Product specification - K2VITAL® 0.2% DELTA Powder

USP compliant to MK-7 preparation monograph

Product number	300005-03 (for 1 kg bags) 300006-03 (for 5 kg bags) 300007-03 (for 25 kg bags)		
Product description	Microencapsulated vitamin K2 all-trans MK-7		
Production site	BASF AS Malmparken 5 2750 Ballerup, Denmark	**Country of origin**	Denmark
Shelf-life	36 months from the date of manufacture in unopened original bags		
Storage	Room temperature, protected from light, excessive heat and moisture in unopened original bags		
Packaging	1 kg or 5 kg or 25 kg aluminium foil bags	**MK-7 CAS No.**	2124-57-4

Test	Specification	Method
Appearance	White to light yellow fine powder	Visual
Identification	To match MK-7 reference standard profile	Based on HPLC/USP MK-7 Preparation monograph
Through Mesh 20 USP (%)	>99.5 %	Sieving
Through Mesh 40 USP (%)	>85 %	Sieving
Through Mesh 100 USP (%)	<20 %	Sieving
Loss on drying	≤5 %	Gravimetric
Total all-*trans* vitamin K2 MK-7	≥0.200 % or ≥2000 ppm	Based on HPLC/USP MK-7 Preparation monograph
Cis isomer content	≤2% (area)	Based on HPLC/USP MK-7 Preparation monograph
MK-6 content	≤10% (of the labelled amount (ppm) of MK-7)	Based on HPLC/USP MK-7 Preparation monograph
Lead (Pb)*	≤0.5 µg/g	ICP-MS/ICP-OES
Cadmium (Cd)*	≤0.2 µg/g	ICP-MS/ICP-OES

Product specification - K2VITAL® 0.2% DELTA Powder

USP compliant to MK-7 preparation monograph

Test	Specification	Method
Mercury (Hg)*	≤0.05 µg/g	ICP-MS/ICP-OES
Arsenic (As)*	≤0.5 µg/g	ICP-MS/ICP-OES
Total aerobic microbial count (TAMC)	$<10^3$ cfu/g	USP/Ph.Eur.
Total yeasts and mould (TYMC)	$<10^2$ cfu/g	USP/Ph.Eur.
E. coli	Absent in 10 g	USP/ Ph. Eur.
Staphylococcus aureus	Absent in 10 g	USP/ Ph. Eur.
Salmonella sp.	Absent in 25 g	ISO6579
Pseudomonas aeruginosa	Absent in 10 g	USP/Ph.Eur.
Enterobacteria	≤100 cfu/g	Petrifilm
Residual solvents**	<0.5%	Headspace GC-FID/ Ph.Eur.
Sum 2CE/EtO*	Expressed as ethylene oxide <0.010 mg/kg	(GC-MS/MS)

** Confirmation based on random sampling*

*** Based on testing of active ingredient MK-7. No solvents are used in the production of K2VITAL® 0.2% DELTA Powder product*

Additional note

The test methods may vary from the USP monograph methods.

Disclaimer

NON-GMO Project's trademarks are registered only in the United States and Canada. Accordingly, the license agreement provides for use of the Project's trademarks in those two countries only.

Change log

Version	Description of changes	Date/ initials
11	EB specification revised to harmonize spec across Balchem portfolio (MOC-REQ-827)	24.04.2025/MSU