




SHANDONG ZHISHANG CHEMICAL CO., LTD.

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Certificate of Analysis

Product	Tadalafil		
Batch No.	16041701	Mfg. date	2016.08.17
App. Date	2016.08.21	Exp. date	2018.08.16
ANALYSIS	STANDARD		RESULT OF ANALYSIS
Character	White or almost white powder		Almost white powder
	Freely soluble in dimethyl sulfoxide, slightly soluble in methylene chloride, practically insoluble in water.		Conforms
Identification	IR spectra should be consistent with the control		Conforms
	The retention time of the test sample was consistent with the control in Impurities A, B and C text items.		Conforms
	Specific optical rotation should be +78.0 ~ +84.0°		+82.14°
Impurities A, B and C	Impurity A ≤ 0.15%		Not detected
	Unspecified Impurities ≤ 0.1%		Not detected
Loss on drying	≤ 0.5%		0.02%
Sulfated ash	≤ 0.1%		0.03%
Related Substance	Any Unspecified Impurities ≤ 0.1%		0.02%
	Total impurity ≤ 0.3%		0.03%
Residual solvent	Methyl Alcohol ≤ 0.3%		Not detected
	methylamine ≤ 0.0116%		Not detected
	N,N-Dimethylformamide ≤ 0.088%		0.05%
	Isopropanol ≤ 0.5%		Not detected
	Triethylamine ≤ 0.032%		Not detected
	Ethyl Acetate ≤ 0.5%		Not detected
Assay	97.5% ~ 102.0%		99.91%
<p>泰安市智尚经贸有限公司 TAI'AN CITY ZHI SHANG TRADE CO.LTD 总经理:  GENERAL MANAGER: WANG DONG JUN</p>			
Conclusion: Conforms to EP8.0			