



化工产品 仅供出口
Chemical Product for Exportation Only

RC-SOP-QS108-01

山东丰金制药有限公司

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CERTIFICATE OF ANALYSIS

PRODUCT NAME	Tadalafil	Batch No.	TD23005
COA Report No	C231103	QUANTITY	100kg
MANUFACTURE DATE	2023-10-28	TEST DATE	2023-11-01
REPORT DATE:	2023-11-08	RETEST DATE	2025-10
TEST ACCORDING	BP		

Test Items	Specifications	Results
Appearance	White or almost white powder	White powder
Identification	(1) IR: IR spectrum is accordant with Tadalafil RS	Conform
	(2) Specific optical rotation: +78.0~+84.0	+81.0
Loss on drying	$\leq 0.5\%$	0.07%
Residue on ignition	$\leq 0.1\%$	0.06%
Impurities A, B and C	Impurity A $\leq 0.15\%$	Not detected
	Unspecified impurities $\leq 0.10\%$	Not detected
Related substances	Unspecified impurities $\leq 0.10\%$	0.04%
	Total impurities $\leq 0.3\%$	0.1%
Assay	97.5%~102.0% (dried substance)	100.2%

Conclusion: Complies with BP

Approved by: *linkang 2023.11.08*

check by: *Mingcheng Ju 2023.11.08*

Test by: *Sunlima 2023.11.08*