

LOTE NO: 200164

MMU (17/02/20)

寿光富康制药有限公司

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CERTIFICATE OF ANALYSIS

REPORT NO: QC19040444

REGISTER NO: ZLJL-0510-02

PRODUCT	Trimethoprim	PHARMACOPOEIA	EP9.0
BATCH NO.	A-20111904042	GROSS WEIGHT	27.5 Kg/Drum
BATCH QUANTITY	2000Kg	NET WEIGHT	25Kg/Drum
MANUFACTURE DATE	APR.19,2019	RETEST DATE	MAR.2024
ANALYSIS DATE	APR.21,2019	REPORT DATE	JUN.12,2019
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%		0.03%
B:			
Any impurity	≤0.10%		0.03%
Total impurities	≤0.2%		0.03%
Impurity K. (GC)	≤5ppm (2.2.28)		0.7ppm
Heavy metals	≤20ppm(2.4.8)		<20ppm
Loss on drying	≤1.0% (2.2.32)		0.14%
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: Huang Shasha

Checker: Jiang Xuan

QA: Li Haijun

黄莎莎 2019.06.12

姜璇 2019.06.12

李海军 2019.06.12