



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

CHECKED BY

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2022.01.08

APPROVED BY

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2022.01.08