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Certificate of Analysis

Product Name	Tadalafil			
CAS.No	171596-29-5	Outer Packing	25kg / drum	
Production Date	2021-02-22	Batch No.	QY20210222	
Expiry Date	2023-02-21	Report Date	2021-02-22	
	·	Original	·	
ITEMS		SPECIFICATIONS	ECIFICATIONS	
Appearance	White powder			Complies
Odor & Tasted	Characteristic		Complies	
Identification	Infrared Absorption		Complies	
Solubility	Insoluble in water or alcohol, soluble in Acetic acid, ethyl ester		Complies	
Specific rotation	+78.0° ~+84.0°		+80.4°	
Citrate		Positive		
IR	IR should com	IR should comply with the reference standard spectrum		
Assay(Dry basis %)		≥ 99 HPLC		
PH		3.0-6.0		
Residue on ignition(%)	≤0.1			0.05
Loss on Drying(%)		≤0.5		
		Heavy Metals		
Heavy Metal(ppm)		≤10		
Pb(ppm)	≤1.0			Complies
As(ppm)	≤1.0			Complies
Hg(ppm)	≤0.1		Complies	
Cd(ppm)	≤1.0		Complies	
	Mic	robiological Tests		
Total Plate Count(cfu/g)		≤ 100		Complies
Yeasts and Moulds(cfu/g)		≤ 10		Complies
E.coli (cfu/g)		Negative		
Salmonella		Negative		
Pathogen		Negative		
Staphylococcus		Negative		
Conclusion	Conform to the stand	lard.	-10	TECU
Packing	25kg/drum		08	H#X C
Storage and Handling	Store in a cool and c	lry place, keep away from direc	t strong and heat.	THE P
Shelf life	Two years if sealed a	and store away from direct sun	light.	