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Olena ROIK

Candidate of Pharmaceutical Sciences, Associate Professor at the Department of Industrial Pharmacy, Kyiv National University of Technology and Design, Mala Shyianovska Street, 2, Kyiv, Ukraine, 01011 (roik.om@kntud.edu.ua)

ORCID: 0000-0002-5988-6577

SCOPUS: 57216831699

Olena ISHCHENKO

Doctor of Technical Sciences, Associate Professor, Professor at the Department of Industrial Pharmacy, Kyiv National University of Technology and Design, Mala Shyianovska Street, 2, Kyiv, Ukraine, 01011 (e.ishchenko5@gmail.com)

ORCID: 0000-0002-9510-6005

SCOPUS: 57200013816

Iryna VLASENKO

Doctor of Pharmaceutical Sciences, Associate Professor, Associate Professor at the Department of Pharmaceutical Technology and Biopharmacy, Shupyk National Healthcare University of Ukraine, Dorohozhytska Street, 9, Kyiv, Ukraine, 04112 (vlasenkoiryna5@gmail.com)

ORCID: 0000-0002-5530-4189

SCOPUS: 57203192786

Anastasiia BEHDAL

Student, Kyiv National University of Technology and Design, Mala Shyianovska Street, 2, Kyiv, Ukraine, 01011 (a.behdai@kyivpharma.eu)

ORCID: 0009-0001-9868-066X

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INVESTIGATION OF THE EFFECT OF TEMPERATURE REGIMES ON THE RHEOLOGICAL PROPERTIES OF DEVELOPED PHOTOPROTECTIVE CREAM

Actuality. The reasons for the rise in skin cancer include excessive ultraviolet radiation (UVR) and an aging population. UVR, which is the primary risk factor for skin cancer, can be modified. One way to protect the skin from excessive UV rays is to use sunscreens with high UVA and UVB protection (Perugini, 2019; Roik, 2019). Thus, the production of sunscreen cosmetic products is a key element in ensuring preventive measures against oncological-dermatological pathology.

The authors have developed a composition for a photoprotective cosmetic product with ultraviolet filters that can provide a broad spectrum of UV protection based on pharmaco-technological research. Given the intended use of the photoprotective cream at higher temperatures than its storage, it was relevant to study the effect of temperature on the rheological properties of the developed cream, which is crucial for ensuring the quality assurance of the final product.

The aim of the study was to determine the rheological (thixotropic) properties of the developed photoprotective cream and the effect of different temperature regimes on its stability.

Material and methods. Rheological parameters of the cream were measured using a Brookfield Model DV-III rheometer (Brookfield, UK).

Research results. The viscosity of cream decreases with increasing shear rate. Such behaviour is typical for many dispersed systems, including emulsions, which are often the basis of creams. It is related to the material's structural breakdown under shear. As temperature increases, viscosity decreases, which is typical for most fluids and viscoelastic materials. It has been established that the developed cream belongs to dispersed structured systems characterized by elastic-plastic-viscous properties. It has been proven that the developed cream exhibits non-Newtonian flow behavior and its flow begins after a certain mechanical stress is applied.

Conclusion. The experimental studies confirmed the rationality of the developed photoprotective cream technology, which showed stability under different temperature regimes at 20, 25°C (storage temperatures), and 32°C (application temperature), ensuring product quality. The determination of thermal stability and colloidal stability of the developed cream indicates its stability.

Key words: structural and mechanical properties, rheology, cream, ultraviolet radiation (UVR), photoprotective effect, skin oncopathology, soft drug for topical application, pharmaceutical technology of soft drug.

Олена РОЙК

кандидат фармацевтичних наук, доцент кафедри промислової фармації, Київський національний університет технологій та дизайну, вул. Мала Шияновська, 2, м. Київ, Україна, 01011 (roik.om@knuutd.edu.ua)

ORCID: 0000-0002-5988-6577

SCOPUS: 57216831699

Олена ІЩЕНКО

доктор технічних наук, доцент, професор кафедри промислової фармації, Київський національний університет технологій та дизайну, вул. Мала Шияновська, 2, м. Київ, Україна, 01011 (e.ishchenko5@gmail.com)

ORCID: 0000-0002-9510-6005

SCOPUS: 57200013816

Ірина ВЛАСЕНКО

доктор фармацевтичних наук, доцент, доцент кафедри фармацевтичної технології і біофармації, Національний університет охорони здоров'я України імені П.Л. Шупика, вул. Дорогожицька, 9, м. Київ, Україна, 04112 (vlaskenkoiryna5@gmail.com)

ORCID: 0000-0002-5530-4189

SCOPUS: 57203192786

Анастасія БЕГДАЙ

здобувач вищої освіти, Київський національний університет технологій та дизайну, вул. Мала Шияновська, 2, м. Київ, Україна, 01011 (a.behdai@kyivpharma.eu)

ORCID: 0009-0001-9868-066X

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ДОСЛІДЖЕННЯ ВПЛИВУ ТЕМПЕРАТУРНИХ РЕЖИМІВ НА РЕОЛОГІЧНІ ВЛАСТИВОСТІ РОЗРОБЛЕНОГО ФОТОЗАХИСНОГО КРЕМУ

Актуальність. Причиною зростання шкірних захворювань є надмірне ультрафіолетове випромінювання (УФВ). Але його вплив, який є основним чинником ризику раку шкіри, можна модифікувати. Одним зі способів захисту шкіри від надмірної дії УФ-променів є використання сонцезахисних кремів із високим ступенем захисту від UVA- та UVB-спектрів. Тому виробництво сонцезахисних косметичних засобів є основним елементом забезпечення стратегії профілактичних заходів онкологічно-дерматологічної патології.

Авторами, на підставі фармакотехнологічних досліджень опрацьовано склад фотозахисного косметичного засобу з ультрафіолетовими фільтрами, які здатні забезпечувати широкий спектр захисту від УФ-променів. Оскільки застосування фотозахисного крему передбачається за більш високих температур, ніж його зберігання, зважаючи на його призначення, актуальним було проведення дослідження впливу температури на реологічні властивості опрацьованого крему, що важливо для забезпечення гарантії якості кінцевого продукту.

Мета дослідження – визначення реологічних (тиксотропних) властивостей опрацьованого фотозахисного крему, впливу різних температурних режимів на його стабільність.

Матеріал і методи. Вимірювання реологічних параметрів крему проводили за допомогою реометра “Brookfield Model DV-III” (Brookfield, Велика Британія).

Результати дослідження. В'язкість крему зменшується зі збільшенням швидкості зсуву. Така поведінка характерна для багатьох дисперсних систем, зокрема емульсій, які часто є основою кремів. Вона пов'язана з руйнуванням структури матеріалу під дією зсуву. Зі збільшенням температури в'язкість зменшується, що є типовим для більшості рідин і в'язкопружних матеріалів. Встановлено, що опрацьований крем належить до дисперсних структурованих систем, для яких характерні пружно-пластично-в'язкі властивості. Доведено, що опрацьований крем має неньютонівський тип перебігу, його плинність починається після застосування деякої механічної напруги.

Висновок. За результатами експериментальних досліджень підтверджено раціональність технології опрацьованого крему фотозахисної дії, яка виявила стабільність за різних температурних режимів, за 20, 25°C (температури зберігання) і 32°C (температура застосування), що гарантує якість продукту. Визначення термостабільності та колоїдної стабільності опрацьованого крему свідчить про його стабільність.

Ключові слова: структурно-механічні властивості, реологія, крем, ультрафіолетове випромінювання (УФВ), фотозахисна дія, онкопатологія шкіри, м'який засіб для зовнішнього застосування, фармацевтична технологія м'яких засобів.

Introduction. Actuality. Skin cancer (SC) is one of the most devastating cancers of the present decade and the fifth most common form of cancer (An, 2021; Hasan, 2023). Skin cancer is the most common form of cancer, and approximately one in five people suffer from skin cancer at some point in their lifetime (Hasan, Nadaf, 2023). It is further predicted to surpass heart disease as the main cause of mortality and the biggest obstacle to extending life expectancy in the coming decades. According to the World Cancer Research Fund information, there were more than 331 722 cases of skin cancer in 2022, including total global skin cancer incidence and rates in 2022, as well as total global skin cancer mortality in 2022 (World Cancer Research Fund, 2022).

The analysis of cancer incidence indicators among the population of Ukraine from 2000 to 2019 showed an increase in the frequency of skin cancer by 24,0% during this period, including melanoma by 77,3%. Mortality from melanoma increased by 30,0% during this period (Gruzieva, 2020). As of June 2024, the Ministry of Health of Ukraine registered 21 885 patients with malignant melanoma of the skin and 93 223 patients with other malignant skin neoplasms. In 2024, melanoma was diagnosed in 3 100 Ukrainians, with over 13 200 patients having malignant skin tumors, and there is a trend of increasing incidence (Annual report, 2022).

The reasons for the rise in skin cancer include excessive ultraviolet radiation (UVR) and an aging population. Excessive UVR exposure, artificial tanning, a large number of moles, fair skin, a history of melanoma, specific diseases, and an age over 65 years are risk factors for melanoma. Excess UVR has a damaging effect on dermal and epidermal cells, causing free radicals that increase the risk of melanoma (Guan, 2021). Sun exposure can not only cause skin cancer but also weaken the body's protective properties, reducing vaccine effectiveness (Hart, 2020). However, UVR, which is the primary risk factor for skin cancer, can be modified (Li, 2019; Lee, 2021). Addressing cancer risk factors is relevant in the context of the modern health strategy "Transforming our world: the 2030 Agenda for Sustainable Development" at global and national levels, according to which cancer control is a mandatory component aimed at overcoming the epidemic of non-communicable diseases (Gruzieva, 2020).

One way to protect the skin from excessive UV rays is to use sunscreens with high UVA and UVB protection (Perugini, 2019; Roik 2019). Thus, the production of sunscreen cosmetic products is a key element in ensuring preventive measures against oncological-dermatological pathology.

The authors have developed a composition for a photoprotective cosmetic product with ultraviolet filters that

can provide a broad spectrum of UV protection based on pharmaco-technological research.

Creams are soft dispersed systems composed of an aqueous phase and a lipid phase that form an emulsion (of the "oil in water" (O/W) or "water in oil" (W/O) type). Their physicochemical properties, in particular their rheological characteristics, can change significantly depending on the temperature. Optimal rheological parameters of the cream ensure even application, rapid absorption, and prolonged emulsion stability (Gladyshev, 2015).

Studying the rheological properties of the cream is crucial for optimising its production, packaging, and application processes. Determining parameters such as viscosity, thixotropy, and plasticity allows for improving emulsion stability, ensuring the even distribution of active components, and enhancing the product's consumer characteristics (Gladukh, 2016).

Understanding the rheological properties of a cream allows for optimizing the processes of its production, packaging, and application to the skin.

For example, to ensure easy spreading of the cream with minimal viscosity, certain technological parameters (specifically temperature regimes) need to be controlled, and a rational composition of components (light oils, emulsifiers, moisturizers) should be selected (Vlasenko, 2024). Given the intended use of the photoprotective cream at higher temperatures than its storage, it was relevant to study the effect of temperature on the rheological properties of the developed cream, which is crucial for ensuring the quality assurance of the final product.

The aim of the study was to determine the rheological (thixotropic) properties of the developed photoprotective cream and the effect of different temperature regimes on its stability.

Materials and methods. Samples of a processed photoprotective cream based on an oil-in-water emulsion were investigated. A combination of two type-1 emulsifiers was used: the lamellar emulsifier Emulsiphos (INCI: Potassium Cetyl Phosphate, Hydrogenated Palm Glycerides) and the non-ionic biomimetic emulsifier Amisol Soft (INCI: Behenyl Alcohol, Glyceryl Stearate, Lecithin, Glycine Soja (soybean) Sterols), within the permitted concentration range (1–5%). This combination of emulsifiers provides stability, enhances the texture and functional properties of the cream, and promotes the even distribution and stability of the UV filters.

To protect the skin from excessive UV radiation, a combination of physical Z-Cote (INCI: Zinc Oxide) and chemical Tinosorb S Lite Aqua (INCI: Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine (and) Acrylates/C12–22 Alkyl Methacrylate Copolymer) filters (BASF,

Germany) was selected, providing durable protection against both UVA and UVB.

For the hydrophobic phase, Jojoba oil (INCI: Simmondsia Chinensis) and special plant-derived emollients were used. Jojoba oil is a liquid wax rather than a traditional oil, and it has a modest natural SPF (approximately 4–6); however, its effectiveness is insufficient for full sun-protective action. Consequently, Jojoba oil is used as a supplement to the main sun-protective filters – such as physical filters (zinc oxide, titanium dioxide) – to enhance overall protection. In addition, its emulsifying properties help improve the stability of the formulation by ensuring the even distribution of the cream.

The hydrophilic phase comprises, in addition to purified water, glycerine and the gelling agent xanthan gum (INCI: Xanthan Gum).

Based on a review of the literature and its availability, betaine and the Cosme-phytamins Green Tea active were chosen as the active components. The ratio of the cosmetic product's components was selected on the basis of biopharmaceutical studies to ensure that the pharmaceutical composition provides photoprotection, antioxidant effects, and moisturising action.

The rheological parameters of the cream were measured using a Brookfield Model DV-III rheometer (Brookfield, UK) in the teaching and research laboratory of molecular pharmacology, chemogenomics, and biogerontology at the Department of Industrial Pharmacy of the Kyiv National University of Technologies and Design. A cream sample weighing approximately 0.5 g was placed into the rheometer cup under the spindle. Rheological parameters were measured at $20 \pm 0,1$, $25 \pm 0,1^\circ\text{C}$, and $32 \pm 0,1^\circ\text{C}$ by rotating the spindle at various shear rates (from 0,2 to 500 sec^{-1}), increasing from low to high and then decreasing again. Therefore, the breakdown of the emulsion was evaluated at the minimal shear rate of $0,2 \text{ s}^{-1}$ and the maximum of 500 s^{-1} . The temperature of 32°C was determined as optimal, as it corresponds to the average surface temperature of human skin. Given that the photoprotective cream is applied directly onto the skin, assessing its rheological properties at this temperature enables an evaluation of its behavior under real-world conditions.

The flow characteristics at 20 , 25°C (storage temperatures) and 32°C (application temperature) were determined according to the Ostwald–de Waele rheological model, which describes the material's plastic behaviour or shear thickening and is calculated using formula (1):

$$\tau = K \cdot \gamma^n, \quad (1)$$

where: τ – is the shear stress (Pa);

K – is the consistency index ($\text{Pa}\cdot\text{s}$);

γ – is the shear rate (s^{-1});

n – is the flow behavior index (dimensionless).

The viscosity of the cream in the studied range of shear rates is determined by equation (2):

$$\eta = K \cdot \gamma^{n-1}. \quad (2)$$

The consistency index is relevant to the fluid's consistency: if $n=1$, the fluid is Newtonian, and the parameter K equals the Newtonian viscosity η . The flow behavior index represents deviations from Newtonian behavior. If $n < 1$, viscosity decreases with increasing shear rate, which is characteristic of non-Newtonian plastic fluids (Czajkowska-Kośnik, 2022).

The mechanical stability of the cream (MS) was calculated using formula (3):

$$MS = \frac{\tau_1}{\tau_2}, \quad (3)$$

where: τ_1 – is the structural strength limit before breakdown; τ_2 – is the structural strength limit after breakdown.

The degree of thixotropy was calculated using formula (4):

$$S = \frac{1}{n} \sum_{i=1}^n \frac{\eta_{li}}{\eta_{0i}} \cdot 100\%, \quad (4)$$

where: S – is the degree of thixotropic recovery of viscosity solutions;

η_{li} – is the viscosity at the i shear rate, measured in a decreasing shear rate gradient mode;

η_{0i} – is the viscosity at the i shear rate, measured in an increasing shear rate gradient mode;

i – is the shear rate;

n – is the number of fixed shear rate gradient values. The study was conducted by both increasing and decreasing the shear rate to determine the degree of thixotropy.

The determination of colloidal stability (for emulsion systems) and thermostability was performed according to DSTU ISO/TR 18811:2019 “Cosmetics. Guidelines for the stability evaluation of cosmetic products” (ISO/TR 18811:2018, IDT).

Results. One of the key rheological characteristics of creams is thixotropy, which describes the material's ability to change its viscosity under mechanical loading or temperature changes. Thixotropy is an essential parameter for cosmetics as it determines the ease of applying the product to the skin and its behavior when mixing or stirring. Temperature changes affect cream viscosity, which can be described in detail through rheological models. The cream sample exhibits a nonlinear dependence of viscosity on temperature. Typically, an increase in temperature reduces viscosity due to decreased interactions among cream components' molecules.

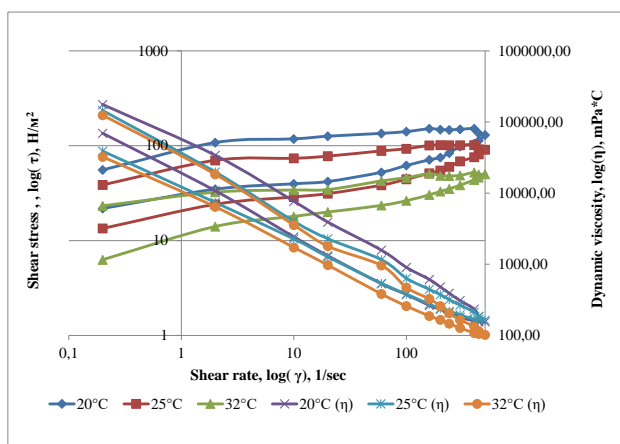


Fig. 1. Rheograms of the flow of the developed photoprotective cream depending on temperature

The graph shows the dependence of shear stress and dynamic viscosity of the cream on shear rate at different temperatures. Both dependencies are descending, indicating non-Newtonian behavior, specifically pseudoplasticity. This means cream viscosity decreases with increasing shear rate (fig. 1). The flow of the tested samples begins only after a certain applied stress is exceeded, which is attributed to the formation and structuring of the material (Romanina, 2016).

Such behavior is typical for many dispersed systems, including emulsions, which are often the basis of creams. It is related to the material's structural breakdown under shear. As temperature increases, viscosity decreases, which is typical for most fluids and viscoelastic materials. This results from an increase in molecular kinetic energy and weakening intermolecular interactions.

The presence of two ordinate axes (shear stress and dynamic viscosity) allows evaluating both structural viscosity (related to structural breakdown) and dynamic viscosity (related to particle friction). The obtained curves suggest using the power-law model of flow to describe the cream's rheological behavior (fig. 2).

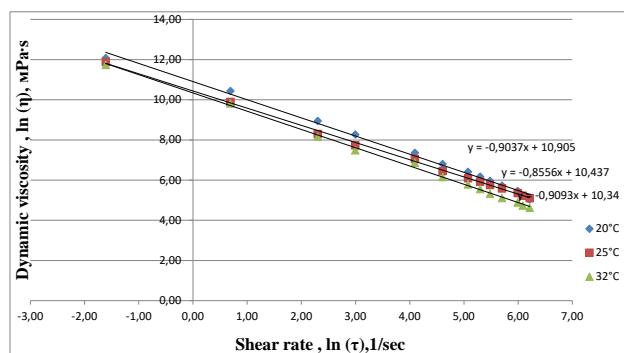


Fig. 2. Dependence of dynamic viscosity (η) of the studied cream on shear rate (Dr) at temperatures 20, 25, and 32°C

Based on the structural-mechanical (rheological) studies conducted and the data obtained during these investigations, the mechanical stability (MS) of the examined cream was determined. The MS index reflects the extent of the system's structural breakdown during irreversible deformations. The research was carried out following the methodology of G.V. Mykhailova, with the mechanical stability calculated as the ratio of the strength of the unbroken system's structure to that of the system which has undergone breakdown. Indicators of the cream's mechanical stability were determined to characterise the degree of structural degradation.

Mechanical stability indices of the gel, which characterize the degree of structural breakdown, were calculated. At 20°C this index was 3,17, at 25°C – 3,54, and at 32°C – 3,4 respectively.

Table
Thermo-rheological indicators of the developed photoprotective cream

Parameters	Temperature, °C		
	20	25	32
Consistency Index K, Pa'	10,91	10,43	10,34
Flow Behavior Index, n	0,096	0,144	0,091
Initial Viscosity, mPa'	54 447	34 098	30 946
Mechanical Stability, MS	3,17	3,54	3,4
Degree of Thixotropy, %	38,02	29,87	28,52

According to the experimental results presented in table, the cream samples had a flow behavior index ranging from 0,091 to 0,144, indicating the plastic nature of their flow. Rheological measurements can be used for quality control of the cream at all stages of its production and storage. Changes in rheological characteristics may indicate a change in the composition or structure of the cream.

The results of the experimental studies confirmed that the system's mechanical stability is determined by its thixotropic properties, which enable the system to recover after mechanical stress. This finding allows the prediction of the long-term stability of the structural-mechanical properties of the developed experimental cream over the specified storage period (Gnitko, 2018).

Overall, the obtained data allow the conclusion that the studied cream exhibits complex rheological behavior, which depends on temperature and shear rate. Understanding these dependencies is crucial for optimizing the processes of cream production and application.

The result of determining the colloidal stability and thermal stability of the processed cream meets the requirements of the physicochemical properties of cosmetic creams, namely, the colloidal stability of the cream samples is stable, the thermal stability of all samples

at a temperature of 50°C is stable. Thus, the obtained cream samples are within the limits that comply with DSTU ISO/TR 18811:2019 “Cosmetics. Guidelines for determining the stability of cosmetic products” (ISO/TR 18811:2018, IDT).

Conclusions. It has been established that the developed cream belongs to dispersed structured systems characterized by elastic-plastic-viscous properties. It has been proven that the developed cream exhibits non-Newtonian flow behavior and its flow begins after a certain mechanical stress is applied.

In summary, the “mechanical stability” value characterises the system as thixotropic, ensuring its recovery after mechanical stress and allowing for the prediction of the stability of its structural-mechanical properties during prolonged storage. The experimental studies confirmed the rationality of the developed photoprotective cream technology, which showed stability under different temperature regimes at 20, 25°C (storage temperatures), and 32°C (application temperature), ensuring product quality.

The determination of thermal stability and colloidal stability of the developed cream indicates its stability.

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Begdai A.O. – experiment.

Електронна адреса для листування з авторами:

roik.om@knu.edu.ua,

vlasenkoiryna5@gmail.com