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PUT KA LEKOVIMA KOJI SU PRILAGOĐENI PACIJENTU: RAZVOJ I ISPITIVANJE „*PULP-SPOON*“ FORMULACIJA ZA PEDIJATRIJSKU POPULACIJU

Ivana Nedelkov*, Mina Stojanović, Ivana Kurćubić, Sandra Cvijić

Katedra za farmaceutsku tehnologiju i kozmetologiju Univerzitet u Beogradu-Farmaceutski fakultet, Beograd, Srbija

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

Razvoj lekova prilagođenih deci, kao posebnoj grupi pacijenata, je od ključnog značaja za obezbeđivanje njihove prihvatljivosti i terapijske efikasnosti [1]. Cilj ove studije bio je da se ispita uticaj sastava na osobine „*pulp-spoon*“ formulacija - smeša praškova koje u kontaktu sa vodom bubre i formiraju mekanu masu, laku za gutanje kod pedijatrijskih pacijenata [2].

Kao sastojci formulacija, ispitivani su različiti polimeri (sredstva za geliranje), sredstva za raspadanje, sredstva za dopunjavanje i zaslađivači, uključujući varijacije u njihovim odnosima, pri čemu je karbamazepin korišćen kao model lekovita supstanca. Na osnovu organoleptičkih svojstava izdvojene su četiri formulacije koje su sadržale guar gumu, Prosolv® i manitol, saharozu i/ili steviju u različitim odnosima, a koje su dalje podvrgnute ispitivanjima sadržaja vlage (odmah nakon pripreme i nakon dve nedelje čuvanja), brzine upijanja vode, pH vrednosti vodenih disperzija, sadržaja i brzine rastvaranja lekovite supstance i analizi teksture.

Vodene disperzije su imale blago kiselu pH vrednost, koja se kretala u uskom opsegu za sve formulacije. Početni sadržaj vlage bio je ispod 5% i pokazao je minimalne promene tokom čuvanja. Uočene su određene razlike u brzini upijanja vode i brzini rastvaranja karbamazepina, pri čemu su formulacije sa većim udelom šećera, kao sredstava za dopunjavanje, pokazale sposobnost bržeg upijanja vode i oslobađanje leka, kao i mekšu i glatkiju teksturu. Istovremeno, njihov sadržaj vlage je ostao stabilan tokom perioda čuvanja.

Dobijeni rezultati ukazuju da se *„pulp-spoon“* formulacije mogu jednostavno pripremiti, čak i u uslovima apoteke, i predstavljaju obećavajući, pacijentu prilagođeni farmaceutski oblik leka za pedijatrijsku primenu.

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TOWARD PATIENT-FRIENDLY MEDICINES: DESIGN AND INVESTIGATION OF PEDIATRIC PULP-SPOON FORMULATIONS

Ivana Nedelkov*, Mina Stojanović, Ivana Kurćubić, Sandra Cvijić

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

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

Designing patient-friendly dosage forms for children is crucial for ensuring their acceptability and therapeutic efficacy [1]. The aim of this study was to assess the influence of composition on the properties of pulp-spoons formulations - powder mixtures that readily swell in contact with water to form a soft mass, easy to swallow for pediatric patients [2].

Different polymers (gel-forming agents), disintegrants, diluents, and sweetening agents, including variations in their ratios, were evaluated, and carbamazepine was used as a model drug. Four promising formulations were selected based on organoleptic properties. These formulations, containing guar gum, Prosolv®, and mannitol, sucrose and/or stevia in varying proportions, were subjected to further testing, including moisture content (immediately after preparation and after two weeks of storage), water uptake rate, pH of aqueous dispersions, drug content, dissolution behavior, and texture analysis.

The aqueous dispersions exhibited slightly acidic pH values within a narrow range across all formulations. The initial moisture content was below 5% and showed minimal change during storage. Certain differences were observed in water uptake and carbamazepine dissolution rates, with formulations containing larger proportions of sugar diluents demonstrating faster hydration and drug release, as well as softer and smoother texture. At the same time, their moisture content remained stable over the storage period.

These findings suggest that pulp-spoon formulations are simple to prepare, even in a compounding pharmacy setting, and represent a promising patient-friendly dosage form for pediatric drug delivery.

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