

FORMULACIJA I KARAKTERIZACIJA MINI TABLETA DESLORATADINA DOBIJENIH FOTOPOLIMERIZACIONOM TEHNIKOM 3D ŠTAMPE LEKOVA

Ivana Adamov*, Teodora Glišić, Đorđe Medarević, Ivana Aleksić, Svetlana Ibrić

Katedra za Farmaceutsku tehnologiju i kozmetologiju, Univerzitet u Beogradu –
Farmaceutski fakultet, Beograd, Srbija

*ivana.adamov@pharmacy.bg.ac.rs

3D štampa lekova, kao aditivna tehnologija, predstavlja jednostavnu i ekonomski prihvatljivu alternativu konvencionalnim metodama, pružajući mogućnost dobijanja inovativnih farmaceutskih oblika i prilagođavanje terapije individualnim potrebama pacijenata (1). Cilj istraživanja bio je da se formulišu i izrade mini tablete desloratadina (DSL) primenom 3D tehnike digitalne obrade svetlosti (engl. *Digital light processing*, DLP) mehanizmom nanošenja materijala "sloj po sloj". Mini tablete DSL (10%, m/m) odabrane su kao farmaceutski oblik leka koji je pogodan za primenu u pedijatrijskoj populaciji, pre svega sa aspekta fleksibilnosti doziranja. Pripremljena je formulacija sa 1% fotoinicijatora i 10% vode, dok su polietilenglikol-diakrilat i polietilenglikol 400 bili prisutni u masenom odnosu 1:1. Kreirani 3D modeli (4,00 × 3,00 mm) uspešno su odštampani primenom *WanhaoD8* štampača. Dobijene su žuto-narandžaste mini tablete uniformnog oblika, debljine i mase (4,16 ± 0,06 × 2,24 ± 0,04 mm; 42,61 ± 1,15 mg). Nepotpuna ekstrakcija DSL iz unakrsno umreženog polimernog matriksa rezultovala je relativno niskim sadržajem lekovite supstance u mini tabletama u odnosu na teorijski sadržaj (72,14 ± 1,04%) (2). Prilikom ispitivanja brzine rastvaranja, nakon 45 min oslobođeno je 50,29 ± 0,14% DSL u 0,1M hlorovodoničnoj kiselini, kao medijumu, uz postizanje platoa nakon 4 sata (81,19 ± 0,63%). Rezultati DSC analize pokazali su da je došlo do amorfizacije lekovite supstance, dok je posmatranjem poprečnih preseka odštampanih mini tableta pod polarizacionim svetlosnim mikroskopom uočeno prisustvo slojevite strukture. DLP tehnika 3D štampe lekova ima potencijal da obezbedi brzu izradu mini tableta odgovarajućih fizičko-hemijskih karakteristika, uz mogućnost postizanja modifikovanog oslobađanja lekovite supstance.

Literatura

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FORMULATION AND CHARACTERIZATION OF DESLORATADINE MINI-TABLETS OBTAINED BY PHOTOPOLIMERIZATION 3D PRINTING TECHNIQUE

Ivana Adamov*, Teodora Glišić, Đorđe Medarević, Ivana Aleksić, Svetlana Ibrić

Department of Pharmaceutical Technology and Cosmetology, University of Belgrade –
Faculty of Pharmacy, Belgrade, Serbia

*ivana.adamov@pharmacy.bg.ac.rs

3D printing as an additive technology represents a simple and economically acceptable alternative to conventional methods and offers the possibility of obtaining innovative dosage forms and individualizing therapy according to the specific needs of patients. (1). The aim of the research was to formulate and manufacture desloratadine mini-tablets (DSL) using digital light processing (DLP) 3D technique based on a successive layering mechanism. Mini-tablets of DSL (10%,w/w) were selected as a dosage form suitable for the pediatric population, particularly because of its flexible dosing. The formulation was prepared with 1% photoinitiator and 10% water, while poly(ethylene glycol) diacrylate and poly(ethylene glycol) 400 were present in a mass ratio of 1:1. The created 3D models (4.00×3.00 mm) were successfully printed using WanhaoD8 printer. Yellow-orange mini-tablets with uniform shape, thickness and mass (4.16±0.06×2.24±0.04 mm; 42.61±1.15 mg) were produced. Incomplete extraction of DSL from the cross-linked polymer matrix resulted in a relatively low content of the drug in the mini-tablets compared to the theoretical content (72.14±1.04%) (2). The dissolution test showed that 50.29±0.14% of DSL was released after 45 minutes in 0.1M hydrochloric acid medium and reached a plateau after 4 hours (81.19±0.63%). The results of DSC analysis showed amorphisation of the drug, while observation of the cross-sections of printed mini-tablets under a polarizing microscope indicated the presence of a layered structure. The DLP technique has the potential to ensure the rapid production of mini-tablets with suitable physicochemical properties and to enable modified release of the drug.

References

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