

# OCTAGON CHEMICALS LIMITED

## CERTIFICATE OF ANALYSIS

Product name	Tadalafil (Cas 171596-29-5)		
Batch No.	19090501	Mfg. date	2019.09.13
Rep. Date	2019.09.08	Exp. date	2021.09.12
Packaging	25kg/Drum	Batch Size	985.9kg
Test Items	Standards: EP9.0		Results
Character	White or almost white crystalline powder		white crystalline powder
	Freely soluble in dimethyl sulfoxide, slightly soluble in methylene chloride, practically insoluble in water.		Conforms
Identification	IR		Conforms
	HPLC		Conforms
	Specific optical rotation: +78.0 ~ +84.0°		+81.56°
Impurity A, B, C	Impurity A: NMT0.15%		ND
	Unknown Impurity: NMT0.1%		ND
Loss on drying	NMT0.5%		0.03%
Sulfated ash	NMT0.1%		0.04%
Related Substances	Any Unspecified Impurities: NMT0.1%		0.004%
	Total impurities: NMT0.3%		0.01%
Residual solvents	Methyl Alcohol: NMT3000ppm		ND
	Methylamine: NMT116ppm		ND
	NMF: NMT880ppm		196ppm
	Isopropanol: NMT5000ppm		ND
	Triethylamine: NMT320ppm		ND
	Ethyl Acetate: NMT5000ppm		ND
	Acetonitrile: NMT410ppm		ND
Assay	97.5%~102.0% (on dried basis)		99.5%
Conclusion	It meets the requirements of EP9.0 Standards		
Storage	Store in a well-closed container at ambient temperature		
Prepared by: LI	Reviewed by: WEI	Released by: Zhang	

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