



API CMO & CDMO Manufacturer

CERTIFICATE OF ANALYSIS

Product Name	Tadalafil	Batch No.	Aea20240228TA
CAS No.	171596-29-5	Specification	USP40
Quantity	130.68KG	Report Date	2024.03.05
MFG. Date	2024.02.28	Expiry Date	2027.02.27

Testing Items	Specifications	Results
Apperance	White or Off-white powder	White powder
Identification	HPLC&IR	Conforms
Specific rotation	rotation +76.0°~+82.0°	78.2°
Solubility 1	The product easy to dissolve in dimethyl sulfoxide	Conforms
Solubility 2	This product is dissolved in acetonitrile	Conforms
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%
Package	Sealed export grade drum & double of sealed plastic bag.	
Storage	Store in a well-closed container away from moisture and direct Sunlight.	
Conclusion	Conform to Specification	

Tested/Date 2024.03.05

Approved by

