



RC-SOP-QS108-01

山东丰金制药有限公司

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化工产品 仅供出口
Chemical Product for Exportation Only

CERTIFICATE OF ANALYSIS

PRODUCT NAME	Tadalafil	Batch No.	TD24003
COA Report No	C240305	QUANTITY	200kg
MANUFACTURE DATE	2024-03-12	TEST DATE	2024-03-14
REPORT DATE:	2024-03-18	RETEST DATE	2026-02
TEST ACCORDING	USP		

Test Items	Specifications	Results
Appearance	White or off-white powder	White powder
Identification	(1) IR:IR spectrum is accordant with Tadalafil RS	Conform
	(2) Retention time of major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the test of Enantiomeric and Diastereomeric Purity	Conform
Loss on drying	$\leq 0.5\%$	0.07%
Residue on ignition	$\leq 0.10\%$	0.04%
Enantiomeric and diastereomeric purity	Impurity A $\leq 0.1\%$	Not detected
	Impurity B $\leq 0.1\%$	Not detected
	Impurity C $\leq 0.1\%$	Not detected
Related substances	Individual impurity $\leq 0.10\%$	0.04%
	Total impurities $\leq 0.3\%$	0.1%
Assay	97.5%~102.5%(dried substance)	99.9%

Conclusion: Complies with USP.

Approved by: *Lin Kang* 2024.03.18 check by: *Mingcheng Ju* 2024.03.18 Test by: *Tan Xiaodong* 2024.03.18