AN INVESTIGATION INTO THE EFFECTS OF PREPARATION METHODS AND COMPOSITION ON THIN FILM CRITICAL QUALITY ATTRIBUTES

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Thin films are relatively new drug forms, which contain one or more active substances, dispersed or adsorbed on a polymeric carrier (1). The aim of this work was to evaluate the effects of the preparation and formulation factors on film critical quality attributes. Films were prepared by solvent-casting and 3D printing of dispersion on a Ultimaker 2+. Dispersion consisted of hydroxypropylcellulose with or without the addition of sodium-alginate. Caffeine and ibuprofen were used as model drugs. The films were characterized in terms of mass, thickness, moisture content (LJ16-Moisture Analizer) and mechanical characteristics (EZ-LKS-Table-TopMachine). Obtained results indicate that 3D films had higher mass and thickness compared to casted films, except for hydroxypropylcellulose/sodium alginate/caffeine sample (37.6 and 59.0 mg/cm^2; 526 and 642 μm). High content of dispersed substances can cause a change in polymer drying behavior, which is reflected in film characteristics. Dissolving ibuprofen in the initial dispersion, led to film increased elasticity and decreased tensile strength, negatively affecting handling and stickiness of the films prepared by either method. Differences between methods were most pronounced in films with dispersed caffeine or sodium-alginate. Sodium-alginate generally decreased, and caffeine increased flexibility. The preparation process did not affect the moisture content in samples, although the polymer drying differed between two preparation methods. Increased moisture content was generally accompanied by decreased flexibility, except for samples with ibuprofen. Obtained results indicate significant effects of the formulation process and composition on the film characteristics. Dissolved or dispersed substance content in formulation should be adapted to the chosen preparation method.

References

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ISPITIVANJE UTICAJA POSTUPKA IZRADE I FAKTORA FORMULACIJE NA KRITIČNA SVOJSTVA KVALITETA TANKIH ORALNIH FILMOVA

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Tanki oralni filmovi predstavljaju noviji farmaceutski oblik leka, koji sadrži jednu ili više aktivnih supstanci dispergovanih ili adsorbovanih na polimernom nosaču (1). Cilj ovog rada bio je ispitivanje uticaja postupka izrade i faktora formulacije na kritična svojstva kvaliteta filmova. Filmovi su izrađivani izlivanjem disperzije u kalupe ili metodom 3D štampe (Ultimaker 2+). Disperzija se sastojala od hidroksipropilceluloze, sa ili bez dodatka natrijum-alginata. Model aktivne supstance bile su kofein i ibuprofen. Karakterizacija filmova obuhvatila je određivanje mase, debljine, udela vlage (LJ16-MoistureAnalyzer) i mehaničkih karakteristika (EZ-LX-Table-TopMachine). Dobijeni rezultati su pokazali da su 3D štampani filmovi imali veću masu i debljinu u odnosu na izlivene filmove, osim u slučaju uzorka hidroksipropilceluloza/natrijum-alginat/kofein (37,6 i 59,0 mg/cm^2; 526 i 642 μm). Visok udeo dispergovanih supstanci u uzorku može uzrokovati promenu u ponašanju polimera prilikom sušenja što se odražava na karakteristike filmova. Rastvaranje ibuprofena dovelo je do povećanja elastičnosti i smanjenja zatezne čvrstine filmova u slučaju oba postupka izrade, što je imalo negativan efekat na lakoću rukovanja i lepljivost. Postupak izrade imao je najveći uticaj na karakteristike filmova sa natrijum-alginatom i filmova koji su sadržali kofein. Natrijum-alginat je generalno smanjivao, a kofein povećavao fleksibilnost filmova. Postupak izrade nije imao uticaj na udeo vlage, iako je sušenje filmova bilo značajno različito kod ova dva postupka. Povećanje udela vlage uglavnom je pratilo smanjenje fleksibilnosti filmova, osim kod uzoraka sa ibuprofenom. Dobijeni rezultati ukazuju na značajan uticaj postupka izrade i sastava formulacije na karakteristike tankih filmova. Udeo rastvorenih ili dispergovanih supstanci u formulaciji moraju biti prilagođeni odabranom postupku izrade.

Literatura

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