



CERTIFICATE OF ANALYSIS (COA)

Product name	Tadalafil	Batch No.	SEH-20220517
CAS No.	171596-29-5	Specification	USP 40
Quantity	808.5kg	Mfg. Date	2022.05.17
Date of Analysis	2022.05.20	Expiry Date	2025.05.16

Test Items	Specification	Test Results	
Description	White or Off-white powder	White powder	
Identification	HPLC&IR	Conforms	
Solubility	The product easy to dissolve in dimethyl sulfoxide	Conforms	
	This product is dissolved in acetonitrile	Conforms	
Specific rotation	+76.0°~+82.0°	78.2°	
Loss on Drying	≤0.5%	0.22%	
Residue on ignition	≤0.1%	0.03%	
Heavy Metal	≤10ppm	Conforms	
Isomer	Impurity A≤0.10%	0.02%	
	Impurity B≤0.10%	Not detected	
	Impurity C≤0.10%	Not detected	
Related substances	Total impurities ≤0.3%	0.02%	
	None specific impurities≤0.1%	Not detected	
Residual solvents	Methanol	≤0.3%	0.11%
	Isopropanol	≤0.5%	0.14%
	Methyl acetate	≤0.5%	Not detected
	Acetic ether	≤0.5%	Not detected
	AceticAcid	≤0.5%	Not detected
	DCM	≤0.06%	Not detected
Assay (HPLC)	97.5%~102.5%	99.98%	
Conclusion	The test product complies with the requirements of specification.		

Analyst: 	Checker: 	Q. C. Director:
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