

Jinlan Pharm-drugs Technology CO.LTD
Hangzhou Royall Import&Export CO.LTD

Certificate of Analysis

Product name:	Biotin	Mfg. Date:	10-MAY-2018
Batch no.:	RYVHUSP180510	Exp. Date:	09-MAY-2020
Quantities:	150kg	Package:	Drums
Molecular Wt.:	C ₁₀ H ₁₆ N ₂ O ₃ S	Molecular Wt.:	244.31
CAS NO.:	58-85-5	Report date:	07-JUN-2018

Item	Specification	Method	Result
Appearance	White or off-white powder	USP	Conforms
Product description	Biotin, D-Biotin, vitamin H.	USP	Conforms
Identification	1)A: 2)B: 3)C:	USP	Conforms
Assay	NLT97.5 % and NMT100.5%	USP	99.21%
Impurities	Individual impurity: NMT 1.0% Total impurities: NMT 2.0%	USP	Conforms
Specific rotation	+89° to +93°	USP	+90.09°
Residual solvents	Meet USP and ICH Q3C requirements	USP	Conforms
Melting range	229°C-233°C	USP	229.4-230.1°C
Loss on drying	NMT 0.5%	EP	0.21%
Bulk density	~ 0.35 g/cm ³	In house	Conforms
Sulfate ash	NMT 0.1%	EP	0.020%
Heavy metals	In line with USA legislation Pb: max 0.5ppm As: max 1ppm Cd: max 1ppm Hg: max 0.1ppm	USP ICP/AAS	Conforms 0.05ppm 0.5ppm 0.01ppm 0.006ppm
Dioxin	WHO-PCDD/F-TEQ/kg product Max: 0.75 ng/kg	Directive 2002/70/EC	Conforms
Particle size	50% min. < 10µm 90% min. < 20µm 98% min. < 30µm	In house	Conforms
Microbials test:	In line with China legislation Total plate count: NMT 1000cfu/g Yeast and mold: NMT 100cfu/g Salmonella: Negative E. Coli. : Negative S. Aureus: Negative Total Coli. : NMT50cfu/g	CP-2015	Conforms 10cfu/g 5cfu/g Negative Negative Negative Negative
Solubility	Very slightly soluble in water	USP	Conforms
Storage & Shelf life	24 months from date of manufacturing in original unopened packaging ,store in tight containers	USP	Conforms
Conclusion	It Complies With updated USP38 Standard.		

Manager: *Esther*

Analyst: *Alicia*

