

# MenaQ7 PharmaPure MCC Powder

## Product Specification



Doc.: SPC-NP-0299-10103-01 Rev. 3

A nature identical, high purity, all-*trans* vitamin K2 as MK-7 free from known allergens.

### Regulatory Compliance

EFSA: Novel Food  
FDA: SaGRAS

### Product description

Product name	MenaQ7 PharmaPure 2000 ppm MCC Powder		
Item code	NP-0299-10103		
Content vitamin K2	2000 mcg K2/g		
Packaging	Aluminium laminated bags with inner liners		
Contaminants	Aflatoxins comply with cUSP/cEP	Pesticides comply with cUSP/cEP	
Product characteristics	White to pale yellow powder	Insoluble in water	
	Typical particle size is 100 % through 40 mesh	Typical bulk density is 0.3 - 0.55 g/cm <sup>3</sup>	

### 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	Keep in original sealed container	Temperature: 5 - 25°C/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	≥ 2000	ppm	HPLC	Every batch
Loss on drying	≤ 8	%	105°C/4hr	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 <sub>203</sub> )	≤ 0,5	ppm	cUSP/cEP	Every third batch
Total aerobic microbial count	≤ 10 <sup>5</sup>	cfu/g	cUSP/cEP	Every batch
Total combined mold and yeast	≤ 10 <sup>2</sup>	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 <sup>2</sup>	cfu/g	cUSP/cEP	Every batch

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