



VCR-24K0705

浙江圣达生物药业股份有限公司

Zhejiang Shengda Bio-Pharm Co., Ltd.

CERTIFICATE OF ANALYSIS

Product name: 1% D-Biotin

Batch number	TS1-2401003	Test No.	CP2401180
Expiry date	Jan.19.2027	Report date	Jan.28.2024
Manufacturing date	Jan.20.2024	Submitted date	Jan.23.2024
Package	25kg per carton	Batch size	10000 Kg
Ref. pharmacopoeia(s)	Q/SHY-009-03	Quantity	10000 Kg

Test Items	Method	Specification	Results
General Description		White powder,odorless	Comply
Appearance	Visual	Fine powder	Fine powder
Carrier		DCP	Comply
Loss on drying	USP<731>	≤8.0%	0.03%
ResidualSolvents(Toluene)	GC	≤890ppm	<50ppm
Heavy Metals	USP<231>	≤10ppm	<10ppm
Lead	AAS	≤2mg/kg	<0.5mg/kg
Arsenic	AAS	≤2mg/kg	<0.5mg/kg
Mercury	AAS	≤0.1mg/kg	<0.05mg/kg
Cadmium	AAS	≤1mg/kg	<0.5mg/kg
Content	HPLC	≥1.0%	1.10%
Particle size		90% pass 80 mesh	Pass
Bulk Density	USP<616>		1.22g/ml
Tapped Density	USP<616>		1.45g/ml
Total plate count	USP<2021>	<100Cfu/g	<10Cfu/g
Yeast and Mold	USP<2021>	<100Cfu/g	<10Cfu/g
Escherichia Coli	USP<2022>	Negative	Pass
Salmonella	USP<2022>	Negative	Pass



Conclusion: This batch complies with the specification of Q/SHY-009-03

Reported by: *[Signature]*

QA: *[Signature]*