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Editor

Prof. Dr Snežana Šerbula

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EFFICIENT DETERMINATION OF UNDECYLENIC ACID CONTENT IN PHARMACEUTICAL PRODUCTS: A NOVEL SIMPLE APPROACH

EFIKASNO ODREĐIVANJE SADRŽAJA UNDECILENSKE KISELINE U FARMACEUTSKIM PREPARATIMA: NOVI, JEDNOSTAVAN PRISTUP

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Abstract

Undecylenic acid (UDA), a medium-chain fatty acid industrially derived from castor oil, naturally occurs in black elderberry. UDA has attracted significant attention due to diverse applications in pharmaceutical formulations, particularly as a topical antifungal agent. Recent research has even hinted potential role of UDA in inducing apoptosis in tumor cells, further elevating its importance in therapeutic contexts.

The primary objective of this study was to design a rapid and straightforward analytical method for determining UDA content in commercially available preparations. The presence of a terminal double bond in UDA enables it to undergo addition reactions, rendering it an invaluable tool for quantifying UDA concentration in commercial products.

In pursuit of this objective, a commercially available liquid preparation, sourced from a U.S.A. manufacturer (AS), was employed as the UDA test sample. This preparation represented a binary mixture of UDA and isopropyl palmitate. Its precise qualitative composition was confirmed by GC-MS analysis subsequent to sample derivatization, in accordance with the ISO 12966-2:2017 procedure. A novel approach for determining UDA content in pharmaceutical preparations was established, drawing upon the ISO 3961:2018 standard method for determining the iodine value of fats and oils. Initially, the density of the AS sample was determined using the pycnometer method. Then, the prescribed AS mass was dissolved in *n*-hexane, and a reaction mixture was prepared by introducing 25.00 mL of iodine monochloride (ICI) solution in glacial acetic acid. Ultrasonic sonication facilitated the reaction at room temperature for 10 minutes. Subsequently, a 10% potassium iodide solution was introduced, and the liberated iodine was titrated using a standard solution of sodium thiosulfate. A blank test (without AS) was concurrently conducted applying the same procedure.

The results of this innovative method showcased a calculated mass/volume concentration of UDA in the tested sample at 25.1% (n=5). This finding closely aligned with results obtained utilizing the European Pharmacopoeia method for UDA assay determination, which yielded a UDA concentration in AS of 25.2% (n=5). This robust correlation underscores the efficacy of the new method for rapid and uncomplicated determination of UDA content in commercial pharmaceutical products devoid of auxiliary substances, which chemically react with the halogenating reagent, ICl [7]. The novel advantage of this method (over conventional chromatographic techniques) lies in its economic accessibility. Eschewing the necessity for analytical instruments, complex sample derivatization, or the procurement of expensive certified reference materials, this method offers a cost-effective solution without compromising accuracy.

In conclusion, the rapidity and simplicity of this innovative method render it as viable option for routine UDA content determination in pharmaceutical preparations. However further research, involving a broader spectrum of pharmaceutical products containing UDA, is mandatory to fully explore the applicability of this technique in routine analytical practice.

Keywords: undecylenic acid, antifungal agent, pharmaceutical analysis, volumetric technique, rapid determination

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