DETERMINATION OF ADEQUATE "OVERAGE" IN THE FORMULATION OF VITAMIN D3 CAPSULES IN DIETARY SUPPLEMENTS

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Many manufacturers of dietary supplements formulate products so that they contain excess nutrients, the so-called “overage” compared to the declared content, in order to compensate for losses due to nutrient degradation during shelf life, and to compensate for the variability of the production process and testing methods (1). For vitamins overage ranges up to + 50%. In order to reduce "overage", having in mind that it is a liposoluble vitamin in a high dose, in the formulation we decided to use powdered vitamin D3 active substance, and the formulation of white hard gelatin capsules in PVC blisters. The content of vitamin D3 by HPLC was analyzed after the production of hard gelatin capsules with a declared 2000 IU (50 mcg), with an overage of 15%, as well as the content after one year of storage at room temperature (finished product warehouse with a temperature of 18-25 ° C and moisture up to 65 RH). The results of the content analysis showed that there was no high percentage of degradation after one year of storage under the stated conditions (half the shelf life of the product). Our results therefore question the need for a high percentage of "overage" for products with vitamin D3 content greater than 2000 IU within the production formula, suggesting that product stability over time can be preserved by proper excipient selection, encapsulation method, use of opaque, white gelatin capsules, even in an aluminum-PVC blister. Certainly, the content analysis should be performed after the expiration date.

References

1. Seong Jae Yoo, Steven L. Walfish. Factors to consider in setting adequate overages of vitamins and minerals in dietary supplements. Pharmacopeial Forum. January 2016

ODREĐIVANJE ADEKVATNOG "OVERAGE-A" U FORMULISANJU KAPSULA VITAMINA D3 U DIJETETSKIM SUPLEMENTIMA

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Mnogi proizvođači dijetetskih suplemenata formulišu proizvode tako da sadrže nutrijente u višku, tzv. "overage" u odnosu na deklarisan sadržaj, kako bi kompenzovali gubitke usled degradacije u toku roka trajanja, i kako bi kompenzovali varijabilnost proizvodnog procesa i metode testiranja (1). Za vitamine overage kreće se i do +50%. U cilju smanjenja "overage-a", imajući u vidu da se radi o liposolubilnom vitaminu u već visokoj dozi, u formulisanju odlučili smo se za korišćenje praškaste vitamin D3 aktivne supstance, i formulisanju tvrdih želatinskih kapsula bele boje u PVC blisteru. Analiziran je sadržaj D3 vitamina HPLC metodom nakon proizvodnje tvrdih želatinskih kapsula sa deklarisanih 2000 IU (50 mcg), uz overage 15%, kao i sadržaj nakon godinu dana čuvanja na sobnoj temperaturi (magacin gotovih proizvoda sa režimom temperature od 18-25°C i vlage do 65 RH). Rezultati analize sadržaja pokazali su da nije bilo visokog procenta degradacije nakon godinu dana skladištenja pod navedenim uslovima (polovina roka trajanja proizvoda). Naši rezultati stoga preispituju nužnost visokog procenta "overage-a" za proizvode sa sadržajem D3 vitamina većim od 2000 IU u okviru proizvodne formule sugerišući da stabilnost proizvoda u roku trajanja može biti očuvana pravilnim odabirom ekscipijenasa, metodom kapsuliranja, upotrebom neprovidnih, belih želatinskih kapsula, čak i u alu-PVC blisteru. Svakako se analiza sadržaja treba izvršiti i po isteku roka trajanja.

Literatura

1. Seong Jae Yoo, Steven L. Walfish. Factors to consider in setting adequate overages of vitamins and minerals in dietary supplements. Pharmacopeial Forum. Januar 2016.