

Product Specification: Vitaquinone 0.2% MCC Powder

Ref. no. SPK/KJ/020

Rev. 01

Date: 14.04.2025

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Vitaquinone

Product name: Vitaquinone® 0.2% MCC Powder, Vitamin K2 as MK-7

SKU code: V020P

Active Ingredient: Menaquinone-7 (MK-7)

Carrier: MCC Powder

CAS number: Menaquinone-7 2124-57-4

MCT oil 73398-61-5

MCC powder 9004-34-6

General information: Synthetic, **solvent free Vitamin K2 as all-trans MK-7*** diluted in oil solution and deposited on the microcrystalline cellulose for use in food and dietary supplements

Country of origin: Poland

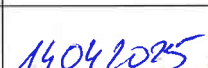
Shelf-life 36 months from manufacture

Storage conditions: The product should be stored at temperature 15-25 °C/59-77 °F, in a dry place. Protect from light.

After opening, store in the original closed container.

Packaging: 1 kg (V020P1) or 5 kg (V020P5) of the product in doypack with zipper bag

* Vitaquinone 99 % Active Ingredient, Vitamin K2 as MK-7, according to SPK/KJ/019.

	Prepared by	Approved by
Position:	QA/QC Director	Production Director
Name:	Agata Pundyk	Andrzej Krukowski
Signature & Date:	 14.04.2025	 14.04.2025

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TESTS	REQUIREMENTS	METHOD
Description	Off-white powder	Visual assessment
Identification		
HPLC	Corresponds to the standard HPLC profile	UPLC method */USP method** ANL/KJ/010
Vitamin K2 (as all-trans MK7) assay	> 0.20 % or > 2000 ppm	UPLC method */USP method** ANL/KJ/010
Limit of Menaquinone-6	Absent	UPLC method */USP method** ANL/KJ/010
Related substances		
Single unknown impurity	≤ 1.0 %	UPLC method * ANL/KJ/010
Total impurities	≤ 1.5 %	
Isomeric purity		
Content of cis-menaquinone-7	≤ 1.0 %	USP method** ANL/KJ/010
Particle size	> 90 % passes through 40 mesh	PB-264 rev.1*
Bulk density	0.30–0.55 g/ml	Ph. Eur. <2.9.34> / USP <616>
Loss on drying	≤ 5.0 %	Ph. Eur. <2.2.32> / USP <731>
Metal content		
Arsenic	≤ 0.5 ppm	
Cadmium	≤ 0.3 ppm	PN-EN-15763:2010
Lead	≤ 0.5 ppm	
Mercury	≤ 0.1 ppm	
Microbiological parameters		
TAMC in 1g	≤ 1 x 10 ³ CFU	Ph. Eur. <2.6.12> / USP <2021>
TYMC in 1g	≤ 1 x 10 ² CFU	Ph. Eur. <2.6.12> / USP <2021>
E. Coli in 1g	Absent	Ph. Eur. <2.6.13> / USP <2022>
Salmonella in 25 g	Absent	Ph. Eur. <2.6.13> / USP <2022>
Staphylococcus aureus in 1g	Absent	Ph. Eur. <2.6.13> / USP <2022>
Bile tolerant gram-negative bacteria in 1g ***	≤ 1 x 10 ² CFU	Ph. Eur. <2.6.13> / USP <2021>

* in-house method

** in accordance with Dietary Supplement Monograph, Menaquinone-7 Preparation, USP-NF

*** bile tolerant gram-negative bacteria include *Enterobacteriaceae*, *Pseudomonas* and *Aeromonas*

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