

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

REPORT NO: A-50111308053-3300

REGISTER NO: ZLJL-0510-02

PRODUCT	Trimethoprim	PHARMACOPEIA	BP2011/USP35
BATCH NO.	A-50111308053-0300	GROSS WEIGHT	29.5 Kg/Drum
BATCH QUANTITY	2000Kg	NET WEIGHT	25Kg/Drum
MANUFACTURE DATE	AUG.17,2013	RETEST DATE	JUL.2018
ANALYSIS DATE	AUG.18,2013	REPORT DATE	AUG.19,2013
TEST ITEM	STANDARDS REQUIRED		TEST RESULTS
Characters	white or yellowish-white powder		Almost white powder
Identification			
C:IR	IR Conforms to the CRS (EP 2.2.24)		Complies
Test			
Appearance of solution	The solution is not more intensely coloured than reference solution BY ₇ (EP 2.2.2, Method II).		Complies
Melting Range	199-203 °C <USP 741>		200.9-201.1 °C
Related substances(HPLC)	(USP 2.2.29)		
A:			
Any impurity	≤0.10%		0.06%
Total impurities	≤0.2%		0.06%
B:			
Any impurity	≤0.10%		0.06%
Total impurities	≤0.2%		0.1%
Impurity K. (GC)	≤5ppm (EP 2.2.28)		<5ppm
Heavy metals	≤20ppm(EP 2.4.8)		<20ppm
Loss on drying	≤1.0% (EP 2.2.32)		0.2%
Sulphated ash	≤0.1%(EP 2.4.14)		0.02%
Assay% on dry basis	98.5%-101.0%(EP 2.2.20)		100.1%
Particle size	90% PASS 300MICRON		Complies

Results: The commodity meets the standard of BP2011/USP35

Examiner: Wang Wenxiang

Checker: Li Baoxing

QA: Wei Xiaoyuan

王文祥

李保兴

魏晓元

Kalchem International, Inc
 224 South Main Street - Lindsay, OK 73052
 Toll Free 888-298-9905 | FAX: 405-756-2373