



CERTIFICATE OF ANALYSIS

Product Name	Tadalafil(Cialis)	Batch No.	SER-220615
CAS No.	171596-29-5	Specification	USP 40
Quantity	502.69kg	Mfg. Date	2022.06.15
Date of Analysis	2022.06.16	Expiry Date	2024.06.16

Inspection Items	Standard	Inspection Result	Conclusion	
Description	White or Off-white powder	White powder	Conforms	
Identification	HPLC&IR	Conforms	Conforms	
Solubility	The product easy to dissolve in dimethyl sulfoxide	Conforms	Conforms	
	This product is dissolved in acetonitrile	Conforms	Conforms	
Specific rotation	+76.0°~+82.0°	78.2°	Qualified	
Loss on Drying	≤0.5%	0.22%	Qualified	
Residue on ignition	≤0.1%	0.03%	Qualified	
Heavy Metal	≤10ppm	Conforms	Qualified	
Isomer	Impurity A≤0.10%	0.02%	Qualified	
	Impurity B≤0.10%	Not detected	Qualified	
	Impurity C≤0.10%	Not detected	Qualified	
Related substances	Total impurities ≤0.3%	0.02%	Qualified	
	None specific impurities≤0.1%	Not detected	Qualified	
Residual solvents	Methanol	≤0.3%	0.11%	Qualified
	Isopropanol	≤0.5%	0.14%	Qualified
	Methyl acetate	≤0.5%	Not detected	Qualified
	Acetic ether	≤0.5%	Not detected	Qualified
	AceticAcid	≤0.5%	Not detected	Qualified
	DCM	≤0.06%	Not detected	Qualified
Assay	97%~103%	99.99%	Qualified	

Conclusion: The test product complies with the requirements of specification.

Analyst: Wu

Checker: Wang

Q.C.Director: Wang Li

