

LORE XCFARMA; 180414

寿光富康制药有限公司

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CERTIFICATE OF ANALYSIS

REPORT NO: QC17041608

REGISTER NO: ZLJL-0510-02

REPORT NO: Q517041000

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PRODUCT	Trimethoprim	PHARMACOPOEIA	EP9.0
BATCH NO.	A-20111704014	GROSS WEIGHT	27.5 Kg/Drum
BATCH QUANTITY	2000Kg	NET WEIGHT	25Kg/Drum
MANUFACTURE DATE	APR.14,2017	RETEST DATE	MAR.2022
ANALYSIS DATE	APR.15,2017	REPORT DATE	APR.18,2017
TEST ITEM	STANDARDS REQUIRED		TEST RESULTS
Characters	white or yellowish-white powder		yellowish-white powder
Identification			
C:IR	IR Conforms to the CRS (2.2.24)		Complies
Test			
Appearance of solution	The solution is not more intensely coloured than reference solution BY ₇ (2.2.2, Method II).		Complies
Related substances(HPLC)	(2.2.29)		
A:			
Any impurity	≤0.10%		0.02%
Total impurities	≤0.2%		0.08%
B:			
Any impurity	≤0.10%		0.03%
Total impurities	≤0.2%		0.05%
Impurity K. (GC)	≤5ppm (2.2.28)		1.6ppm
Heavy metals	≤20ppm(2.4.8)		<20ppm
Loss on drying	≤1.0% (2.2.32)		0.3%
Sulphated ash	≤0.1%(2.4.14)		0.02%
Assay% on dry basis	98.5%-101.0%(2.2.20)		100.4%
Results: The commodity meets the standard of EP9.0. COS No. R1-CEP 2005-115-Rev 01.			

Examiner: Wang Xiaohong

王小红

Checker: Liu Xiaoping

刘小平

QA: Li Jian

李健