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**CERTIFICATE OF ANALYSIS**

# CoA K2 content in Sunday- Vitamin K2 MK7 200µg drops

**Objective:** Analysis of K2 (all-*trans* MK-7) content
**Date of analysis:** 14.02.2019

**Analysis Method:** *USP38 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).

**Sample/Result:**

| **Sample** | | |
|---|---|---|
| **Marketer** | Sunday | |
| **Product name** | Vitamin K2 MK7 200µg | |
| **Batch no.** | 3949 | |
| **Expiry** | March 2020 | |
| | | |
| **Analysis** | **Label claim K2 (all-*trans* MK-7/item)** | **Result** |
| K2 (all-*trans* MK-7) content | 200 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 200µg/batch 3949, 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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**Change History:**

| | |
|---|---|
| Version 1 (22.02.19) | First version |
| Version 2 (15.03.19) | Second version, drop weight corrected |
| Version 3 (08.05.19) | Third version, comment added |

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| 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 |
| ***E. coli*** | Absent in 1 g | USP 2022/Ph. Eur. 2.6.13 or equivalent | Absent in 1 g |
| ***Staphylococcus aureus*** | Absent in 1 g | USP 2022/Ph. Eur. 2.6.13 or equivalent | Absent in 1 g |
| ***Salmonella sp.*** | Absent in 10 g | USP 2022/Ph. Eur. 2.6.13 or equivalent | Absent in 10 g |
| **Bile-tolerant gram-negative bacteria*** | $\leq 10^2$ cfu/g | USP <62> or equivalent | <10 cfu/g |

*includes members of the family Enterobacteriaceae, Pseudomonads and Aeromonas