

Is cheap Vitamin K₂ legal in EU?

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The vitamin category—and vitamin D₃ and K₂ market in particular—is a very lucrative slice of the pie over which the largest players fiercely compete. Unfortunately, analysis of marketplace products shows that not everyone is playing fair.

Quality control of vitamin K₂

Menaquinone-7 (MK-7) is a mixture of isomers, where only the trans isomer has significant biological activity. Isomerization of the vitamin can occur during production, regardless of whether it is produced by synthetic or biotechnological methods, therefore obtaining raw material 100% "all-trans" MK-7 is difficult to achieve.

Currently, the most common method of MK-7 quality control is that contained in the USP monograph⁽²⁾. The method, developed in 2010–2012, reflected the early state of technical knowledge on the purity of vitamin K₂ at that time. Significant progress was made in this field over the following years, largely thanks to the work of Polish scientists from the Pharmaceutical Institute, led by Dr. Łukasz Jedynak, who presented a new methodology for verification of assay and purity of vitamin K₂. The method⁽³⁾ allowed for a significantly greater determination of impurities than the USP method, "handling", so to speak, the *residual impurities* parameter that is missing in USP.

Raw materials tested by the USP method may have an overestimated assay of *trans* MK-7, and simultaneously an underestimated total of residual impurities in the production process. What's more, the USP method of determining isomeric purity imposes only one acceptance criterion (*cis* isomer content), causing many manufacturers to ignore the more important assessment related to consumers' health and the novel food authorization criteria: a safe limit of unknown impurities.

Market reality

"The vitamin category, particularly vitamin D₃ and K₂ market, is a very lucrative slice of the pie, over which the largest players fiercely compete. A large part of the market is made up of products presented in the form of drops and twist-off capsules aimed at the

elderly and children. Unfortunately, analysis of marketplace products shows that not everyone is playing fair". High sales increase the temptation to save costs, even at the expense of consumer's safety. Lab results reveal samples failing to meet Novel food criteria, with unknown impurities as high as double digits. What does this mean for the consumers? It means that each dose (usually 100mcg) serves an additionally significant portion of post-process contaminants to unaware consumers, and contrary to the law, is not disclosed on the supplement label. In result consumers purchasing vitamin K₂ products are misled and their purchasing decisions are not fully informed choices.

A tightly-knit duo

Manufacturers who expect a finished product of the highest quality should choose their raw material from a supplier strictly compliant with the latest and most sensitive quality control methods. One such supplier is Vitasynth sp. z o.o. of Warsaw, a provider that has managed to expand on Dr Jedynak's methodology, adopting it for oil vit. K₂ dilutions used for the production of soft capsules and drops, as well as powder dilutions for the production of tablets, sachets and hard capsules. The raw material under the Pharmaquinone® brand is offered on perfectly inert MCT and MCC carriers giving a perfectly pure HPLC image. All the above-mentioned finished forms containing vitamin K₂ can be best produced in a private label format in cooperation with the sister company Europharma Alliance, which has extensive experience and a modern production plant near Wrocław.

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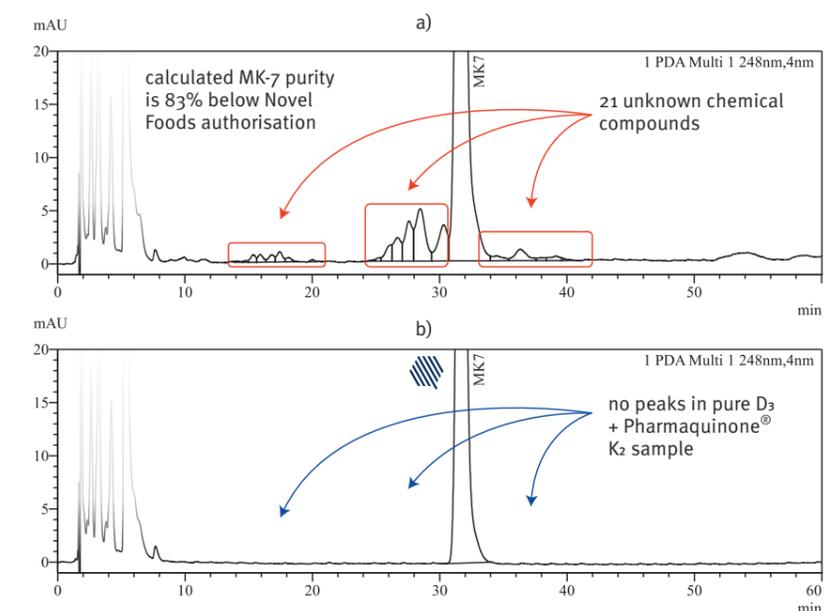


Figure 1 Product comparison: a) Chromatogram of a sample of a leading brand taken from the market (product with D₃ and K₂-MK7), showing 21 additional, unknown impurities, and b) a correct sample of D₃ and Pharmaquinone® K₂-MK7 reference product

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