



SHENZHEN ENZYME BIOPHARM CO., LTD.

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Enzyme Biopharm

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CERTIFICATE OF ANALYSIS

| | | | |
|------------------|--------------|-------------|-------------|
| Product Name | Coenzyme Q10 | Reference | USP2021 |
| Batch No. | LT220103 | Quantity | 304.81 kg |
| Manufacture Date | Jan.02,2022 | Retest Date | Jan.01,2025 |

| ITEMS | SPECIFICATION | | RESULTS | STANDARD |
|-----------------------|--|-------------|----------------------------------|-------------|
| Appearance | Yellow to orange yellow crystalline powder | | Orange yellow crystalline powder | Visual |
| Solubility | Soluble in ether; trichloromethane and acetone; very slightly soluble in dehydrated alcohol; practically insoluble in water | | Complies | USP |
| Identification | IR: Consistent with USP standard | | Complies | USP<197K> |
| | HPLC: Consistent with the spectrogram | | Complies | USP<621> |
| Water(KF) | ≤0.20% | | 0.08% | USP<921>IC |
| Residue on ignition | ≤0.10% | | 0.03% | USP<281>IC |
| Melting Point | 48°C-52°C | | 49.5°C-50.6°C | USP<741> |
| Particle Size | 90% pass through 80 meshes | | 95.6% pass through 80 meshes | USP<786> |
| Assay | 98.0-101.0% (on the anhydrous basis) | | 99.3% | USP<621> |
| Impurities | Procedure 1: Q7.8.9.11 related impurities: ≤1.0% | | 0.74% | USP<621> |
| | Procedure 2: isomer and related impurities: ≤1.0% | | 0.10% | USP<621> |
| | Total impurities 1+2 ≤1.5% | | 0.84% | USP<621> |
| Residual Solvents | Methanol | ≤3000 ppm | 29.2 ppm | USP<467> |
| | Ethyl alcohol | ≤5000 ppm | 64.0 ppm | USP<467> |
| | N-hexane | ≤290 ppm | 4.9 ppm | USP<467> |
| | Isopropyl ether | ≤300 ppm | Absent | USP<467> |
| Elemental Impurities | Total heavy metals | ≤10 ppm | < 10 ppm | USP<2231>II |
| | Arsenic(As) (inorganic) | ≤1.5 ppm | < 1.5 ppm | USP<2232> |
| | Cadmium(Cd) | ≤0.5 ppm | < 0.5 ppm | USP<2232> |
| | Lead(Pb) | ≤0.5 ppm | < 0.5 ppm | USP<2232> |
| | Mercury (total) | ≤1.5 ppm | < 1.5 ppm | USP<2232> |
| Microbiological Tests | Total Aerobic Microbial Count | ≤1000 cfu/g | < 10 cfu/g | USP<2021> |
| | Total Mold & Yeast Count | ≤50cfu/g | < 10 cfu/g | USP<2021> |
| | Escherichia coli | Absent /10g | No detected | USP<2022> |
| | Salmonella | Absent /25g | No detected | USP<2022> |
| | Staphylococcus aureus | Absent /25g | No detected | USP<2022> |
| Conclusion | The items inspected in this batch of product conform to the standard. | | | |
| Storage | Preserve in well-closed, light-resistant containers, not more than 25C. Keep it out of direct sunlight and away from heat source | | | |

REPORTED BY

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2022.01.08

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