



VIVATIS PHARMA  
Artikel: 126735

## CERTIFICATE OF ANALYSIS

Report Date: DEC.29, 2020

Name : Coenzyme Q<sub>10</sub>  
Batch No. : 51-2012153  
Package : 5kgs/tin\*2tins/carton  
Quantity : 500kgs

Specification : USP41/ EP8.0/ JP17  
Manu. Date : DEC.22, 2020  
Expiry Date : DEC.21, 2023

ITEM	SPECIFICATION	RESULT
1. Appearance	Yellow or orange, crystalline powder	Complies
2. Identification A: IR B: Color Reaction C: HPLC	Corresponds qualitatively to the reference A blue color appears Corresponds qualitatively to the reference	Complies Positive Complies
3. Melting Point	48.0°C-52.0°C	51.0°C-52.0°C
4. Water	≤0.2%	0.02%
5. Residue on Ignition	≤0.1%	0.03%
6. Particle Size	Not less than 90% pass 80 mesh	Complies
7. Heavy Metal	≤10ppm	<10ppm
8. Arsenic	≤1ppm	Complies
9. Lead	≤1ppm	Complies
10. Mercury	≤0.1ppm	Complies
11. Cadmium	≤1ppm	Complies
12. Residue Solvents	Must comply	Complies
13. Chromatographic purity	Test 1: Sum of all impurities: ≤1.0% Test 2: Sum of all impurities: ≤1.0% Test 1 & Test 2: Sum of all impurities: ≤1.5%	0.45% 0.05% 0.50%
14. Related Substances	Single impurity: not more than 0.5% Sum of all Impurities: not more than 1.0%	Complies
15. Impurity F	≤0.5%	Complies
16. Microbial Limit Test		
(1) Standard Plate Count	≤1000cfu/g	<10cfu/g
(2) Yeast & Mold	≤50cfu/g	<10cfu/g
(3) Coliforms	≤3MPN/g	<3MPN/g
(4) E. Coli	Negative/10g	Negative
(5) Salmonella	Negative/25g	Negative
(6) S.aureus	Negative/25g	Negative
17. Content (%)	Not less than 98.0% and not more than 101.0% of C <sub>59</sub> H <sub>99</sub> O <sub>4</sub> calculated on the anhydrous basis	99.80%

**Conclusion:** Complies with the requirements of USP41/ EP8.0/ JP17.

**Storage:** Store in tightly closed original container, protected from light, in a dry place at low temperature (≤ 25°C).

All details as received from our supplier

VIVATIS PHARMA GmbH – Hamburg, 12.02.2021

The above data are no warranty in regard to the suitability of the product for a concrete purpose and do not release the user from his obligation of testing within the usual good inward inspection and the legal regulations.

Erstellt:

Geprüft: