

CERTIFICATE OF ANALYSIS

Test	Specification	Reference Method	Results
Appearance	Clear, pale yellow oil solution	Visual	Clear, pale yellow oil solution
Identification	To match MK-7 reference standard profile	HPLC/USP38-NF33 MK-7 Preparation	Conforms
Total all-trans vitamin K2 MK-7	>5.00 %	HPLC/USP38-NF33 MK-7 preparation	5.12 %
Lead (Pb)	<3.0 µg/g	ICP-MS/ICP-OES, USP 233 or equivalent	<0.02 µg/g
Cadmium (Cd)	<1.0 µg/g	ICP-MS/ICP-OES, USP 233 or equivalent	<0.004 µg/g
Mercury (Hg)	<0.1 µg/g	ICP-MS/ICP-OES, USP 233 or equivalent	<0.01 µg/g
Arsenic (As)	<2.0 µg/g	ICP-MS/ICP-OES, USP 233 or equivalent	<0.01 µg/g
Total plate count	<10 ³ cfu/g	USP 2021/Ph. Eur. 2.6.12 or equivalent	<10 cfu/g
Total Moulds and yeasts	<10 ² cfu/g	USP 2021/Ph. Eur. 2.6.12 or equivalent	<10 cfu/g
<i>E. coli</i>	Absent in 1 g	USP 2022/Ph. Eur. 2.6.13 or equivalent	Absent in 1 g
<i>Staphylococcus aureus</i>	Absent in 1 g	USP 2022/Ph. Eur. 2.6.13 or equivalent	Absent in 1 g
<i>Salmonella sp.</i>	Absent in 10 g	USP 2022/Ph. Eur. 2.6.13 or equivalent	Absent in 10 g
Bile-tolerant gram-negative bacteria*	≤10 ² cfu/g	USP <62> or equivalent	<10 cfu/g

*includes members of the family Enterobacteriaceae, Pseudomonads and Aeromonas

CoA K2 content in Sunday- Vitamin K2 drops

Objective: Analysis of K2 (all-*trans* MK-7) content and isomeric purity
Date of analysis: 25.03.2019
Analysis Method: USP41 Menaquinone-7; Content of Menaquinone-7 Method2
 The amount of K2 (MK-7) in the material is determined by HPLC (qualified instrument Agilent 1260), with UV detection at 268 nm, using external standard calibration method. MK-7 is released from the matrix by adding THF and EtOH to the product (drops).

USP41 Menaquinone-7; Isomeric purity
 Determination of MK-7 isomeric purity by HPLC. The all-*trans* MK-7 isomer is quantified as % area of the total MK-7 peak area in the chromatogram.

Sample/Result:

Sample		
Marketer	Sunday	
Product name	Vitamin K2 MK7 100 µg 100% all-trans	
Batch no.	3948 (L02901)	
Analysis	Label claim K2 (all- <i>trans</i> MK-7/item)	Result
K2 (all- <i>trans</i> MK-7) content	100 µg/drop	Complies

Drop weight of 28 mg/drop used in the calculation (provided by manufacturer)

The investigation has shown that the product Vitamin K2 MK7 100 µg 100% all-trans/batch 3948 (L02901), with respect to content of vitamin K2 MK-7 all-*trans*, meets the product specifications given on the label.

Prepared by:

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