

寿光富康制药有限公司

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CERTIFICATE OF ANALYSIS

REPORT NO: QC20030015

REGISTER NO: SMR-QC-018a0

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PRODUCT	Trimethoprim	PHARMACOPOEIA	EP10.0
BATCH NO.	A-20112002035	GROSS WEIGHT	27.5 Kg/Drum
BATCH QUANTITY	2000Kg	NET WEIGHT	25Kg/Drum
MANUFACTURE DATE	FEB.28,2020	RETEST DATE	JAN.2025
ANALYSIS DATE	MAR.02,2020	REPORT DATE	MAR.20,2020
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%		0.04%
Total impurities	≤0.2%		0.07%
B:			
Any impurity	≤0.10%		0.03%
Total impurities	≤0.2%		0.03%
Impurity K. (GC)	≤5ppm (2.2.28)		1.0ppm
Loss on drying	≤1.0% (2.2.32)		0.1%
Sulphated ash	≤0.1%(2.4.14)		0.04%
Assay% on dry basis	98.5%-101.0%(2.2.20)		100.2%
Results: The commodity meets the standard of EP10.0. COS NO. R1-CEP 2005-115-Rev 01.			

Examiner: Zhang Yingchao

张颖超 20.03.20

Checker: Huang Shasha

黄莎莎 20.03.20

QA: Li Haijun

李海军 20.03.20