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Research on the development of a cosmetic product in a soft dosage form based on an extemporaneous suspension for the treatment of acne using carbomer

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Abstract: *acne is a chronic skin disease with a complex multifactorial pathogenesis, which is widespread and requires a long-term combination therapy. Local application of drugs is the standard method of treating acne. One of the drugs for external use, which is recommended by dermatologists-cosmetologists, is a solution for shaking or suspension that is extemporaneously manufactured and contains chloramphenicol, ichthyol, menthol, talc, zinc oxide, and ethanol. The disadvantages of suspensions are their instability during storage, the need for constant shaking before use. This can often lead to a violation of the ratio of active pharmaceutical ingredients and, accordingly, their dosage, as well as inconvenience during use. To improve the stability of this drug, it is advisable to increase the viscosity of the system by changing the dosage form: prepare a gel from a suspension. The research work is devoted to the research on the development of the composition of a cosmetic product in the form of a gel, which was obtained on the basis of the component composition of an extemporaneously manufactured medicinal product in the form of a shake-up solution, which is used topically for the treatment of acne. The composition was developed using triethanol amine as a neutralizer and two brands of gelling agents – carbomers Carbopol 974 P and Carbopol 980, which are most often used as gelling agents in the production of gels. In the research work, when obtaining a cosmetic product in the form of a gel using two brands of carbomer, the optimal amount of triethanolamine was determined, on which the pH value of the gel and its structural and rheological properties depended. Also, during the experiment, 6 series of studied samples of the cosmetic product were obtained, which contained gelling agents in three different concentrations (1%, 1.5% and 2%) in order to select the most optimal one, which would ensure sedimentation resistance and uniformity of the gel dosage during its application. We investigated such indicators of the obtained samples of the cosmetic product as homogeneity and dispersion using the microscopy method, pH value potentiometrically, colloidal stability by centrifugation and viscosity using a rotational viscometer. Their consumer characteristics were also studied, which concerned the quality of application, distribution and sensation on the skin that remained after applying the studied samples to its surface, namely: tightness, moisturization, stickiness or cooling. Series 2 of the studied cosmetic product, which includes 1.5% of carbomer of the Carbopol 974 P brand, had the best pharmaco-technological properties and consumer characteristics. It had the appearance of a homogeneous mass of mousse consistency, which was easily applied and*

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evenly distributed on the surface of the skin, while not tightening it or drying it, leaving a feeling of moisture and cooling on it. It had a pH value of 7.0 and a viscosity of 13782 mPas.

Keywords: Acne Vulgaris; Carbomer [Supplementary Concept]; Cosmetics; Suspensions; Skin Diseases; extemporaneous gel, gelling agents, soft dosage form.

Introduction

Acne is a quite common polymorphic inflammatory skin disease (hair follicles and sebaceous glands), which most often manifests itself on the face (in 99% of cases), on the neck (60%) and chest (15%) [1]. According to statistics, about 80% of the population aged 12 to 25 years and 30-40% of people over 25 years of age suffer from acne [2, 3, 4, 5]. Acne significantly affects the psycho-emotional sphere of the patient, his social adaptation and social status, which indicates the relevance of this problem and the need to create new and improve existing medicines (drugs) for the treatment and prevention of this disease.

The standard of acne treatment is topical therapy [1], which uses both industrially produced drugs [3, 6] and drugs manufactured in pharmacies. A shake-up mixture in the form of an extemporaneous suspension containing chloramphenicol, ichthyol, menthol, talc, zinc oxide and ethanol is one of the drugs that is often prescribed by dermatologists-cosmetologists for the topical treatment of acne. Suspensions are complex or microheterogeneous systems with a liquid dispersion medium in which one or more fine powdered active pharmaceutical ingredients (APIs), which are not dissolved in the dispersion medium, are distributed [7].

This product contains a combination of active pharmaceutical ingredients with well-studied medical uses and has been traditionally manufactured extemporaneously for over 30 years. It remains a popular choice among dermatologists because of its comprehensive composition and proven efficacy. It is also a suitable prescription for patients who cannot use retinoids in acne treatment.

Aim

To conduct research on the development of a cosmetic product in a soft dosage form based on the component composition of an extemporaneous suspension for the treatment of acne, to determine the optimal brand and concentration of carbomer and the amount of triethanolamine for its neutralization, which will provide the best quality indicators and consumer characteristics of the developed cosmetic product.

Materials and methods

A cosmetic product in a soft dosage form based on an extemporaneous suspension for the treatment of acne was selected for the study. Two brands of carbomers: Carbopol 974 P and Carbopol 980 NF as gelling agents, and triethanolamine as neutralizator have been studied at the development of the gel. The quality indicators of the obtained cosmetic product and its consumer characteristics were studied in order to determine the optimal brand of carbopol and its concentration, as well as the amount of triethanolamine required for its neutralization, which will provide the best properties of the gel-like product.

Results and discussion

The main goal in the manufacture of complex dosage forms is to obtain a homogeneous system – a uniform distribution of components, which is achieved by grinding and mixing, as well as stability during use and storage by selecting special excipients, such as bases, emulsifiers and gelling agents [7, 8, 9]. To develop a cosmetic product in a soft dosage form for the treatment of acne, we took as a basis the component composition of the API of the extemporaneous shaking solution in the form of a suspension, which contains the following components:

Ichthyol	1,50	mg
Menthol	0,02	mg
Levomycetin	7,00	mg
Zinc oxide	7,00	mg
Talc	7,00	mg
Ethanol 70%	50,0	mg
Purified water	80,0	mg

This medicinal cosmetic product is a coarse suspension, which has its disadvantages, namely:

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rapid settling of undissolved substances, which can complicate the dosing of API, so it must be shaken before each use. Also, the inconvenience of using is the need to use a cotton pad or gauze napkin to apply to the skin in the presence of a large amount of liquid. A cotton pad or gauze napkin absorbs a significant amount of a liquid phase with each selection for application, and this leads to a change in the composition of the medicinal cosmetic product during its use, and after a while there is almost no liquid phase left, which completely changes the ratio of components in the suspension. Also, when applying this product to the skin of the face, visible spots and lumps of insoluble powdered API remain on it.

To increase the stability of this product during use and for the convenience of its application, as well as to improve its consumer characteristics, its aqueous dispersion medium has to be changed to gel-like. For this, it was necessary to select the brand and concentration of the gelling agent, as well as the amount of triethanolamine needed for neutralization.

As a gelling agent, two grades of carbomers were chosen: Carbopol 974 P and Carbopol 980 NF, which are high molecular weight polymers of acrylic acid chemically cross-linked with polyalkenyl alcohols or divinyl glycol. They are characterized by high relative viscosity, short flow, and high suspension's ability [10]. Both grades are used for the production of gels for external use. The main difference between the above polymers is related to the type of substituent, the density of cross-linking, and the presence of hydrophobic comonomers. When using carbomer grades Carbopol® 980 NF and Carbopol® 974P NF, transparent gels and stable suspensions are formed upon neutralization. They are compatible with a wide range of active ingredients and other excipients.

During the study, 6 series were obtained using a gel base: three based on the Carbopol 974 P brand with different gelling agent concentrations (1, 1.5 and 2%), and three based on the Carbopol 980 NF brand also with gelling agent concentrations of 1, 1.5 and 2%. Triethanolamine was used to neutralize the carbomer, the amount of which was determined experimentally, since the maximum viscosity is achieved in a neutral environment and the pH value of the gel should be within 5.0-7.0.

Triethanolamine was added to the gel dropwise with constant stirring, and the pH value was measured using a potentiometer (State Pharmacopoeia of Ukraine, 2.0., Vol. 1, p. 2.2.3) [11]. The results of the study are given in Table 1.1.

Table 1.1 – Results of the study of the pH value of gel bases with different brands and concentrations of carbomer after neutralization with triethanolamine.

№	Carbomer grades	C, %	y1	y2	y3
1	Carbopol 974 P	1,0	19	0,80	5,40
2	Carbopol 974 P	1,5	22	0,92	5,56
3	Carbopol 974 P	2,0	30	1,26	5,52
4	Carbopol 980 NF	1,0	20	0,84	5,88
5	Carbopol 980 NF	1,5	27	1,13	5,06
6	Carbopol 980 NF	2,0	34	1,43	4,95

Note: C – the concentration of carbomer, %;
y1 – the number of drops of triethanolamine;
y2 – the mass of triethanolamine, g,
y3 – the pH value of the gel base.

The experimental data shows that as carbomer concentration increases, the amount of triethanolamine required for neutralization increases.

After preparing gel with satisfactory technological properties, a cosmetic product was prepared on a gel basis using the following technology. In ethanol solution menthol and chloramphenicol were dissolved. Zinc oxide and talc were dispersed in a mortar and mixed with alcohol solution using a pestle until homogeneity was achieved, then added Ichthyol last. The mixture of active pharmaceutical ingredients ground to homogeneity was carefully added in portions to gel base with constant stirring [7, 12, 13].

We received 6 series of cosmetic products for which a number of studies were conducted, including their appearance, pH value, colloidal stability, rheological properties (viscosity), and

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homogeneity. Consumer characteristics that have been investigated include ease of application and uniform distribution of the cosmetic product on the surface while applying it, and the sensation of tightness, dryness, or hydration on the skin after application [9, 11, 13-15]. The results of the study are given in Table 1.2.

We determined the pH value of the studied samples of the received cosmetic product, since the APIs added to the gel base could cause a shift in the pH value. The pH value of the skin, which ranges from 3 to 7, is the primary factor in choosing cosmetic preparations. The pH of acne patients' skin was found to shift towards an alkaline pH in 89.5% of patients according to literature data [3].

Therefore, we considered the best series of the studied cosmetic product to be the one whose pH [9, 11] value shifted the least to the alkaline side, i.e. series 2; the following were series 1 and series 6, the worst in terms of this indicator were series 3 and 4. But, in general, all series fall within the range of 6.5-7.5 in terms of pH value [3].

An OPn-3 centrifuge was used to determine colloidal stability. The study was conducted at a centrifuge speed of 6000 rpm for 5 min and was visually evaluated on a 5-point system.

The best series was considered to be the one where the liquid layer separated from the mass was the smallest (5 points), while the worst was 1 point. It was determined that series 6 is the most stable, followed by series 5, and lastly series 2. The worst stability was observed for series 4. Series 3 is not significantly better than it in terms of colloidal stability.

The next stage of our research was the study of rheological indicators, namely viscosity, which was carried out using a MYR VR 3000 rotational viscometer. The tests were carried out at a temperature of (20 ± 0.5) °C. A sample weight of about 150 g in measuring cups was placed in a thermostat. The required test temperature was set to (20 ± 0.5) °C and maintained for 20 minutes.

After that, the required rotor (depending on the viscosity of the sample) and its rotation speed were set on the rotational viscometer, and the viscosity was measured. The obtained values were expressed in mPa·s [8, 9, 11].

Series 1, 3, and 4 are characterized by a heterogeneous structure and low viscosity. The 6th series is considered the most acceptable viscosity and has optimal rheological properties. Series 5 and 2 are ranked second and third in terms of viscosity.

Volunteers were used to conduct consumer characteristics studies, where a small amount of each series sample was applied to the skin surface and subjective sensations were described. The assessment of the product was done on a five-point scale, which included ease of application, even distribution, absence of tightness and dryness of the skin, and a feeling of skin hydration.

Series 1: easy to apply (5 points), evenly distributed (5 points), does not tighten or dry the skin (5 points). *Series 2*: easy to apply (5 points),

Table 1.2 – Results of a study of the effect of the brand and concentration of the gelling agent on the properties of a soft dosage form based on an extemporaneous suspension for the treatment of acne.

№	Carbomer grades	C, %	y1	y2	y3	y4	y5	y6
1	Carbopol 974 P	1,0	7,16	3	2890	5	5	5
2	Carbopol 974 P	1,5	7,00	4	13782	5	5	5
3	Carbopol 974 P	2,0	7,36	2	7830	5	4	5
4	Carbopol 980 NF	1,0	7,33	1	2963	5	4	5
5	Carbopol 980 NF	1,5	7,24	4,5	14950	5	5	5
6	Carbopol 980 NF	2,0	7,18	5	33900	4	4	3

Note: C – concentration of gelling agent, %; y1 – pH value; y2 – colloidal stability, score (1-5); y3 – viscosity, mPas; y4 – ease of application, score; y5 – uniform distribution during application, score; y6 – subjective sensations on the skin after application, score.

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evenly distributed (5 points), does not tighten or dry, but on the contrary – moisturizes the skin (5 points). *Series 3*: easy to apply (5 points), after distribution, traces remain on the skin (4 points), does not tighten or dry the skin (5 points). *Series 4*: easy to apply (5 points), evenly distributed after a while (4 points), does not tighten or dry the skin, moisturizing effect (5 points). *Series 5*: easy to apply (5 points), evenly distributed (5 points), does not tighten or dry the skin (5 points). *Series 6*: harder to apply (4 points), harder to distribute (4 points), tightens the skin (3 points).

So, according to consumer characteristics, series 1, 2 and 5 were recognized as the best; according to colloidal stability, the series of the studied cosmetic products can be placed in descending order: 6, 5, 2, 1, 3 and 4; according to rheological characteristics, series 6 was the best, series 2 and 5 also had an acceptable viscosity value; series 2 had the closest pH value to neutral.

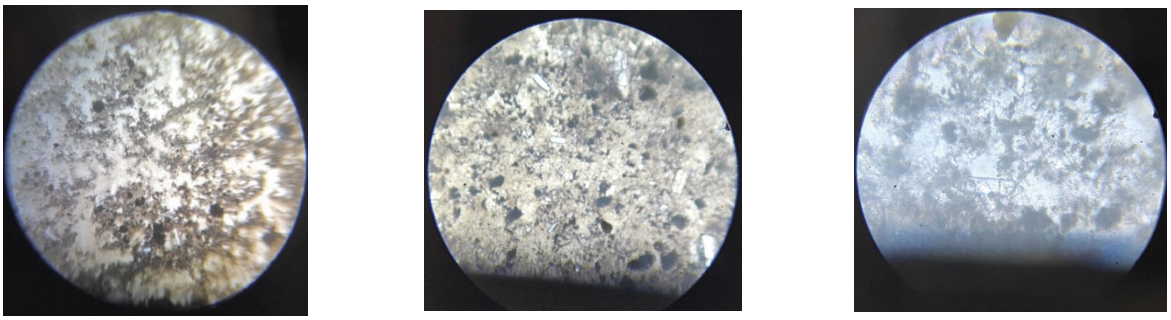
To study the homogeneity and dispersion of the obtained cosmetic products, the microscopy method was used using the Levenhuk Rainbow 2L NG Amethyst microscope. Photographs of cosmetic product (C) samples were obtained at 3 magnifications, namely at x4, at x10 and at x40, which were visually evaluated [15].

Photographs of samples of 6 series are shown in Fig. 1.1-1.6.

Figure 1.1 depicts photographs of sample series 1 of the cosmetic product being studied, which exhibit heterogeneity, a characteristic of suspensions.

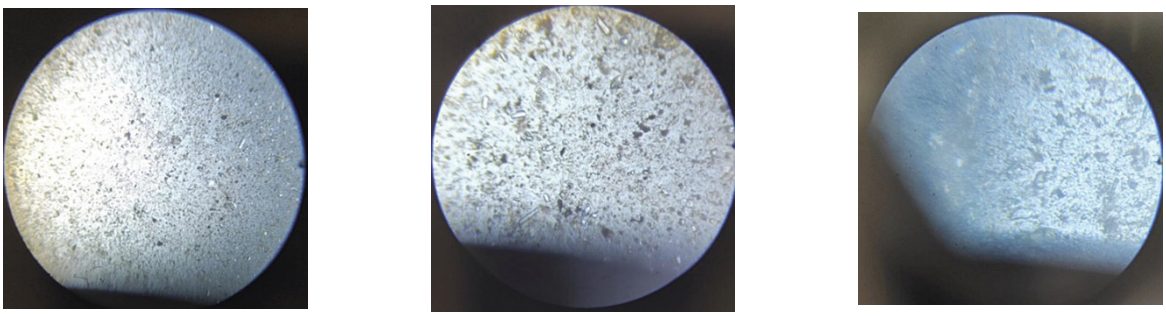
However, at a magnification of «x 4» it is visible that the particles of the dispersed phase are collected in large conglomerates, there are also single coarse particles, which are already more clearly visible at a magnification of «x 10». The dispersed phase is observed as a loose mass and single needle-shaped crystals at 40x magnification.

Fig. 1.2 shows photographs of a sample of series 2 of the studied cosmetic product, which show the homogeneity of the studied agent, the dispersed phase is finely dispersed and evenly distributed throughout the entire field of the microscope, which is very clearly visible at a



a b c

Figure 1.1 – Photographs of a sample of cosmetic product series 1 (based on 1% Carbopol 974 P), obtained at different magnifications: a – x4, b – x10, c – x40.



a b c

Figure 1.2 – Photographs of a sample of cosmetic product series 2 (based on 1.5% Carbopol 974 P), obtained at different magnifications: a – x4, b – x10, c – x40.

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magnification of «x 4». At a magnification of «x 10» single, slightly larger particles are visible, which are distributed evenly. In the photo at a magnification of «x 40» the studied agent has the appearance of a finely dispersed, loose homogeneous mass.

Fig. 1.3 shows photographs of a sample of series 3 of the studied compacted concrete. At a magnification of «x 4», the sample is homogeneous, with isolated larger particles, but compacted.

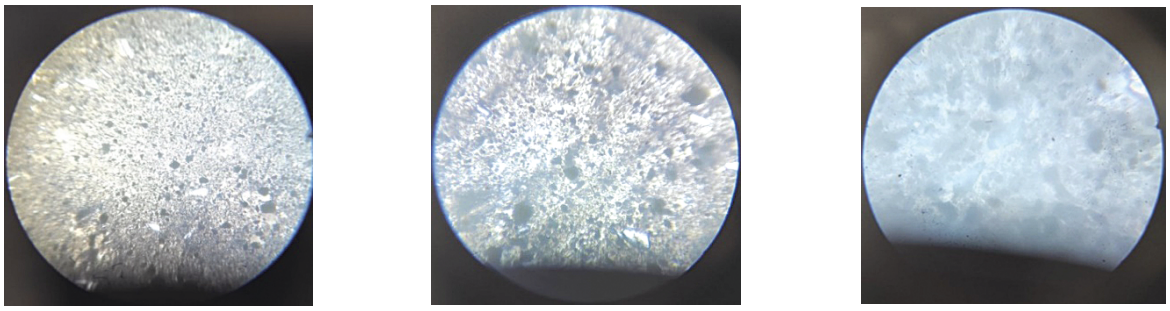
More dense conglomerates can be observed at a magnification of «x 10», also here large particles are more clearly visible. At a magnification of «x 40» – this is a loose mass with fuzzy edges of the dispersed phase.

Photographs of a sample of series 4 of the studied cosmetic product are shown in Fig. 1.4. From the photos, it can be concluded that this series is quite dense at all magnifications. This sample is homogeneous with the inclusion of single large particles of regular shape. At a magnification of «x 40» a loose inhomogeneous dispersed phase without clear contours is visible.

Fig. 1.5 shows photographs of a sample of series 5 of the studied cosmetic product, which show its density, and a significant number of large-crystalline particles and their conglomerates are also observed. At a magnification of «x 10», single needle-shaped crystals stand out, and at «x 40» – a loose, heterogeneous dispersed phase.

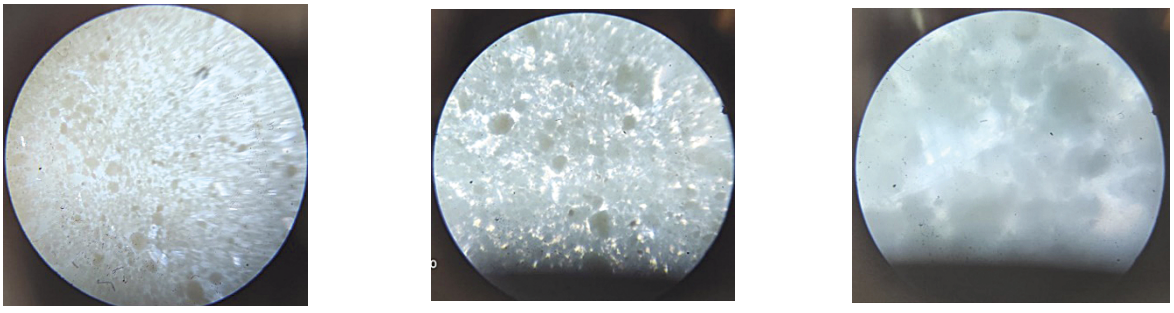
Photographs of a sample of series 6 of the studied cosmetic product are shown in Fig. 1.6, which show its dense structure with a certain number of coarse particles evenly distributed throughout the entire field of the microscope. Only at a magnification of «x 40» is a loose, heterogeneous dispersed phase with large conglomerates of particles visible.

According to the conducted microscopic studies, it was found that most of the samples of the studied cosmetic product were homogeneous in the field of view of the microscope, some with partial compaction and stratification of the dispersed phase. Samples of series 4, 5 and 6 turned out to be quite dense; samples of series 2, 3 and 4, 5 were homogeneous.



a b c

Figure 1.3 – Photographs of a sample of a cosmetic product series 3 (based on 2% Carbopol 974 P), obtained at different magnifications: a – x4, b –x10, c – x40.



a b c

Figure 1.4 – Photographs of a sample of a cosmetic product series 4 (based on 1% Carbopol 980 NF), obtained at different magnifications: a – x4, b – x10, c – x40.

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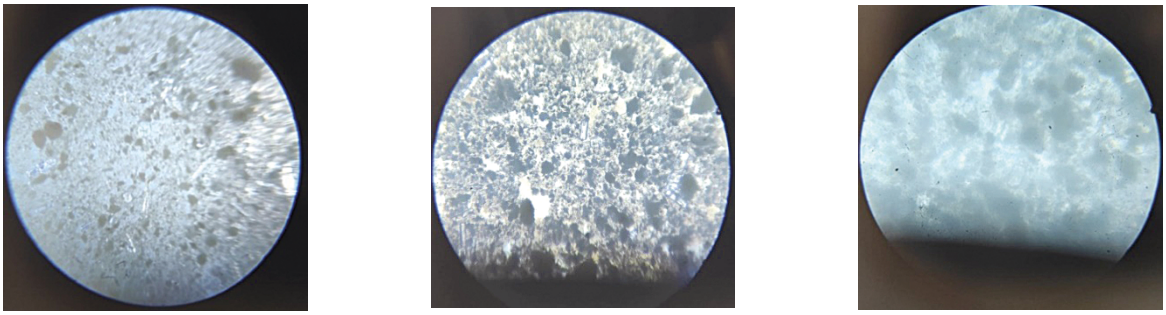
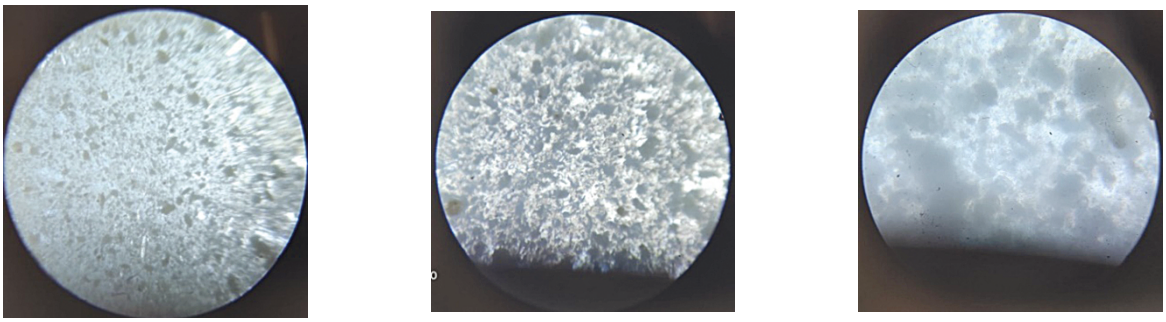


a b c

Figure 1.5 – Photographs of a sample of a cosmetic product series 5 (based on 1.5% Carbopol 980 NF) obtained at different magnifications: a – x4, b – x10, c – x40.



a b c

Figure 1.6 – Photographs of a sample of a cosmetic product series 6 (based on 2% Carbopol 980 NF), obtained at different magnifications: a – x4, b – x10, c – x40.

Conclusions

The effect of gelling agents in different concentrations on the technological and consumer properties of the obtained cosmetic product for the treatment of acne was studied. It was established that the best is series 2 of the studied cosmetic product, which includes 1.5% carbomer of the Carbopol 974 R brand. In appearance, it is a homogeneous mass of mousse consistency, which is easily applied and evenly distributed on the surface of the skin, while not tightening or drying the skin, leaving a feeling of hydration and cooling on the skin; pH value is 7.0 and viscosity – 13782 mPa·s.

The improved form of this cosmetic product, namely the gel, has better consumer characteristics and stability, which, in turn, ensures uniformity and accuracy of dosing. This prescription is relevant when prescribed by dermatologists for the treatment of acne due to the complex, well-studied composition of the API, and the new form will provide greater practicality and comfort for daily use.

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Conflict of interest

The authors declare no conflict of interest.

Consent to publication

All authors have reviewed and consented to manuscript publication.

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A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of article

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Дослідження з розробки косметичного засобу у м'якій лікарській формі на основі суспензії екстемпорального виготовлення для лікування акне із використанням карбомеру

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Анотація: *акне або вугрова хвороба – це хронічне захворювання шкіри зі складним мультифакторним патогенезом, яке є широко поширене і потребує тривалої комбінованої терапії. Місцеве застосування лікарських засобів є стандартом лікування акне. Одним із препаратів для зовнішнього застосування, який рекомендується дерматологами-косметологами, є розчин для збовтування або суспензія екстемпорального виготовлення, яка містить левоміцетин, іхтіол, ментол, тальк, цинку оксид і етанол. Недоліком суспензій є їх нестабільність при зберіганні, потреба постійного струшування перед використання. Це може часто призводить до порушення співвідношення активних фармацевтичних інгредієнтів і, відповідно, їх дозування, а також незручність при застосуванні. Щоб покращити стабільність даного препарату доцільно збільшити в'язкість системи шляхом зміни лікарської форми: із суспензії отримати гель. Дослідницьку роботу присвячено дослідженню з розробки складу косметичного засобу у формі гелю, який було отримано на основі компонентного складу лікарського засобу екстемпорального виготовлення у формі розчину для збовтування, яка застосовується місцево для лікування акне, із використанням двох марок карбомеру: Carbopol 974 P і Carbopol 980, які найчастіше використовуються в якості гелеутворювачів при виробництві гелів. У дослідницькій роботі при отриманні косметичного засобу у формі гелю із використанням двох марок карбомеру було визначено оптимальну кількість триетаноламіну, від якої залежало значення pH гелю і його структурно-реологічні властивості. Також, в ході експерименту було отримано 6 серій досліджуваних зразків косметичного засобу, до складу яких водилися гелеутворювачі у трьох різних концентраціях (1 %, 1,5 % та 2 %) з метою вибору найбільш оптимальної, яка б забезпечила седиментаційну стійкість і однорідності дозування гелю при його застосуванні. Ми дослідили такі показники отриманих зразків косметичного засобу, як однорідність і дисперсність за допомогою методу мікроскопії, значення pH потенціометрично, колоїдну стабільність методом центрифугування і в'язкість за допомогою ротаційний віскозиметра. Також було вивчено їх споживчі характеристики, які стосувалися якості нанесення, розприділення і відчуття на шкірі, які залишалися після нанесення на її поверхню досліджуваних зразків, а саме: стягнутості, зволоженості, липкості або охолодження. Серія 2 досліджуваного косметичного засобу, до складу якої входить 1,5 % карбомеру марки Carbopol 974 P, мала найкращі фармако-технологогічні властивості і споживчі характеристики. Вона мала вигляд однорідної маси мусової консистенції, яка легко наносилася і рівномірно розподілялася на поверхні шкіри, при цьому не стягувала її і не сушила, залишала відчуття зволоженості і охолодження на ній. Вона мала значення pH рівне 7,0 і в'язкість – 13782 mPas.*

Ключові слова: акне, гель, гелеутворювачі, косметичний засіб, карбомер, м'яка лікарська форма, суспензія екстемпорального виготовлення.