

ANALIZA ZASTUPLJENOSTI I SASTAVA ORALNO-DISPERZIBILNIH TABLETA DOSTUPNIH NA TRŽIŠTU ZEMALJA EVROPE

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Oralno-disperzibilne tablete (ODT) predstavljaju relativno nove čvrste farmaceutske oblike koji se brzo raspadaju u usnoj duplji, bez dodatka vode (1). Cilj ovog istraživanja bio je da se analiziraju ODT preparati dostupni na tržištu evropskih zemalja (Nemačka, Španija, Slovenija, Hrvatska, Srbija). Istraživanje je zasnovano na pretrazi komercijalno dostupnih ODT-a i njihovog sastava. Utvrđeno je da je u Nemačkoj dostupno 563 preparata tipa ODT (28 različitih lekovitih supstanci), dok je u Srbiji prisutno samo 19 ODT-a (8 različitih lekovitih supstanci). Većina ODT preparata sadrži lekovite supstance iz grupe antipsihotika (26,6–54,2%), najčešće olanzapin, što se može objasniti boljim prihvatanjem terapije. Izuzetak je Španija, gde su ODT sa antimigrenicima najčešće (22,3%), verovatno usled lakše primene i gutanja ODT preparata (1,2). Analizom sastava ODT-a primećeno je da se kombinacija manitol-mikrokristalna celuloza najčešće dodaje kao sredstvo za dopunjavanje (69,1%). Brza dezintegracija, kao kritično svojstvo kvaliteta ODT-a, postiže se različitim pristupima. Većina preparata (66,0%) sadrži krosповidon kao superdezintegrator. Prijatan ukus ODT obezbeđen je kombinovanjem zaslađivača i aroma. Aspartam je veoma zastupljen u preparatima (74,2%), i do devet puta češće od ostalih zaslađivača. Veća razlika među preparatima uočena je u slučaju aroma: komercijalno dostupne ODT sadržale su aromu pepermintna (39,2%), pomorandže (20,6%), itd. Međutim, 17,5% ODT nije sadržalo aromu, što ukazuje da je prijatan ukus postignut pomoću sredstva za dopunjavanje i zaslađivača (npr. manitol, saharoza). Veliki broj komercijalno dostupnih ODT preparata ukazuje na prednosti za pacijente, posebno u slučaju psihijatrijskih bolesti i migrene. Tipičan predstavnik ODT preparata na tržištu sadrži manitol-mikrokristalnu celulozu, krosповidon, aspartam i aromu.

Literatura

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AN INVESTIGATION INTO REPRESENTATION AND COMPOSITION OF COMMERCIALY AVAILABLE ORODISPERSIBLE TABLETS ON THE MARKET OF EUROPEAN COUNTRIES

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Orodispersible tablets (ODTs) are relatively new solid dosage forms that disintegrate rapidly in the oral cavity, without the addition of water (1). The aim of this research was to analyze ODTs available on the market in representative European countries (Germany, Spain, Slovenia, Croatia, Serbia). The research was based on investigation of commercially available ODTs and their composition. In Germany, 563 ODT products are available (28 different active ingredients), while only 19 ODTs are present in Serbia (8 different active ingredients). The majority of ODTs contain antipsychotic drugs (26.6–54.2%), particularly olanzapine, presumably due to better patient compliance. The only exception is Spain, where antimigraine ODTs are the most frequent (22.3%), which may be attributed to easier administration and swallowing (1,2). Regarding ODT composition, the mannitol-microcrystalline cellulose combination was mostly used as a filler/diluent (69.1%). Fast disintegration, as ODT critical quality attribute, is achieved by different approaches. Crospovidone was found in the majority of formulations (66.0%). In order to ensure a pleasant taste, sweeteners and flavors are combined. Aspartame was present up to nine times more than other sweeteners (74.2%). More flexibility was observed regarding flavoring and ODTs contained peppermint (39.2%), orange (20.6%), etc. However, 17.5% of products contained no flavoring, indicating that pleasant taste was achieved by fillers and sweeteners, e.g., mannitol and sucrose. The high number of ODTs available on the market indicates the advantages for patients, particularly in the case of psychiatric diseases and migraine. A typical ODT product contains mannitol-microcrystalline cellulose, crospovidone, aspartame and a flavor.

References

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