SADRŽAJ RETINIL-PALMITATA I BETA-KAROTENA U TEČNIM FARMACEUTSKIM OBLICIMA ZA PERORALNU UPOTREBU

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Retinil-palmitat je sintetski oblik vitamina A, dok je beta-karoten njegov provitamin i često se koriste u dijetetskim suplementima namenjenim deci i odraslima zbog fizioloških uloga koje ostvaruju u organizmu. U tečnim farmaceutskim oblicima za peroralnu upotrebu, prisutni su zajedno sa drugim aktivnim supstancama i ekscipijensima što čini njihovu analizu složenom (1). Cilj ovog rada bio je razvijanje postupka pripreme uzoraka za simultanu HPLC analizu ova dva biološki aktivna jedinjenja u farmaceutskim oblicima tipa sirupa. Hromatografsko razdvajanje je urađeno na Restek Ultra IBD C18 koloni na 30°C. Mobilna faza se sastojala od smeše rastvarača acetonitril:dihlormetan:metanol=7:2:1 (v/v/v) u izokratskom režimu rada. UV detekcija je izvedena na 325 nm za retinil-palmitat i 455 nm za beza-karoten. Uzorci su pripremljeni ekstrakcijom na čvrstoj fazi na kertridžu HR-P (Marcherey-Nagel). Razvijena metoda ekstrakcije i izabrani HPLC uslovi omogućili su dobro razdvajanje retinil-palmitata i beta-karotena i njihovo selektivno određivanje bez interferencija ekscipijenasa. Srednje retenciono vreme retinil-palmitata bilo je 5.50±0.05 min, dok je za beta-karoten bilo 5.06±0.03 min što ukazuje na mogućnost analize uzoraka za veoma kratko vreme. Dve vrste farmaceutskih oblika sirupa su analizirane: multivitaminski sirup za decu i sirup za pušače. Drugi uzorak je sadržao i retinil-palmitat i beta-karoten, dok sirup za decu nije sadržao beta-karoten. Nađeni sadržaj retinil-palmitata i beta-karotena u sirupu za pušače bio je 3.1±0.03 mg/100 mL i 2.3±0.08 mg/100 mL. Sadržaj retinil-palmitata u sirupu za decu bio je 4.45±0.27 mg/100 mL. Za oba analizirana uzoraka nađene koncentracije ova dva vitamina odgovarale su deklarisanom sadržaju od strane proizvođača.

Literatura

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RETINYL-PALMITATE AND BETA-CAROTENE CONTENT IN LIQUID ORAL PHARMACEUTICAL DOSAGE FORMS

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Retinyl-palmitate (RP) is a synthetic form of vitamin A while beta-carotene (BC) has provitamin A activity. They are often used in dietary supplements for children and adults because of their physiological roles in the humans. The presence of other active substances and excipients are making their analysis more complex (1). The aim of this research was to develop a sample preparation procedure for simultaneous HPLC determination of these two bioactive compounds in pharmaceutical syrups. Chromatographic separation was performed on the Restek Ultra IBD C18 column at 30°C. The mobile phase consisted of acetonitrile:dichloromethane:methanol=7:2:1 (v/v/v) in isocratic mode. UV detection was conducted at 325 nm for RP and 455 nm for BC. Samples were prepared by using solid-phase extraction on a cartridge type HR-P (Macherey-Nagel). The developed extraction method and selected HPLC conditions enabled selective determination without interferences from the excipients. The mean retention time of retinyl-palmitate was 5.50±0.05 min, while for beta-carotene it was 5.06±0.03 min, which indicates that the samples can be analyzed in a very short time. Multivitamin syrup for children and syrup for smokers were analyzed. The latter contains both retinyl-palmitate and beta-carotene, while the syrup for children does not contain beta-carotene. The found contents of RP and BC in syrup for smokers were 3.1±0.03 mg/100 mL and 2.3±0.08 mg/100 mL respectively. The content of RP in syrup for kids was found to be 4.45±0.27 mg/100 mL. For both analyzed pharmaceutical syrups, the found concentration of these two vitamins corresponded to the content declared by the manufacturers.

References

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