

**FORMULACIJA I FIZIČKOHEMIJSKA
KARAKTERIZACIJA U/V KREMOVA KAO NOSAČA ZA
NOVU KOZMETIČKI AKTIVNU SUPSTANCU –
LAKTOBIONSKU KISELINU**

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Laktobionska kiselina (LK) je nova kompleksna polihidroksi kiselina, koja pripada grupi alfa hidroksi kiselina (AHAs). In vitro i kliničke studije pokazale su da LK ostvaruje bolji "anti-age" efekat od glikolne i mlečne kiseline (dobar ovlaživač kože i antioksidans, doprinosi obnavljanju integriteta kože).

Usled velikog broja hidroksilnih grupa izrazito je higroskopna i ispoljava visok potencijal za vlaženje kože, ali higroskopnost i kisela priroda njene molekule, predstavljaju veliki problem u formulisanju stabilnog preparata, namenjenog dužem kontaktu sa kožom.

Cilj ovog rada bio je da se formulišu kiselo-stabilni višefazni u/v kremovi sa 6% (m/m) LK na bazi dva nova šećerna emulgatora (MontanovTM 68-M68 i MontanovTM 82-M82. Emulgatori su upotrebljeni u koncentraciji od 7%(m/m) u kombinaciji sa 16.5% više-komponentne masne faze, dok su za kostabilizaciju primenjeni 0.5% ksantan gume ili 1.5% šećernog koemulgatora, MontanovaTM 14-M14. U cilju izbora optimalne formulacije sa LK za in vivo studiju, sprovedena je fizičkohemijska karakterizacija 4 uporedne serije uzoraka (svaka serija sadržala je placebo, krem sa LK i neutralisani LK krem), primenom polarizacije i svetlosne mikroskopije, kontinualne i oscilatorne reologije, teksturalne analize i merenjem pH i električne provodljivosti.

Rezultati ispitivanja ukazuju na kompleksnu koloidnu strukturu placebo uzoraka, baziranu na sinergizmu lamelarne tečno-kristalne i gel kristalne faze, kao i značajan procenat vezane vode. Reološka i teksturalna merenja potvrdila su organoleptički nalaz o porastu konzistencije uzoraka sa LK (pH 2.50-2.90) u odnosu na placebo uzorke (pH 5.40-6.20), dok uzorci sa korigovanim pH (iznad 3.50) imaju viskozitet nešto viši od placebo kremova.

Preliminarna razmatranja ukazala su da krem baziran na 7% emulgatora M82 i 1.5% koemulgatora M14, uz dobru fizičku stabilnost, ima najbolje aplikativne i estetske karakteristike, na osnovu čega je izabran za in vivo studiju efikasnosti.

**FORMULATION AND PHYSICOCHEMICAL
CHARACTERISATION OF O/W CREAM VEHICLES FOR
NOVEL COSMETIC ACTIVE SUBSTANCE – LACTOBIONIC
ACID**

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Lactobionic acid (LA) is a new complex polyhydroxy acid, belonging to the class of alpha hydroxyacids (AHAs). In vitro and clinical studies have showed that LA produces better anti-age effects than glycolic and lactic acids (good moisturizer and antioxidant, contributing to the skin integrity restoration).

A number of hydroxyl groups make it hygroscopic, giving a distinct potential for skin hydration, but alongside with the acidic nature, it represents the additional problem in formulating the stable preparation, feasible for the skin application.

The intention of this study was to formulate the acidic-stable multiphase o/w creams with 6% (w/w) of LA based on two novel sugar emulsifiers (MontanovTM 68-M68 and MontanovTM82-M82). The emulsifiers were used in concentration of 7% (w/w) with 16.5% of multicomponent oil phase, whereas for the creams' costabilization 0.5% of xanthan gum or 1.5% of sugar co-emulsifier, MontanovTM 14-M14 were applied. In order to select an optimal formulation with LA for the in vivo study, physicochemical characterization was performed for four comparable series of samples (each contained placebo, LA-containing cream and neutralized LA cream), employing the polarization and light microscopy, continual and oscillatory rheology, textural analysis and measuring the pH and electrical conductivity.

The results of investigations point at the complex colloidal structure of placebo samples mirrored in the synergism of lamellar liquid-crystal and gel-crystalline structure and significant percentage of fixed water. The rheological and textural analysis were in line with findings of visual introspection, proving an increase of consistency in LA-loaded samples (pH 2.50-2.90), compared with placebo creams (pH 5.40-6.20), whereas the samples with adjusted pH (above 3.50) have the viscosity somehow higher than placebo creams.

The preliminary considerations implied that a cream based on 7% of M82 emulsifier and 1.5% of M14 co-emulsifier, accompanied with a good physical stability and the best applicative and esthetic characteristics could be an optimal choice for an in vivo efficacy study.