Arh. farm 2022; 72: S404–S405 ***PTC-PP12***

FORMULATION AND EVALUATION OF GEL VEHICLES FOR ORAL ADMINISTRATION OF PELLETS WITH DICLOFENAC

Aneta Stojmenovski[1*], Maja Mirjanić[1], Biljana Gatarić[2], Nataša Bubić Pajić[2], Anđelka Račić[2]

[1]University of Banja Luka – Faculty of Medicine, Department of Pharmacy, Banja Luka, The Republic of Srpska, Bosnia and Herzegovina
[2]University of Banja Luka – Faculty of Medicine, Department of Pharmaceutical Technology and Cosmetology, Banja Luka, The Republic of Srpska, Bosnia and Herzegovina

*aneta.stojmenovski@student.med.unibl.org

To address the administration difficulties associated with use of solid or non-viscous oral dosage forms, oral gels have been proposed as a promising formulation approach (1). The aim of this study was formulation and evaluation of gels for oral administration of diclofenac pellets, using carbomer (0.5 % w/w) (G1), sodium alginate (5% w/w) (G2), and gelatin (2.5% w/w) (G3) as viscosity increasing agents. Pellets containing 75 mg diclofenac (25 mg in gastro-resistant pellets and 50 mg in prolonged-release pellets) were extracted from commercially available capsules and dispersed in 10 g of the gel vehicle. Physicochemical properties (appearance, clarity, pH, viscosity) of the prepared formulations were tested. Dissolution tests were performed using basket apparatus (100 rpm), in two phases (acidic and basic, using 0.1 M HCl and phosphate buffer (pH 7.5), respectively), during 24 h. The clarity, pH and viscosity of all formulations were in an acceptable range for oral gels (2). Different dissolution patterns were observed for the reference product and tested formulations, except formulation G3. The preserved high viscosity of a carbomer gel in a phosphate buffer, inhibited the dissolution of diclofenac. The amount of the drug dissolved at the end of the experiment was increased compared to the commercial capsules (80.1%) and was 92.0% (G2) and 100.8% (G3), respectively. Diclofenac-loaded pellets were successfully incorporated in oral gels. The gels of sodium alginate and gelatin have potential to facilitate swallowing and can be considered as an appealing formulation strategy for overcoming the administration problems of other oral dosage forms.

References

1. Kulkarni S, Londhe V, Oral jelly of metformin hydrochloride – Formulation development using Design of Experiments and characterization, *J Drug Deliv Sci Technol,* 2021: 102519
2. Freerks L, Sucher W, Tarnow MJ. *et al.* Vehicles for Drug Administration to Children: Results and Learnings from an In-Depth Screening of FDA-Recommended Liquids and Soft Foods for Product Quality Assessment. *Pharm Res*, 2022**:** 497–509

Acknowledgements

The authors would like to acknowledge the financial support from the Ministry for Scientific-Technological Development, Higher Education and Information Society, Republic of Srpska, through the Project 19.032/961-149/19.

FORMULACIJA I PROCJENA GEL VEHIKULUMA ZA ORALNU PRIMJENU PELETA SA DIKLOFENAKOM

Aneta Stojmenovski[1*], Maja Mirjanić[1], Biljana Gatarić[2], Nataša Bubić Pajić[2], Anđelka Račić[2]

[1]Univerzitet u Banjoj Luci – Medicinski fakultet, odsijek Farmacija, Banja Luka, Republika Srpska, Bosna i Hercegovina
[2]Univerzitet u Banjoj Luci – Medicinski fakultet, Katedra za farmaceutsku tehnologiju i kozmetologiju, Banja Luka, Republika Srpska, Bosna i Hercegovina

*aneta.stojmenovski@student.med.unibl.org

Oralni gelovi su predloženi kao potencijalno koristan pristup u cilju prevazilaženja poteškoća koje se javljaju prilikom primjene čvrstih ili neviskoznih oralnih farmaceutskih oblika (1). Cilj ovog istraživanja je bio formulisanje i karakterizacija gelova za oralnu primjenu peleta sa diklofenakom, korišćenjem karbomera (0,5% m/m) (G1), natrijum-alginata (5% m/m) (G2) i želatine (2,5% m/m) (G3) kao sredstava za povećanje viskoziteta. Pelete koje sadrže 75 mg diklofenaka (25 mg u gastrorezistentnim peletama i 50 mg u peletama sa produženim oslobađanjem) su ekstrahovane iz komercijalno dostupnih kapsula i dispergovane u 10 g gel vehikuluma. Ispitivane su fizičko-hemijske osobine (izgled, bistrina, pH, viskozitet) izrađenih formulacija. Ispitivanja brzine rastvaranja ljekovite supstance iz izrađenih gelova su vršena pomoću aparature sa korpicama (100 rpm), u dvije faze (kiseloj i baznoj, uz upotrebu 0,1M HCl i fosfatnog pufera (pH 7,5), redom), u trajanju od 24 h. Bistrina, pH i viskozitet svih formulacija bili su u prihvatljivom opsegu za oralne gelove (2). Ispitivane formulacije su pokazale različite profile brzine rastvaranja u odnosu na referentni proizvod, izuzev formulacije G3. Visoki viskozitet karbomernog gela u fosfatnom puferu, inhibisao je rastvaranje diklofenaka. Količina lijeka rastvorenog na kraju eksperimenta povećana je u odnosu na komercijalne kapsule (80,1%) i iznosila je 92,0% (G2) i 100,8% (G3), redom. Pelete sa diklofenakom su uspješno inkorporirane u oralne gelove. Gelovi natrijum-alginata i želatine imaju potencijal da olakšaju gutanje i mogu se smatrati korisnom strategijom za prevazilaženje problema sa primjenom drugih farmaceutskih oblika za oralnu primjenu.

Literatura

1. Kulkarni S, Londhe V, Oral jelly of metformin hydrochloride – Formulation development using Design of Experiments and characterization, *J Drug Deliv Sci Technol,* 2021: 102519
2. Freerks L, Sucher W, Tarnow MJ. *et al.* Vehicles for Drug Administration to Children: Results and Learnings from an In-Depth Screening of FDA-Recommended Liquids and Soft Foods for Product Quality Assessment. *Pharm Res*, 2022**:** 497–509

Zahvalnica

Autori se zahvaljuju na finansijskoj podršci Ministarstva za naučno-tehnološki razvoj, visoko obrazovanje i informaciono društvo Republike Srpske kroz Projekat 19.032/961-149/1