

## KARAKTERIZACIJA GEL-EMULZIJE SA MELOSIKAMOM

**Elena Drakalska Sersemo<sup>1\*</sup>, Aleksandar Cvetkovski<sup>1</sup>, Bistra Angelovska<sup>1</sup>, Dijana Miceva<sup>1</sup>, Liljana Makraduli<sup>1,2</sup>**

<sup>1</sup> Fakultet medicinskih nauka, Univerzitet „Goce Delčev“ - Štip,  
Republika Severna Makedonija

<sup>2</sup> AD „Replek“- Skoplje, Republika Severna Makedonija

\*elena.drakalska@ugd.edu.mk

Meloksikam je jedan od najpotentnijih nesteroidnih antiinflamatornih lekova, generalno indikovan za lečenje reumatoидног artritisa, osteoartritisa i juvenilног artritisa i komercijalno dostupan u obliku tableta i rastvor za intravensku primjenu sa preporučenom dnevnom dozom od 7,5-15 mg. Nažlost, dugotrajna primena obično u većim dozama je povezana sa povećanim rizikom od gastrointestinalnog krvarenja, srčanog zastoja i moždanog udara. Alternativni pristup za prevazilaženje ovih ograničenja je dizajn farmaceutskih oblika za lokalnu/topikalnu primenu. Cilj ovog rada je karakterizacija i evaluacija gel-emulzije sa meloksikatom. Ova studija je fokusirana na razvoj gel-emulzije u čijem sastavu se nalaze *Tego Carbomer* 134 kao sredstva za geliranje, propilen glukol kao solubilizatora i humektans, *Tween* 60 i *Span* 60 kao emulgatora, tečnog parafina kao sastojka masne faze, trietanolamina kao regulatora pH. mentol kao rubefacijent. Pripremljena gel-emulzija je okarakterisana sadržajem meloksikama, pH, razmazivošću, viskozitetom i ispitivanjem mikrobioloшког kvaliteta. Dobijeni rezultati su pokazali homogenu, lako razmazivu, providnu gel-emulziju. Vizuelnim pregledom nije primećeno razdvajanje faza. Procenat sadržaja leka u gel-emulziji bio je 103%, razmazivost 9,2 cm, a viskozitet 25 500 cP. Izmereni pH bio je 6,45 što je pogodno za dermalnu primenu bez rizika od iritacije. Pored toga, utvrđeno je odsustvo specifičnih testiranih mikroorganizama: *Escherichia coli*, *Salmonella*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Clostridia* i *Candida albicans*. Ispitana formulacija je bila fizičko-hemijski stabilna i adekvatnog mikrobioloшког kvaliteta nakon tri meseca pripreme, međutim potrebna su dalja istraživanja kako bi se utvrdila bezbednost razvijene gel-emulzije.

### Literatura

1. Mwangi AN, Njogu PM, Maru SM, Njuguna NM, Njaria PM, Kiriiri GK, Mathenge AW 2021. Meloxicam emulgels for topical management of rheumatism: Formulation development, in vitro and in vivo characterization. Saudi Pharm J. 2021 Apr;29(4):351-360. doi: 10.1016/j.jps.2021.03.005. Epub 2021 Mar 23. PMID: 33994830; PMCID: PMC8093581.

## CHARACTERIZATION OF MELOXICAM LOADED GEL-EMULSION

**Elena Drakalska Sersemoval<sup>1\*</sup>, Aleksandar Cvetkovski<sup>1</sup>, Bistra Angelovska<sup>1</sup>, Dijana Miceva<sup>1</sup>, Liljana Makraduli<sup>1,2</sup>**

<sup>1</sup> Faculty of Medical Sciences, Goce Delcev University, Stip, North Macedonia

<sup>2</sup> JSC,, Replek"-Skopje, Republic of North Macedonia

\*elena.drakalska@ugd.edu.mk

Meloxicam is one of the most potent non-steroidal anti-inflammatory drugs, generally indicated for treatment of rheumatoid arthritis, osteoarthritis, and juvenile arthritis and commercially available in form of tablets and solution for IV use with recommended daily dose 7.5-15 mg. Unfortunately, long-term administration usually in higher doses is associated with increased risk of gastro-intestinal bleeding, cardiac arrest, and stroke. An alternative approach to overcome these limitations is the design of topical forms. The aim of this study is characterization and evaluation of gel-emulsion with meloxicam. The present study is focused on elaboration of gel-emulsion composed of TEGO Carbomer 134 as gelling agent, propylene glycol as solubilizer and humectant, Tween 60 and Span 60 as emulsifiers, liquid paraffin as vehicle of oil phase from gel-emulsion, triethanolamine as pH adjuster and menthol as rubefacient whereby meloxicam is incorporated as free drug in oil phase. Prepared gel-emulsion was characterized by meloxicam content, pH, spreadability, viscosity and evaluation of microbiological quality. Obtained results showed homogenous, easy spreadable, translucent gel-emulsion. Upon visual examination, no phase separation was observed. The percentage of drug content in gel-emulsion was 103%, spreadability was 9.2 cm and viscosity was 25 500 CP. Measured pH was 6.45 which is suitable for dermal application without risk of irritation. Additionally, absence of the specific microorganisms Escherichia coli, Salmonella, Pseudomonas aeruginosa, Staphylococcus aureus, Clostridia and Candida albicans was determined. The tested formulation was physicochemically stable and of adequate microbiological quality after three months of preparation, however, further research is needed to determine the safety of the developed gel-emulsion.

### References

1. Mwangi AN, Njogu PM, Maru SM, Njuguna NM, Njaria PM, Kiriiri GK, Mathenge AW 2021. Meloxicam emulgels for topical management of rheumatism: Formulation development, in vitro and in vivo characterization. Saudi Pharm J. 2021 Apr;29(4):351-360. doi: 10.1016/j.jsps.2021.03.005. Epub 2021 Mar 23. PMID: 33994830; PMCID: PMC8093581.