

## Vitamin K2 as MK-7 (10000 ppm)-W Menaquinone-7 USP grade

**vitaMK7®**

### PRODUCT SPECIFICATIONS

Code: 0-V18

Ed. 006

Date: 03/07/2019

Carrier: Maltodextrins

#### TESTS

#### SPECIFICATIONS

#### ANALYTICAL METHOD REFERENCE

Description

Light yellowish powder

MK-7 Identification (HPLC)

Positive

USP &lt;621&gt; / GN VK-001

Vitamin K2 (*all-trans* MK-7) assay (HPLC)  
(calculated with reference to the dried substance)

≥ 10000 µg/g

USP &lt;621&gt; / GN VK-001

Purity

- MK-6

≤ 1.0 %

- Cis-MK-7

≤ 1.0 %

USP &lt;621&gt;

- Single unknown impurity

≤ 1.0 %

- Total impurities

≤ 2.0 %

Loss on drying

≤ 5.0 %

Ph. Eur. 2.2.32

Heavy metals

≤ 10 ppm

Ph. Eur. 2.4.8, method C

Lead

≤ 0.5 ppm

Ph. Eur. 2.2.58 or 2.2.57 / USP &lt;233&gt;

Cadmium

≤ 0.5 ppm

Ph. Eur. 2.2.58 or 2.2.57 / USP &lt;233&gt;

Mercury

≤ 0.1 ppm

Ph. Eur. 2.2.58 / USP &lt;233&gt;

Arsenic

≤ 1.5 ppm

Ph. Eur. 2.2.58 or 2.2.57 / USP &lt;233&gt;

Bulk density

0.3 – 0.7 g/ml

Ph. Eur. 2.9.34

Microbial limits:

- Total aerobic microbial count

≤ 10<sup>3</sup> CFU/g

USP &lt;2021&gt;

- Total combined yeasts &amp; molds count

≤ 10<sup>2</sup> CFU/g

USP &lt;2021&gt;

- E. coli

Absent / 10 g

USP &lt;2022&gt;

- Salmonella Sp.

Absent / 10 g

USP &lt;2022&gt;

- S. aureus

Absent / 10 g

USP &lt;2022&gt;

#### Packing:

LDPE (low-density polyethylene) bag put inside an aluminium compound foil bag, sealed under vacuum, and placed in a suitable external container.

#### Storage conditions:

Carefully protect from light

#### Packing size:

1 kg, 5 kg, 25 Kg

#### Re-testing period:

48 months

Gnosis Spa  
Quality Management



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