

寿光富康制药有限公司

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CERTIFICATE OF ANALYSIS

REPORT NO: QC21120320

REGISTER NO: SMR-QC-018a0

PRODUCT	Trimethoprim	PHARMACOPOEIA	USP-NF
BATCH NO.	A-50112111051-1300	GROSS WEIGHT	29.5 Kg/Drum
BATCH QUANTITY	100Kg	NET WEIGHT	25Kg/Drum
MANUFACTURE DATE	NOV.23,2021	RETEST DATE	OCT.2026
ANALYSIS DATE	NOV.24,2021	REPORT DATE	DEC.15,2021
TEST ITEM	STANDARDS REQUIRED	TEST RESULTS	
Characters	white or yellowish-white powder	yellowish-white powder	
Identification			
A:IR-spectroscopy	IR Conforms to standard <USP Monograph 197K>	Complies	
B: Ultraviolet Absorption	Absorptivities, calculated on the dried basis, differ by NMT 3.0%. <USP Monograph 197U>	Complies	
Test			
Appearance of solution	Not more intensely coloured than reference solution BY ₇ (EP Monograph 2.2.2,Method II).	Complies	
Melting Range or Temperature	199-203°C <USP Monograph 741>	199.4-201.3°C	
Loss on drying	≤0.5% <USP Monograph 731>	0.1%	
Residue on ignition	≤0.1% <USP Monograph 281>	0.02%	
Related substances(HPLC)			
A:	<USP Monograph 621>		
Impurity E(USP Related Compound A)	≤0.1%	Not detected	
Impurity B(USP Related Compound B)	<0.1%	Not detected	
Impurity F	<0.1%	0.03%	
Any other impurity	<0.10%	0.02%	
Total impurities	≤0.2%	0.07%	
B:	(EP Monograph 2.2.29)		
Impurity F	≤0.1%	0.03%	
Impurity I	≤0.1%	Not detected	
Any other impurity	≤0.10%	Not detected	
Total impurities	≤0.2%	0.03%	
Impurity K. (GC)	≤4.7ppm (EP Monograph 2.2.28)	1ppm	
Assay% on dry basis	98.5%-101.0% <USP Monograph 541>	100.3%	
Particle size	D90 <20 μm	7 μm	
Results: The commodity meets the standard of USP-NF.			

Examiner: Hyang Shasha

Checker: Liu Cuixia

QA: Ma Chao

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