

寿光富康制药有限公司
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CERTIFICATE OF ANALYSIS

REPORT NO: QC18050397

REGISTER NO: ZLJL-0510-02

PRODUCT	METFORMIN HYDROCHLORIDE		PHARMACOPOEIA	EP9.0
BATCH NO.	A-81411805003	GROSS WEIGHT	27.5Kg/Drum	
BATCH QUANTITY	2000KGS	NET WEIGHT	25Kg/Drum	
MANUFACTURE DATE	MAY.03,2018	RETEST DATE	APR.2021	
ANALYSIS DATE	MAY.04, 2018	REPORT DATE	MAY.07, 2018	
TEST ITEM	STANDARDS REQUIRED		TEST RESULTS	
Characters				
Appearance	White or almost white crystals		white crystals	
Identification				
B:IR-spectrum	Consistent with the spectrum of metformin-hydrochloride CRS. (2.2.24)		Complies	
E: reaction of chlorides	It gives reaction of chlorides. (2.3.1)		Complies	
Test				
Appearance of solution	Clear(2.2.1) and colorless(2.2.2 Method II)		clear and colorless	
Related substances	(2.2.29)			
Cyanoguanidine(imp.A)	≤0.02%		0.005%	
Any other impurity	≤0.05%		0.005%	
Total impurities	≤0.2%		0.03%	
Impurity F	≤0.05%		0.003%	
Heavy metals	≤10ppm (2.4.8)		<10ppm	
Loss on drying	≤0.5% (2.2.32)		0.09%	
Sulphated ash	≤0.1% (2.4.14)		0.04%	
Residual solvents				
Methanol	≤3000ppm		658ppm	
Assay% on dry basis	98.5—101.0%(2.2.20)		100.0%	

Results: The commodity meets the standard of EP9.0.

Examiner: Jiang Xuan

Checker: Zhao Guangtian

QA: Dong Linqing