



Pharmaquinone

1. Characteristics:

1.1 Product name:

Pharmaquinone® 1% MCT Oil
Vitamin K2 as MK-7

1.2 SKU code: 100L

1.3 Chemical name:

Menaquinone-7 (MK-7)

1.4 Common name:

Vitamin K2

1.5 Carrier:

MCT Oil

1.6 General product information:

Synthetic vitamin K2 diluted in oil solution for use in food and dietary supplements

1.7 Country of origin : Poland

2. Shelf-life:

30 months from manufacture

3. Storage conditions:

The packed Product should be stored in temperature 5-25 °C and humidity 30-50%. Protect from the light.

4. Packaging:

1 kg or 5 kg of Product in aluminium bottle with tamper evident PP screw cap closure with foam/aluminium liner and LDPE plug.

Product Specification

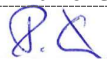
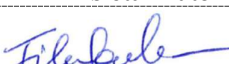
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5. Requirements:		
Tests	Requirements	Method
5.1 Appearance	Light yellow to yellow oil	Visual assessment
5.2 Identification	Corresponds to the standard HPLC profile	UPLC method* / USP <621>
5.3 Total Vitamin K2 as MK-7 (as-is)	> 1.00% or > 10 000 ppm	UPLC method*
5.4 Related substances		UPLC method*
Total impurities	Not more than 1.50%	
5.5 Total Vitamin K2 as MK-7 (as-is)	> 1.00% or > 10 000 ppm	USP <621>
5.6 Isomeric purity		USP <621>
Content of cis-menaquinone-7	≤ 1.50%	
5.7 Density (in 20°C)	0.944 +/- 1.5% g/ml	PN-EN ISO 6883:2017-03
5.8 Water solubility	Insoluble	Ph. Eur. <General Notices> / USP <General Notices>
5.9 Weight tolerance limit	Not less than 100% of the declared weight	Each unit container is weighed Sampling/emptying allowance is added to each unit container
5.10 Uniformity of mix	All samples must pass assay test (5.3)	$\sqrt{n} + 1$ unit containers are drawn from each production batch
5.11 Heavy metals		
Arsenic***	≤ 0.5 ppm	Ph. Eur. <2.2.58> / USP <233>
Cadmium***	≤ 0.3 ppm	Ph. Eur. <2.2.58> / USP <233>
Lead***	≤ 0.5 ppm	Ph. Eur. <2.2.58> / USP <233>
Mercury***	≤ 0.1 ppm	Ph. Eur. <2.2.58> / USP <233>
5.12 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>
6. Related documents:		
- *<A novel method for the determination of chemical purity and assay of menaquinone-7. Comparison with the methods from the official USP monograph> by Jedynek et al.		
- P-23.00.00 "Procedure for the release of raw materials, semi-finished products, packaging and finished products"		
- I-23.01.00 "Sampling of raw materials and semi-finished products"		
- P-25.00.00 "Testing of raw materials, semi-finished products and finished products"		
** BILE TOLERANT GRAM NEGATIVE BACTERIA INCLUDE ENTEROBACTERIACEAE, PSEUDOMONAS AND AEROMONAS		
*** EVERY THIRD BATCH IS TESTED		

Validation workflow		
	Prepared by	Approved by
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Signature & Date:	 01.04.2021	 01.04.2021

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