# MenaQ7 PharmaPure MCC Powder



# **Product Specification**

Updated 29.10.18

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 10,000 ppm MCC Powder

Item codeNP-0299-10104Content vitamin K210,000 mcg K2/g

Packaging 1 kg or 5 kg - aluminium laminated bags with inner liners

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	≥ 10,000	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)	≤ 0,5	ppm	cUSP/cEP	Every third batch
Total aerobic microbial count	≤ 10³	cfu/g	cUSP/cEP	Every batch
Total combined mold and yeast	≤ 10²	cfu/g	cUSP/cEP	Every batch
Escherichia coli	Absent in 1	g	cUSP/cEP	Every batch
Salmonella spp.	Absent in 10	g	cUSP/cEP	Every batch
Staphylococcus aureus	Absent in 1	g	cUSP/cEP	Every batch
Bile-tolerant gram-negative bacteria*	≤ 10²	cfu/g	cUSP/cEP	Every batch

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

