LOT ACOFAQHA: JTO 034

寿光富康制药有限公司

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GMP APPROVED http://www.shouguangpharm.com e-mail: sgfkph@public.wfptt.sd.cn

CERTIFICATE OF ANALYSIS

The number of the GMP certificate:M0813 and this certificate remains valid till 2016-05-03
GMP certificate was issued by State Drug Administration and as per Chinese gmp ruels was inspected.
We,(Shouguang Fukang Pharmaceutical Co.,Ltd.) as the manufacturer of Trimethoprim hereby certify that this batch has been manufactured by us in full compliance with GMP requirements of the local Regulatory Authority
Date of the certificate:JUL.19,2013
REPORT NO:A-20111307063 REGISTER NO:ZLJL-0510-02

PRODUCT	Trimethoprim	PHARMACOPOEIA	EP7.0
BATCH NO.	A-20111307063	GROSS WEIGHT	27.5 Kg/Drum
BATCH QUANTITY	2000Kg	NET WEIGHT	25Kg/Drum
MANUFACTURE DATE	JUL.17,2013	RETEST DATE	JUN.2018
ANALYSIS DATE	JUL.18,2013	REPORT DATE	JUL.19,2013
TEST ITEM	STANDARDS REQUIRED		TEST RESULTS
Characters	white or yellowish-white powder		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:			
Impurity F	≤0.1%		0.05%
Any impurity	≤0.10%		Not detected
Total impurities	≤0.2%		0.05%
B:			
Any impurity	≤0.10%		0.05%
Total impurities	≤0.2%		0.05%
Impurity K. (GC)	≤5ppm (2.2.28)		<5ppm
Heavy metals	≤20ppm(2.4.8)		<20ppm
Loss on drying	≤1.0% (2.2.32)		0.2%
Sulphated ash	≤0.1%(2.4.14)		0.02%
Assay	98.5%-101.0%(2.2.20)		99.9%

Results: The commodity meets the standard of EP7.0. COS No. R1-CEP 2005-115-Rev 00

Examiner Liu Fang 刘芳

Checker: Li Baoxing 李宝兴

QA :Ren Lihua 任丽华