 |
| No. 6 | 65.69±0.17 | 257.33±2.44 | 49.23±0.32 | 47.93±0.84 |

Note: IV – Index of viscosity.

Samples based on a combination of cyclomethicone and dimethicone with the addition of aristoflex (No. 3, 4) have the highest strength (density).

Cohesiveness describes the strength of the internal structural bonds of soft medicine phases, which, thanks to the interaction of molecules, allow the cream to maintain a stable shape. This parameter demonstrates the simulated deformation force required to extrude the sample. As you can see, for stronger (dense) and viscous systems, it is necessary to apply more effort to squeeze (extrude) the cream from the package.

Another important property of local soft medicines is their application to the skin (spreadability). This parameter was also measured using a Texture Analyzer equipped with special conical probes. When the cone-shaped probe penetrates the sample, the device simulates the action of a human finger touching its surface. The results of the spreadability test are shown in the Table 4.

According to the results of this test (Table 4), all samples have a slight difference in the “strength” indicator. However, the sample based on dimethicone with 1.5 % xanthan gum content (No. 6) has the best spreadability value. It was also established that less strong (viscous) samples have better values of adhesion characteristics (samples No. 5, 6 and No. 1) in contrast to samples with a stronger structure (samples #3 and No. 4).

To clarify the results, the viscosity was determined at different spindle rotation speeds (Fig. 1).

The results of determining the viscosity by the direct method using a rotary viscometer (Fig. 1) allowed us to conclude that samples 3 and 4 had the highest viscosity indicators only at a low degree of mechanical influence. With a further increase in the speed of rotation of the spindle, sample No. 3 collapses, and sample No. 4 is equal to the viscosity of sample No. 6.

Table 4

The results of spreadability of samples

| Sample | Firmness, g | Spreadability, g·sec | Adhesive force, g | Adhesiveness, g·sec |
|--------|-------------|----------------------|-------------------|---------------------|
| No. 1 | 28.41±2.32 | 30.13±3.04 | 23.74±1.98 | 11.39±0.47 |
| No. 3 | 30.78±1.79 | 36.53±2.32 | 14.40±0.17 | 6.01±0.32 |
| No. 3A | 31.96±0.78 | 36.81±1.37 | 18.21±0.65 | 9.84±0.13 |
| No. 4 | 28.83±5.29 | 32.38±4.48 | 27.46±7.47 | 11.33±1.08 |
| No. 4K | 30.27±1.41 | 44.31±1.36 | 24.35±2.17 | 13.56±0.53 |

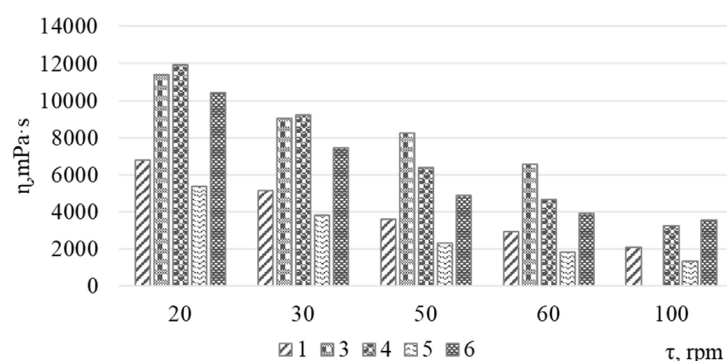


Fig. 1. Graph of the dependence of the structural viscosity of the experimental samples on the spindle speed

The most important aspect of any prosthesis is the quality of the connection between the remaining limb (stump) and the artificial prosthesis. The part of the prosthesis that fits tightly to the remaining limb, the “socket”, determines the amputee’s comfort and ability to control the prosthesis. Therefore, the next stage of our work was the study of the adhesive properties of the investigated compositions, which determines the possibility of their retention between the surface and the stump with the help of interfacial forces for a long time and the reduction of frictional forces during imitation of sweating (adding sodium chloride solution) at a temperature of 37 °C. The results of the adhesion test are shown in Table 5.

Table 5

Indicators of adhesiveness at different temperatures

| Sample | 25 °C | | 37 °C+NaCl | |
|--------|------------------------------|-------------------------|------------------------------|-------------------------|
| | Peak force (adhesiveness), N | Work of adhesion, N·sec | Peak force (adhesiveness), N | Work of adhesion, N·sec |
| 1 | 1.00±0.05 | 0.73±0.40 | 0.72±0.03 | 0.59±0.02 |
| 3 | 0.90±0.06 | 0.71±0.01 | 1.84±0.39 | 0.71±0.03 |
| 4 | 1.79±0.03 | 0.97±0.01 | 1.40±0.43 | 0.50±0.01 |
| 5 | 0.45±0.02 | 0.32±0.00 | 0.48±0.09 | 0.29±0.00 |
| 6 | 0.70±0.02 | 0.47±0.12 | 0.74±0.07 | 0.70±0.01 |

The results of research at 25 °C showed that sample No. 4 has the highest indicators of adhesiveness. Samples No. 1 and No. 3 had values almost 2 times lower. The lowest adhesion values were found in samples No. 5, 6.

To determine the ability to distribute the cream, the ability to spread was determined (Table 6).

Table 6

Sample spreading rates

| Diameter, mm | No. 1 | No. 3 | No. 4 | No. 5 | No. 6 |
|--------------------------|----------|----------|----------|----------|----------|
| <i>d</i> 1 | 60.0±0.1 | 34.0±0.1 | 40.0±0.1 | 45.0±0.2 | 40.0±0.1 |
| <i>d</i> 2 | 60.0±0.2 | 45.0±0.1 | 46.0±0.1 | 50.0±0.2 | 40.0±0.2 |
| <i>K=d</i> 1/ <i>d</i> 2 | 1.0 | 1.32 | 1.15 | 1.11 | 1.0 |

According to the ratio of the initial diameter (*d*1) and the diameter after loading (*d*2), sample No. 3 has the greatest ability to spread, samples No. 1 and No. 6.

Reducing the friction between the prosthesis and the stump is an important aspect when creating an amputee care product. For this purpose, the static and dynamic coefficients of friction of the samples were determined (Table 7).

Table 7

Static and kinetic coefficients of friction of cream samples

| Parameter | No. 1 | No. 3 | No. 4 | No. 5 | No. 6 |
|-----------|-------|---------|-------|--------|--------|
| SC | 0.018 | 0.00311 | 0.5 | 0.0013 | 0.0001 |
| DC | 0.67 | 0.032 | 0.003 | 0.0013 | 0.0001 |

The sample with the addition of aristoflex No. 4 had a dynamic coefficient value of 0.003,

and sample No. 6 had the lowest coefficient value. When determining the initial angle of inclination for sample spreading, it was established that only samples No. 1, 5, 6 started their movement up to 50°. Aristoflex-based samples started moving only at an angle higher than 50° and did not have a uniform distribution on the surface of the plate. From the results given in the Table 7, it can be concluded that the lowest values of friction coefficients are found in samples containing xanthan gum as a thickener.

5. Discussion of research results

The delamination of samples No. 2, 7–16 can be explained by instability due to a large excess of surface energy on their interfacial surface. Therefore, samples without signs of delamination with a satisfactory consistency were selected for further research – No. 1, 3–6.

The higher strength value of sample No. 3 compared to sample No. 4 can be explained by the higher content of aristoflex in the sample composition, which also acts as a viscosity regulator for the formed system. The obtained values correlate with the results of the analysis of viscous properties – samples No. 3, 4 were also characterized by the highest viscosity. The obtained data are confirmed by the results of studies on the influence of the aristoflex polymer on the physicochemical properties of soft drugs [24].

This is also confirmed by the results of the “consistency” and “viscosity index” indicators, which also describe the fluidity and degree of strength of the viscous material – higher values of consistency usually characterize a stronger (dense) structure of the product. However, from a biopharmaceutical point of view, products with a low consistency are better applied to the skin and easily penetrate through it (absorbed). The lowest consistency was determined in samples based on dimethicone with xanthan gum (samples No. 5, 6). It is interesting that sample No. 1 is made only on dimethicone, according to the “strength”, “consistency” and “viscosity index” indicators, it is characterized by a stronger (dense) structure than the samples containing xanthan gum, which also plays the role of a thickener. Although according to the results of the viscosity analysis, the viscosity of sample No. 6 (containing 1.5 % xanthan gum), on the contrary, is higher than that of sample No. 1. The results of our research correlate with the data of the study of textural characteristics and rheological parameters of emulsion based on dimethicone. Emulsions containing dimethicone show lower viscosity than those without additional thickeners. This is an important feature, and dimethicone does not change the rheological profile; however, its addition can affect the stability of this indicator, both when the action of external forces increases and when it is stored [25].

The better-spreading value of sample No. 6 confirms previous findings that a less strong structure of the cream will lead to easier distribution and better application of the cream to the skin surface. The explanation for the better values of adhesion characteristics in samples No. 5, 6, 1, in contrast to samples with a stronger structure (No. 3, 4), is that the higher the cohesiveness, the stronger the internal intermolecular bonds in the cream samples and the lower the adhesion to the device tool. In

turn, less viscous systems with lower cohesion are characterized by higher adhesion.

Analyzing the viscosity indicators at different rotation speeds (Fig. 1), we can conclude that sample No. 6 will retain its structure under constant load. The obtained results are correlated with the literature data on establishing the characteristics of emulsion systems structured with xanthan gum, which had high strength, noticeable elastic behaviour, typical of structured solid systems. This allows us to conclude about the possibility of obtaining a stable emulsion system using xanthan gum [26].

Excessive sweating commonly affects amputees and affects their daily life. Increased energy expenditure during daily activities compared to able-bodied individuals and reduced skin surface area for cooling contribute to this problem. Prosthetic liners worn on residual limbs can also increase sweating at the residual limb interface because they have low thermal conductivity and low permeability. Therefore, during the study of adhesion indicators during imitation of sweating (Table 5), it was established that in samples No. 1, 4 there was a drop in adhesion indicators during moistening, which can be explained by the dilution of the system, which will make their uniform application impossible and will have an unsatisfactory effect on consumer characteristics. For samples No. 5, 6, on the contrary, a slight increase in adhesiveness was observed, and in sample No. 3, this indicator increased by 2 times, which will make it possible to ensure reliable contact between the remaining limb and the prosthesis, thanks to increased moisture resistance. The obtained data are confirmed by the spreading test (Table 6). Therefore, it can be stated that the type of polymer will significantly affect the viscosity of emulgel bases and the speed of miscibility with sweat, as well as their physical stability. The obtained data correlate with the literature data regarding the effect of xanthan gum and aristoflex to be evenly distributed on the skin and maintain physical stability under the influence of external forces [27].

Friction at the stump border affects the comfort of amputees because it directly affects the pain and functionality of the prosthesis. Therefore, the coefficients of friction (static (SC) and dynamic (DC)) were determined (Table 7). The obtained results can be explained by the formation of a film due to xanthan gum, which acquires sliding properties when the surface meets electrolytes. It is the addition of this polymer that increases the wetting ability of dimethicone, contributes to the formation of a satisfactory lubricating layer between the tissue of the stump and the prosthesis, and thus will reduce friction and patient discomfort [28].

Practical significance. The practical value of the research lies in the creation of a drug that is planned to be used in patients with amputated limbs. It will contribute to their socialization, improving their quality of life. In addition, the results obtained during the work will allow to create a basis for expanding the domestic assortment of drugs due to the possibility of including in the composition of soft medicinal forms of substances that were previously considered for another pharmacological direction.

Study limitation. The limitation of this research is the lack of possibility to compare the obtained results with the results of research of other scientists. In the literature, there are results from the study of silicone gels. There are no studies of emulsion bases, where silicones of different viscosity are used as the oil phase.

Prospects for further research. The results of the work should be used in further research on the development of soft medicine for the care of stumps after prosthetics.

6. Conclusion

A study was conducted on the selection of the basis of a soft medicine used in the care of a stump after prosthetics. The effect of the type of thickener on the structural and mechanical properties was studied. It was established that samples containing xanthan gum had the lowest consistency value, and in terms of viscosity, they were close to samples containing aristoflex. It has also been found that the addition of xanthan gum contributes to a better distribution and application to the skin surface. The results of the research allow for predicting a reduction in the force of friction between the stump and the prosthesis when they are used. Therefore, for further research on the development of a soft medicinal product for the care of the stump after prosthetics, it is advisable to use samples containing xanthan gum.

Conflict of interests

The authors declare that they have no conflict of interest related to this research, whether financial, personal, authorship or otherwise, that could affect the research and its results revealed in this article.

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Data availability

Data will be made available at a reasonable request.

Use of artificial intelligence

The authors confirm they did not use artificial intelligence technologies when creating the current work.

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