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Annals of Medicine

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/iann20

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To cite this article: Carla Ferreira, Alexandra Figueiredo, Guilhermina Moutinho, Maria D. Auxtero, Isabel Margarida Costa & Alexandre Quintas (2021) Improving methodology to determine vitamin D_3 in food supplements, Annals of Medicine, 53:sup1, S78-S78, DOI: 10.1080/07853890.2021.1897427

To link to this article: https://doi.org/10.1080/07853890.2021.1897427

Published online: 28 Sep 2021.

Improving methodology to determine vitamin D_3 in food supplements

Carla Ferreira[a,b], Alexandra Figueiredo[c], Guilhermina Moutinho[c], Maria D. Auxtero[c], Isabel Margarida Costa[c] and Alexandre Quintas[a,b]

[a]Laboratório de Ciências Forenses e Psicológicas Egas Moniz, Centro de Investigação Interdisciplinar Egas Moniz (CiiEM), Egas Moniz Cooperativa de Ensino Superior, Caparica, Portugal; [b]Molecular Pathology and Forensic Biochemistry laboratory, Centro de Investigação Interdisciplinar Egas Moniz (CiiEM), Egas Moniz Cooperativa de Ensino Superior, Caparica, Portugal; [c]PharmSci Lab, Centro de Investigação Interdisciplinar Egas Moniz (CiiEM), Egas Moniz Cooperativa de Ensino Superior, Caparica, Portugal

ABSTRACT

Introduction: Nowadays, there is a trend to enrich food and food supplements (FS) with Vitamin D_3. Economic operators who places FS on the market does not have to perform running safety trials, but only to comply with the food safety regulations applicable in the European Union [1]. This scenario may present public health and legal issues. To overcome these challenges, it is mandatory to know accurately the amount of vitamin D_3 in FS and if it corresponds to the label value. HPLC methods are a preferential approach to determine accurately the content of vitamin D_3 in pharmaceuticals and supplements. Actually, HPLC/MS has become the technique of choice for vitamin D_3 determination in complex matrixes. Notwithstanding, this analysis must be preceded by time-consuming sample preparation. In fact, the success to measure accurately vitamin D_3 depends heavily in a reliable sample preparation. Moreover, it becomes even more critic when dealing with different formulations of vitamin D_3, such has gel pills, solid pills, liquid or cutaneous applications. There are literature validating methodology to determinate vitamin D_3 in various matrixes according to the International Conference on Harmonisation (ICH) guidelines by HPLC-UV [2]. However, this published study does not use an internal standard (IS). The internal standard is useful to improve the precision of quantitative analysis, removing the error of losing sample during sample preparation. Our aim is to test o-cresol as an internal standard to future validation the methodology.

Materials and methods: Vit D_3 present in FS was analysed by HPLC/DAD. Sample was spiked with internal standard (*o*-cresol) and liquid extraction coupled to an ultrasound bath was used has an extraction procedure. After a centrifuged step the supernatant was filtered. The separation was performed using a C18 column with a solvent gradient consisted in (A) 0.1% formic acid and (B) acetonitrile. The acquisition was performed on DAD-detector at 265 nm.

Results: Figure 1 shows a chromatogram of a FS containing Vit D_3. Two major peaks are present, corresponding to *o*-cresol (RT 5.45 min) and Vit D_3 (RT 11.20 min).

Discussion and conclusions: The results show the capacity of the chromatographic method to separate and resolve the two chromatographic peaks. These preliminary results show that o-cresol can be used as an internal standard to determine Vit D3 in FS, normalising the loss of Vit D3 during preparation step. Since in Europe and USA, the association of vitD toxicity with the use of FS has been described, this methodology will be useful to confirm the VitD composition stated on the label.

CONTACT Alexandre Quintas alexandre.quintas@gmail.com

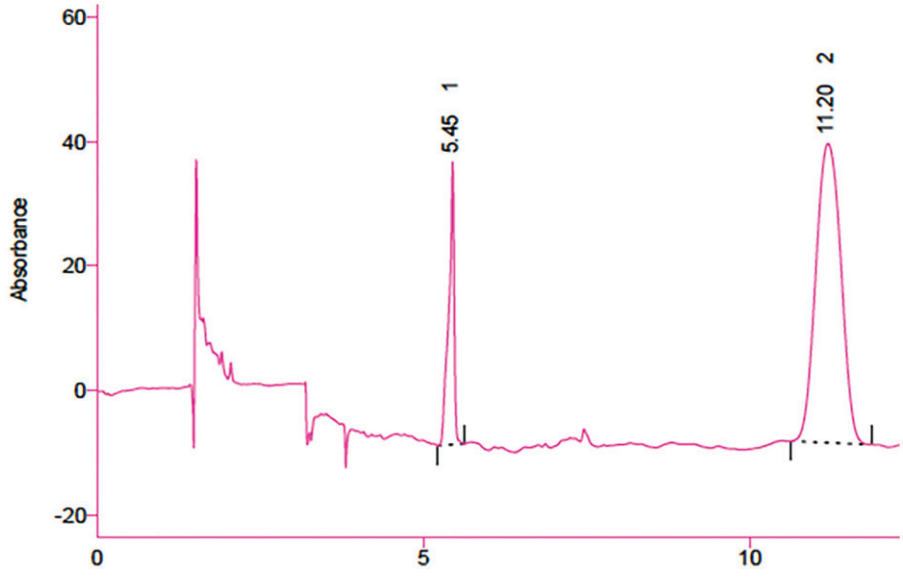

Figure 1. HPLC/DAD chromatogram of FD with IS (RT = 5.45 min) and Vit D_3 (tr = 11.20 min).

Acknowledgements

This study was funded by Cooperativa de Ensino Superior Egas Moniz.

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DOI: 10.1080/07853890.2021.1897427

Information System for Tablets Identification (ISTI)

M. E. Torres[a,b], A. Figueiredo[a,c], C. Família[a,b], I. M. Costa[a,c], D. P. Tavares[a] and A. Quintas[a,b]

[a]Centro de Investigação Interdisciplinar Egas Moniz (CiiEM), Egas Moniz Cooperativa de Ensino Superior, Monte de Caparica, Caparica, Portugal; [b]Laboratório de Ciências Forenses e Psicológicas Egas Moniz, Centro de Investigação Interdisciplinar Egas Moniz (CiiEM), Egas Moniz Cooperativa de Ensino Superior, Caparica, Portugal; [c]PharmSci Lab – Innovative Solutions in Pharmaceutical Sciences, Centro de Investigação Interdisciplinar Egas Moniz (CiiEM), Egas Moniz Cooperativa de Ensino Superior, Caparica (CiiEM), Caparica, Portugal

ABSTRACT

Introduction: This study aims to develop a software application (App) for the identification of drugs of abuse from visual information retrieved from pills: Information System for Tablets Identification (ISTI). The consumption of anxiolytics and hypnotics, in particular, benzodiazepines (BZD) and similar products, as reached record levels in Portugal, with 10.5 million packages of these products being sold in 2018 [1]. The high prescription of BZD presents a risk to public health [2,3]. An Information system like ISTI will provide an enormous importance on pills' identification at crime scenes (e.g. homicidal attempts) or premeditated intoxications [4,5].

Materials and methods: Tablets from benzodiazepine derivates (ATC codes: N05BA; national pharmacotherapeutic classification: 2.9.1. Anxiolytic, sedatives and hypnotics) were purchased from portuguese pharmacies.

In the database were introduced the commercial name, the active substance name, the dose and also photographs were taken from the front, back and side and several physical characteristics of each pill were determined, namely: shape, surface elevation, logo and imprint description, break line, colour, coating, diameter, thickness, weight, horizontal, vertical and side view.

The ISTI core is an identification algorithm targeted to matching results by score. The application is being prepared in a way that can either be accessed from a computer or from a mobile device. If economically viable, an image search and request by the users algorithm will be included, so that a photo can be an input, in a query which may prove particularly important to field in the future work. Furthermore, the system is being designed to be easily maintained, through a simple backoffice, and if necessary, agreements will be proposed to national regulatory authorities in order to assure that its data is effectively up to date.

Results: The prototype developed application allows us to identify pills that may possibly be lost or out of their original packaging. This identification is made through a wide range of tablet features. The person who wants to identify a pill can access the ISTI and through answers to simple questions can find correspondence with the concerning tablet.

Discussion and conclusions: The purpose of ISTI is to help health technicians, like doctors, nurses and pharmacists, and agents of authority to identify medicines pills which are not inside the original packaging. Although in the USA there are several Apps with the same objective, to the best of the authors knowledge, ISTI is the first App with this purpose in Portugal.

CONTACT M. E. Torres etorres@egasmoniz.edu.pt

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