

MenaQ7 PharmaPure MCT Oil

Product Specification

MenaQ7
Vitamin K2 as MK-7

Doc.: SPC-NP-0299-20202-01 Rev. 3

MenaQ7 PharmaPure is a high purity, nature identical, all-*trans*, vitamin K2 as MK-7 derived by synthesis.

Regulatory Compliance

EFSA: Novel Food
FDA: SaGRAS

Product description

Product name	MenaQ7 PharmaPure 1500 ppm MCT Oil	
Item code	NP-0299-20202	
Content vitamin K2	1500 mcg K2 as MK-7/g.	
Packaging	Material packed in food grade aluminium bottles with tamper evident sealing.	
Contaminants	Aflatoxins comply with cUSP/cEP	Pesticides comply with cUSP/cEP
Product characteristics	Colorless to pale yellow oil	Insoluble in water

Shelf life, storage and handling

Shelf life	Best before 30 months from manufacturing date if unopened and kept in correct storage conditions	
Light sensitivity	The product is very light sensitive and exposure may deteriorate K2 activity	
Storage temperature	Keep in original sealed container	Temperature 5 - 25°/41 - 77°F 30 - 50% relative humidity

Parameters to be tested and reported on COAs

Parameters	Specification	Unit	Procedure	Test frequency
Identity	To match standard HPLC Profile	ppm	HPLC	Every batch
Total Vitamin K2	≥ 1500	ppm	HPLC	Every batch
Lead (Pb)	≤ 0,5	ppm	cUSP/cEP	Every third batch
Mercury (Hg)	≤ 0,1	ppm	cUSP/cEP	Every third batch
Cadmium (Cd)	≤ 0,3	ppm	cUSP/cEP	Every third batch
Arsenic (As)	≤ 0,5	ppm	cUSP/cEP	Every third batch
Total aerobic microbial count	≤ 10 ⁵	cfu/g	cUSP/cEP	Every batch
Total combined mold and yeast	≤ 10 ²	cfu/g	cUSP/cEP	Every batch
<i>Escherichia coli</i>	Absent in 1	g	cUSP/cEP	Every batch
<i>Salmonella spp.</i>	Absent in 10	g	cUSP/cEP	Every batch
<i>Staphylococcus aureus</i>	Absent in 1	g	cUSP/cEP	Every batch
<i>Bile-tolerant gram-negative bacteria</i> *	≤ 10 ²	cfu/g	cUSP/cEP	Every batch

**Bile-tolerant gram-negative bacteria* include members of the family *Enterobacteriaceae*, *Pseudomonads* and *Aeromonas*.