COMPARISON OF TEXTURE PROFILES OF EMULGEL AND CREAM STABILIZED WITH THE MIXED EMULSIFIER OF NATURAL ORIGIN

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Due to the ability to be carriers for both hydrophilic and lipophilic substances, creams as a type of emulsion are extremely popular carriers in the production of pharmaceutical and cosmetic preparations. On the other hand, emulgels, as newer types of emulsions in which the aqueous phase is gelled with gelling agent, are increasingly being investigated. The aim of this study was to examine the differences between textural characteristics and evaluate the stability of emulsion systems stabilized with mixed emulsifier Myristyl Alcohol and Myristyl Glucoside – cream and emulgel whose water phase was gelled with Cellulose gum. Textural analysis was carried out after the preparation of the samples, as well as after one month and after 6 months from the making of the samples. The Brookfield CT3 Texture Analyzer was used to perform texture analysis, for determining the following parameters: hardness cycle 1, hardness cycle 2, adhesiveness, cohesiveness, resilience, and springiness. The results showed that at the beginning of the study, the value of hardness and resilience of cream and emulgel was similar, but the cream had higher cohesiveness and lower adhesiveness and springiness than emulgel. However, during the study, there was a change in the parameters of the emulgel, which were statistically significant during the first month after the production of the emulgel, when an increase in hardness, adhesiveness and springiness appeared. On the repeated measurement after 6 months, there were no significant differences compared to the results after the first month, leading to conclusion that it took less than a month for the emulgel to reach its final structure.

Keywords: emulgel, cream, texture analysis, hardness, cohesiveness

Introduction

Topical semi-solid formulations are extremely popular due to the fact that the largest human organ, the skin, represents one of the most convenient routes for drug administration. In addition, cosmetics that are applied directly to the skin are often formulated in this way [1].

As biphasic systems consisting of immiscible liquids with different polarities stabilized by a suitable emulsifier, emulsions are most commonly used as delivery systems thanks to their ability to incorporate both hydrophobic and hydrophilic compounds [2-4]. The most popular type of emulsions is oil-in water (o/w), but there are also several other types like water-in-oil (w/o), double emulsions (w/o/w and o/w/o) and Pickering emulsions. Since one of the phases (internal phase) is dispersed as droplets in the other phase (external phase), the emulsions are thermodynamically unstable systems, and prone to various destabilization reactions such as flocculation, coalescence, creaming, phase inversion, Ostwald ripening and sedimentation.

Those problems are solved by addition of surfactants, viscosity controllers and other stabilizers into the emulsions [5,6].

When external phase of the emulsion is gelled with a proper gelling agent, the emulgel is formed. Different gelling agents can be used for formulation of emulgel, such as polyacrylic acid, cellulose derivatives (hydroxypropylmethylcellulose, ethylcellulose, cellulose gum) and gums (xanthan gum). The gel phase increases the stamina of semisolid structure due to its three-dimensional nature. There are several techniques for emulgel preparations, but all of them are based on heating, mixing and high sheer homogenization, since sufficient amount of energy is needed for blending gel phase with the emulsion [7-11].

The creams as semi-solid emulsions and emulgels as novel emulsion variants can widely be found on the market, and many studies are exploring the properties, advantages and fields of application of these vehicles. Emulsions can act as drug reservoirs from which their

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controlled delivery is possible, since the active substance can be stored in water or oil phase. The active substance and nature extracts, regardless of the polarity can be incorporated into emulsions. Moreover, the attractive and smooth appearance of emulsions is probably the biggest reason for their acceptance among consumers. On the other hand, emulgel is reported to be thixotropic, non-greasy and easy to spread, which is all due to the nature of the gel. In addition, muco-adhesive property of the gel can prolong the contact time of the preparation over the skin [7,12-15].

Textural analysis provides numerical values of textural parameters, and therefore this type of study offers an objective insight into the mechanical characteristics of topical semi-solid preparations [16,17]. The other commonly used way of determination of mechanical characteristics is sensory analysis including subjective responses of panelists, where subjective perception of the texture consistency can be evaluated. The mechanical characteristics of the semi-solid preparations, like hardness, spreadability and adhesiveness, are valuable from the aspect of consumer acceptance but can also influence on drug delivery and effectiveness of the formulation [8]. Mechanical properties of preparations could also be applied in the quality-by-design approach, where characteristics of vehicles can be varied in order to obtain the formulation of the desired characteristics [18]. Moreover, analysis of emulsion mechanical properties, such as rheological and texture analysis, can be a valuable tool for determination of the stability of formulations [8, 19-21]. The aim of this study was to compare the textural characteristics of cream (emulsion) and emulgel, whose water phase was gelled with cellulose gum. Both formulations were stabilized with the mixed emulsifier (myristyl alcohol and myristyl glucoside) and the texture analysis was conducted after preparation of the formulations as well as after one month and after six months of preparation of the formulation. In this way, mechanical characteristics would serve as an additional tool for stability profile evaluations and comparisons.

Material and Methods

Materials

The raw materials used to make the cream and emulgel are stated in Table 1.

Table 1. Formulation of the cream and emulgel

INCI name	Trade name, Company name, Company headquarters	Cream	Emulgel	Role in the formulation
Cetyl Ethylhexanoate	SABODERM CSO (Sabo S.p.A, Italy)	5	5	Emollient
Decyl Oleate	SABODERM NDO (Sabo S.p.A, Italy)	10	10	Emollient
Caprylic/Capric Triglyceride	Myritol® 318 (BASF, Germany)	10	10	Emollient
Myristyl Alcohol (and) Myristyl Glucoside	MONTANOV™ 14 (Seppic, France)	5	5	Emulsifier
Stearyl Alcohol	Lanette® 18 (BASF, Germany)	2	2	Co-emulsifier
Cetyl Alcohol	Lanette® 16 (BASF, Germany)	2	2	Co-emulsifier
Phenoxyethanol (and) Ethylhexylglycerin	Euxyl PE 9010 (Ashland, Delaware, United States)	1	1	Preservative
Tocopheryl Acetate	Tocopheryl Acetate (Merck, Germany)	1	1	Antioxidant
Glycerin	Glycerol (Merck, Germany)	10	10	Humectant
Water	Purrified water (Faculty of Medicine, University of Niš)	54	53	Solvent
Cellulose gum	Blanose™ 7MF (DKSH, Switzerland)	-	1	Gelling agent

Preparation of the cream and emulgel

The cream was prepared according to standard emulsion preparation process. All components of the oil phase were weighed on a laboratory scale and heated to a temperature of 70 ˚C, while the water phase, prepared separately, was heated to 75 ˚C. After heating, these two phases were homogenized and mixed until cooling using T18 basic Ultra-Turrax ® Homogenizer (IKA Werke, Breisgau, Germany) and RW 16 basic propeller rotary laboratory stirrer (IKA Werke, Breisgau, Germany). The emulgel was prepared in a similar way, with the difference that cellulose gum was added to the aqueous phase before the phases were combined. During the study, the formulations were stored at room temperature, in adequate packaging and protected from light.

Stability analysis

Stability analysis was carried out for a period of 6 months, at following time intervals: 24 hours after cream and emulgel preparation, 1 month after cream and emulgel preparation and 6 months after cream and emulgel preparation. The parameters such as color and phase separation were evaluated organoleptically, while pH and conductivity were measured using appropriate instruments.

Measurement of the pH of the cream and emulgel

The pH value was determined potentiometrically using pH meter (pH 211 Microprocessor pH Meter, Hanna Instruments, Woonsocket, Rhode Island, USA) from their 5.00% water solution.

Measurement of conductivity of the cream and emulgel

The conductivity was measured by direct immersing of conductometer (CDM 230, Radiometer, Denmark) probe into the samples.

Texture analysis of cream and emulgel

The texture analysis of the samples was performed three times – 24 hours after the preparation, one month after preparation and six months after preparation of cream and emulgel. After filling the sample cups three-quarters full with the samples, avoiding the introduction of air, the analysis was carried out on the instrument CT3 Texture Analyzer (Brookfield, AMETEK Inc., USA). The experimental conditions were set as following: 10 kg load cell, 1.5 mm/s test speed, 5mm target value and 5g trigger load. Texture Profile Analysis (TPA) was chosen and the cone probe TA-STF was used. As the result of the calculations after double immerging of the probe into samples, hardness cycle 1, hardness cycle 2, cohesiveness, adhesiveness, resilience and springiness were measured. TPA was performed in triplicate and the mean values and standard deviations of parameters were calculated.

Results and Discussion

The emulsion-based systems that were examined in the study were stabilized by emulsifier Myristyl Alcohol and Myristyl Glucoside, alkylpolyglucoside and consistency factor from natural origin that is used to stabilize and thicken all types of O/W emulsions via forming lamellar liquid crystals [22]. This emulsifier is approved by ECOCERT, COSMOS and Natrue and can be used in products for skin and hair care, sunscreens, hygiene and make up products [23]. As co-emulsifiers cetyl alcohol and stearyl alcohol were used. During period of 6 months both cream and emulgel preserved its stability in terms of pH and conductivity, as well as consistency in color, which remained white in both cases. In addition, no phase separation was observed during the whole period. The results of texture analysis (portrayed in Figures 1-6) showed that some parameters have changed over time, but those changes refer only to the period between formulation of the emulgel and the measurements that were taken after 1 month. Other texture parameters stayed constant for emulgel (on second and third measurement), while the cream texture parameters were preserved during the whole period of study. The reason of this might be the changes in gelling structure formed in water phase of emulgel.

Hardness, as a force needed for deformation, was measured during both cycles of compression when the probe was inserted in the sample [24]. The results have shown that there are not statistically significant differences between the hardness cycle 1 and hardness cycle 2 values, which indicates that the structure of both cream and emulgel was preserved during compression. The same trend was observed when comparing hardness cycle 1 and hardness cycle 2 after 1 month and after 6 months.

The time didn't influence hardness of cream – there was a slight decrease in hardness observed, which was not statistically significant ($p>0.05$). In the first moment, the cream and emulgel showed comparable values of hardness (Figure 6). However, there was a significant increase ($p<0.05$) in hardness after one month of preparation of emulgel compared to basal values, resulting in a significant difference between the hardness of cream and emulgel after 1 month of preparation. After 6 months, the hardness of emulgel slightly decreased, but that change was not statistically significant ($p>0.05$).

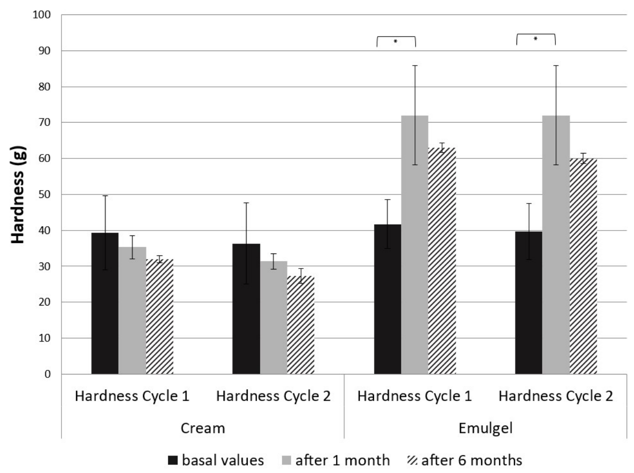

Figure 1. Hardness values of tested cream and emulgel (basal values, values measured after 1 month and values measured after 6 months). Significant differences are being marked with * ($p<0.05$)

The results of adhesiveness indicate that the presence of gelling agent leads to more "sticky" formulation. This texture parameter shows how well the formulation adheres to the skin or the extent to which the skin resists separation when fingers are moved apart while rubbing the product between them [25]. While the adhesiveness didn't change much during the time for both cream and emulgel (Figure 2), there was a significant difference between adhesiveness of cream and emulgel ($p<0.05$). Higher adhesiveness of the emulgel may indicate that emulgels could be the vehicles more suitable for active substances that are intended to have longer contact with the skin and possibly achieve prolonged delivery.

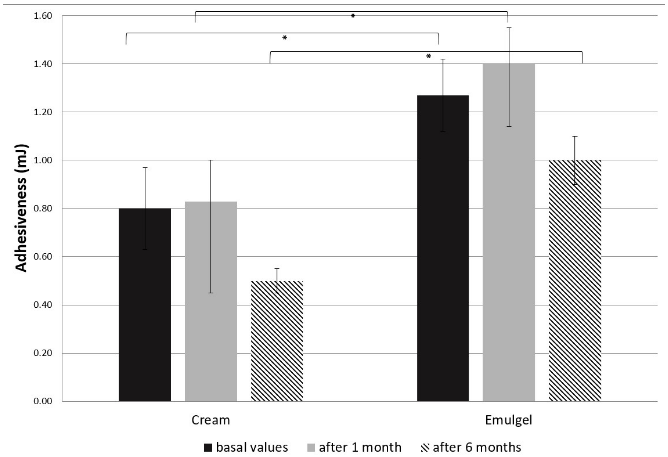

Figure 2. Adhesiveness values of tested cream and emulgel (basal values, values measured after 1 month and values measured after 6 months). Significant differences are being marked with * ($p<0.05$)

The strength of the internal bonds within the product is shown by cohesiveness [24]. This texture parameter can be obtained only after 2 cycles of compression as a ratio between areas under the curve of the second and first compression cycle portrayed on the texture diagram. While creams showed constancy of this parameter over time, that was not the case with the emulgel (Figure 3). The cohesiveness of the emulgel increased over time, with a considerable increase noticed after one month ($p<0.05$). The changes of this parameter are in correlation with the changes observed for hardness.

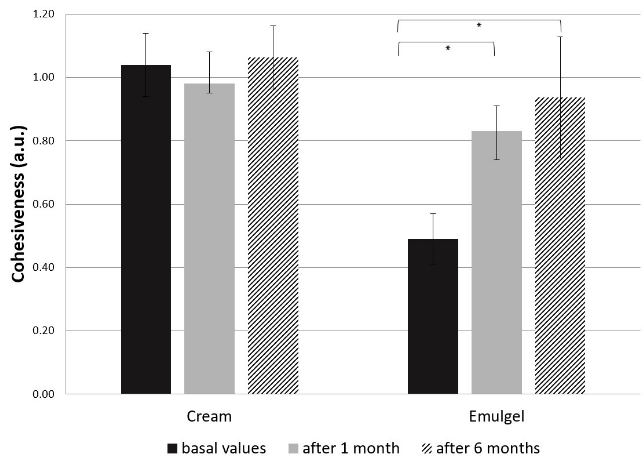

Figure 3. Cohesiveness values of tested cream and emulgel (basal values, values measured after 1 month and values measured after 6 months). Significant differences are being marked with * ($p<0.05$)

Resilience pertains to the energy required for elastic recovery and reflects a product's inclination to revert to its original position following compression [26]. Resilience of cream and emulgel didn't differ much, and was constant over the time (Figure 4).

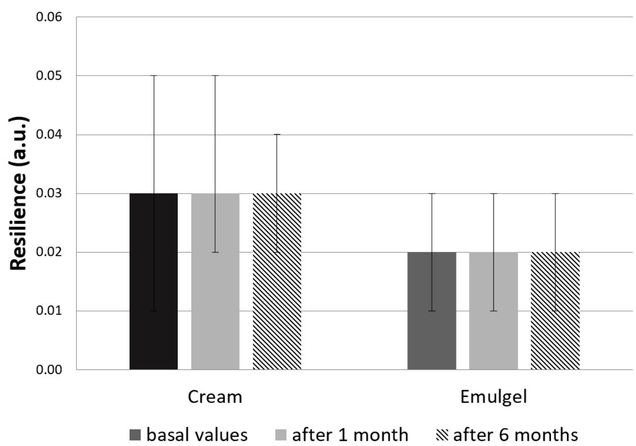

Figure 4. Resilience values of tested cream and emulgel (basal values, values measured after 1 month and values measured after 6 months). Significant differences are being marked with * ($p<0.05$)

On the other hand, there were some differences in springiness analogue to those observed for hardness and cohesiveness. Namely, there was an increase in this parameter, over time in case of the emulgel, while the springiness of the cream didn't change with each measurement (Figure 5). In addition, initially, the emulgel had lower springiness compared to cream, but after 6 months, the values for both cream and emulgel were similar. This parameter refers to the quotient of the height of the product before and after deformation [26].

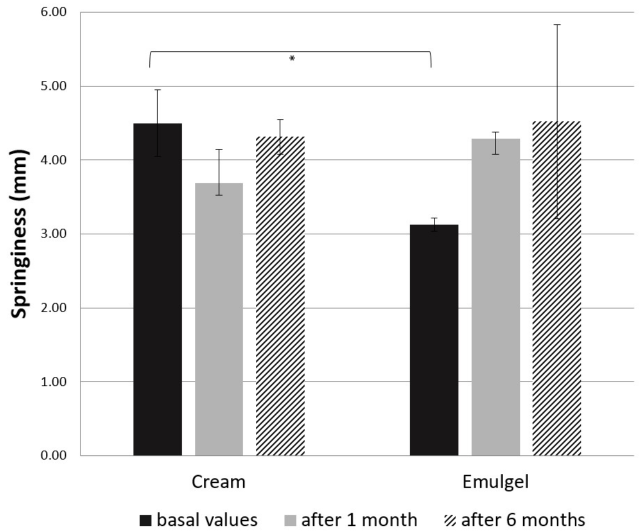

Figure 5. Springiness values of tested cream and emulgel (basal values, values measured after 1 month and values measured after 6 months). Significant differences are being marked with * ($p<0.05$)

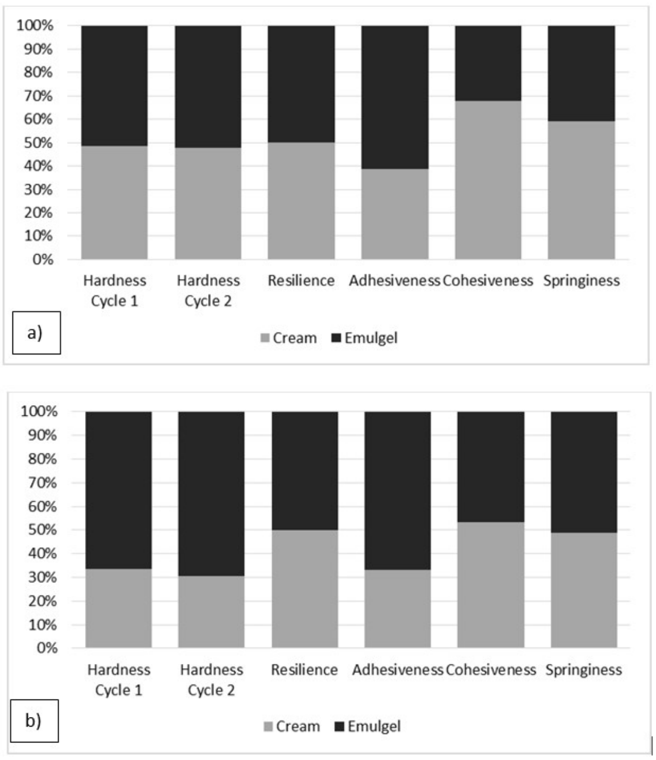

Figure 6. Relative differences of texture parameters between cream and emulgel - comparison of basal values (a) and values after 6 months (b)

On the other hand, the results of the comparative texture analysis are shown in Figure 6 where relative differences of texture parameters between cream and emulgel were portrayed. When the textural properties of creams and emulgels are compared, it can be seen that after production, emulgels have greater adhesiveness and springiness compared to creams, and lower cohesiveness. Nonetheless, after one month, the hardness, adhesiveness and springiness of emulgel increase, resulting in different texture characteristics of emulgel and cream. These properties are perserved even after six months.

The differences between cream and emulgel were also examined in other studies. In the sensory analysis, the panelists described emulgel as preparations with better applicative properties [27]. When penetration of acyclovir was investigated, the cream proved to be better penetration enhancer. However, that was not the case with ketoconazole, where the emulgel as a vehicle enhanced the skin penetration [28]. On the other hand, in the study where herbal active substances were incorporated in different emulsion-based vehicles, enhanced delivery from emulgel compared to the cream was observed [27]. More studies are needed to be conducted regarding comparison between cream and emulgel.

Conclusion

The results of texture analysis that lasted for 6 months following the moment of formulation of cream and emulgel with cellulose gum showed that the texture parameters of cream remained constant over time, while some parameters of emulgel changed. The hardness, cohesiveness and resilience of emulgel increased over time, most significantly during first month, while adhesiveness and springiness remained the same. These results indicate that the structuring of the emulgel takes place within the first month of the preparation. When it comes to the comparative analysis of creams and emulgels, it can be concluded that after 6 months there is only a significant difference in hardness and adhesiveness in favor of emulgel, which indicates the potential of emulgels for use in preparations intended to stay longer on the skin. However, it is necessary to conduct more textural, sensory and stability studies in which other gelling agents for the production of emulgels will be examined in various time frames from the preparation of the emulgel, in order to better understand the influence of the gelling agent on the function and use of the prepared emulgel and to establish broader, generalizable conclusions about their performance and stability.

Acknowledgments

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Izvod

POREĐENJE TEKSTURNIH KARAKTERISTIKA EMULGELA I KREMA STABILIZOVANIH MEŠOVITIM EMULGATOROM PRIRODNOG POREKLA

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Kremovi kao polučvrste emulzije su izuzetno popularni kada je u pitanju proizvodnja farmaceutskih i kozmetičkih preparata, jer mogu biti nosači i hidrofilnih i lipofilnih supstanci. S druge strane, sve više se istražuju emulgeli, kao novije vrste emulzija u kojima je vodena faza gelirana gelirajućim sredstvom. Cilj ovog rada bio je da se ispitaju razlike između teksturnih karakteristika i stekne uvid u stabilnost emulzionih sistema stabilizovanih mešanim emulgatorom (Miristil Alkohol i Miristil Glukozid) – krema i emulgela čija je vodena faza gelirana karboksimetil celulozom. Tekstualna analiza je izvršena nakon izrade uzoraka, kao nakon mesec dana i 6 meseci od izrade uzoraka. Za teksturnu analizu korišćen je Brookfield CT3 Texture Analyzer, i to za određivanje sledećih parametara: ciklus tvrdoće 1, ciklus tvrdoće 2, adhezivnost, kohezivnost, elastičnost i rezilijentnost. Rezultati su pokazali da je na početku istraživanja vrednost tvrdoće i elastičnosti krema i emulgela bila slična, ali je krem imao veću kohezivnost i manju adhezivnost i elastičnost od emulgela. Međutim, tokom istraživanja došlo je do promene parametara emulgela, koji su bili statistički značajni tokom prvog meseca nakon proizvodnje emulgela, kada je došlo do povećanja tvrdoće, adhezivnosti i elastičnosti. Na ponovljenom merenju posle 6 meseci nije bilo značajnih razlika u odnosu na rezultate posle prvog meseca, što je dovelo do zaključka da je bilo potrebno manje od mesec dana da emulgel dostigne konačnu strukturu.

Ključne reči: emulgel, krem, teksturna analiza, tvrdoća, kohezivnost

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